# Tematica pentru ocuparea postului de cercetator stiintific, CS, domeniul *Ingineria Resurselor Vegetale si Animale*

1. Analiza ciclului de viata (LCA- *Life Cycle Assessment*)
2. Limita de detectie si limita de cuantificare a metodelor analitice

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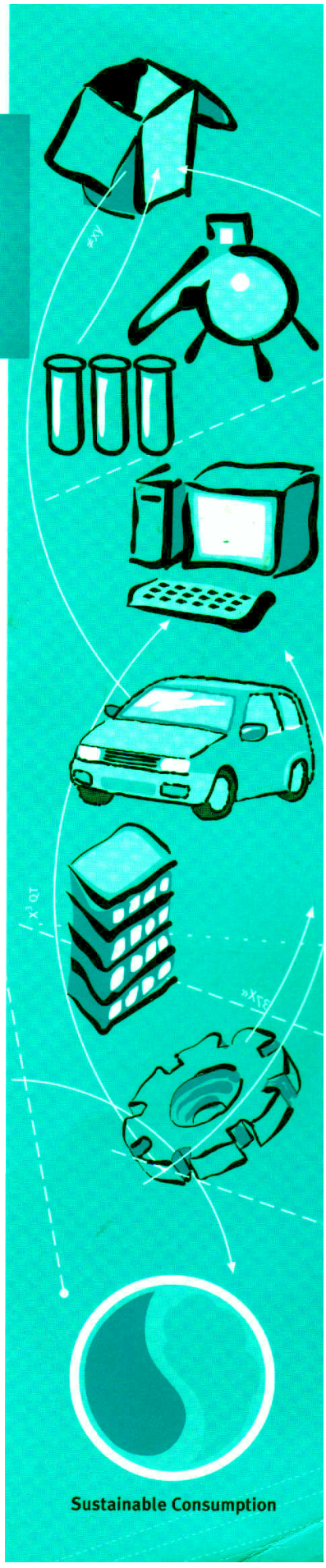
United Nations Environment Programme
Division of Technology, Industry and Economics
Production and Consumption Branch

# Evaluation of Environmental Impacts in Life Cycle Assessment




## Meeting report

**Brussels, 29-30 November 1998, and**
**Brighton, 25-26 May 2000**

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via Roma 71
26812 Borghetto Lodigiano (LO) - I
lafenicegrafica@libero.it

# EVALUATION OF ENVIRONMENTAL IMPACTS IN LIFE CYCLE ASSESSMENT

**United Nations Environment Programme**
**Division of Technology, Industry and Economics (DTIE)**
**Production and Consumption Unit**
**39-43, Quai André Citroën**
**75739 Paris Cedex 15**
**France**
Tel: +33 1 44 37 14 50
Fax: +33 1 44 37 14 74
E-mail: unep.tie@unep.fr
URL: http://www.uneptie.org

**In collaboration with:**

United States
Environmental Protection
Agency
401 M Street, S.W.
Washington, D.C. 20460
United States
http://www.epa.gov

Center of Environmental Science
Leiden University
Einsteinweg 2
P.O. Box 9518
2300 RA Leiden
The Netherlands
http://www.cml.leidenuniv.nl

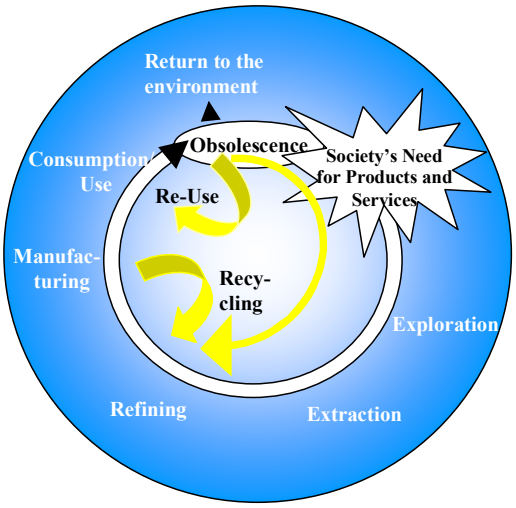
Environmental Analysis and
Management Group
Fundació URV - STQ
University Rovira i Virgili
Av. dels Països Catalans s/n
43007 Tarragona
Spain
http://www.etseq.urv.es/aga

"We have at our disposal the human and material resources to achieve sustainable development, not as an abstract concept but as a concrete reality". Our efforts "must be linked to the development of cleaner and more resource efficient technologies for a life cycle economy".

Malmö Declaration, 1st Global Ministerial Environment Forum

"Consumers are increasingly interested in the world behind the product they buy. Life cycle thinking implies that everyone in the whole chain of a product's life cycle, from cradle to grave, has a responsibility and a role to play, taking into account all the relevant external effects. The impacts of all life cycle stages need to be considered comprehensively when taking informed decisions on production and consumption patterns, policies and management strategies."

Klaus Toepfer, Executive Director, UNEP



# Foreword

In 1998 and 2000, UNEP joined forces with US-EPA and CML to facilitate an international discussion forum on two specific issues of scientific development in the field of Life Cycle Assessment - first, the level of sophistication in impact assessment and second, the type of environmental indicators to use. To this end, two international expert workshops were held. The present document provides an introduction to the workshop topics, a report of these two workshops, and some resources for further information. It has been published with the kind support of US-EPA. Our goal with this publication is to bring the overall issues, and the specific discussions and outcomes of both workshops to a broader audience.

In 2002, UNEP continued to facilitate an international forum for life cycle approaches with the launch of the UNEP/ SETAC Life Cycle Initiative, also with the involvement of US-EPA and CML. This new initiative responds to the call of the "Malmö Declaration", the agreement signed by the world's environment ministers at the 1st Global Ministerial Environment Forum, for a life-cycle economy. The relevance of life cycle analysis for changing unsustainable consumption and production patterns was emphasized in the plan of implementation emanating from the World Summit of Sustainable Development in 2002.

UNEP hopes to foster the application of life cycle assessment in public and private decision making for the benefit of the consumer and the sake of the environment. Therefore, UNEP is promoting supply chain responsibility and sustainable procurement to business and governments in order to create a need for life cycle information. Capacity building on life cycle approaches will be undertaken via regional programmes falling under the UNEP/SETAC Life Cycle Initiative.

The development of a consistent methodology framework, internationally accepted, is a priority to promote Life Cycle Assessment. Environmental Product Declarations would stand to benefit from such an approach. We also know that it is important to develop Life Cycle Management approaches. Finally sharing information and results obtained from Life Cycle Assessment studies is crucial to progress towards a life cycle economy. These are also subjects that will be addressed by the UNEP/ SETAC Life Cycle Initiative.

We in UNEP hope that this publication, as well as our other activities, will help to raise awareness of life cycle approaches around the world and assist in their effective implementation.

Jacqueline Aloisi de Larderel
Assistant Executive Director, UNEP
Director, DTIE

# Contents

# Guidance for readers

The mission of UNEP's Division of Technology, Industry and Economics (UNEP DTIE) is to help decision makers in governments, industry and local authorities develop and adopt policies, strategies and practices that are cleaner and safer, and make efficient use of natural resources; ensure adequate management of chemicals; incorporate environmental costs, and reduce pollution risks to people and the environment.

Within the Division, the Production and Consumption Unit aims to reduce the environmental consequences of industrial development and the pollution arising from the ever-increasing consumption of goods and services. The Unit's sustainable consumption activities apply a life cycle approach to consumer's needs. The focus is on understanding the driving forces behind consumption – using them to inspire cost-effective improvements, thereby raising the quality of life and reducing environment damage.

In the Malmö declaration more than 100 Ministers of Environment, gathered at the first Global Ministerial Environment Forum in the year 2000, emphasized the importance of the life-cycle economy as the overall objective for the development of cleaner and more resource efficient technologies. Life Cycle Assessment (LCA) has proved itself a valuable quantitative tool to support the way towards a life cycle economy by documenting the environmental considerations that need to be part of decision making for a sustainable development, which here is understood as satisfying the needs of the present generation without compromising the needs of future generations. Sustainability includes taking into account three aspects:

1. Economic: we need economic growth; to assure our material welfare;
2. Environmental: we need to minimize environmental damage, pollution, and exhaustion of resources;
3. Social: this is equity; the world's resources should be better shared between the rich and the poor.

There is evidence that LCA is not being utilized to its full potential, even in those countries that are most involved in its development and application. A major goal is therefore to increase worldwide the availability of information on LCA and to foster its use.

In 1996, UNEP published *Life Cycle Assessment: What it is and How to do it* to provide background information on the LCA concept and examples of current practice. In 1999, UNEP published *Towards the Global Use of Life Cycle Assessment,* connected to the workshop held in San Francisco the previous year.

This present meeting report – *Evaluation of environmental impacts in Life Cycle Assessment* – is based on workshops held in Brussels, 29-30 November 1998, and Brighton, 25-26 May 2000. It has been produced with the support of the United States Environmental Protection Agency (US-EPA). Its four main sections elaborated in cooperation among AGA, CML, US-EPA and UNEP provide a concise overview of the current status of the theory and practice of Life Cycle Impact Assessment (LCIA), document the improvements in the evaluation of impacts in Life Cycle Assessment, and discuss the challenges and opportunities for its wider application. LCIA provides a framework standardized by ISO 14042 for the systematic evaluation of environmental impacts in LCA. In this report, evaluation is meant in its broad sense; unlike ISO, here evaluation includes not only the formal step weighting, but the whole topic of assessing environmental stressors in a life cycle perspective. Several approaches for different types of environmental impacts have been developed in recent years.

Guidance for readers

## Readers's guide

This report is divided into four parts:

**Part One** provides a brief overview of the concept of life cycle thinking and LCA methodology with focus on Life Cycle Impact Assessment for those not familiar with the approach and identifies the potential users of LCA.

**Part Two** gives an introduction to the evaluation of environmental impact in LCA and describes the basic elements in Life Cycle Impact Assessment (LCIA) presenting a brief definition of the main concepts and steps in the LCIA based on ISO 14042. This chapter analyses as well the concept of sophistication in LCIA and the factors involved in its determination. An important aspect within sophistication is the definition of midpoints and endpoints and their different approaches. Both concepts will be presented and analyzed in this chapter providing different examples, theories and approaches.

**Part Three** analyses the results of the international expert workshops held in Brussels and Brighton under the umbrella of UNEP. The first was held to give an opportunity for international experts to address the issues related to Life Cycle Impact Assessment sophistication in an open format. The second addressed issues on the implications of midpoints versus endpoints indicators in LCIA with respect to uncertainty, transparency and the ability to subsequently resolve trade-offs across impact categories using weighting techniques.

**Part Four** reviews the main challenges in the current state of LCA and recommends ways to overcome them. The special aim is to reach a more widespread use of the Life Cycle Impact Assessment phase in the LCA studies.

**Appendices** to this report comprise a thematic bibliography, main internet resources, existing software and a list of key institutions involved in Life Cycle Assessment, as well as the lists of participants in the Brussels and Brighton workshops.

This report is written for both those unfamiliar with the LCIA framework and the LCA community familiar with the different aspects of the evaluation of environmental impacts in LCA.

Readers who are totally unfamiliar with LCA should start with Part One and the section of the appendix "LCA for beginners." Based on this information they should be able to understand Part Two and Part Four. Moreover, they will find interesting resources for further information on LCA in the appendix that could be a necessary support to completely follow the ongoing scientific discussions of the LCIA community researchers presented in Part Three.

LCA commissioners and practioners who want to know about LCIA can start with Part Two which gives a trouble-free insight into the issues related to the evaluation of environmental impacts in LCA. Part Three may, or may not, be attractive for them, depending on their interest in the more detailed questions of LCIA development.

LCIA experts are referred to Part Three and Four in order to learn about the scientific discussions and recommendations regarding the topics of the two international workshops on LCIA. Additonally two articles of workshop summaries published in a scientific journal are added in the appendix.

# Acknowledgements

This publication is based on the material provided by the speakers of the international expert workshops held in Brussels on November 29-30, 1998 and in Brighton on May 25-26, 2000 under the umbrella of UNEP, the workshop summaries prepared by Jane C. Bare (US-EPA), Patrick Hofstetter (ORISE Research Fellow, US-EPA), David W. Pennington (former ORISE Research Fellow, US-EPA; now EPFL) and Helias A. Udo de Haes of the Centre of Environmental Science (CML) at the Leiden University in the Netherlands (Bare et al., 1999; Bare et al., 2000 and EPA, 2000) and a background report provided by Guido W. Sonnemann and Francesc Castells of the Environmental Analysis and Management Group (AGA) at the Fundació URV – STQ of the University Rovira i Virgili in Tarragona/ Spain.

The Editorial board of the production comprised Jacqueline Aloisi de Larderel, Bas de Leeuw and Anne Solgaard of UNEP DTIE as well as Jane Bare of US-EPA. Thanks are also to Patrick Hofstetter (former ORISE Research Fellow, US-EPA) Helias A. Udo de Haes (CML), Olivier Jolliet (EPFL) and David W. Pennington (former ORISE Research Fellow, US-EPA; now EPFL) for their advice and comments.

Financial support for the project was provided by the US-EPA who also edited the text.

Part One

# The Framework of Life Cycle Assessment (LCA)

## Life Cycle Thinking

Life cycle thinking is a way of addressing environmental issues and opportunities from a system or holistic perspective. In this way of thinking, a product or service is evaluated or designed with a goal of reducing potential environmental impacts over its entire life cycle. Life cycle thinking does not generally normalize the results to a functional unit, as is done as part of a Life Cycle Assessment study. The concept of life cycle thinking implies the linking of individual processes to organized chains starting from a specific function.

Life cycle thinking implies that everyone in the whole chain of a product's life cycle, from cradle to grave, has a responsibility and a role to play, taking into account all relevant external effects. From the extraction of the raw material through refining, manufacturing, use or consumption to its reuse, recycling or disposal, individuals must be aware of the impact that this product has on the environment and try to reduce it as much as possible. The impacts of all life cycle stages need to be considered when taking informed decisions on the production and consumption patterns, policies and management strategies. This is also the idea behind the global aim of the life cycle economy mentioned in the Malmö declarations of more than 100 Ministers of Environment on 31 May 2000.

## Overview of LCA methodology

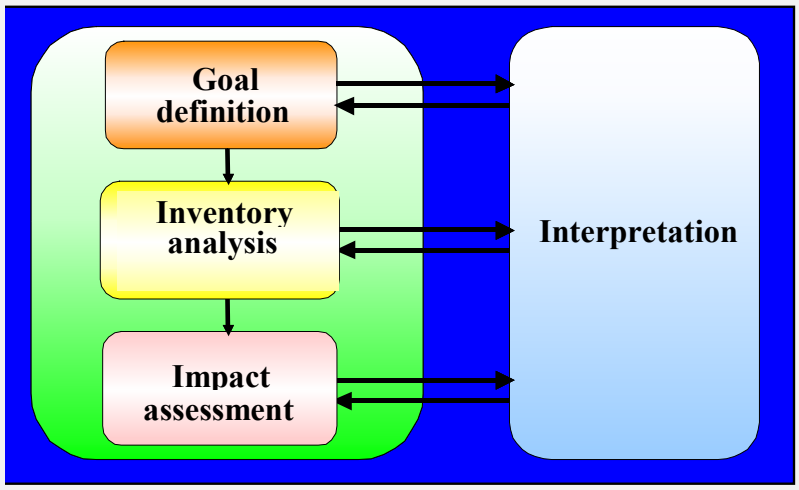
The technical framework for the Life Cycle Assessment methodology has been standardized by the International Standards Organization (ISO). According to ISO 14040, LCA consists of four phases, as presented in Figure 1:

1. Goal and Scope Definition
2. Inventory Analysis
3. Impact Assessment
4. Interpretation

These phases are not simply followed in a single sequence. This is an iterative process, in which subsequent iterations (rounds) can achieve increasing levels of detail (from screening LCA to full LCA), or lead to changes in the first phase prompted by the results of the last phase. Life Cycle Assessment has proven to be a valuable tool to document and analyze environmental considerations of product and service systems that need to be part of decision making towards sustainability.

ISO 14040 provides the general framework of LCA. ISO 14041 provides guidance for determining the goal and scope of an LCA study, and for conducting a life cycle inventory. ISO 14042 is about the life cycle impact assessment phase, and ISO 14043 provides guidance for the interpretation of results from an LCA study. Technical guidelines exist that illustrate how to apply the standards.

# Part One




**Goal and scope definition:** the product(s) or service(s) to be assessed are defined, a functional basis for comparison is chosen and the required level of detail is defined.

**Inventory analysis:** the energy carriers and raw materials used, the emissions to atmosphere, water and soil, and different types of land use are quantified for each process, then combined in the process flow chart and related to the functional basis.

**Impact assessment**: the effects of the resource use and emissions generated are grouped and quantified into a limited number of impact categories which may then be weighted for importance.

**Interpretation**: the results are reported in the most informative way possible and the need and opportunities to reduce the impact of the product(s) or service(s) on the environment are systematically evaluated.

FIGURE 1: THE PHASES OF LIFE CYCLE ASSESSMENT ACCORDING TO ISO 14040

## LCA USERS

LCA can be used by: industry and other types of commercial enterprises, governments at all levels, non-governmental organizations such as consumers organizations and environmental groups, and consumers. The motivations for use vary among the user groups.

An LCA study may be carried out for operational reasons, as in the assessment of individual products, or for strategic reasons, as in the assessment of different policy scenarios, waste management strategies or design concepts. LCA may be used for internal or external applications.

Part Two

# Introduction to Life Cycle Impact Assessment (LCIA)

## BASIC ELEMENTS IN LCIA

Life Cycle Impact Assessment (LCIA) is the third phase of Life Cycle Assessment described in ISO 14042 and further outlined with examples in ISO TR 14047. The purpose of LCIA is to assess a product system's Life Cycle Inventory to better understand its environmental significance. It also provides information for the interpretation phase.

The LCIA phase provides a system-wide perspective of environmental and resource issues for product system. It assigns Life Cycle Inventory results via characterization to impact categories. Characterization of emissions, resources extractions and land use means the aggregation by adequate factors of different types of substances or other interventions in a selected number of environmental issues, or "impact categories" such as resource depletion, climate change, acidification or human toxicity. For each impact category the indicators are selected and the category indicator results are calculated. The collection of these results provides information on the environmental impact of the resource use and emissions associated with the product system.

The general framework of the LCIA phase is composed of several mandatory elements that convert LCI results to indicator results. In addition, there are optional elements. The LCIA phase is only one part of a total LCA study and shall be coordinated with other phases of LCA. An overview of the mandatory and optional elements is given in Figure 2.

Separation of the LCIA phase into different elements is necessary for several reasons:

1. Each LCIA element is distinct and can be clearly defined.
2. The LCA study goal and scope definition phase can consider each element.
3. A quality assessment of the LCIA methods, assumptions and other decisions can be conducted for each LCIA element.
4. LCIA procedures, assumptions, and other operations within each element may be transparent for critical review and reporting.
5. Values and subjectivity – value choices – within each element have to be made transparent for critical review and reporting, if applied.

The mandatory LCIA elements are listed below:

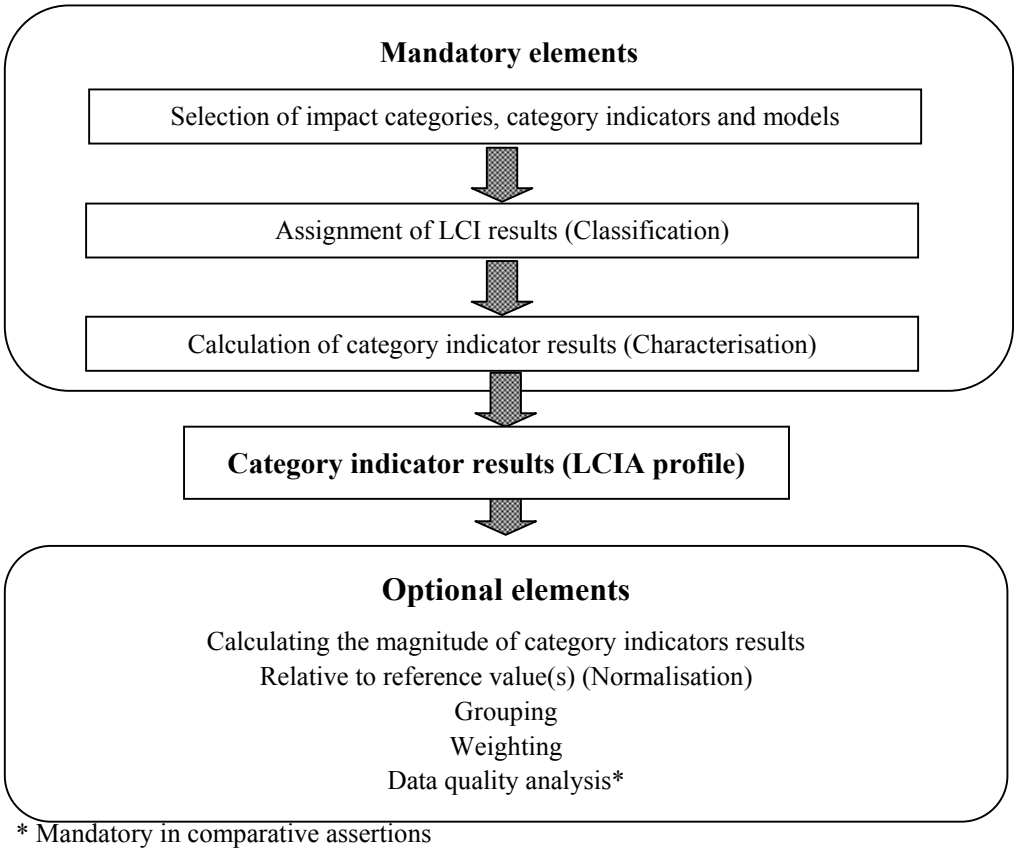
- Selection of impact categories, category indicators, and models.
- Assignment of LCI results (Classification) to the impact category. That is, the data from the inventory table are grouped together into a number of impact categories.
- Calculation of category indicator results (Characterization). Analysis and estimation of the magnitude of the impacts on the ecological health, human health, or resource depletion for each of the impact categories.

The indicator results for different impact categories together represent the LCIA profile for the product system.

There are optional elements and information that can be used depending on the goal and scope of the LCA study:

# Part Two

- Calculating the magnitude of category indicator results relative to reference value(s) (Normalization). All impact scores–contribution of a product system to one impact category–are related to a reference situation.
- Grouping; sorting and possibly ranking of the indicators.
- Weighting; aiming at prioritizing and possibly aggregating indicator results across impact categories. It is a quantitative comparison of the seriousness of the different impact potentials of the product systems, in general with the aim to obtain a single index of environmental performance.
- Data quality analysis; understanding better the reliability of the LCIA results.




* Mandatory in comparative assertions

FIGURE 2: MANDATORY AND OPTIONAL ELEMENTS OF LCIA ACCORDING TO ISO 14042

The use of models is necessary to derive the characterization factors. The applicability of the characterization factors depends on the accuracy, validity and characteristics of the models used. For most LCA studies no models are needed because existing impact categories, indicators and characterization factors will be selected from available sources. As can be seen in Figure 3 models reflect the cause-effect chain (environmental mechanism) of an impact category by describing the relationship between the LCI results, indicators and if possible category endpoint(s), i.e. the receptors that are damaged. For each impact category, the following procedure is proposed in ISO 14042:

Part Two

- Identification of the category endpoint(s).
- Definition of the indicator for given category endpoint(s).
- Identification of appropriate LCI results that can be assigned to the impact category, taking into account the chosen indicator and identified category endpoint(s).
- Identification of the model and the characterization factors.

This procedure facilitates an adequate inventory analysis and the identification of the scientific and technical validity, assumptions, value choices and the degree of accuracy of the model. The resulting indicators may vary in precision among impact categories due to the differences between the model and the corresponding environmental mechanism. The use of simplifying assumptions and available scientific knowledge influences the accuracy of the indicators.

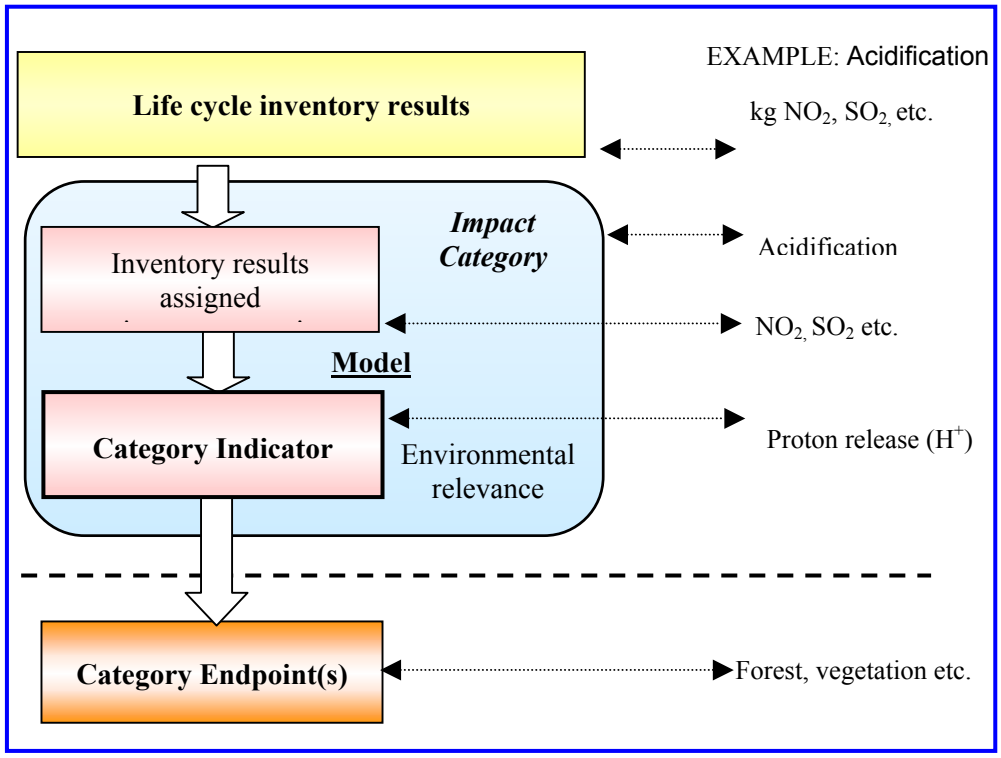



FIGURE 3: THE CONCEPT OF INDICATORS (ISO 14042). THE RELATIONSHIP BETWEEN THE LIFE CYCLE INVENTORY RESULTS, CATEGORY INDICATORS AND CATEGORY ENDPOINT(S) IS ILLUSTRATED FOR THE EXAMPLE OF ACIDIFICATION. THE INVENTORY RESULTS RELEVANT FOR ACIDIFICATION AS $NO_2$ AND $SO_2$ ARE ASSIGNED TO THIS CATEGORY. THEY ARE THEN RELATED TO THE CATEGORY INDICATOR (PROTON RELEASE) BY THE CHARACTERIZATION FACTORS CALCULATED BASED ON A MODEL. THE CLOSENESS OF THE INDICATOR TO THE CATEGORY ENDPOINTS DETERMINES ITS ENVIRONMENTAL RELEVANCE.

The relationship of the category endpoints as physical elements to the societal values behind them has been contemplated in the concept of Areas of Protection (AoP). In the first report of the Second SETAC Working Group on Life Cycle Impact Assessment (Udo de Haes et al., 1999), an AoP is defined as a class of category endpoints. In ISO 14042 three of such classes are mentioned, be it in a rather implicit way: human health, natural environment and natural resources.

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Another term used is the expressive term "safeguard subject", introduced by Steen and Ryding (1992). It is important to note that these two terms exactly convey the same message: they relate to the category endpoints as physical elements, not to the societal values behind.

AoPs enable a clear link with the societal values which are the basis for the protection of the endpoints concerned. Table 2 gives an overview of the AoPs with underlying societal values as presented by Udo de Haes et al. (1999), including man-made environment, i.e. damages to crops and materials. AoPs are the basis for the determination of relevant endpoints, their definition implies value choices. Thus, there is not one correct way to define a set of AoPs.

TABLE 2: AREAS OF PROTECTION AND UNDERLYING SOCIETAL VALUES (UDO DE HAES ET AL., 1999)

| **Areas of Protection** | **Societal values** |
|---|---|
| 1. Human Health | Intrinsic value of human life, economic value |
| 2. Natural Environment | Intrinsic value of nature (ecosystems, species), economic value of life support functions |
| 3. Natural Resources | Economic and intrinsic values |
| 4. Man-made Environment | Cultural, economic and intrinsic values |

Normally damages to elements within the economy that do not involve environmental processes are excluded from LCIA. An example concerns material damage caused by car accidents. In fact, these types of impact are part of the product system itself. A product system therefore not only fulfils a function, but also can lead to internal damage within the product system itself without any involvement of processes in the environment. In principle, LCA can include also the analysis of these types of impact, but in general these are considered to be additional to the environmental impacts that are part of the scope of an environmental management tool.

## LEVEL OF SOPHISTICATION IN LCIA

### What does sophistication mean?

The level of sophistication corresponds to the level of detail used in the impact assessment. In accordance with Bare et al. (1999) sophistication in LCIA can be considered as the ability to provide very accurate and comprehensive reports to help decision making in each particular case. In language more consistent with recent ISO publications, the practitioners of LCA are faced with the task of trying to determine the appropriate level of sophistication in order to provide a sufficiently comprehensive and detailed approach to assist in environmental decision-making. Sophistication has many dimensions and, dependent upon the impact category, may simulate the fate and exposure, effect and temporal and spatial dimensions of the impact. It has the ability to assess the validity and accuracy of the models used in LCIA (Udo De Haes et al., 1999; Owens et al., 1997; Udo de Haes, 1996; Fava et al., 1993).

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Traditionally LCIA uses linear modeling, takes the effects of the substances into account, but not their background concentrations and the geographical dependency on fate, and aggregates the environmental consequences over:

- time,
- locations, ⇨ "potential impact"
- chemicals.

All this only allows calculating potential impact scores, not actual damages.

Therefore, the appropriate level of sophistication of LCIA involves quite a number of issues. An overview of these different levels of detail in the characterization step of LCIA is given in Figure 4. A major point concerns the extension of the characterization modeling to include the dispersion or fate of the emitted substances as well as their exposure, and not only the physical damages to endpoints by dose-response functions. Exposure is the concentration increase due to the emission plus the background. More sophisticated possibilities arise which use multimedia modeling, take background levels of substances into account and make use of non-linear dose-response functions in the effect analysis. An important question for the quantification of the effect is whether there are real science-based thresholds that can be exceeded, or whether these thresholds are always of a political origin. Another issue concerns a possible differentiation in space and time. Studies can include impact models that use data just at world level and do not specify time periods; in contrast, more recent options involve spatial details of impacts and distinguish between different time periods.

A further question relates to the role and practicality of including uncertainty and sensitivity analysis. According to Bare et al. (1999) sensitivity analysis is increasingly included in LCA studies; but this is not yet the case for uncertainty analysis. Finally, there is the question of how to apply these different options for sophistication of LCIA, which applications can afford to keep it simple, and for which applications a more detailed analysis is needed.

## Factors involved in the determination of the level of sophistication

The important issue of deciding the appropriate level of sophistication is not typically addressed in LCA. Often, the determination of sophistication is based on considerations that may, or may not, be appropriate, but which may include practical reasons for limiting sophistication (e.g., the level of funding). A discussion of the most appropriate ways of determining sophistication will include (Bare et al., 1999):

- Study objective
- An uncertainty and/ or sensitivity analysis
- The inventory data and their specifications
- Depth of knowledge and comprehension in each impact category
- The quality and availability of modeling data
- Available supporting software
- The level of financial resources

### WHAT IS THE MEANING OF MIDPOINTS AND ENDPOINTS?

Although the terms "midpoints" and "endpoints" have yet to be clearly defined, in line with Bare et al. (2000) midpoints are considered to be points in the cause-effect chain (environmental mechanism) of a particular impact category, between stressors and endpoints. For midpoints characterization factors can be calculated to

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reflect the relative importance of an emission or extraction in a Life Cycle Inventory (e.g., global warming potentials defined in terms of radioactive forcing and atmospheric half-life differences). That is, midpoints are located anywhere between the stressors and the endpoints and allow calculation in a relative way the environmental impact of any stressor defined in the Life Cycle Inventory. Historically, the midpoint approaches have set the scene in LCIA, taken as prominent examples the CML thematic approach (Heijungs et al., 1992), the Sandestin workshop on LCIA (Fava et al., 1993), the Nordic LCA guide (Lindfors et al., 1995), the Eco-indicator 95 method, (Goedkoop, 1995), and the EDIP model (Wenzel et al., 1997). They also have mostly structured the thinking and examples chosen in ISO 14042.

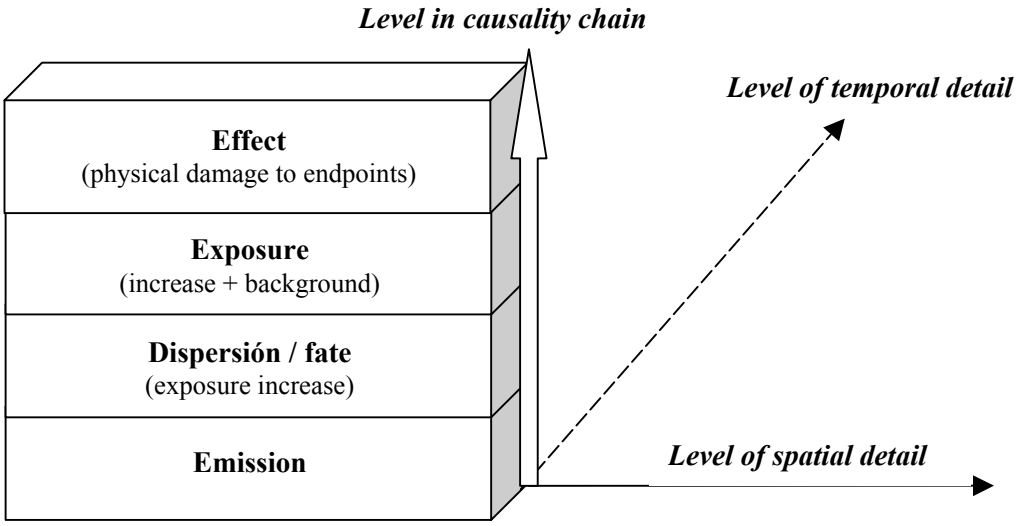


FIGURE 4: LEVELS OF DETAIL IN IMPACT CHARACTERISATION (POTTING, 2001)

According to Udo de Haes and Lindeijer (2001), endpoints are those elements of an environmental mechanism that are in themselves of value to society. ISO 14042 mentions forests and coral reefs as examples; this in contrast to ambient concentrations of hazardous substances. Other examples are physical aspects of human health, like lifetime or bodily functions; plant or animal species; or natural resources like fossil fuels and mineral ores.

Since the middle of the nineties the endpoint approach has been on the agenda Particularly in LCA studies that require the analysis of tradeoffs between and/ or aggregation across impact categories, endpoint-based approaches are gaining popularity. They already had a history, particularly in the EPS approach from Steen and Ryding (1992) and Steen, (1999), but got strong impetus from Switzerland (Mueller-Wenk, 1997) and again from the Netherlands in the Eco-indicator 99 approach (Goedkoop and Spriensma, 1999). In Japan, impact assessment models are currently developed according this approach (Itsubo and Inaba, 2000). This approach starts from the main values in society, connected with Areas of Protection, or Safeguard Subjects. From these values and connected endpoints the modeling goes back to the emissions and resources consumptions.

In Figure 5, Bare et al. (2000) show the steps that can be involved if a practitioner wishes to take an LCA study from the inventory stage, via impact assessment, to a single comparison metric using weighting techniques (both economic and/ or panel

approaches). Two different routes are presented, representing the routes taken when using midpoint and endpoint approaches. One of the key differences between midpoint and endpoint approaches is the way in which the environmental relevance of category indicators is taken into account. In midpoint approaches, the environmental relevance is generally presented in the form of qualitative relationships, statistics and review articles; however, it could similarly be quantified using endpoint methods to provide insights to the decision maker. In endpoint approaches there is no need to deal separately with the environmental relevance of the category indicators, because the indicators are chosen at an endpoint level and are generally considered more understandable to the decision makers.

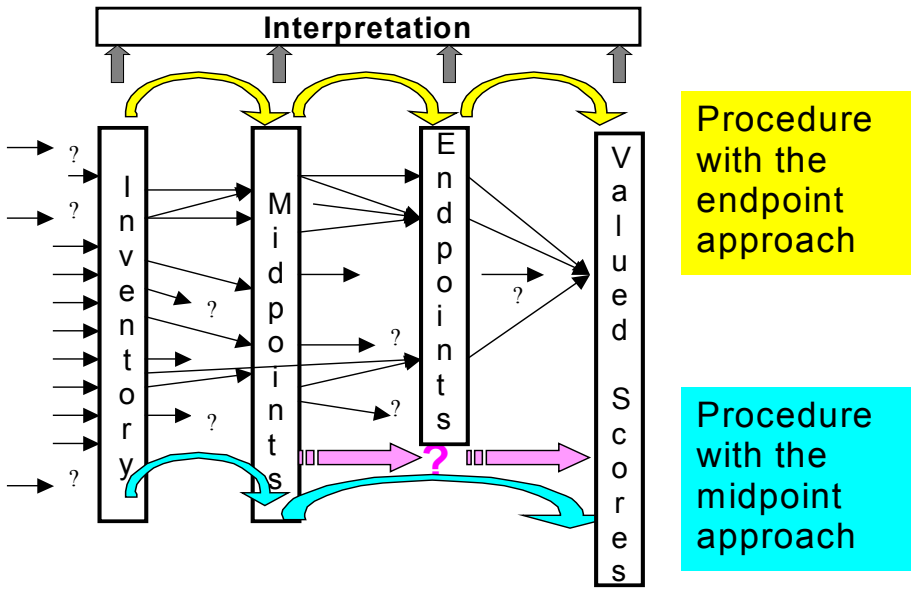


FIGURE 5: SOME BASIC DIFFERENCES BETWEEN THE MIDPOINT (LOWER ROW OF SWINGING ARROWS) AND THE ENDPOINT APPROACH (UPPER ROW OF SWINGING ARROWS). THE SMALL ARROWS REPRESENT MODELS THAT ADD INFORMATION IN A CAUSE-EFFECT FRAMEWORK. THE QUESTION MARKS INDICATE INFORMATION THAT WAS AVAILABLE BUT COULD NOT BE FURTHER MODELLED. SUCH CASES INCLUDE UNMEASURED EMISSIONS, UNCONSIDERED TYPES OF RELEASES SUCH AS OCCUPATIONAL ACCIDENTS, AND SUBSTANCES WHERE ENDPOINT MODELS HAVE STILL TO BE ESTABLISHED, E.G. NEUROTOXIC EFFECTS ON HUMAN HEALTH. (BARE, BRIGHTON WORKSHOP 2000)

Endpoint modeling may facilitate more structured and informed weighting, in particular science-based aggregation across categories in terms of common parameters (for example, human health impacts associated with climate change can be compared with those of ozone depletion using a common basis such as DALYs – Disability Adjusted Life Years).

As said by Bare et al. (2000) proponents of midpoint modeling believe, however, that the availability of reliable data and sufficiently robust models remains too limited to support endpoint modeling. In addition, many believe that extending the models to endpoints reduces their level of comprehensiveness and that such extensions will be based on a significant number of additional, unsubstantiated

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assumptions (which may not reflect the viewpoint of other experts and/or the user) to fill in missing knowledge gaps. One major concern is that uncertainties may be extremely high beyond well-characterized midpoints, resulting in a misleading sense of accuracy and improvement over the midpoint indicators when presented to weighting panels and decision makers. Many modelers believe that the additional complexity and detail of endpoint approaches is only warranted if they can be demonstrated to provide an improvement in the decision-making basis.

### EXAMPLES OF MIDPOINT AND ENDPOINT APPROACHES

In the previous sections we have introduced concepts such as classification and characterization as mandatory steps in any LCIA, and normalization and weighting as optional steps. These concepts are of crucial importance, but may not be completely clear for those unfamiliar with the field of Life Cycle Assessment. Hence, we now provide a brief introduction to midpoints indicators by the means of the example Global Warming Potential (GWP) to facilitate the understanding of classification, characterization, normalization and weighting. Moreover, we have chosen the Eco-indicator'99 as example for an endpoint method to illustrate the differences between the two approaches.

## Example of midpoint approach: Global Warming Potential (GWP)

Most of the energy that the earth receives from the sun in the form of short-wave radiation is reflected directly or re-emitted from the atmosphere, or the surface of the earth, as longer wave infrared (IR) radiation. The "man-made" greenhouse effect causes increases in temperature on top of the above natural greenhouse effect, caused by man-made emissions of substances or particles that can influence the earth's radiation balance.

Mandatory steps: Classification and Characterization

Many of the substances emitted to the atmosphere as a result of human activities contribute to this man-made greenhouse effect and have to be classified in this impact category. The most important are, in order, the following (Hauschild and Wenzel, 1998):

- $CO_2$ (carbon dioxide)
- $CH_4$ (methane)
- $N_2O$ (nitrous oxide or "laughing gas")
- Halocarbons (hyrdrocarbons containing chlorine, fluorine or bromine)

Moreover, a number of substances act indirectly, often with a positive effect, as greenhouse gases by influencing the efficiency of one or more of the above direct greenhouse gases (carbon monoxide, non-methane hydrocarbons, sulphur dioxide).

The potential contribution to global warming is computed with the aid of a procedure that expresses the characteristics of the substance relative to those of the other gases. For use in political efforts to optimize initiatives to counter man-made global warming, the Intergovernmental Panel of Climate Change (IPCC) has developed a characterization factor system that can weight the various substances according to their efficiencies as greenhouse gases.

The system allocates the various substances to GWP, which is calculated as the anticipated contribution to global warming over a chosen time period (20, 100 or 500 years) from a given emission of the substance divided by the contribution to warming from an emission of a corresponding quantity of $CO_2$. Multiplying a known emission of greenhouse gas by the relevant GWP yields the magnitude of

the $CO_2$ emission that, under the chosen conditions, will result in the same contribution to global warming, i.e. the emission of the greenhouse gas expressed on $CO_2$-equivalents.

$CO_2$ was chosen by the IPCC as reference substance because it is the substance that makes by far the most significant contribution to the man-made greenhouse effect. The expected contribution to warming from a greenhouse gas is calculated on the basis of knowledge of its specific infrared (IR) absorption capacity and expected lifetime in the atmosphere. The GWP is internationally accepted, well documented, and provides characterization factors for all substances encountered in a life cycle assessment. See Table 3 below with an example of GWP values for direct contribution of the three substances mentioned before ($CO_2$, $CH_4$ and $N_2O$).

TABLE 3: GWP FOR SOME SUBSTANCES DEPENDING ON TIME HORIZON (HOUGHTON ET AL., 1995)

| Substance | Formula | GWP (kg $CO_2$/kg substance) | | |
|---|---|---|---|---|
| | | 20 years | 100 years | 500 years |
| Carbon dioxide | $CO_2$ | 1 | 1 | 1 |
| Methane | $CH_4$ | 62 | 24.5 | 7.5 |
| Nitrous oxide | $N_2O$ | 290 | 320 | 180 |

Optional steps: Normalization and Weighting

The scores obtained for each impact category are compared to a specific reference. That means the relative contributions of the product system to the different impact categories are calculated. An impression is thus gained of which of the environmental impact potentials are relatively large and which are relatively small. This allows a comparison of the various environmental impacts from a product system.

Normalization has two objectives:

1. To provide an impression of the relative magnitudes of the environmental impact potentials.
2. To present the results in a form suitable for subsequent weighting

Weighting factors are used for the prioritization of one impact category (e.g. global warming) with other impact categories such (e.g. stratospheric ozone depletion). The prioritization of impact categories depends in general on subjective definitions of main concerns like political targets or business strategies.

Due to the subjective character of the weighting factors they are often obtained by means of an expert or policy-maker panel (Udo de Haes, 1996). In principle, public opinion can be asked, too. This is the idea behind the monetisation method based on Willingness-To-Pay (WTP), see for instance European Commission (1995).

## Other impact categories and proposed indicators (midpoints)

Table 4 gives an overview of some impact categories that are currently used in LCIA; for each impact category a possible midpont indicator is shown.

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TABLE 4: IMPACT CATEGORIES AND POSSIBLE INDICATORS (UDO DE HAES, 1996 AND UDO DE HAES ET AL., 1999)

| **Impact categories** | **Possible indicator** |
|---|---|
| *Input related categories* | |
| **Extraction of abiotic resources** | Scarcity of resource |
| **Extraction of biotic resources** | Scarcity of resource, considering replenishment rate |
| *Output related categories* | |
| **Climate change** | Kg $CO_2$ as equivalence unit for the Global Warming Potential (GWP) |
| **Stratospheric ozone depletion** | Kg CFC-11 as equivalence unit for the ozone depletion potential (ODP) |
| **Human toxicity** | Human Toxicity Potential (HTP) |
| **Eco-toxicity** | Aquatic Eco-Toxicity Potential (AETP). |
| **Photo-oxidant formation** | Kg ethene as equivalence unit for photochemical ozone creation potential (POCP) |
| **Acidification** | Release of $H^+$ as equivalence unit for the Acidification Potential (AP) |
| **Nutrification** | Stoichiometric sum of macro-nutrients as equivalence unit for the Nutrification Potential (NP) |

Udo de Haes et al. (1999) propose as input-related categories extraction of abiotic resources and extraction of biotic resources. Moreover, they suggest considering land use as an impact category consisting of three subcategories: increase of land competition, degradation of life support functions and bio-diversity degradation. As output related categories they propose climate change, stratospheric ozone depletion, human toxicity, eco-toxicity, photo oxidant formation, acidification and nutrification.

The impacts of the different categories have consequences on the environment and human welfare on different spatial scales. This has nothing to do with the importance of the categories, but with a need of spatial differentiation within the fate and exposure for some impact categories. Since economic processes are spread worldwide, local impacts have a global extension as well.

The climate change and the stratospheric ozone depletion are phenomena that affect the whole planet. In principle, this holds true also for the extraction of abiotic and biotic resources. However, not all regions of the world have the same need of all resources. Acidification, nutrification and photochemical oxidant formation are generally caused by pollutants whose residence time in the atmosphere permits a continental dispersion. The impact categories human and ecotoxicity can be considered to have a regional dimension. Depending on the characteristics of the pollutant and the medium where it is emitted, fate can be considered continental or local. Finally the impacts caused by photo-oxidant formation and land use are totally dependent on the local situation, meteorological conditions and land characteristics. The need for spatial differentiation in the fate and exposure analysis in different impact categories is illustrated in Figure 6.

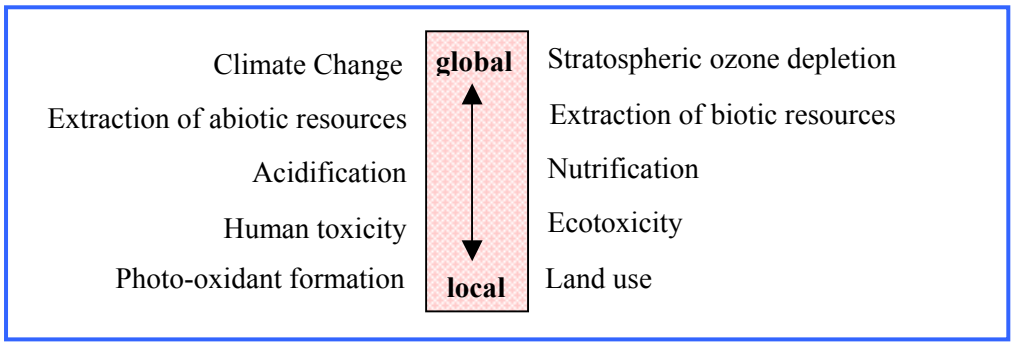


FIGURE 6: NEED FOR SPATIAL DIFFRENTIATION IN DIFFEREENT IMPACT CATEGORIES

## Example of endpoint approach: Eco-indicator 99

As an example of methods oriented to damage level, that is those focusing at endpoints level, we have chosen the Eco-indicator 99 method developed by a European team of experts from 1997 to 1999 (Goedkoop and Spriensma, 1999).

The Eco-indicator 99 method is a complete "top-down" impact assessment method with four clearly detailed steps: fate, exposure, effect and damage analysis. That means the methodology develops these further steps based on the values of the decision maker. This is in contrast with the "bottom up" approach that can be found in the more traditional midpoint methods, where the modeling starts with the release of the pollutant to the environment, the use of land and the extraction of resources.

Corresponding to this "top-down" approach the most fundamental problem is the definition of possible values of the decision maker To deal with the fact that in the valuesphere (value choices and weighting), a single truth simply does not exist, three perspectives are used: the hierarchist, the individualist and the egalitarian. The Table 5 specifies some different characteristics per perspectove.

The Eco-indicator 99 methodology allows for an analysis of the relative contribution of the different impact category indicators to one of the three endpoints without any weighting, using the values of the three perspectives. The methodology may include rather complex environmental models with possibly high uncertainties, but the developers of this method claim that the ease of interpretation compensates for this problem.

In the development of the Eco-indicator 99 methodology, the weighting step is considered to be the most difficult, controversial and uncertain, in addition to the uncertainty of the endpoint modeling. To simplify the weighting procedure, damage categories had to be identified, and as a result new damage models were developed that link inventory results into *three damage categories*:

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TABLE 5: THE THREE CULTURAL PERSPECTIVES USED IN ECO-INDICATOR 99 (HOFSTETTER, BRUSSELS WORKSHOP 1998)

| Perspective | Time perception | Manageability | Required level of evidence |
|---|---|---|---|
| *Hierarchist* | Balance between short and long term | Proper policy can avoid many problems | Inclusion based on consensus |
| *Individualist* | Short time | Technology can avoid many problems | Only proven effects |
| *Egalitarian* | Very long term | Problems can lead to catastrophe | All possible effects |

Damage to Human Health

Damage models were developed for respiratory and carcinogenic effects, the effects of climatic change, ozone layer depletion and ionizing radiation. In these models for Human Health, four steps are used:

1. **Fate analysis**, linking an emission to a temporary change in concentration.
2. **Exposure analysis,** linking this temporary concentration change to a dose.
3. **Effect analysis,** linking the dose to a number of health effects, such as occurrence and type of cancers.
4. **Damage analysis,** links health effects to DALYs (Disability Adjusted Life Years) using estimates of the number of Years Lived Disabled (YLD) and Years of Life Lost (YLL); it includes a first weighting step.

Damage to Ecosystem Quality

Damages to Ecosystem Quality are expressed as percentage of species disappeared in a certain area due to environmental load (Potentially Disappeared Fraction or PDF). The PDF is then multiplied by the area size and the time period to obtain damage. This damage category consists of:

1. **Ecotoxicity** expressed as the percentage of all species present in the environment living under toxic stress.
2. **Acidification and Eutrophication** treated as one single category. Damage to target species in natural areas is modeled.
3. **Land use and land transformation** based on empirical data. Both damages related to land occupation and transitions in land use are taken into account.

Damage to resources

Damage to resources, minerals and fossils fuels, are expressed as surplus energy for the future mining of resources:

1. **For minerals,** geo-statistical models are used that relate availability of a resource to its concentration.
2. **For fossil fuels,** surplus energy is based on future use of oil shale and tar sands.

The Eco-indicator 99 methodology used basically three types of models:

1. Modeling in the technosphere for the inventory phase.
2. Modeling in the ecosphere for the impact assessment phase.
3. Modeling in the valuesphere as the all-encompassing sphere for weighting and ranking, as well as to deal with unavoidable value choices (Hofstetter, 1998)

Figure 7 gives an overview of the Eco-indicator 99 method.

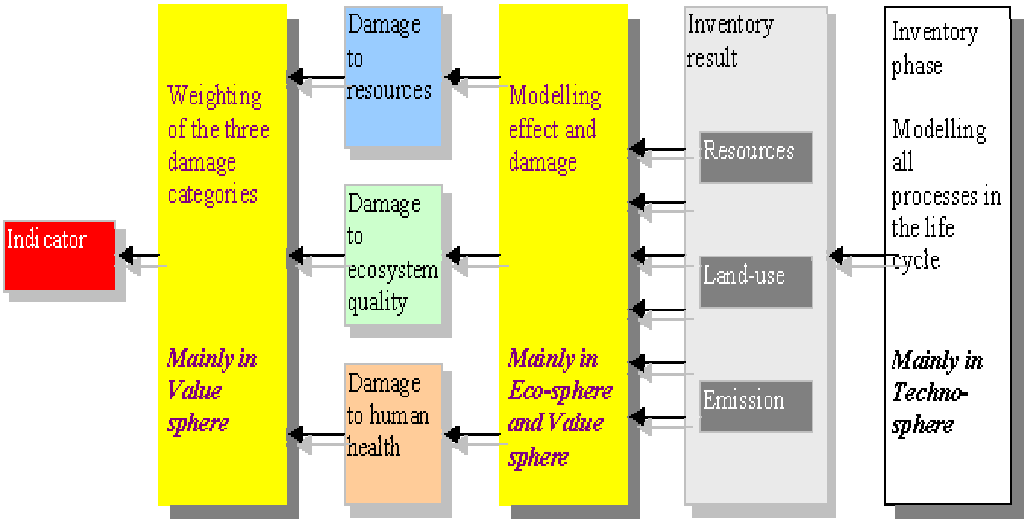


FIGURE 7: OVERVIEW OF THE ECO-INDICATOR 99 METHOD. THE TERM SPHERE IS USED TO INDICATE THAT THE METHOD INTEGRATES DIFFERENT FIELDS OF SCIENCE AND TECHNOLOGY (GOEDKOOP AND SPRIENSMA, 1999). THE MODELING OF THE DAMAGE TO HUMAN HEALTH INCLUDES A FIRST WEIGHTING STEP.

A similar method based on the same principles bas been developed by Steen (1999): A Systematic Approach to Environmental Priority Strategies in Product Development (EPS) - Version 2000.

## Other methods orientated at the damage level (endpoints)

Other endpoint approaches developed in recent years have their origin in the environmental risk assessment methodology and in the evaluation of external costs. The exposure assessment phase in the evaluation of human health risk estimates the probability that adverse effects to human health may occur as a consequence of the exposure to one or more substances. Environmental damages and resulting social costs are estimated by following the endpoint modeling approach called impact pathway analysis. This approach was used within the ExternE project (funded by the European Commission, 1995); it was expected to provide science-based estimates of environmental externalities by monetary valuation of welfare losses. ExternE should be used to design appropriate market based internalization instruments (like energy tax or emission tax).

Similar to some LCIA methods, ExternE aimed at quantifying the marginal impacts of an additional unit of electricity generation at a given site, which requires information on site-specific conditions (e.g. meteorology, distribution and sensitivity of receptors) and on background conditions (e.g. existing level of air pollution or acid deposition) to be considered in the impact assessment. Experience from ExternE shows that considerable resources are required to establish an operational set of relevant models and provide all the relevant site-specific input data. However, once such a model system is set up, it very much helps to

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understand, for example, the influence of site-specific parameters on the expected impacts, and also the potential influence of environmental policy measures (which might affect background conditions) on the impact (Udo de Haes and Lindeijer, 2001).

## Site-dependent impact assessment methods

The LCIA approaches have been adapted recently to allow site-dependent impact assessments. As in site-specific approaches fate, exposure and effect information are taken into account, but indicators are calculated that are valid for wider spatial areas. There is a trade-off between the accuracy of the impact assessment and the practicability of spatial desegregation for impact assessments in a life-cycle perspective.

Developments for site-dependent impact assessment have been made for acidification and eutrophication, such as Potting (2000) as well as Huijbregts and Seppälä (2000). Moreover, several approaches are presented for human health effects due to airborne emissions. Exemplary damage factors for a number of European sites are provided by Spadaro and Rabl (1999). Potting (2000) establishes impact indicators that take into account different release heights, population density and substance characteristics such as atmospheric residence time. The release height is statistically linked to several industrial branches. Moriguchi and Terazono (2000) present an approach for Japan where the meteorological conditions are set to be equal for all examples. Nigge (2000) presents a method for statistically determined population exposures per mass of pollutant that considers near-range and long-range exposure separately and allows addressing the local dispersion and population distribution systematically. Impact indicators are derived that depend on the settlement structure class and the stack height.

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# Recent methodological discussions on the evaluation of environmental impacts in LCA

## BRUSSELS AND BRIGHTON WORKSHOPS

### The Brussels Workshop

On November 29 - 30, 1998 in Brussels, an international workshop was held to discuss Life Cycle Impact Assessment (LCIA) Sophistication. Approximately 50 LCA and Risk Assessment experts attended the workshop from North America, Europe, and Asia. Prominent practitioners and researchers were invited to present a critical review of the associated topics, including the current limitations of available impact assessment methodologies and a comparison of the alternatives in the context of uncertainty. Each set of presentations, organized into three sessions, was followed by a discussion session to encourage international discourse with a view to improving the understanding of these crucial issues. The discussions were focused around small working groups of LCA practitioners and researchers, selected to include a balance of representatives from industry, government and academia

At the beginning of this workshop Bare stressed that Life Cycle Impact Assessment can be effective in supporting environmental decision making, but only if the data and methods are sufficiently scientifically defensible. Scientifically defensible was defined as being dependent upon the level of sophistication, the level of certainty (including both data and model certainty), the level of comprehensiveness, and data availability. The participants were challenged to address several additional questions throughout the two days of discussions including: What is "scientifically defensible?" In the sphere of determining whether impact assessment is based on sound science, where does one draw the line between sound science and modeling assumptions? (EPA, 2000)

This workshop provided the first opportunity for international experts to address the issues related to LCIA sophistication in an open format. Among the topics addressed were (Bare et al., 1999):

1. Context of sophistication,
2. Necessity and practicality regarding the sophistication of the uncertainty analysis,
3. Role of various types of uncertainty analysis,
4. Difficulty of assessing and capturing the comprehensiveness of the environmental health impact category,
5. Implications of cultural/ philosophical views,
6. Meaning of terms like science-based and environmental relevance in the ISO 14042 LCIA standard,
7. Dichotomy of striving for consistency while allowing the incorporation of state-of-the-art research,
8. Implications of allowing impact categories to be assessed at "midpoint" versus at "endpoint" level, and
9. Role of supporting environmental analyses (e.g., risk assessments).

Many of these topics addressed the need for increased sophistication in LCIA, but recognized the conflict this might have in terms of the comprehensiveness and holistic character of LCA, and LCIA in particular.

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## The Brighton Workshop

On May 25 – 26, 2000 in Brighton (England), the second in a series of international workshops was held under the umbrella of UNEP addressing issues in Life Cycle Impact Assessment (LCIA). The workshop provided a forum for experts to discuss midpoint vs. endpoint modeling. The topics addressed in this workshop included the implications of midpoint versus endpoint indicators with respect to uncertainty (parameter, model and scenario), transparency and the ability to subsequently resolve trade-offs related to weighting across impact categories using weighting techniques. The Brighton workshop was conceived to present both sides of the midpoint versus endpoint argument to an international group of approximately 50 experts and to allow these participants adequate time to discuss the relative merits and limitations of the approaches.

Bare opened this workshop by suggesting that there are advantages and disadvantages to each approach and suggested that both midpoint and endpoint approaches might be used together to provide more information (Figure 8) than just the typical ensemble of midpoint indicator results (Figure 9) (Bare et al., 2000).

Figure 8 illustrates the additional information that is obtained by the combined use of midpoints and endpoints for the case of the Ozone Depletion Potential (ODP). The emissions of CFCs and Halons cause chemical reactions that release $Cl^-$ and $Br^-$. The ODP measures the potential of the released ions to destroy ozone. The endpoint approach provides information of the damages that correpond to the ODP. Less ozone in the stratosphere allows increased UVB radiation that can be related directly to damages at the endpoint. These damages are an increase of skin cancer, cataracts, crop damage, immune system suppression, damage to materials like plastics, and marine life damage.

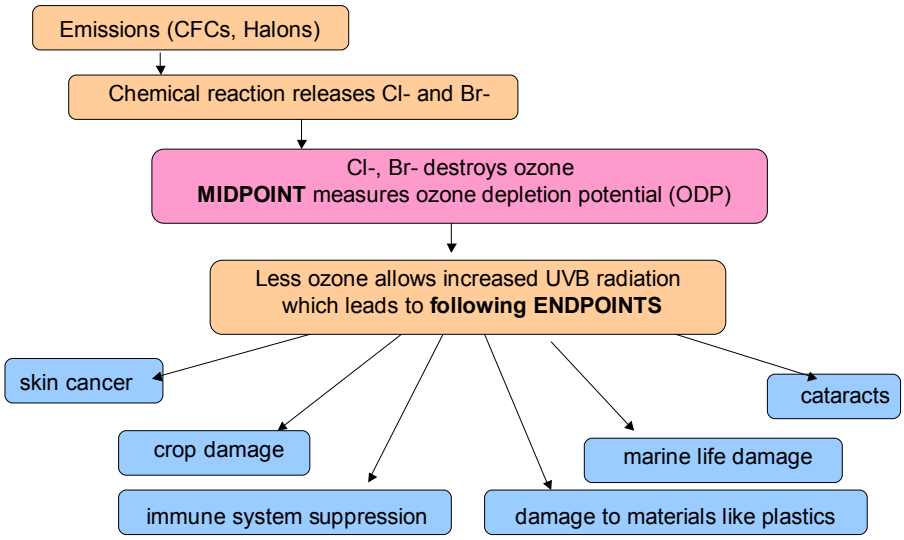


FIGURE 8: USING ENDPOINT AND MIDPOINT APPROACHES TOGETHER TO PROVIDE MORE INFORMATION, EXAMPLE OF OZONE DEPLETION POTENTIAL (BARE, BRIGHTON WORKSHOP 2000)

Figure 9 gives an overview of the ensemble of midpoints indicators in a way in which it is often used in LCA studies. Damage informaton related to the impacts behind the potentials is not available. Aggregations of damage values across the impact categories are not possible since category-specific potentials are presented.

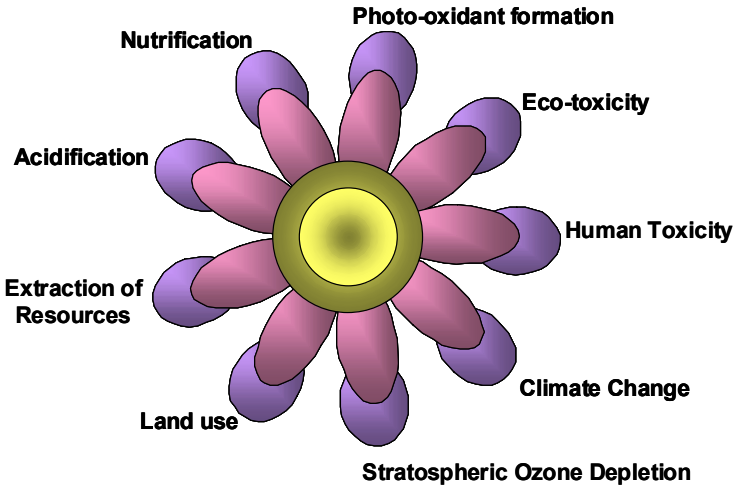


FIGURE 9: ENSEMBLE OF MIDPOINT INDICATORS (ADAPTED FROM VAN DE MEENT, BRIGHTON WORKSHOP 2000)

To use current midpoint and endpoint approaches together would require the use of models that have incompatible data sets, impact assessment methodologies, and modeling assumptions. Analogous to the idea of using midpoint and endpoint approaches in parallel, some practitioners suggested in the workshop conducting studies using available, multiple methodologies (and even inventory databases) to determine whether this affected the results. Others voiced frustration with available software and warned that decision makers will not accept conflicting models next to each other. Further investigation would then be required to resolve contradictory results.

As said in Bare et al. (2000), faced with the benefits and limitations of midpoint and endpoint approaches, the workshop closed with a consensus that both midpoint and endpoint methodologies provide useful information to the decision maker, prompting the call for developing one encompassing framework that includes both midpoint and endpoint indicators, so that the results of the two approaches can be compared with each other. The user could then see the comparative results at the midpoint level, as well as at the endpoint level. It was noted that this is analogous to the use of endpoint methodologies to provide a default basis for cross-comparison among midpoint category indicators.

## UNCERTAINTY AND COMPREHENSIVENESS

Uncertainties in LCIA remain high. There was a recognition that at least two types of uncertainty exist: model uncertainty and parameter uncertainty. Model uncertainty reflects the accuracy of the model, as determined through evaluation studies. Parameter uncertainty is the uncertainty associated with the input data, as commonly determined using tools like Monte-Carlo analysis. Many participants expressed concern that model uncertainties are often ignored in LCA, and the limited efforts to date have only focused on parameter uncertainty (Bare et al., 1999). Therefore, the aspect of scenario uncertainty was broadly discussed at the workshop.

In the Brussels workshop (EPA, 2000), Hertwich presented the purpose of uncertainty analysis: “to develop confidence in an analytical result, as an input to formal decision analysis techniques and as a tool to refine impact assessment methods.” He noted that uncertainty analysis includes:

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- Parameter uncertainty (errors in the resolution of instrumentation, sampling errors of entire population model uncertainty, and biases introduced through experimental design or instruments);
- Decision rule uncertainty (whenever there is ambiguity about how to quantify or compare social objectives).

In the Brighton workshop, Hertwich derived from the concept of covariance that indicators for some products might be better distinguished at midpoint and for others at endpoint level. For some product systems a distinction might be even sufficient through the identifiable differences in the stressors of the inventory.

Norris stated in the Brussels workshop that the level of sophistication should be partially dependent upon the inventory data and its uncertainty, upon the appropriate models and upon decisions about weighting. He suggested using Input/ Output-based upstream LCI databases to answer many of the common questions that practitioners face, such as "How many sites, with how much geographic dispersion, contribute significantly to inventory totals?" And "What are the expected shapes of these distributions?" He also cautioned participants against trying to draw conclusions about the advantages of more detailed LCIA, based on a Probability Density Function diagrams, pointing out that further simulations may be required. Finally, he discussed the difference between analyzing uncertainty in weighting and in characterization modeling and the need to treat these issues jointly in the determination of the level of sophistication and decision support (EPA, 2000)

In the Brighton workshop Norris stressed the importance and decision support value of calculating and maintaining uncertainty information at each stage in the impact assessment, and suggested iterative tests for dominance at each impact assessment modeling stage. He pointed out the rapidly changing nature of modeling in LCIA, noting how quickly we have moved from midpoint potentials to endpoint models, and he predicted we would soon be using more sophisticated estimates of uncertainty within our models.

There was recognition that there is also uncertainty regarding the adequate level of relevance for the presentation of the results. This is referred to as scenario or decision rule uncertainty by some researchers. (This was also presented as "What we know" vs. "What we want.") There was an overall belief that endpoint models may be more relevant, but less certain (i.e., higher model and parameter uncertainty) but that midpoint modeling may be more certain (i.e., lower model and parameter uncertainty), but less relevant to what the decision makers really want to know.

During the Brighton workshop Krewitt said in his presentation "Advantages and limitations of endpoint modeling – experiences from the ExternE project" that is well acknowledged in ExternE (European Commission, 1995) that there is an increasing level of uncertainty when going from the quantification of stressors towards the assessment of impacts to the final weighting. Data uncertainty and model uncertainty basically are of scientific nature, and thus are amenable to analysis by statistical methods. Uncertainty due to a lack of knowledge (e.g. future change in background conditions) or subjective judgments (e.g. valuation of increased risk of death) should be addressed in a sensitivity analysis. Statistical uncertainty was analyzed by taking into account uncertainties resulting from all steps of the impact pathway, i.e. the quantification of emissions, air quality modeling, dose-effect modeling, and valuation (Rabl and Spadaro, 1999).

Then Krewitt asked how to treat impact categories that (currently) cannot be quantified. He pointed out that ExternE discussed a long list of 'un-quantifiable'

impacts, included the most important ones labeled as 'not quantified' in the result tables, and presented 'sub-totals' of external costs (rather than 'totals') in the summary tables, indicating that the reported external costs do not include all impacts. As ExternE was explicitly confined to the assessment of marginal damage costs by using individuals' willingness-to-pay, for the purpose of methodological consistency other valuation approaches were not considered. But in particular in the case of very uncertain impacts the use of society's revealed preferences is considered as a good alternative approach for economic valuation. Although the expected damage is not well known, there exist policy defined environmental targets (e.g. $CO_2$ reduction). The (known) costs for achieving these targets can be interpreted as society's willingness-to-pay to avoid the anticipated impacts.

In the Brussels workshop, Hofstetter addressed the question of "What is science?" in the presentation: "The Different Levels of Uncertainty Assessment in LCIA: The Case of Carcinogenic Effects." He stated that the development of models is dependent on the perspective of the modeler. The perspective is responsible for the respective attitude towards the manageability of unknown damage and unknown causalities in relation to the acceptable damage and the damage due to unknown causalities (Figure 10).

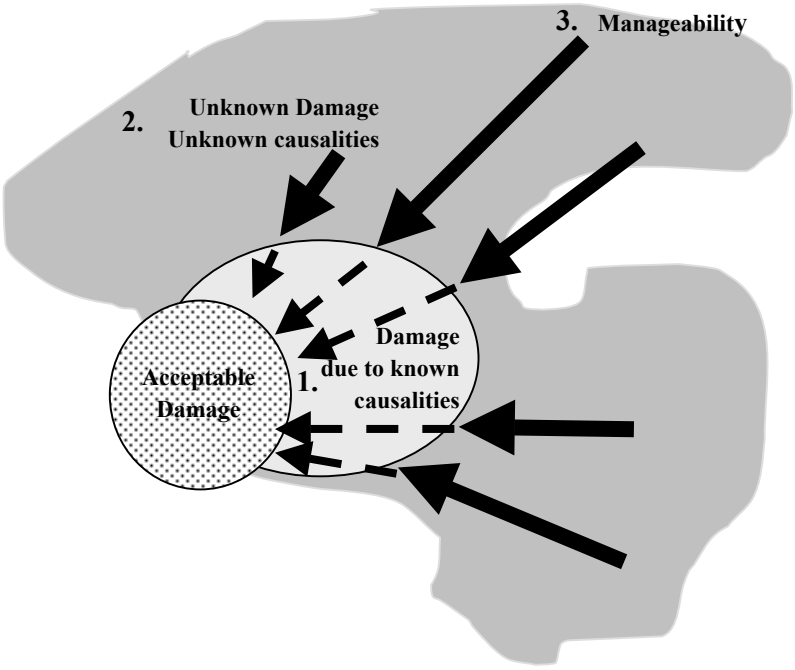


FIGURE 10: THE MODELING FRAMEWORK FOR THE ECOSPHERE. THE ARROWS – THE THIRD MODELING LEVEL OF 'MANAGEABILITY' – SYMBOLIZE THE DYNAMIC ASPECTS OF A DAMAGE REDUCTION TOWARDS AN ACCEPTABLE DAMAGE. (HOFSTETTER, BRUSSELS WORKSHOP 1998)

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The relative comprehensiveness of the midpoint and endpoint indicators was discussed. In general, midpoint indicators will be more comprehensive because they will be relevant for a wider variety of impacts at endpoint level, although these impacts on endpoint level are not modeled and may not be specified or known. Generally, endpoint models will focus on a smaller number of pathways because of the requirement to model them quantitatively. Although some "gaps" are qualitatively "known", the experts in the associated domains may not be confident about assessment beyond well-characterized midpoints up to endpoint effects. Pathways that carry significant knowledge gaps prohibiting quantification can be considered within endpoint modeling by making assumptions within the cause-effect chain modeling itself, by leaving pathways out of consideration, or by using parallel precautionary indices. In contrast, midpoint approaches do not address these knowledge gaps, but allow their consideration within the weighting and decision making phases. It was also noted that for both midpoint and endpoint approaches, participants in a weighting process may not even be qualitatively aware of all of the primary or secondary effects associated with each impact category (Bare et al., 2000).

### Areas of Protection

During the Brighton workshop, Udo de Haes suggested, Life Support Functions (LSF) might be seen as having intrinsic value in their own right (see Figure 11). The Life Support Functions concern the major regulating functions of the natural environment, which enable life on earth (both human and non-human). These particularly include the regulation of the earth climate, hydrological cycles, soil fertility and the bio-geo-chemical cycles. Like the Natural Resources, the Life Support Functions are of functional value for society. From a value perspective, these two are therefore of a fundamentally other nature than the AoPs with intrinsic value to society, such as in particular those connected with human health, with biodiversity and with works of art.

Starting from the distinction between intrinsic and functional values it is proposed to differentiate within the AoP Natural Environment between Biodiversity and Natural Landscapes and Life Support Functions. Now there are two ways to deal with this. One is to define two new AoPs instead of one, each with their own indicators. The other is to regard it still as one AoP, within which different indicators are defined related to the different societal values. Udo de Haes and Lindeijer (2001) see the latter as the most generally applicable structure; therefore they follow this line, also in order to keep the result simple. But then there is indeed little reason to keep the Natural Resources as a separate AoP. Rather it can be seen as a third sub-category within the AoP Natural Environment. The links between these three sub-categories are quite strong and the boundaries not sharp.

According to Udo de Haes and Lindeijer (2001), the question, whether or not to include the Life Support Functions as a separate sub-AoP, is not only of academic significance. Suppose, one wants to choose the category indicators at endpoint level (i.e., at the level of physical damage) in direct relationship to societal values. If one would only include AoPs that have intrinsic value to society, then it would suffice to select indicators for Human Health and for Biodiversity, just as for instance is done in the Eco-indicator 99 approach (Goedkoop and Spriensma, 1999). But if one also wants to include functional values, then it becomes relevant to also include indicators for the Natural Resources and the Life Support Functions.

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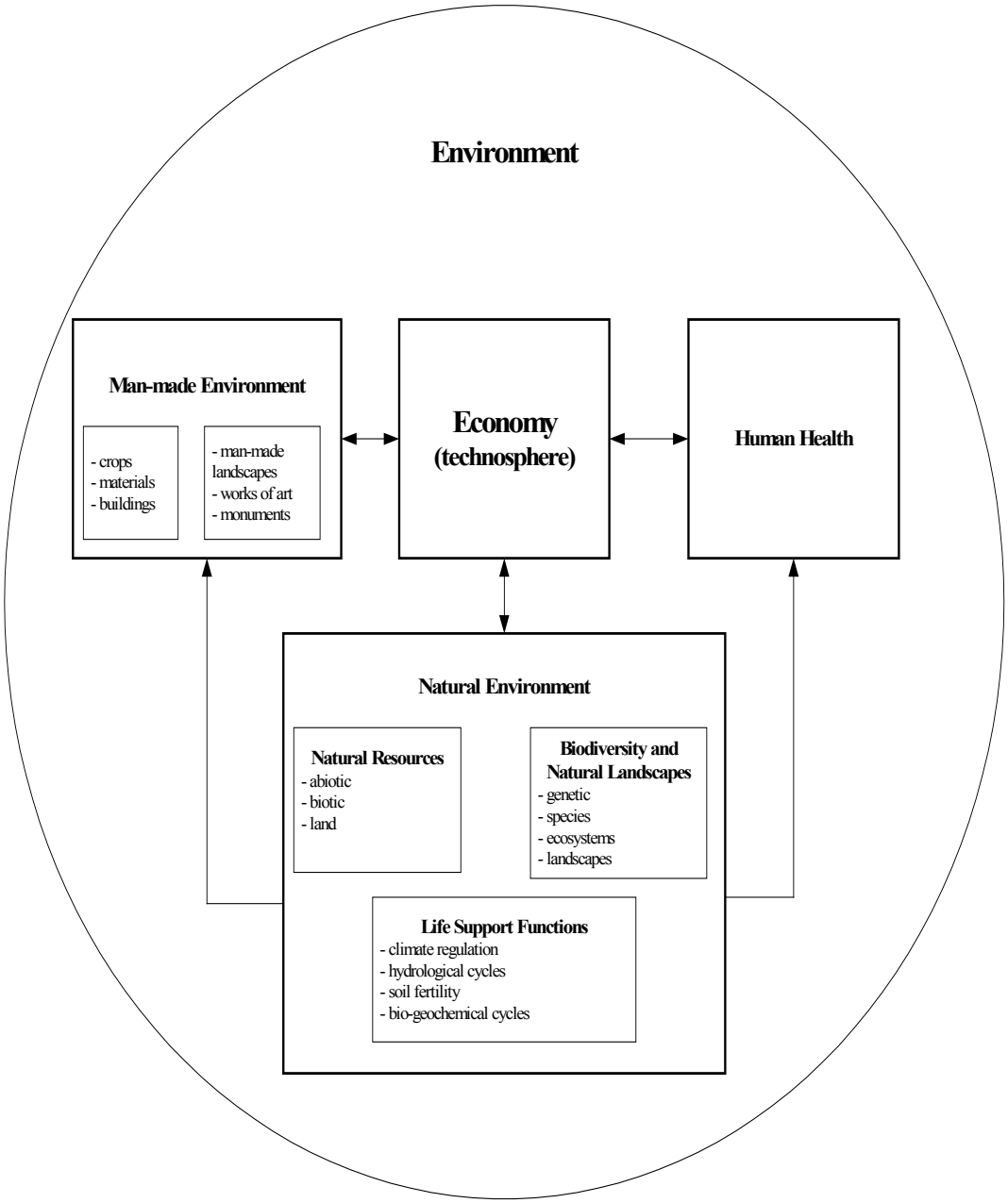


FIGURE 11: CLASSIFICATION OF AREAS OF PROTECTION ACCORDING TO SOCIETAL VALUES. ARROWS POINTING BOTH WAYS EXPRESS INTERACTIONS BETWEEN ECONOMY AND AOPS. OTHER ARROWS INDICATE MAIN RELATIONSHIPS BETWEEN AOPS. (UDO DE HAES AND LINDEIJER, 2001)

A few remarks should be added about the possible sub-AoP Life Support Functions. Firstly, it should be clear that it is in the same way as other sub-AoPs composed of a number of subclasses, which cannot easily be represented with one indicator, thus giving further shape to a hierarchical set-up. To be more precise, this sub-AoP may well cover more impact categories, each with its own category indicator. Secondly, it is interesting to compare this sub-AoP with the "Unknown Damage," as introduced by Hofstetter (1998). Although there is resemblance, there are also differences. Hofstetter's "Unknown Damage" is in fact based on a negative definition; it shrinks with increasing knowledge. Here a positive description is

used, based on the natural regulation functions, and of comparable value as the natural resources. Thirdly, it should be recognized that the inclusion of a sub-AoP Life Support Functions implies, that the elements involved are to be regarded as endpoints.

For example, the Global Warming Potential is a midpoint measure in the context of impacts to humans and ecosystems in the event of climate change. The GWPs also relate to the integrity of the global climate as a LSF - an area of protection in its own right, being supportive to life on earth in a broad sense; still the GWPs may be regarded as midpoint indicators, but now with a high environmental relevance (Udo de Haes and Lindeijer, 2001).

### TRANSPARENCY

The more complex the model, the harder it is to maintain transparency and the greater the level of required documentation. For example, it is not always obvious which toxicological effects are taken into consideration in some endpoint methodologies or which assumptions and value choices are made in the associated chemical fate and exposure models. It may be clarifying to learn that human health effects on endpoint level due to climate change are considered to be mainly due to the expected increase of malaria. A specific problem may be that the value choices encoded into the methodology may not reflect those of the decision maker. Similar arguments may exist in the context of midpoint indicators, including ozone depletion potentials and global warming potentials, but are probably less abundant. It was suggested that methodologies should be as transparent as possible whilst still providing the desired level of accuracy. In the case of complex models, there has to be sufficient consensus within the scientific community that the approaches are acceptable and that the general user does not require detailed documentation. De Leeuw stated for UNEP, "It is not necessary to know how the engine works to drive a car."

Based on the level of modeling alone, the level of transparency associated with midpoint indicators can be considered higher than in endpoint approaches. However, when weighting is required to compare and aggregate across impact categories, the implicit links between the midpoint indicators and the endpoint effects may not always be expressed clearly or represented in a structured fashion. This may impact the robustness of the weighting exercise and the final result. This is another reason to support the use of midpoint and endpoint indicators in one consistent framework (Bare et al., 2000).

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## Human Health and Ecotoxicity

A chemical's fate in the media is the result of numerous complicated processes. Fate models have been developed to simulate transport among and within multiple environmental media. These models are referred as multi-media fate models and are used to evaluate possible damages due to human and ecotoxicity in risk assessment. The cause-effect chain for impacts to ecosystems and human health is presented in Figure 12. This figure shows the influence of human activities on the environment. It illustrates the different paths that cause the total exposure.

In the Brussels workshop, Hertwich opened the session on human and ecotoxicity with his presentation: "A Framework for the Uncertainty Analysis of the Human Toxicity Potential." A framework for uncertainty analysis, which was originally developed for risk assessment (Finkel, 1990) is applied to the exposure modeling component of the Human Toxicity Potential (HTP) (Hertwich, 1999). The HTP is a characterization factor, similar to that goal warming potential, that is used to multiply emissions in a life cycle inventory to obtain a single metric representing the human health hazard (Heijungs et al., 1992). The HTP presents evaluations of hazard based on the toxic potency of a substance and the potential dose in a so-called unit world. In this example, the exposure is calculated using CalTOX (McKone, 1993; Maddalena et al., 1995), a risk assessment model that integrates a multimedia l fate model with a multiple pathway exposure model. He presented various examples of uncertainty analysis as they might pertain to modeling for human toxicity impact assessment in LCIA. He pointed out that simply conducting a sensitivity analysis can often provide valuable insights about the significance of the multiple uncertainties involved in the decision and can help refine impact assessment techniques (Hertwich, 1999).

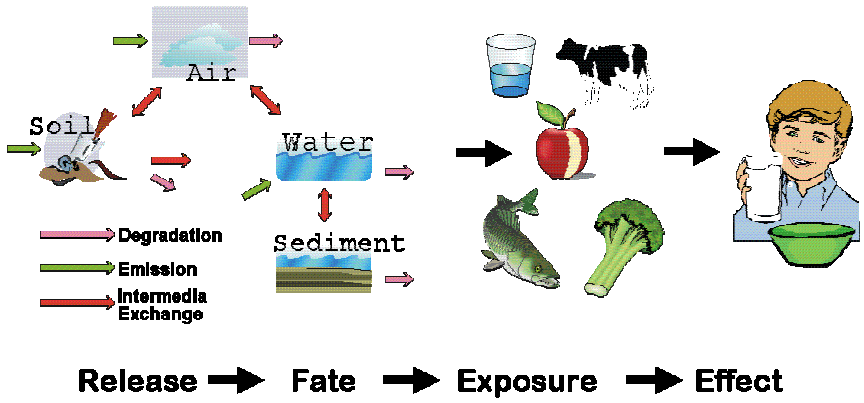


FIGURE 12: CAUSE EFFECT CHAIN FOR ECOSYSTEM AND HUMAN HEALTH (PENNINGTON, BRIGHTON WORKSHOP 2000)

According to EPA (2000), McKone presented "Midpoint vs. Endpoint Modeling of Human Health." McKone compared the two levels by saying that one represented greater relevancy (endpoints) while the other represented greater reliability (midpoints). He pointed out that the field of human health modeling is much more complex than most LCA researchers might realize. Human effects can be deterministic (i.e., effect and severity directly related to exposure, as in a sunburn) or stochastic (i.e. the severity is a question of probability in relation to the effect caused by exposure, as in cancerous effects). He stated that there is a dearth of information in this area - fewer than 30 chemicals have human carcinogenic data

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available, while only approximately 200 chemicals have animal carcinogenic test data. For other chemicals and other types of health effects we have to make highly uncertain estimates of dose-response relationships. He concluded that midpoint models provide more opportunities for scientific validation than endpoint models (e.g., for acidification it is easier to measure pH than to measure affected species) and eventually, midpoint models could be extrapolated into endpoint approaches so long as the resulting loss of reliability is addressed.

Pennington presented "Midpoint vs. Endpoint Issues: Toxicological Burden on Aquatic Ecosystems" in the Brighton workshop. He opened with a discussion that some straightforward approaches based on indicators of implicit concern (usually midpoint indicators such as persistence, bioaccumulation and toxic potency scores) could be used to double check the results of models in LCA that attempt to more explicitly represent the fate and exposure mechanisms of a chemical in the environment, similar to the parallel precautionary index used to check for gaps by Hofstetter (1998). In one cited case study, the limited representation of the aquatic food web in a multimedia model (example Figure 12) had resulted in misleadingly low characterization factors for some chemicals. He concluded that uncertainties (parameter, model and scenario) must be stated before distinctions among alternatives can be expressed and that extreme caution is required when adopting complex LCIA methodologies, as they may not be scientifically robust and can be built on assumptions that add little additional information, or even increase uncertainty.

According to Bare et al. (1999) Jolliet discussed "Human Toxicity and Ecotoxicity Modelling vs. Scoring" in the Brussels workshop. He started by saying, "Tell me your results and I will tell you who paid you!" Then he called for the identification of best available practice regarding impact assessment methods to reduce the ability to provide LCAs that support such malpractice. He also proposed that this process should try to meet the ISO 14042 requirements to be "scientifically and technically valid" and "environmentally relevant." After comparing different human toxicity modeling efforts, he pointed out parameters and model characteristics that are important in human and ecotoxicity modeling, including exposure and fate uncertainties, that can be responsible for significant uncertainty and which open options for reduction of modeling uncertainty by proper empirical or experimental validation. He concluded by saying that modeling comparisons should be made based on model characteristics, consistent data and field validation.

In the Brussels workshop Huijbregts presented a paper on "Priority Assessment of Toxic Substances in LCA: A Probabilistic Approach" (Huijbregts et al., 2000). Citing previous publications (e.g. Guinée et al., 1996 and Hertwich et al., 1998), he suggested that the following specific improvements are needed: a review of default values with the possibility of using more realistic values, an inclusion of all relevant environmental compartments through multimedia models, like (E)USES (Guinée et al., 1996 and Berding et al., 1999), and use of a Monte Carlo type of uncertainty analysis. He presented a probabilistic simulation of weighted human, aquatic and terrestrial Risk Characterization Ratios (RCRs) for 1,4-dichlorobenzene and 2,3,7,8-TCDD (dioxins) and demonstrated that only a few substance-specific parameters are responsible for the uncertainty in results. Finally, Huijbregts concluded that variability is not of significance if it is identical for all options being compared and asked that researchers continue to explore the issue of when data uncertainty/ variability cancel out in relative comparison applications.

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One of the basic limitations of the current state-of-the-science of LCIA of human and ecotoxicity is the inability to effectively deal with potential combinatory effects of chemical mixtures. Toxicologists operate under the assumption that chemicals acting on the same organ can be considered to have an additive effect, but often LCIA impact categories are much broader than a focus on target organs. Therefore, the same assumptions used in risk assessment are not applicable to LCIA. This is especially an issue when practitioners try to incorporate threshold levels for individual chemicals into LCIA. Because mixtures are not well characterized in LCIA, effects may be occurring at much lower levels than the accepted threshold levels of the individual chemicals. Practitioners often try to compensate for these and other model deficiencies by adopting the precautionary principle.

Particularly in human and ecotoxicity, availability and quality of both inventory and chemical data to support the modeling of a large number of chemicals can be frustrating. These impact categories are a good example of where less sophisticated screening techniques may, with an appropriate degree of caution, prove to be useful (Bare et al., 1999).

## Acidification and Eutrophication

A highly simplified example for an acidification environmental mechanism is shown in the Figure 13. $SO_2$ and NOx are converted, by sunlight or hydrolysis, into acids that then are transported in the air and cause acid rain. Depending on the soil neutralizing capacity a lake is or is not acidified. Finally, the acidification of the lake kills fishes what is considered as one or the endpoints of this environmental mechanism.

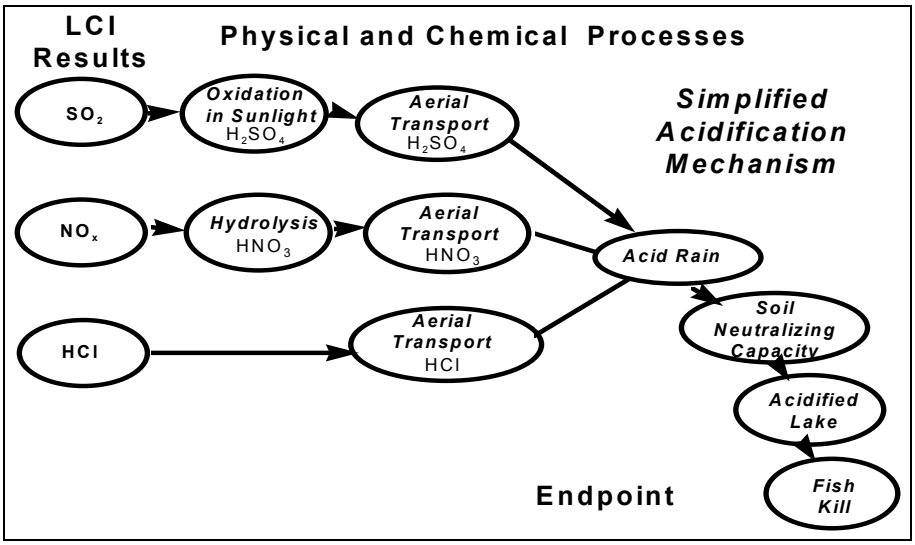


FIGURE 13: EXAMPLE FOR AN ENVIRONMENTAL MECHANISM: ACIDIFICATION (OWENS, BRUSSELS WORKSHOP 1998)

In the Brighton workshop, Norris presented "Midpoint -> Endpoint: Changes in Relative Importance of Pollutant, Location, and Source." Using acidification as an example, he pointed out an analysis in which the location was even more important than the pollutant characteristics. He indicated source class as a possible indicator of location discussed its correlation with other important factors including exposure efficiency. He suggested that source class related information might be used to fill in some of the existing holes in LCA (Bare et al., 2000).

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Potting spoke about different levels of sophistication in Life Cycle Impact Assessment both in the Brussels and the Brighton workshop, taking especially acidification as an example. She suggested a combination of the spatial differentiated or site-dependent midpoint modeling with the site-generic endpoint modelling. Presenting a case study she demonstrated the potential need for site-specific simulations, including emission dispersion and deposition patterns, background depositions on receiving ecosystems, and the sensitivity of receiving ecosystems. She announced that easy-to-use acidification factors had been established for 44 European regions and suggested that utilizing this site dependent approach for acidification resulted in a significant reduction in uncertainty. The level of sophistication in impact assessment can, as mentioned few times during the Brussels workshop, be understood in two ways (see also Potting et al., 1997):

1. The extent to which relevant parameters in the causality chain are taken into account in the characterization factors (i.e. whether the characterization factors are based on no, some or full fate and exposure modeling).
2. The extent to which spatial (and temporal) variation is allowed in each parameter of the modeling underlying the characterization factors

The acidification factors from Potting et al. (1998) are sophisticated in both senses. They cover all the relevant parameters in the causality chain, and they allow a high degree of spatial variation. The application of these acidification factors in life cycle impact assessment is quite straightforward. Each emission is multiplied with the acidification factor for the relevant substance and region. Next the product from all emissions times acidification factors are summed-up to arrive at the total acidifying impact from the analyzed product. Application of the acidification factors from Potting et al. (1998) requires data additional to current impact assessment: The geographical site or region where an emission takes place. The requirement of this additional data is often put forward as an objection against spatial differentiation. However, the geographical site or region where an emission takes place is often provided by current life cycle inventory analysis. Nevertheless, this spatial differentiation may not always be possible or desired. While forehand processes might need a certain degree of site-dependency, this is generally not the case for backhand processes. The mentioned acidification factors can be used also to establish default value per substance and region. It is necessary to adapt LCA software for the application of such factors.

Another approach for region-specifc fate factors was proposed by Huijbregts and Seppälä (2000). Their approach establishes European fate factors for airborne nitrogen compounds that cause aquatic eutrophication.

In the Brussels workshop, in accordance with EPA (2000), Finnveden presented two topics – “Eutrophication – Aquatic and Terrestrial – State of the Art,” and “Thresholds/ No Effect Levels/ Critical Loads.” First, he showed the site dependency of eutrophication in three models, developed since 1993. Then, in his second presentation, Finnveden proposed that thresholds may, at the macro-level, have no scientific basis and in fact may just be “acceptable” levels of risk and thus constitute value choices. Acidification and human toxicity were used as examples of impact categories that should not ignore “below threshold values.” In line with this, he proposed that threshold values should not exist in LCIA for any impact category.

As said in Bare et al. (1999) practitioners have tried to incorporate background levels in LCA studies in the past but there was a lot of discussion that this practice may or may not be appropriate. In line with the point raised by Finnveden, thresholds do exist and if so, one of the questions at hand is whether emissions do

occur above or below thresholds. Another issue concerned the fear that defining backgrounds and thresholds will lead to treating certain environments as infinite sinks when in reality nature's ability to absorb the impact may be exceeded in the future. The distinction was also made that thresholds may be less strict, because of the presence of very sensitive species or human individuals. Thresholds may also not be protective enough in environments in which the combined effects of chemicals may cause impacts at a level lower than the threshold. On the other hand, some participants believed that thresholds might be valuable indicators of relative potency for many chemicals and that thresholds had been derived with statistically sound methods. Further clarification of the decision-making context may be necessary to determine the value of thresholds in particular LCIA applications.

## APPLICATION DEPENDENCY OF LCIA

The reason to perform an LCA study is essentially to use it in support of a decision. A decision gives rise to a change somewhere in society compared to a scenario in which this decision was not taken. The key requirement for LCA in any application is, therefore, that it shall reflect the environmental change caused by the decision. It is found that the need to differentiate LCA methodology for the use in different applications is born by a few key characteristics of the decision to be supported. LCA may have several applications including life cycle management, strategic planning, product development, process design, green procurement and public purchasing, product comparison and marketing.

Life Cycle Impact Assessment as part of an overall LCA can be used to:

- Identify and assist the prioritization of product system improvements,
- Characterize or benchmark a product system and its unit processes over time,
- Make relative comparisons among product systems based on selected category indicators, or
- Indicate environmental issues where other techniques can provide complementary environmental data and information useful to decision makers.

According to Wenzel in his presentation during the Brussels workshop (EPA, 2000) the three governing dimensions of LCIA applications are its time scale, its spatial scale and the need for certainty, transparency and documentation (Figure 14). For instance, eco-labelling is an application that needs certainty, transparency and documention due to the social and economic consequence of the decision, but no time- or site-diferentiation, while for product development the time scale is very important and the spatial scale plays a role. The need for certainty, transparency and documention depends on the specific product.

Furthermore, a key characteristic of the application dependency of LCIA is the environmental consequence of the decision, i.e. the nature and extent of the environmental change caused by the decision, thus giving rise to different requirements, primarily for the scoping of the LCIA. Another key characteristic is the context in which the decision is taken, including the decision maker and interested parties, implicitly influencing impact assessment and weighting.

Goedkoop discussed "Impact Assessment for Ecodesign" in the Brussels workshop (EPA, 2000). He pointed out that the point of conducting an LCA study is typically to determine whether A is better than B. He then presented three problems with LCA and ecodesign:

1. LCA studies are too time consuming;

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2. LCA studies are hard to interpret; and
3. Designers never become LCA experts, but remain dependent upon experts.

His proposed solution for these problems was to calculate pre-defined single scores for the most commonly used materials and processes, and to incorporate uncertainty into the modeling. He also discussed the sometimes hidden role of societal values in characterization modeling, even for internationally agreed upon models. As an example, he presented the three classes of carcinogenics (proven, probable and possible) and pointed out that the practitioner must make a decision about whether to include one, two, or all three classes. He proposed that a single truth does not exist and that modeling is dependent upon the chosen perspective.

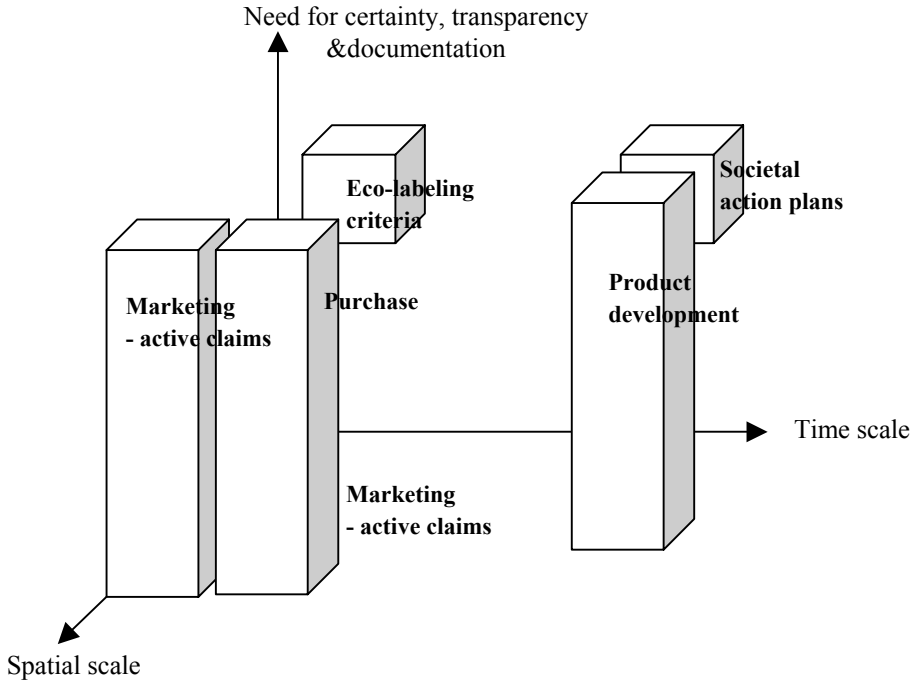


FIGURE 14: LCIA APPLICATIONS IN THREE GOVERNING DIMENSIONS (WENZEL, BRUSSELS WORKSHOP 1988)

Pennington discussed two extremes of LCIA sophistication in the Brussels workshop (EPA, 2000). One extreme he called the "Contribution or Burden" approach, which is comparable to what has been historically used in LCIA (reflecting the precautionary principle and the combinatory potential to cause impacts). As the other extreme, he noted the "Consecutive Risk Assessment" approach, as being particularly recommendable for use in areas with high stakes, such as comparative assertions, but as often limited to the assessment of chemicals in isolation.

## COMPARATIVE ASSERTIONS AND ENVIRONMENTAL CLAIMS

In the Brussels workshop (EPA, 2000), Owens spoke about comparative assertions (i.e., public comparisons between product systems) and the requirements for LCIA under ISO 14042. He stated that ISO 14042 requires a sufficiently comprehensive set of internationally accepted category indicators, a comparison conducted indicator by indicator (i.e. no weighting) and that LCIAs should not be the sole basis for comparative assertions. Current language in ISO 14042 states that

subjective scores, such as weighting across categories, shall not be used for comparative assertions, that category indicators shall be scientifically defensible and environmentally relevant and that sensitivity and uncertainty analyses shall be conducted.

ISO 14040 defines a comparative assertion as an environmental claim regarding the superiority or equivalence of one product versus a competing product that performs the same function. The ISO 14020 series establishes several principles for any environmental claim, including comparative assertions: information will be accurate, verifiable, relevant, and non-deceptive; scientific methods will be used to generate the results; the process is open and participatory; the information is transparent and available to all (e.g., purchasers, interested parties, etc.); any claim is based on measurable differences including consideration of variations and uncertainty; and clear explanatory statements justify and qualify the claim. The 14040 LCA standards and draft standards include these principles.

According to ISO, public comparative assertions have to be based on a full LCA, including an impact assessment phase. They require equivalence between compared systems for functional unit, methodological considerations, performance, system boundaries, data quality, allocation procedures, decision rules on inputs and outputs, and the presence of an impact assessment phase. Together, these requirements establish a fair comparison in the inventory phase that is technically sound, transparent, and non-deceptive.

Each of the mandatory steps used to derive an indicator must be scientifically and technically valid: grouping into impact categories (Classification), converting LCI results (1$^{st}$ Characterization step), and aggregating converted LCI results within an impact category (2$^{nd}$ step). This may present difficulties for several current practices such as aggregation of different types of effects, aggregation of a similar effect from different places and times, and the use of subjective scores. For example, an expert panel to toxicologists of the International Life Science Institute states that it is inherently impossible to make a purely scientific comparison of qualitatively or quantitatively different toxicity impacts (ILSI, 1996). Instead, they suggested explicitly weighing the severity of the different types of impact.

For environmental relevance, ISO 14042 establishes key criteria to meet: the indicator will reflect the actual consequences of the system operation on the category endpoint(s), at least qualitatively. In addition, the category model must incorporate environmental data or information, including: environmental condition of the category endpoint(s); intensity of environmental changes; spatial and temporal aspects such as duration, residence time, persistence, timing, etc.; reversibility; and uncertainty.

ISO also established the requirements for a critical review of any study used for public comparative assertions so that methods used will be consistent with ISO, all methods are scientifically and technically valid, the data are appropriate and reasonable, study interpretations reflect the limitations, and the study report is transparent and consistent. The panel members should be familiar with ISO and have scientific/ technical expertise to address the impact categories covered. There are also extensive reporting requirements for the conduct of a study to ensure transparency, the critical review panel report must be included in the study report, and the report must be made available to all upon request.

In the Brussels workshop (EPA, 2000) there was a belief that the ISO standard on LCIA, specifically for the comparative assertions to be disclosed to the public, is too demanding in the areas of scientific validity and certainty. Examples were given of some other modeling arenas that face the same challenges (e.g., economic modeling, risk assessment studies). In these fields large uncertainties or agreed-

upon value choices are accepted, expected and (sometimes) clearly documented. There was also a concern that the rigor expected of the impact categories without a working international acceptance (e.g., human toxicity) exceeds the rigor and certainty requirements compared with the impact categories that benefit from having international consensus (e.g., global warming potentials).

In the Brighton workshop, Hertwich began his presentation "Judging Environmental Harm: What Evidence should be included?" by stating that all environmental concerns are public and pointed out that statements about the relative or absolute importance of environmental stressors contain three different types of truth claims (Table 6): factual claims, which are based on natural science; normative claims, which refer to preference values; and relational claims, which address the proper relation between factual knowledge and values. Objective arguments can be made about each type of claim. The distinction among different types of claims is important because the methods used to evaluate the credibility of each type differ. Factual truth claims can be assessed using the scientific method. Normative claims can be based on ethical arguments. The values of individuals or groups can be assessed using various social science methods. Relational claims must follow the rules of logic (Herwich et al., 2000).

TABLE 6: THE TYPES OF TRUTH CLAIMS IN LCA AND THEIR ASSOCIATED VALIDITY REQUIREMENTS (HERTWICH, BRUSSELS WORKSHOP 2000)

| | **Factual truth claim** | **Normative claim** | **Relational claim** |
|---|---|---|---|
| **Description** | relates to the correctness of the data and scientific models used in LCA | relates to the representativeness, consistency and appropriateness of (preference) values in LCA | relates to the appropriate use of scientific data and models as well as elicited values to represent our concern about something (relevance, consistency of aggregation) |
| **Example** | The persistence of $CO_2$ in the atmosphere is higher than that of $CH_4$. | We are more concerned about the near-term effects of climate change than about the long-term effects. | Our concerns about climate change are appropriately reflected by the increased infrared absorption resulting from the emissions of a unit of a greenhouse gas integrated over the next 100 years. |
| **Requirement** | Scientific validity<br>An LCA method is scientifically valid if the factual claims contained in it are scientifically valid. | Normative validity<br>An LCA method is normatively valid if the preference values contained in it represent the preferences of actual persons and can be shown to be acceptable in a discussion. | Technical validity<br>An LCA method is technically valid if it combines scientific data and models and preference values in a way that is appropriate, logically correct, consistent, and in agreement with the intentions of LCA. |

According to Hertwich, from the presence of normative elements in LCA, it follows that there exists no unique best impact assessment method. There are different, legitimate sets of preference values and alternative, logically consistent ways of making judgments about facts (Ran, 1998). In addition, our concerns about the environment demand that we include issues about which no scientific consensus exists, e.g. about the causes of observed forest damage. In cases of scientific uncertainty, alternative, legitimate scientific hypotheses may become the factual basis for the assessment (Casman et al., 1999). Contextual and constitutive values will influence the method choice (Shrader-Frechette, 1991).

LCA can be seen as a systematic approach to judging the environmental consequences of consumption (Scheringer, 1999). It is based on factual evidence, but also on a careful consideration and weighting of competing interests and values. The question of the Brighton workshop, whether to model impacts at the midpoint or the endpoint levels, is hence according to Hertwich, ultimately a question about the standard of evidence, but it also concerns the assessment approach and the underlying philosophical perspective (Bare et al., 2000). In contrast to this, Udo de Haes pointed out the need for identifying best available practice, both regarding the factual and the normative aspects. This includes its dependence on the type of application and its time and space characteristics.

### RELATIONSHIP WITH DECISION SUPPORT

The LCIA terminology rather closely connects with terminology used in decision analysis (Keeney, 1992; Hertwich and Hammit, 2001), which starts from the values which are affected. In the framework of these authors the terms stressor, insult, stress, consequence and value lost are used, and in addition the terms attribute and means-ends objective network. In Table 7 the correspondence is given with the terms used in LCIA.

TABLE 7: CORRESPONDENCE BETWEEN TERMS FROM DECISION ANALYSIS WITH THE TERMINOLOGY USED IN LCIA (KEENEY, 1992; HERTWICH AND HAMMITT, 2001).

| Terms used in decision analysis | Corresponding terms used in LCIA |
|---|---|
| Stressor | Environmental intervention (emissions and resources consumption) |
| Insulta and stress | Midpoint |
| Consequence | Endpoint |
| Value lost | Area of Protection |
| Attribute | Category indicator |
| Means-ends objective network | Environmental relevance |

Moreover, according to Bare et al. (2000), communication of the results was recognized as an important factor. For example, indicators at a midpoint level may be preferred for specific communication purposes (e.g. it may be politically preferable to speak in terms of global warming potentials rather than in terms of DALYs.). In general, indicators at endpoint level are often considered to lead to more understandable results; in fact this is connected with the environmental relevance of the indicators, already discussed above. However, indicators at a midpoint level may be more readily communicated in the sense that they will less readily lead to unwarranted conclusions. For instance, global warming potentials

will not lead to an unproven suggestion that malaria will increase in certain regions, in contrast to results in DALYs, which do assume this. In contrast, other practitioners liked the idea of increased specificity of the modeling of associated effects, stating that it may result in increased awareness of the implications of consumption patterns.

When aggregation was considered desirable, there was recognition that conducting comparisons across categories is difficult. Three examples of weighting strategies were discussed at the Brighton workshop:

1. Using normalized midpoint indicators,
2. Using normalized midpoint indicators and in addition using endpoint measures to provide default insights into the relative importance of certain midpoint categories, or
3. Using endpoint indicators.

Many supported the use of both midpoint and endpoint approaches when conducting a weighting exercise.

As also said in Bare et al. (2000) Hofstetter in his presentation during the Brighton workshop pointed to the complications associated with panel methods and the severe limitations in current LCA practices related to their use with both midpoint and endpoint factors. Consequently, during the larger group discussions, the present quality of default weighting factors between impact categories was questioned. Hofstetter stated that endpoint indicators would in general be better understandable to the public. However, he suggested at the same time that it was rather the coverage in the mass media that counts. Therefore, both midpoint and endpoint results can in principle be useful by non-experts, depending on attention they obtain in the mass media.

A far-reaching remark by Hofstetter was that in the weighting stage quantitative and readily available information will have much more influence than qualitative or not-presented information. This would affect both midpoint and endpoint modeling in the moment that they provide qualitative information on environmental relevance (with the midpoint models) or on the gaps of current modeling capacities (in the endpoint models). Norris went even one step further, arguing that non-quantified information cannot and should not be included in a weighting process because it will influence the decision in an uncontrollable way. In order to get clarity on this important issue there is a high need to learn more from experiences in related science fields (Bare et al., 2000).

# Challenges in the current state of LCA and especially LCIA and recommendations on how to overcome them to broaden its use

Part Four

## CHALLENGES

The potential of LCA and therefore also of LCIA as a decision-supporting tool is constrained by a number of barriers both within and outside the LCA community. UNEP identified the costs of LCA studies, the need for methodological expertise and a lack of communication strategies as basic barriers for a broader use of LCA (UNEP, 1999). The relative importance of the barriers differs between countries, between diverse users and between different applications. Countries with less LCA practice are first of all confronted with the absence of any perceived need for LCA, while countries with more extensive LCA experience suffer more from the shortage of data and methodology sharing.

The lessons learned from the workshops demonstrate that in the area of Life Cycle Impact Assessment generally agreed methodological choices would enhance the inclusion of this phase in LCA studies. This is going further than the ISO standard and technical guideline in that field. A framework for the combination of both midpoints and endpoints and an inadequate detailing of questions with respect to time and space is missing. Moreover, there is a lack of easy assessable high-quality LCI data that would also improve the reliability of LCIA outcomes. Finally, guidance is required on the interactions and interfaces of LCIA with other tools as environmental risk assessment, since various experiences in companies have shown that the use of LCA as a stand alone tool is limited to some applications in environmental management and that the results of the application of different tools might even be contradictory.

To overcome these barriers, action is needed in education and communication, in public policies, and in the further scientific clarification and development of Life Cycle Impact Assessment, LCA in general and related "ecotools." Therefore recommendations have been elaborated for appropriate actions based on the outcomes of the UNEP workshops, further discussions within the LCA community and cooperation with the Society of Environmental Toxicology and Chemistry (SETAC), particularly the working group on LCIA (Udo de Haes et al., 1999). This working group expressed a clear need for best or recommended practice regarding LCIA.

### Absence of a perceived need for LCA

A general lack of environmental awareness and a lack of drivers for chain management are the most fundamental barriers to the use of LCA. The level of the driving forces also differs considerably among countries, and among organizations and companies. The lack of commitment to LCA, or more generally to environmental chain management, at the top of these institutions and the lack of a procedural incorporation of LCA in policy strategies are major barriers.

Political problems may arise in the case of policies based on life-cycle considerations, for example in the shape of eco-labels or ecotaxes on products. One major impediment for life-cycle-based policies is the "Stockholm Principle," which states that every country is responsible for its own resources, as long as it causes no harm to any other country. Life-cycle considerations may thus be regarded as undue meddling in other countries' internal affairs. A related complication is the

Part Four

World Trade Organization agreement that forbids discrimination – especially when domestic production is favored, either intentionally or unintentionally, for instance on the basis of environmental information.

### Scarcity of LCA expertise/ know-how

The scarcity of expertise for performing and understanding LCA studies is a particular problem in developing countries, as well as for Small and Medium-sized Enterprises (SMEs) and policy makers. Communication about the LCA methodology and the LCA outcome is also a problem. The complexity of the LCA model often makes decision makers lose sight of the overall picture because they cannot follow how the outcomes are reached and what the implications are of some particular choices. Also the small number of participants from the Southern hemisphere in the UNEP workshops on LCIA demonstrates the need for a global technology transfer.

### Costs of LCA studies

The high level of expert knowledge required by the method complexity (including LCIA issues), the large data demand, and the related costs for the experts and the purchasing of data from commercial databases (intellectual property) creates a picture of LCA as a very costly affair. In addition, the ISO requirements on review procedures increase the cost burden of LCA. This may result in the perception that the cost/ benefit ratio for carrying out an LCA is too high.

### Difficult access to high-quality data

Data quality and availability is one of the major practical bottlenecks in LCA studies. This is especially true for developing countries and SME's. Some data for LCA studies is in the public domain, others not; their value depends on their quality and on their relevance to the user's needs and options. Especially, there is a lack of consistent and peer reviewed international level databases of Life Cycle Inventories on a wide range of processes, materials and products, since in the present globalized economy the products are traded worldwide. Also for improving the reliability of the applications of LCIA methods in LCA studies the availability of high-quality data is an indispensable requirement.

### Lack of user-friendly and widely recognized LCIA methodologies

Methodological barriers in LCIA are related to the lack of generally agreed methodological choices, an inadequate detailing of available methods with respect to time and space, and the complexity of the method itself. This may imply that subjective choices are made, which may influence the outcome. The ISO standardization does not solve this problem. Moreover, scientific knowledge from related multidisciplinary fields as collected and discussed in SETAC (e.g. Udo de Haes et al., 1999), is insufficiently incorporated into Life Cycle Impact Assessment methods.

The workshops showed that the uncertainties are high in the current models and derived factor, which does not stimulate decision makers in relying on them. In general, there is a trade-off between the accuracy of impact assessment and the practicability of spatial differentiated methods for use in a life cycle perspective. A minimum requirement is transparency. The need has been identified for international guidance on levels of sophistication and for a consistent and encompassing framework of environmental processes and Areas of Protections enabling the choice of category indicators at different midpoint and endpoint levels.

## Unclear perception of the applications of LCA in relation to other tools

There is an unclear perception of the applicability of LCA and its relationship to other tools. Sophisticated LCIA methods for example are frequently compared to environmental risk assessment studies. Only a few integrated approaches have been proposed so far. Expectations of LCA as a universal tool may lead to disappointments, which can be a drawback for the general acceptance of the LCA tool. Furthermore, the adoption of LCA for investment- and strategy-oriented decisions requires broadening the scope of LCA. These types of decisions often deal with multiple functions not yet specified, and concern long-term questions with changing surrounding technologies. An international agenda for companies to orient their life cycle related activities is missing. This would also put LCIA in a broader picture (Wrisberg et al., 2002).

### RECOMMENDATIONS

The fundamental barrier is the absence of a perceived need for LCA and hence also for LCIA. The easiest way to address this would be by developing a broader market for LCA, recognizing that LCA does not always serve the objectives of prospective users. A distinction can be made between the following necessary steps: raising environmental awareness, understanding LCA, acceptance of LCA, and creating incentives. This implies activities such as the launching of communication and education programmes; the diffusion of LCA studies and experiences to make decision makers aware of the benefits; the involvement of stakeholders in LCA processes to improve their acceptance of the LCA outcome, and the procedural incorporation of LCA in policies to stimulate its use in the public arena.

Furthermore, one should aim at a targeted promotion. The ecological gatekeepers, the intermediate actors between industry and consumers, should advocate environment orient chain management. LCA is a decision-supporting tool, but its role in the decision making process is not sufficiently developed. LCA should be incorporated into procedures such as Environmental Management Systems, and policy makers should start to incorporate LCA into environmental policy making. A further point is that the economic incentives can be enhanced by subsidies to developing countries and SMEs to enhance LCA capacity.

In the purpose of stimulating the global use of LCA and overcoming the identified challenges, in April 2002, UNEP and SETAC, the Society of Environmental Toxicology and Chemistry, the leading scientific association in the field of LCA, launched the Life Cycle Initiative on approaches and best practice for a life cycle economy. Folllowing the ideas of the initative the focus in the area of Life Cycle Impact Assessment should be on best practice with regard to the characterization of emissions, resources extractions and land use, that means on the aggregation by adequate factors of different types of substances in a selected number of environmental issues, or impact categories such as resource depletion, climate change, acidification or human toxicity. The methodology should be adapted in general to fulfill also the requirement of developing countries.

# Conclusions

There have been a number of advances made in the evaluation of environmental impacts in Life Cycle Assessment in recent times:

- The framework for Life Cycle Impact Assessment has become standardized in ISO, enhancing the comparability and avoiding unnecessary variation between studies.
- The fate of substances is increasingly taken into account, in particular using multimedia modeling as a basis for characterization.
- The results of different characterization procedures for the same category are compared among each other and they show convergence.
- Better distinctions are being made between scientific information and value choices.

These developments are leading to advances in the practice of LCIA, but the major limitations and uncertainties cannot be expected to go away in the near future. Instead, practitioners must learn how to best address the concerns and limitations of the methodologies. As in risk assessment, there is great attention to being true to the science, but in the interest of practicality, a great need for simplifying assumptions. An increasing level of sophistication can increase model certainty, but, in some cases, may reduce the comprehensiveness.

There is a general agreement that one cannot validate the results of a single LCIA study, because of the lack of temporal and spatial specification associated with the inventory data, and an inability to accurately model complex interactions in the environment, including the combinatory effects of chemical mixtures. However, input data can be quality checked, and elements in the models can be compared with models developed in the context of other applications such as environmental risk assessment. Thresholds reflect value choices about what is regarded acceptable, rather than science based parameters.

A consensus was reached by the LCIA experts that both midpoint and endpoint level indicators have complementary merits and limitations:

- Both types of approaches have their specific value.
- Midpoint approaches give results which are relatively certain (although sometimes still quite uncertain), but which generally are less environmentally relevant because they focus on variables that are generally far removed from the endpoints, which directly matter to society.
- Endpoint approaches on the other hand give results that are expressed in very relevant terms, but are relatively (to extremely) uncertain.
- It would be an important step further if one encompassing framework could be developed, including the most important variables of both types of approaches, thus enabling modeling along the two approaches and comparing the results with each other.

The level of sophistication might depend upon the type of application and the availability of data; a consistent internationally accepted methodology framework would help to make easier the comparability between studies. However, the establishment of methods as basis for best practice should not discourage further research efforts. Besides, certain studies may only require life cycle thinking and therefore, are not subject to sophisticated methodologies.

# Appendices

Appendix 1: LCA for beginners

# LCA for Beginners

LCA methodology according ISO 14040 consists of the following phases:

The **Goal and Scope Definition** phase is designed to obtain the required specifications for the LCA study: what questions do we want to answer and who is the intended audience? The following steps must be taken:

1. *Defining the purpose of the LCA study*, ending with the definition of the functional unit, which is the quantitative reference for the study.
2. *Defining the scope of the study,* which includes the drawing up of a flowchart of the unit processes that constitute the product system under study, taking into account a first estimation of their inputs from and outputs to the environment (the elementary flows or burdens to the environment).
3. *Defining the data required*, which includes a specification of the data required both for the Inventory Analysis and for the subsequent Impact Assessment phase.

The **Inventory Analysis** collects all data of the unit processes of the product system and relates them to the functional unit of the study. The following steps must be taken:

1. *Data collection*, which includes the specification of all input and output flows of the processes of the product system, both product flows (i.e. flows to other unit processes) and elementary flows (from and to the environment).
2. *Normalization* to the functional unit, which means that all data collected are quantitatively related to one quantative output of the product system under study, most typically 1 kg of material is chosen, but often other units like a car or 1 km of mobility are preferable.
3. *Allocation*, which means the distribution of the emissions and resource extractions of a given process over the different functions which such a process, e.g. petroleum refining, may provide.
4. *Data evaluation*, which involves a quality assessment of the data, e.g. by performing sensitivity analyses.

The result of the Inventory Analysis, consisting of the elementary flows related to the functional unit, is often called the "Life Cycle Inventory (LCI) table".

The **Impact Assessment** phase aims to make the results from the Inventory Analysis more understandable and more manageable in relation to human health, the availability of resources, and the natural environment. To accomplish this, the inventory table will be converted into a smaller number of indicators. The mandatory steps to be taken are:

1. *Selection and definition of impact categories*, which are classes of a selected number of environmental such as global warming or acidification.
2. *Classification*, comprising the assignment of the results from the Inventory Analysis to the relevant impact categories.
3. *Characterization*, which means the aggregation of the inventory results in terms of adequate factors, so-called characterization factors, of different types of substances in the impact categories, therefore a common unit is to be defined for each category, the results of the characterization step are entitled the environmental profile of the product system.

The **Interpretation** phase aims to evaluate the results from either Inventory Analysis or Impact Assessment and to compare them with the goal of the study defined in the first phase. The following steps can be distinguished:

1. *Identification* of the most important results of the Inventory Analysis and of the Impact Assessment.

2. *Evaluation* of the study's outcomes, consisting of a number of the following routines: completeness check, sensitivity analysis, uncertainty analysis and consistency check.

3. *Conclusions, recommendations and reporting*, including a definition of the final outcome; a comparison with the original goal of the study; the drawing up of recommendations; procedures for a critical review, and the final reporting of the results.

The results of the Interpretation may lead to a new iteration round of the study, including a possible adjustment of the original goal.

**Users** of the LCA methodology are:

### Industry

At present, LCA is primarily used by companies (company internal use) to support their environmental decision making. The most frequent applications are related to:

- design, research and development,
- comparison of existing products with planned alternatives, and
- providing information and education to consumers and stakeholders.

Companies first of all use LCA for incremental product improvements and not for real product innovation, i.e. so far LCA is barely used for the complete redesign of existing concepts and even less for alternative fulfillment of functionality.

**Case Study. Higher materials and transport efficiency by compact detergents (UNEP, 1999)**

In Germany in 1994, Procter & Gamble compared conventional and compact detergents, and were able to show that compact detergents yearly save 815,000 tones (30%) of raw materials, 40,700 tours of trucks and 53 million MJ of energy. The company fosters the production and marketing of compact detergents.

Increasingly, the manufacturer of a product is held responsible for its manufacturing operations as well as for the uses of the product and how it is disposed. This chain responsibility has been formalized in some countries as an obligation to 'take back' the product and its packaging (electrical and electronic industry in EU, for example). This responsibility can also extend to the upstream process of a product. Companies are increasingly looking at supply chain management as a way to improve environmental performance. For a producer to address these concerns, an LCA can play a critical role in helping them to identify and quantify the issues involved.

### Government

At present the main role of LCA in policy development is in environmental labeling and the formulation of regulations on product policy and waste management. However, there are high expectations of its future significance in a number of other policy areas – such as green government purchasing, eco-

management, green design guidelines and awards, and sector benchmarking. The significance of LCA will increase when it is a part of a standard decision-making procedure.

The public sector is undertaking LCAs in relation to policy development, for example in product and waste policy (UK and Germany); for procurement of environmentally preferable products (USA); in directives for waste management (EU waste directive) and cleaner production (EU IPPC- Integrated Pollution Prevention and Control). Furthermore, LCA has been used in sector covenants between the public and industrial sectors, such as the Dutch packaging covenant

Overall, governments are seen to have a responsibility in promoting LCA because of its potential to achieve environmental improvements for a sustainable development. LCA is one of the few tools that can be applied to both the economic and environmental aspects of a product. The use of a well-developed LCA framework will allow governments to address social and economic sustainability indicators on a product level.

### Consumers and consumers organizations

Consumers and consumer organizations express their need for environmental information in order to make (ecological) product choices and to establish guidelines for how to achieve a more sustainable consumption pattern. However, consumers do not make environmental assessments entirely by themselves, but rely to a large extent on consumer organizations and on other organizations issuing ecolabels. The use of LCA by consumer organizations is not very widespread due to their limited resources and access to data: however, when LCAs are available, their results are used to support decisions related to products, investments or strategy development. LCA may indirectly, through ecolabeling and comparative publications by consumer organizations, support consumers in their decision-making in relation to product- and investment-oriented decisions.

**Case Study. Successful application of LCA by a public body: The Dutch Packaging Covenant (UNEP, 1999)**

A number of LCA studies comparing one-way packaging systems with recycling systems have been carried out in the context of the Dutch packaging covenant, involving different actors in the packaging chain. The results were quite different for various application situations. For instance, hybrid systems consisting of one-way packaging in combination with a durable container at home, scored relatively well. Moreover, the LCA studies identified environmental weak points in packaging, which have lead to product improvements in a number of cases.

Besides the standards related to Life Cycle Assessment there are other environmental management ISO 14000 standards that are valid for product systems. These are especially ISO 14020 and 14021 as well as ISO 14024 and 14025 that are defining standards for using environmental labels. An overview of relevant ISO 14000 standards for evaluating product systems is given in the Table.

TABLE: ISO 14000 STANDARDS RELATED TO PRODUCT SYSTEMS

| Using environmental declarations and claims  | Conducting life cycle assessment (LCA)  | Understanding the standards  |
|---|---|---|
| **ISO 14020**<br>This document provides general principles which serve as a basis for the development of ISO guidelines and standards on environmental claims and declarations. | **ISO 14040**<br>This document provides the general principles, framework and methodological requirements for the LCA of products and services. | **ISO 14050**<br>This document helps an organization to understand the terms used in the ISO 14000 series standards. |
| **ISO 14021**<br>This document provides guidance on the terminology, symbols and testing and verification methodologies an organization should use for self-declaration of the environmental aspects of its products and services. | **ISO 14041**<br>This document provides guidance for determining the goal and scope of an LCA study, and for conducting a life cycle inventory. | |
| | **ISO 14042**<br>This document provides guidance for conducting the life cycle impact assessment phase of an LCA study. | |
| **ISO 14024**<br>This document provides the guiding principles and procedures for third-party environmental labeling certification programs. | **ISO 14043**<br>This document provides guidance for the interpretation of results from an LCA study. | |
| **ISO/ TR 14025**<br>This document provides guidance and procedures on a specialized form of third-party environmental labeling certification using quantified product information labels. | **ISO /TR 14047**<br>This document provides illustrative examples on how to carry out Life Cycle Impact Assessment. | |
| | **ISO /TR 14048**<br>This document provides information regarding the formatting of data to support life cycle assessment. | |
| | **ISO /TR 14049**<br>This document provides examples that illustrate how to apply the guidance in ISO 14041. | **ISO Guide 64:1997**<br>This document helps the writers of product standards to address environmental aspects in those standards. |

Appendix 2: Bibliography

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This bibliography covers recent LCA publications and is divided into the following sections:

- References for citations in the text
- Introductory Reading
- General Methodology and Development
- Software and Life Cycle Inventory data
- Life Cycle Impact Assessment
- Possible Applications
- Case Studies
- Regional Activities on LCA

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Appendix 3: Internet Resources

# Internet Resources

CHAINET - European network on chain analysis for environmental decision support.
http://www.leidenuniv.nl/interfac/cml/chainet/

ECOCYCLE, A newsletter that shares information on policy and technical issues related to product environmental life-cycle management (LCM). Last issue Fall/Winter 1999.
http://www.ec.gc.ca/ecocycle/

Ecosite - The self acclaimed "World Wide Resource for LCA" that has not been updated since 1997.
http://www.ecosite.co.uk/

European Environment Agency - Use Search to find LCA information
http://www.eea.eu.int/

Global Development and Environment Institute at Tufts University
http://ase.tufts.edu/gdae/

International Network for Environmental Management
http://www.inem.org/

LCANET European Network for Strategic Life Cycle Assessment Research & Development. Last update 1997.
http://www.leidenuniv.nl/interfac/cml/lcanet/hp22.htm

Life Cycle Assessment Links – Broad spectrum of information for further details
http://www.life-cycle.org

Official ISO Technical Committee (TC) 207 site
http://www.tc207.org/home/index.html

SPOLD - The Society for Promotion of Life-cycle Assessment
http://www.spold.org/

Sustainable Development - Large index of Sustainability web sources.
http://www.ulb.ac.be/ceese/meta/sustvl.html

The Global LCA Village An electronic conference that serves as an intelligent platform for discussing leading topics in the area of LCA.
http://www.ecomed.de/journals/lca/village/aboutLCAvillage.htm

The L C A hotlist - A comprehensive list of LCA sources.
http://www.unite.ch/doka/lca.htm

The LCA Website - Steve Young's not so old LCA website updated in January of 1998:
http://www.trentu.ca/faculty/lca

WWW site associated with LCA and ecodesign - Another site that has not been updated since 1998:
http://love.kaist.ac.kr/~kcr/links.htm

Appendix 4: LCA based electronic Tools

# LCA based electronic Tools

The tools have been divided into four sections:

## Life Cycle Inventory Tools:

- ***The Boustead Model***

  A basic MS DOS based software package with one of the largest database available. All information is collected from industry through questionnaires. Data from over 23 countries is available which makes Boustead a very international oriented tool.

  Contact details:

  Tel: +44 1403 864561
  Boustead Consulting
  Fax: +44 1403 865284
  http://www.boustead-consulting.co.uk

- ***Euklid***

  The Euklid developers limit the process to an inventory. The software package is based on SQL Database with object oriented program structure.

  Contact details:

  Frauenhofer-Institut für Lebensmitteltechnologie und Verpackung
  Tel: +49 8161 491 300
  Fax: +49 8161 491 33
  http://www.ilv.fhg.de

- ***JEM-LCA***

  Inventory tool aimed at the electronics sector with a limited database developed at NEC. Software system based on an inventory and process tree principle.

  Contact details:

  Ecology based Systems Research Laboratory, NEC Corporation
  Tel: +81 3 38327085
  Fax: +81 3 38327022
  http://www.nec.co.jp

## Full LCA:

- ***EDIP LCV tool:***

  Developed for use in product development, EDIP is a software tool based on three groups: database, modeling tool and calculation facilities. Available in English and Danish.

  Contact details:

  Institute for Product Development (IPU)
  Tel: +45 45 932522
  Fax: +45 45 932529
  http://www.dtu.dk/ipu

# Appendix 4: LCA based electronic Tools

- ***LCAiT:***

  Simple graphics based software that allows the user to set up a product life cycle graphically and allows material and input/output balances. Because of a windows-type drop and drag system, copying cards between different studies is possible and easy to do.

  Contact details:

  Chalmers Industriteknik CIT
  Tel: + 46 31 7724000
  Fax: + 46 31 827421
  http://www.lcait.com

- ***GaBi:***

  Software system designed to create Life Cycle balances, covering both environmental and economical issues. The structure can be set up to support the ISO 14040 standards. Two possible databases and further add-on modules.

  Contact details:

  Institut für Kunststofprüfung und Kunststofkunde & Product Engineering GmbH (IKP), Universität Stuttgart
  Tel: +49 711 6412261
  Fax: +49 711 6412264
  http://www.ikp.uni-stuttgart.de

- ***KCL ECO:***

  KCL ECO operates on a process of modules and flows, each flow consists of a number of equations that represent masses and energies moving between two modules. The software works especially well when applied to small products and has a clear presentation style.

  Contact details:

  The Finnish Pulp and Paper Research Institute KCL
  Tel: +358 9 43711
  Fax: +358 9 464305
  http://www.kcl.fi

- ***LCAdvantage:***

  The software system consists of a graphical interface based on links, representing material and energy flows between modules that represent components out of products. The software also has a report generator, and contains a high degree of transparency and documentation on the information provided.

  Contact details:

  Pacific Northwest National Laboratory
  Tel: +1 509 3724279
  Fax: +1 509 3724370
  http://www.battelle.com

- ***PEMS:***

  It is based on graphical flowcharts representing a product life cycle in four units: manufacture, transportation, energy generation and waste management. The database is transparent and allows the user to insert new information.

Contact details:
PIRA International
Tel: +44 1372 802000
Fax: +44 1372 802245
http://www.pira.co.uk

- ***Simapro:***

  The database is transparent and the program allows the results to be displayed in different formats such as after classification or characterization. Simapro is a software package that comes with extensive instruction material, which includes an operating manual for the program, the database and the methodology itself.

  Contact details:
  Pré Consultants BV
  Tel: +31 33 4555022
  Fax: +31 33 4555024
  http://www.pre.nl

- ***TEAM:***

  TEAM is a software package with an extensive database and a powerful and flexible structure that supports transparency and sensitivity analyses of studies. Ecobalance offers to insert company data into the database.

  Contact details:
  The Ecobilan Group / Pricewaterhouse Coopers
  Tel: +44 1903 884663
  Fax: +44 1903 882045
  http://www.ecobalance.com

- ***Umberto:***

  Umberto is a multi-purpose Life Cycle Assessment package capable of calculating material flow networks. Uses a modular structure and offers clear transparent results. User starts by setting up a life cycle model after which the process units and materials can be selected.

  Contact details:
  IFEU Institut für Energie und Umweltforschung Heidelberg GmbH
  Tel: +49 6221 47670
  Fax: +49 6221 476719
  http://ourworld.compuserve.com/homepages/ifeu_heidelberg/ifeu_eng.htm

## Abridged LCA:

- ***Eco-indicator:***

  It is a manual for designers with background information on life cycle assessment. It contains a limited amount of data but allows simple Life Cycle Impact evaluation studies and helps designers understand the fundamentals of life cycle thinking.

  Contact details:
  PRé Consultants BV
  Tel: +31 33 4555022
  Fax: +31 33 4555024
  http://www.pre.nl

# Appendix 4: LCA based electronic Tools

- ***MET Matrices Method:***

  The MET matrices are a simple method of assessing and prioritizing environmental impacts of products or processes. By filling in two simple 4X4 matrices, the main causes of environmental impact can be determined (a reasonable level of background knowledge is required).

  Contact details:

  See: Brezet, H & van Hemel, C. Ecodesign: a promising approach to sustainable production and consumption , ISBN 928071631X, UNEP, Paris.

- ***AT&T product improvement matrix and target plot:***

  It is similar to the MET matrices, but it is more systematic. The matrix consists of questions and a scoring system, requiring the user to grade certain aspects of a product or process design. The scoring system produces a target plot that indicates the areas most suited for improvement.

  Contact details:

  Method available in book "Industrial Ecology" by T.E. Graedel, 1995, New Jersey: prentice Hill.

- ***Ecoscan 2.0:***

  Ecoscan is a software tool that produces LCA studies of products and processes only in evaluated format. This simplified approach allows evaluation and comparison of products through evaluation methods only and provides no information on characterization or classification level.

  Contact details:

  Martin Wielemaker
  Tel: +31 10 2651178
  Fax: +31 10 4651591
  http://www.luna.nl/turtlebay

## Specialized LCA tools:

Specialized LCA tools are basically the same as normal LCA tools, but the databases are oriented towards a particular product. The majority is for the packaging sector and waste management, but they can be used and adapted for other products (most of them have an interactive database that you can add to yourself).

- ***Ecopack 2001-06-22:***

  The successor of Ecopack 2000, based on the data sets created by the Swiss EPA, BUWAL. The sets SRU 133 and SRU 250 are based on material production, energy carriers and transportation, all used in packaging industry.

  Contact details:

  Max Bolliger Consulting
  Tel: +41 41 6722477
  Fax: +41 41 6722477

- ***Ecopro 1.4:***

  Software based on flow chart principle, systems can be built out of either process or transport modules. The user can add own information to the database and several methods of impact assessment are available.

# Appendix 4: LCA based electronic Tools

Contact details:
EMPA / Sinum GmbH
Tel: +41 71 2747474
Fax: +41 71 2747499
http://www.empa.ch

- ***Repaq:***

  Life Cycle Inventory tool with database containing information on packaging materials from US. User can set up functional unit type description of packaging system, specify materials/ fabrication method and insert additional information.

  Contact details:
  Franklin Associates Ltd.
  Tel: +1 913 6492225
  Fax: +1 913 6496494
  http://www.fal.com/

- ***EIME:***

  It has been developed for the design of electronic products. By using a network set-up, the tools allows environmental managers to select priority issues which will be enforced by "to do" and "do not" reminders during the design process.

  Contact details:
  The Ecobilan Group / Pricewaterhouse Coopers
  Tel: +33 1 53782347
  Fax: +33 1 53782379
  http://www.ecobalance.com

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Appendix 5: Scientific Articles

# Scientific Articles

## Life Cycle Impact Assessment Sophistication – International Workshop

**Jane C. Bare[1], David W. Pennington[2], and Helias A. Udo de Haes[3]**

[1]Corresponding author: U.S. Environmental Protection Agency, National Risk Management Research Laboratory, Cincinnati, Ohio 45268, USA. Email: bare.jane@epa.gov

[2]ORISE Research Fellow, U.S. Environmental Protection Agency, National Risk Management Research Laboratory, Cincinnati, Ohio 45268, USA.

[3]Centre of Environmental Science (CML), Leiden University, P.O. Box 9518, NL-2300 RA Leiden, Netherlands.

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### Abstract

On November 29 - 30, 1998 in Brussels, an international workshop was held to discuss Life Cycle Impact Assessment (LCIA) Sophistication. Approximately 50 LCA experts attended the workshop from North America, Europe, and Asia. Prominent practitioners and researchers were invited to present a critical review of the associated factors, including the current limitations of available impact assessment methodologies and a comparison of the alternatives in the context of uncertainty. Each set of presentations, organized into three sessions, was followed by a discussion session to encourage international discourse with a view to improving the understanding of these crucial issues. The discussions were focused around small working groups of LCA practitioners and researchers, selected to include a balance of representatives from industry, government and academia.

This workshop provided the first opportunity for International experts to address the issues related to LCIA Sophistication in an open format. Among the topics addressed were: 1) the inclusion or exclusion of backgrounds and thresholds in LCIA, 2) the necessity and practicality regarding the sophistication of the uncertainty analysis, 3) the implications of allowing impact categories to be assessed at "midpoint" vs. at "endpoint" level, 4) the difficulty of assessing and capturing the comprehensiveness of the environmental health impact category, 5) the implications of cultural/philosophical views, 6) the meaning of terms like science-based and environmental relevance in the coming ISO LCIA standard, 7) the dichotomy of striving for consistency while allowing the incorporation of state-of-the-art research, 8) the role of various types of uncertainty analysis, and 9) the role of supporting environmental analyses (e.g., risk assessments). Many of these topics addressed the need for increased sophistication in LCIA, but recognized the conflict this might have in terms of the comprehensiveness and holistic character of LCA, and LCIA in particular.

### Introduction

A UNEP Workshop titled "Towards Global Use of LCA" was held on June 12 - 13, 1998 in San Francisco. The purpose of the San Francisco workshop was to develop recommendations and an action plan that would lead towards a greater use

of LCA in the context of sustainable development. At the end of the San Francisco workshop, each of the participants was asked what actions could lead to greater development and use of LCA in sustainable development decision making. One of the many ideas suggested was to provide a forum for an International discussion of the appropriate practice of LCIA. LCIA Sophistication was taken up as subject of the workshop held in Brussels, which was attended by approximately fifty LCA practitioners and experts from various countries.

Practitioners of LCA are faced with the task of trying to determine the appropriate level of sophistication in order to provide a sufficiently comprehensive and detailed approach to assist in environmental decision making. Sophistication has many dimensions and dependent upon the impact category, may simulate the fate and exposure, effect and temporal and spatial dimensions of the impact. (Udo De Haes, 1999a, Owens, et al., 1997, Udo de Haes, 1996, Fava, et al., 1993) In the context of the Brussels workshop, sophistication was considered to be the ability of the model to accurately reflect the potential impact of the stressors, or in language more consistent with recent ISO publications, the ability to reflect the environmental mechanism with scientific validity. (ISO, 1999)

The impact assessment phase of LCA, termed LCIA, helps decision-makers interpret inventory data in the context of a number of impact categories and to bring them into a more surveyable format. Ideally, an LCIA would be based on high quality data. All impact categories and processes in the environmental mechanism of each of these categories would be considered using state-of-the-art techniques, which would fully account for spatial and temporal variation. In such an Ideal World, decisions would be made based on these assessments with a high level of confidence and certainty. However, real world practitioners have to deal with limitations (e.g., budget, and poor quality data) and simplifications are made. Some modifications may include: 1) reduction in spatial and temporal discrimination (or ignoring these dimensions altogether), 2) ignoring fate, 3) assuming linear dose-response curves and/or 4) eliminating an impact category because appropriate data or assessment methodologies do not exist.

While ideally an impact assessment should be sophisticated in all dimensions, this high level of sophistication requires exhaustive time, data, and resources and generally cannot be reached due to limitations in methodology and data available. Hence, the scope of the assessment needs to be defined, possibly iteratively, to provide the appropriate level of sophistication, including the required level of detail and accuracy, together with an uncertainty analysis practical for individual studies, and the specification of value choices within the framework of the LCA. Appropriate definition of this scope, including sophistication, uncertainty analysis, and comprehensiveness is the key to effective environmental decision making.

Many practitioners in the past have attempted to evaluate impacts to support broad LCA-based decisions, but have oversimplified the impact assessment step. Unfortunately, limitations in simulation sophistication lead to a reduced ability of the study to answer the questions at hand with a high degree of certainty. In the absence of accompanying uncertainty analysis, and validation (which addresses model uncertainty) many LCAs are conducted at such a low level of simulation sophistication that they are ineffectual in differentiating the very options they are trying to evaluate. (Coulon, 1997; Potting, 1997, Udo de Haes, 1996) Workshop participants also discussed the dichotomy of sophistication and comprehensiveness. As an example, very simplistic methods such as relying solely on toxicity data may allow a larger chemical database set than a more sophisticated approach which would require additional chemical and physical properties to determine the relative human health potentials.

More recently, researchers are recognizing the many types of uncertainty involved in environmental decision making. Two types of uncertainty discussed at this workshop were model uncertainty and data uncertainty. Data uncertainty may be estimated by the propagation of uncertainty and variability of the input parameters. Model uncertainty can only be characterized by comparison of the model prediction with the actual response of the system being addressed. As data uncertainty is relatively easy to characterize, whereas model uncertainty is difficult, especially in a field like LCIA, the presentation of data uncertainty alone may not appropriately be used to compare two methodologies. For example, a simplistic approach utilizing only persistency, bioaccumulation, and toxicity data may appear to be more certain when compared in terms of data uncertainty to a more complex multimedia/human exposure approach, but the unaddressed model uncertainty may significantly overshadow the data uncertainty.

The specification of value choices has a bearing on the level of sophistication and has been the subject of many recent papers. (Owens, 1998, Finnveden, 1997, Volkwein, 1996a, Volkwein, 1996b, Powell, 1996, and Grahl, 1996) Some practitioners are uncomfortable with the subjectivity of the Valuation Process, but fail to recognize the role of subjectivity in other phases of the LCA framework. All LCAs are conducted under the influence of subjective decisions. In fact, subjective decisions, value choices, or scientific or engineering judgements are made throughout the LCA process. Thus, the selection, aggregation, or disaggregation of impact categories and the determination of the methodologies to quantify the potential impacts are all influenced by value choices. The Brussels workshop was chosen to explicitly address the incorporation of value choices within the LCA process.

Unfortunately, the important issues of deciding the appropriate level of sophistication often remain unaddressed in LCIA. The determination of the level of sophistication is often not based on sound and explicit considerations, but on practical reasons (e.g. the level of funding, level of in-house knowledge). The workshop was therefore formulated to allow a more explicit discussion of the many factors outlined above that can influence the choice of the level of sophistication of a study, including:

- The project objective
- The perceived value placed on the specific impact categories
- The availability of inventory data and accompanying parameters
- The depth of knowledge and comprehension in each impact category
- The quality and availability of modeling data
- The uncertainty and sensitivity analyses
- The level of validations
- The available supporting software
- The level of funding

This paper provides a summary of the results of this workshop, including discussion on many of the above topics. An attempt is made to provide short reviews of the presentations and discussions. However, in documenting the workshop it was not possible to capture the full detail of the many points raised. For a more detailed coverage including overheads and summary papers, the reader is encouraged to e-mail the corresponding author.

Appendix 5: Scientific Articles

## Workshop Logistics

On the 29th and 30th of November, 1998 in Brussels, Belgium an international workshop was held to discuss Life Cycle Impact Assessment (LCIA) Sophistication. Approximately 50 LCA experts attended the workshop, coming from Europe, Asia and the USA. Several prominent practitioners and researchers were invited to present a critical review of the associated factors, including the current limitations of available impact methodologies and a comparison of the alternatives in the context of uncertainty. Each set of presentations, organized into three sessions, was followed by a discussion session to encourage international discourse with the aim to improve the understanding of these crucial issues. The discussions were focused around small working groups of LCA practitioners and researchers, deliberately selected to include a balance of representatives from industry, government and academia. Each group was given the charge to address the questions that most interested them, as opposed to assigning specific groups with specific questions.

## Introductory Session

Jane Bare of the U.S. Environmental Protection Agency (EPA) opened the workshop noting that many of the participants had been involved in previous meetings as LCIA experts, sometimes even discussing related issues in the development of ISO 14000 series and SETAC Working Groups on LCA and LCIA. Requirements are being developed under ISO 14042 to specify a high level of sophistication for Comparative Assertions, including language concerning the scientific validity, environmental relevance, and the role of value choices. Within SETAC-Europe efforts are on going to develop a document related to the selection of the "state-of-the-art" impact assessment methodologies. Bare asked that participants consider the present workshop as a more open format than either of these settings to allow a completely uninhibited technical exchange. She stressed that Life Cycle Impact Assessment can be effective in supporting environmental decision making, but only if the data and methods are sufficiently scientifically defensible. Scientifically defensible was defined as being dependent upon the level of sophistication, the level of certainty (including both data and model certainty), the level of comprehensiveness, and data availability. The participants were challenged to address several additional questions throughout the two days of discussions including: What is "scientifically defensible"? In the sphere of determining whether impact assessment is based on sound science, where does one draw the line between sound science and modeling assumptions?

Garrette Clark from the United Nations Environment Programme (UNEP) then provided a short history of UNEP's involvement in the area of LCA, which includes providing technical assistance to developing countries and the development of an associated guidance document for LCA (UNEP, 1996). She stated that LCA is considered by UNEP to be an important tool for achieving cleaner production and consumption. She also summarized findings from the recent LCA workshop in San Francisco in June 1998 (UNEP, 1998).

David Pennington discussed two extremes of LCIA sophistication. One extreme he called the "Contribution or Burden" approach, which is comparable to what has been historically used in LCIA (reflecting the Precautionary Principle and the combinatory potential to cause impacts). The other extreme, the "Consecutive Risk Assessment" approach, he noted as being particularly recommendable for use in areas with high stakes, such as comparative assertions, but as often limited to the assessment of chemicals in isolation. He introduced the question concerning the need for spatial differentiation and asked when site-specific differentiation was

appropriate. He also pointed out that the category indicators are chosen at different points in the environmental mechanism (or cause-effect chain), and stated that the U.S. EPA has been using the term of "midpoint" to address indicators that stop short of expected effects on the final "endpoint" of the environmental mechanism. He presented acidification as an example of a category with the indicator at "midpoint" level and human health as a possible example of a category with the indicator at "endpoint" level. He concluded by asking about the different levels of sophistication. What is possible? What is required? When to use the various levels of sophistication?

## Session One: Overview

Willie Owens of Procter and Gamble spoke about comparative assertions (i.e., public comparisons between product systems) and the requirements for LCIA under ISO 14042. He stated that ISO 14042 requires a sufficiently comprehensive set of category indicators, a comparison conducted indicator by indicator (i.e. no weighting) and that LCIAs should not be the sole basis for comparative assertions. Current language in ISO 14042 states that subjective scores, such as weighting across categories, shall not be used for comparative assertions; that category indicators be scientifically defensible and environmentally relevant and that sensitivity and uncertainty analyses shall be conducted.

Mark Goedkoop of Pré Consultants discussed LCIA for ecodesign. He pointed out that the point of conducting an LCA is typically to determine whether A is better than B. He then presented three problems with LCA and ecodesign: 1) LCA studies are too time consuming, 2) LCA studies are hard to interpret, and 3) Designers never become experts, but remain dependent upon experts. His proposed solution for these problems was to calculate pre-defined single scores for the most commonly used materials and processes, and to incorporate uncertainty into the modeling. He also discussed the sometimes hidden role of societal values in characterization modeling, even for internationally agreed models. As an example, he presented the three classes of carcinogens (proven, probable and possible) and pointed out that the practitioner must make a decision about whether to include one, two, or all three classes. He proposed that a single truth does not exist and that modeling is dependent upon the chosen perspective. He then introduced three different views of the world based on values: egalitarian, hierarchical and individualist. (A topic discussed later in more detail by Patrick Hofstetter.) He pointed out that if A is not better than B in all three cases then the result is dependent upon the perspective.

Henrik Wenzel of the Technical University of Denmark discussed the application dependency of LCIA. He mentioned several applications including life cycle management, strategic planning, product development, process design, green procurement and public purchasing, and marketing. In addition, he discussed three main variables governing application dependency: the environmental consequence of the decision (including spatial and temporal scale), the socio-economic consequence and the decision context. He discussed the application dependency of uncertainty, transparency, documentation and the inclusion of temporal and spatial resolution. He stated that the need for sophistication of LCIA is largest in decisions with the highest requirements for certainty. He also stated that the decision-maker might impact the choice of normalization and weighting. (Wenzel, 1998)

Helias Udo de Haes wrapped up this first session by providing a summary of some of the key points covered and challenging the participants to address the questions provided during the small group discussions. Workshop participants were asked to

address the following questions and to provide additional questions to aid discussion:

1. What are the most common methods by which the level of sophistication is determined?
2. Which methods are considered more acceptable? Why?
3. What are the barriers to using the acceptable methods? What can be done to overcome these barriers?
4. To what extent should LCIA be application dependent?
5. What are the expectations regarding the level of sophistication for the various LCA applications (e.g., by government, by industry, for public communication, and for internal use)?
6. When should LCIAs be as detailed as possible, aiming at the maximum level of accuracy? And when is it better to limit the scope of LCA to addressing questions on a macroscopic scale, leaving spatial and threshold considerations to other analytical tools?
7. How do practitioners deal with the trade-offs necessary when sophistication and comprehensiveness are "at odds" (e.g., choosing a detailed modeling approach that may limit the comprehensiveness vs. a scoring approach that may limit the sophistication)?
8. What case studies are available using uncertainty analyses within LCIA? And what are the major findings to date (levels of uncertainty discovered)? When is the uncertainty determined to be unacceptable?

Questions Added at Workshop:

9. What is scientifically and technically valid, as included in the requirements of ISO 14042?
10. If LCIA is an iterative process, what drives the decision on the level of sophistication (e.g., uncertainty analysis, relevance, and existence of trade-offs)?
11. Define uncertainty in the context of LCIA. What parameters must be analyzed?
12. How do we incorporate background levels into LCIA? Should we define working points (as in Mark Goedkoop's presentation)? Should this be done for individual chemicals or combined?
13. What is the best currently available method to represent the combined effect of chemicals without double counting, or inappropriately allocating?
14. How do we incorporate (or should we incorporate) the differing philosophical views in characterization?

### First Session Discussion Summary

An aggregation of the resultant views is presented below:

*Determination of Sophistication* – Many different groups commented on the appropriate level of impact assessment sophistication. One group commented that some sound decisions may be/have been made on the basis of LCA studies, which did not have very sophisticated LCIAs, but these tended to be more obvious cases. They recommended using the most sophisticated impact assessment models that provide information closest to the endpoint. Another group commented that sophistication is dependent upon a number of things including: inventory data availability, the availability of characterization models and data to support these models, objective, the application dependency, the decision maker's sphere of

influence and the impact category. A third group stated that the choice of sophistication depends upon an iterative process, where the iterations may be dependent upon uncertainty, the environmental relevance of the results and the minimum level of certainty required to support a decision. Several participants commented that sophistication is often limited by budget, inventory data availability, ease of use of impact assessment methods and in-house knowledge.

These participants stressed the practical side of LCA and recognized the difficulty in data collection and the structuring of public databases to support more sophisticated analyses.

*Application Dependency* - There was a general belief that LCIA sophistication is application dependent, according to the type of application and not the individual user. For example, screening level LCA studies may not require the rigorous use of sophisticated impact assessment techniques but final comparative assertions may require much more rigor, particularly if the benefits are not apparent. LCIA studies should be performed based on the type of question or decision at hand and the purposes that the LCIA may be serving.

*Validating the Results of LCIAs* – There was agreement that one cannot validate the results of a single LCIA study, because of the lack of temporal and spatial specification associated with the inventory data, and an inability to accurately model complex interactions in the environment, including the combinatory effects of chemical mixtures. However, input data can be quality checked, and elements in the models can be compared with models developed in the context of other applications such as environmental risk assessment. It was also noted that validation might not be as important in the context of LCIA since models simply reflect a relative comparison as opposed to an absolute assessment.

*Backgrounds and Thresholds* - Practitioners have tried to incorporate background levels in LCA studies in the past but there was a lot of discussion that this practice may or may not be appropriate. One of the questions at hand is whether emissions do occur in above or below threshold situations. Another issue concerned the fear that defining backgrounds and thresholds will lead to treating many environments as infinite sinks (e.g., for acidic chemicals) when in reality nature's ability to absorb the impact may be exceeded at some future time. The distinction was also made that thresholds may be less strict, because of the presence of very sensitive species or human individuals. Thresholds may also not be protective enough in many environments in which the combined effects of chemicals may cause effects at a level much lower than the threshold effect. Finally, practitioners were cautioned not to use LCIA to the exclusion of recognizing the problem of hot spots surrounding facilities. (See the following point for more information on mixtures). On the other hand, some participants believed that thresholds might be valuable indicators of relative potency for many chemicals and that thresholds had been derived with statistically sound methods. Further clarification of the decision-making context may be necessary to determine the value of thresholds and backgrounds in particular applications of LCIA.

*Mixtures* - One of the basic limitations of the current state-of-the-science of LCIA of human and ecotoxicity is the inability to effectively deal with potential combinatory effects of chemical mixtures. Toxicologists operate under the assumption that chemicals acting on the same organ can be considered to have an additive effect, but often LCIA impact categories are much broader than a focus on target organs. Therefore, the same assumptions used in risk assessment are not applicable to LCIA. This is especially an issue when practitioners try to incorporate threshold levels for individual chemicals into LCIA. Because mixtures are not well characterized in LCIA, effects may be occurring at much lower levels

than the accepted threshold levels of the individual chemicals. Practitioners often try to compensate for these and other model deficiencies by adopting the Precautionary Principle.

*Data Gaps* – There was a concern that data gaps can be significant. Particularly in human and ecotoxicity, availability and quality of both inventory and chemical data to support the modeling of a large number of chemicals can be frustrating. These impact categories are a good example of where less sophisticated screening techniques may, with an appropriate degree of caution prove useful.

*Uncertainty Analysis* - LCIA still faces great challenges before fully addressing uncertainty analysis. Some of these challenges include the lack of awareness, lack of associated methodology, and the perceived difficulty of presenting the results to decision-makers. Specifically, practitioners need better knowledge of uncertainties in existing methods within the different impact categories and of the potential for improvement, if any, by using methods with greater sophistication. Many participants acknowledged a need for a better understanding of the uncertainty involved in each of the impact assessment methodologies for each of the impact categories, noting that uncertainty is associated with the models as well as the input data. The potential trade-off in available models between increased sophistication (i.e., detail) and reduced comprehensiveness (e.g., number of stressors simulated) was again noted.

*Unnecessary Rigor?* – There was a belief that the ISO standard on LCIA, specifically for the comparative assertions to be disclosed to the public, is too demanding in the areas of scientific validity and certainty. Examples were given of some other modeling arenas that face the same challenges (e.g., economic modeling, risk assessment studies). In these fields large uncertainties are accepted, expected and (sometimes) clearly documented. There was also a concern that the rigor expected of the impact categories without a working international acceptance (e.g., human toxicity) exceeds the rigor and certainty requirements compared with the impact categories that benefit from having international consensus (e.g., global warming potentials).

*Model uncertainty vs. data uncertainty* – Some participants commented that the current disparity in levels of uncertainty analysis may have lead to the false impression that the more sophisticated models have increased uncertainty when compared to less sophisticated techniques. Typically this is not the case. Usually, with a more sophisticated model the model uncertainty has decreased and the ability to model data certainty quantitatively has increased. Deceptively (since model uncertainty is not typically characterized) the increased characterization of data certainty may have seemed to increase total uncertainty. (Additional details on uncertainty analysis may be found in Edgar Hertwich's presentations.)

*Standardization* – While it was recognized that the level of sophistication might depend upon the type of application and the availability of data, there was a belief that consistency of approach or methodology may be an important priority to allow comparability between studies. Some participants pointed out that certain studies may only require Life Cycle Thinking and therefore, should not be subject to the standardized methodologies. Others addressed the idea of approach hierarchies that differentiate between screening and more intensive techniques but noted that the approaches could be consistent within these tiers. It was similarly noted that there could be a trade-off between sophistication and comprehensiveness, while one approach provides a more complete picture but with low level of detail, another may provide a higher level of detail but at the expense of comprehensiveness. It was further noted that there is continual development of methods and standardization should not discourage further research efforts.

*More Focused Research* - More energy needs to be expended to ensure that LCA research is focused on areas that will have the greatest impact. Research needs to be conducted in deriving better methodologies for more relevant indicators. Specifically, land use, habitat alteration, and environmental toxicity were mentioned as examples of impact categories requiring much more research.

## Session Two: Human Health and Ecotoxicity

Edgar Hertwich of the University of California, Berkeley opened the session on Human and Ecotoxicity with his presentation: "A Framework for the Uncertainty Analysis of the Human Toxicity Potential". He presented the purpose of uncertainty analysis: “to develop confidence in an analytical result, as an input to formal decision analysis techniques and as a tool to refine impact assessment methods.” He noted that uncertainty analysis includes: parameter uncertainty, model uncertainty, decision rule uncertainty and variability. He then presented various examples of each of these as they might pertain to modeling for human toxicity impact assessment in LCIA. Finally, he pointed out that simply conducting a sensitivity analysis can often provide valuable insights about the significance of the multiple uncertainties involved in the decision and can help refine impact assessment techniques. (Hertwich, et al., 1993; Hertwich, 1999)

Patrick Hofstetter of the Swiss Federal Institute of Technology in Zurich addressed the question of “What is science?” in the presentation: “The Different Levels of Uncertainty Assessment in LCIA: The Case of Carcinogenic Effects.” He stated that the development of models is dependent on the perspective of the modeler. Three perspectives were described: hierarchist, individualist and egalitarian. An individualist optimizes the spending of resources based upon the known or certain types of harm that can be modeled (e.g., only choosing to include IARC Group 1 Carcinogenics in an analysis). A hierarchist could be closest to the operating positions typically held by government and international organizations and would include Group 1 and Group 2 Carcinogens. Egalitarians tend to take a more risk aversive and preventive standpoint and thus would include Groups 1, 2, and 3 in a carcinogenic analysis. Similarly, these different perspectives would derive different discount rates for use within an assessment in terms of the Disability Adjusted Life Years (DALY). An illustration showed the combination of the assumptions of all three cultural perspectives in an eco-index probability graph. Finally, he concluded that LCIA could be made simple to use and yet robust by incorporating the values associated with various perspectives and allowing an analysis of the related technical, methodological and epistemological uncertainties. (Hofstetter, 1998)

Olivier Jolliet of the Swiss Federal Institute of Technology in Lausanne discussed “Human Toxicity and Ecotoxicity Modeling vs. Scoring.” He opened by saying “Tell me your results and I will tell you who paid you!” Then he called for the identification of best available practice regarding impact assessment methods to reduce the ability to provide LCAs that support such malpractice. He also proposed that this process should try to meet the ISO 14042 requirements to be “scientifically and technically valid” and “environmentally relevant.” After comparing different human toxicity modeling efforts, he pointed out parameters and model characteristics that are important in human and ecotoxicity modeling, including exposure and fate uncertainties, that can be responsible for significant uncertainty and which open options for reduction of modeling uncertainty by proper empirical or experimental validation. He concluded by saying that modeling comparisons should be made based on model characteristics and consistent data.

Mark Huijbregts of the University of Amsterdam presented a paper on "Priority Assessment of Toxic Substances in LCA: A Probabilistic Approach." Citing previous publications (e.g., Guinée, et al., 1996 and Hertwich, et al., 1998), he suggested that the following specific improvements are needed: a review of default values with the possibility of using more realistic values, an inclusion of all relevant environmental compartments and inclusion of a Monte Carlo type of uncertainty analysis. He presented a probabilistic simulation of weighted human, aquatic and terrestrial Risk Characterization Ratios (RCRs) for 1,4-dichlorobenzene and 2,3,7,8-TCDD and demonstrated that only a few substance-specific parameters are responsible for the uncertainty in results. Finally, Huijbregts concluded that variability is not of significance if it is identical for all options being compared and asked that researchers continue to explore the issue of when data uncertainty/variability cancel in relative comparison applications.

**Second Session Discussion Summary**

Workshop participants were asked to address the following questions and to provide additional questions to aid discussion.

1. In human toxicity and ecotoxicity, when is spatial and/or temporal differentiation necessary? If necessary, what spatial and/or temporal details are recommended (e.g. indoor/outdoor, height of emission point)?
2. With respect to ecotoxicity what is the best approach to addressing multiple species? If suggested, what are recommended representative species?
3. With respect to human toxicity and ecotoxicity, what are the greatest barriers to conducting uncertainty analysis?
4. What are recommendations for research and development in these impact categories?

An aggregation of the groups' views is presented below:

*Standardization* – Again the question of standardization was discussed. Specifically, if the practitioner or study commissioner can have such a strong influence on the final results of the study, then perhaps some standardization would be useful to provide comparability between studies. However, what perspective or aggregation of perspectives should be represented in a standardized approach? Should central tendency assumptions or worst-case assumptions be used? Some participants stated that additional time was needed to ferment an opinion in this area. Others contended that "allowing" for too many methods and approaches could undermine the credibility of LCIA. However, many believed that now is the time to capture the state-of-the art in a document, while still allowing room for advances in the future. Several participants expressed interest in being involved in the current SETAC-Europe Working Group on Life Cycle Impact Assessment. (Udo de Haes, et al, 1999a and Udo de Haes, et al, 1999b).

*Midpoint vs. Endpoint Level* – In further discussion of the concepts of midpoints vs. endpoints, many participants discussed the advantages of making all impact assessment models as close as possible to the final endpoints of the environmental mechanism of the impact categories (e.g., quantifying fish kills and trees lost as opposed to the acidification potential of the substances). One benefit of this approach would be to allow more common endpoints for the valuation process, perhaps even opening the door to allowing more economic valuation of endpoints. Others pointed out that this might be unnecessary in a relative comparison context. They stated that extending the models to the endpoints will narrow down the comprehensiveness of the impacts considered, and will include many more assumptions and value judgements into the assessment. This may subsequently

increase the uncertainty of the results and reduce credibility by further mixing "science and value judgements."

*Ecotoxicity* – There was a strong call for research in this area. There was a recognized need to extrapolate ecotoxicity in a manner similar to human toxicity with representative species but also a realization that representative species may vary within different areas. However, there was also some discussion that LCA is a very macroscopic tool and, can not be expected to accurately model local issues. Perhaps, ecotoxicity is so specific to the locality affected that an attempt should not even be made to include it as an impact category. The most widely held view on this topic seemed to be that ecotoxicity should continue to be included, for the sake of providing a more holistic picture, and that the potential for more site-specific approaches should be considered further.

*Potentially Affected Fraction of Species (PAFs)* – Mark Goedkoop gave an impromptu presentation on PAFs. He stated that PAFs are different from PNECs in that they take the background level of the substances into account and thus enable non-linear modeling of impact on the species composition. Many in principle liked the idea of PAFs and combined PAFs that represent the combined effect of chemicals. However, there were concerns related to the possibility of identifying PAFs, due to the limited availability of dose response curves and of background concentration data for so many chemicals. A discussion of Eco-Indicator 98's relationship to PAFs was held. (Goedkoop, 1998)

*Borrowing from Risk Assessment* - Concern was voiced that LCIA for human toxicity is often based on typical risk assessment practice (e.g., the use of toxicological benchmarks). Caution was particularly high in the context of deterministic safety factors used in the toxicity component of the characterization factors, many of which compensate for low test species numbers. As this reduces the equity and comparability of chemicals, participants suggested that LCIA must be careful when adopting deterministic risk assessment perspectives.

*Research into Increasing Sophistication and the Role of Other Assessment Techniques* – One group asked for increasing temporal modeling, real ground concentration measurement, incorporation of population density into simulations and better representation of food webs. In this group, there was a concern that the current direction of research in multimedia modeling would not address these areas. However this must be viewed in the context of the aims which are to be met by LCA as opposed to the types of analytical tools. Thus, another group stressed that perhaps practitioners are too concerned with detail. Perhaps the focus should remain on macro differentiation of substances in terms of their persistent bioaccumulative and toxic (PBT) properties. This could be subsequently complimented (if required) by local scale analysis using other tools, and would help to include a larger set of chemicals at a sufficient level of differentiation.

## Session Three: Acidification, Eutrophication and Inventory

Greg Norris of Sylvatica, North Berwick, Maine, USA, presented a "Value-of-Information Approach." [He pointed out that uncertainty analysis allows some additional information (e.g., confidence intervals associated with data uncertainty) within the decision-making framework.] Norris stated that the level of sophistication should be partially dependent upon the inventory data and its uncertainty, upon the appropriate models and upon decisions about weighting. He suggested using Input/Output-based upstream LCI databases to answer many of the common questions that practitioners face, such as "How many sites, with how much geographic dispersion, contribute significantly to inventory totals?" And "What are the expected shapes of these distributions?" He also cautioned

participants against trying to draw conclusions about the preferability of more detailed LCIA, based on a Probability Density Function (PDF) or Cumulative Density Function (CDF) diagram, pointing out that further simulations may be required. Finally, he discussed the difference between analyzing uncertainty in weighting and in characterization modeling and the need to treat these issues jointly in the determination of the level of sophistication and decision support.

José Potting of the Technical University of Denmark presented "Levels of Sophistication in Life Cycle Impact Assessment of Acidification." Potting presented a case study comparing alternative locations for copper production and demonstrated the potential need for site-specific simulations, including emission dispersion and deposition patterns, background depositions on receiving ecosystems, and the sensitivity of receiving ecosystems. [She used the Regional Air pollution INformation System (RAINS) model (from IIASA) with calculations based on Critical Loads provided by the National Institute of Public Health and the Environment (RIVM) in the Netherlands and transfer-matrices from EMEP MSC-W at the Norwegian Meteorological Institute.] She announced that easy-to-use acidification factors had been established for 44 European regions and suggested that utilizing this site dependent approach for acidification resulted in a significant reduction in uncertainty.

Göran Finnveden of Stockholm University presented two topics - "Eutrophication – Aquatic and Terrestrial – State of the Art," and "Thresholds/No Effect Levels/Critical Loads." Finnveden discussed the site dependency of eutrophication in three models, developed since 1993. He presented additional topics for discussion and research related to eutrophication. In his second presentation, Finnveden proposed that thresholds may, at the macrolevel, have no scientific basis and in fact may just be "acceptable" levels of risk and thus constitute value choices. Acidification and human toxicity were used as examples of impact categories that should not ignore "below threshold values." In line with this, he proposed that threshold values should not exist in LCIA for any impact category.

The third session was concluded with the large group documenting some of the earlier topics and discussing the value of conducting future similar workshops. An on-site workshop summary was presented by two of the co-chairs.

## Conclusions

In meetings and journals world wide, practitioners have debated the utility of conducting Life Cycle Assessment studies. The debate has often hinged on the appropriate level of sophistication. While some have advocated abandoning LCA altogether, since it is not achievable in its most sophisticated form, others have supported the concept of conducting LCA studies at a more holistic level, while making the limitations and uncertainties transparent. This workshop discussed many of the issues of dealing with the appropriate level of sophistication in the Life Cycle Impact Assessment phase of an LCA study.

A number of prominent practitioners and researchers presented a critical review of the associated factors, including the current limitations of available impact methodologies and a comparison of alternatives in the context of model and data uncertainty. On the one hand the workshop addressed the various factors which are connected with an increase of sophistication in LCIA. Examples include the need for better fate and effect models and the role of spatial and temporal differentiation therein; the identification of background levels and thresholds, but also the need to specify value-laden aspects such as connected with different cultural perspectives. On the other hand, the holistic and comparative character of LCA was stressed. In this context, many questioned whether LCA should aim to conduct sophisticated

site specific risk assessments, particularly when this high level of detail may give a false impression of great confidence, especially when it is not presented with a stringent uncertainty analysis. Moreover, it was recognized that thresholds reflect value choices about what is regarded acceptable, rather than science based parameters. And finally, increasing level of detail can increase model certainty, but, in some cases, may reduce the comprehensiveness.

Workshop speakers and participants discussed the way that philosophical views may affect not only the valuation process, but also the impact assessment phase by including assumptions that include values based on the differing perspectives. This further complicates the question of what is "science-based" and what are "reasonable" modeling assumptions. Arguments were raised both for and against striving for consistency at this time in the effort to standardize some of the methods and assumptions to allow comparability between studies.

There was much discussion about the decision-making framework and the role of other environmental analyses, such as risk assessment. From the sophisticated uncertainty analyses presented it was obvious that great advances are being made, but there are many very basic principles that still lack consensus (e.g., the use of threshold values and background concentrations). As in risk assessment, there is great attention to being true to the science, but in the interest of practicality, a great need for simplifying assumptions.

There was consensus that the workshop was very valuable and that this exchange should be continued through e-mail discussions and periodic workshops (next target workshop in Brighton, U.K. in May 2000). Several topics were mentioned for future workshops, including: LCIA at strategic levels of decision making (including sustainable development decision support), community planning using LCIA-type indicators, the role of value choices in characterization modeling, and the state-of-the-science for characterizing ecotoxicity in LCIA.

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# Appendix 5: Scientific Articles

Appendix 5: Scientific Articles

# LIFE CYCLE IMPACT ASSESSMENT WORKSHOP SUMMARY - MIDPOINTS VERSUS ENDPOINTS: THE SACRIFICES AND BENEFITS

**Jane C. Bare[1], Patrick Hofstetter,[2] David W. Pennington,[3] and Helias A. Udo de Haes[4]**

[1]U.S. Environmental Protection Agency (EPA), National Risk Management Research Laboratory, Cincinnati, Ohio 45268, USA. Email: bare.jane@epa.gov

[2]ORISE Research Fellow, U.S. EPA, National Risk Management Research Laboratory, Cincinnati, Ohio 45268, USA.

[3]Laboratory of Ecosystem Management, Ecole Polytechnique Fédérale de Lausanne (EPFL), CH-1015 Lausanne, Switzerland.

[4]Centre of Environmental Science (CML), Leiden University, P.O. Box 9518, NL-2300 RA Leiden, Netherlands.

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## Abstract

On May 25 – 26, 2000 in Brighton (England), the third in a series of international workshops was held under the umbrella of UNEP addressing issues in Life Cycle Impact Assessment (LCIA). The workshop provided a forum for experts to discuss midpoint vs. endpoint modeling. Midpoints are considered to be links in the cause-effect chain (environmental mechanism) of an impact category, prior to the endpoints, at which characterization factors or indicators can be derived to reflect the relative importance of emissions or extractions. Common examples of midpoint characterization factors include ozone depletion potentials, global warming potentials, and photochemical ozone (smog) creation potentials. Recently, however, some methodologies have adopted characterization factors at an endpoint level in the cause-effect chain for all categories of impact (e.g., human health impacts in terms of disability adjusted life years for carcinogenicity, climate change, ozone depletion, photochemical ozone creation; or impacts in terms of changes in biodiversity, etc.). The topics addressed at this workshop included the implications of midpoint versus endpoint indicators with respect to uncertainty (parameter, model and scenario), transparency and the ability to subsequently resolve trade-offs across impact categories using weighting techniques. The workshop closed with a consensus that both midpoint and endpoint methodologies provide useful information to the decision maker, prompting the call for tools that include both in a consistent framework.

## Introduction

In June 1998 in San Francisco (USA), the workshop "Towards Global Use of LCA" was held to develop recommendations and an action plan that would lead towards greater use of LCA in the context of sustainable development, including its use in developing countries. (UNEP, 1999) In November 1998 in Brussels participants of the "Life Cycle Impact Assessment Sophistication" workshop addressed the need for increased sophistication in LCIA, whilst recognizing the conflict that this might have in terms of the comprehensiveness and holistic character of LCIA, as well as the increase in data need in the LCI phase. (Bare, et al., 1999) One of the key issues raised – midpoint versus endpoint modeling – became the focus of the third international workshop, held in Brighton on May 25 – 26, 2000, and summarized in this paper.

Although the terms have yet to be rigorously defined, midpoints are considered to be a point in the cause-effect chain (environmental mechanism) of a particular impact category, prior to the endpoint, at which characterization factors can be calculated to reflect the relative importance of an emission or extraction in a Life Cycle Inventory (LCI) (e.g., global warming potentials defined in terms of radiative forcing and atmospheric half-life differences). Examples of methodologies based on midpoint characterization factors include Heijungs et al. (1992) and EcoIndicators '95 (Goedkoop, 1995). However, particularly in LCA studies that require the analysis of tradeoffs between and/or aggregation across impact categories, endpoint-based approaches are gaining popularity. Such methodologies include assessing human health and ecosystem impacts at the endpoint that may occur as a result of climate change, ozone depletion, as well as other categories traditionally addressed using midpoint category indicators. Examples of endpoint methodologies include Steen et al. (1992), ExternE (1995), ESEERCO (1995), and EcoIndicators '99 (Goedkoop & Spriensma 1999).

Figure 1 shows the steps that can be involved if a practitioner wishes to take an LCA study from the inventory stage, via impact assessment, to a single comparison metric using weighting techniques (both economic and/or panel approaches). Two different routes are presented, representing the routes taken when using midpoint and endpoint approaches. One of the key differences between midpoint and endpoint approaches is the way in which the environmental relevance of category indicators is taken into account. In midpoint approaches, the environmental relevance is generally presented in the form of qualitative relationships, statistics and review articles; however, it could similarly be quantified using endpoint methods to provide insights to the decision maker. In endpoint approaches there is no need to deal separately with the environmental relevance of the category indicators, because the indicators are chosen at an endpoint level and are generally considered more understandable to the decision makers. As a result different types of results are presented to the decision maker.

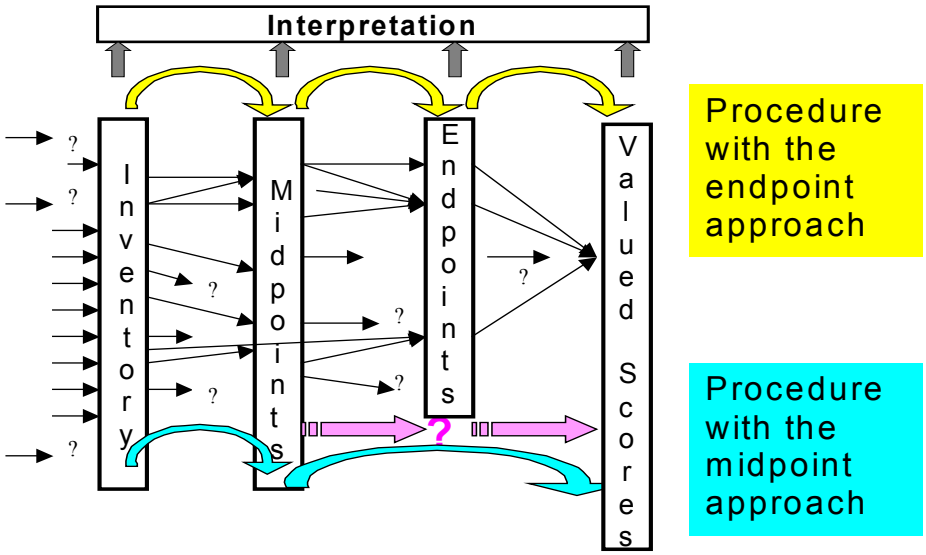



FIGURE 1. GRAPHICAL REPRESENTATION OF SOME BASIC DIFFERENCES BETWEEN THE MIDPOINT (LOWER ROW OF SWINGING ARROWS) AND THE ENDPOINT APPROACH (UPPER ROW OF SWINGING ARROWS). THE SMALL ARROWS REPRESENT MODELS THAT ADD INFORMATION IN A CAUSE-EFFECT FRAMEWORK. THE QUESTION MARKS INDICATE INFORMATION THAT WAS AVAILABLE BUT COULD NOT BE FURTHER MODELED. SUCH CASES INCLUDE UNMEASURED EMISSIONS, UNCONSIDERED TYPES OF RELEASES (OCCUPATIONAL, ACCIDENTAL), AND SUBSTANCES WHERE ENDPOINT MODELS HAVE STILL TO BE ESTABLISHED (E.G. NEUROTOXIC EFFECTS ON HUMAN HEALTH).

Endpoint modeling may facilitate more structured and informed weighting, in particular science-based aggregation across categories in terms of common parameters (for example, human health impacts associated with climate change can be compared with those of ozone depletion using a common basis such as DALYs – Disability Adjusted Life Years). Proponents of midpoint modeling believe, however, that the availability of reliable data and sufficiently robust models remains too limited to support endpoint modeling. Many believe that extending the models to endpoints reduces their level of comprehensiveness (the number of pathways and endpoints in the cause-effect chains that are represented beyond well characterized midpoints) and that such extensions will be based on a significant number of additional, unsubstantiated assumptions and/or value choices, (which may not reflect the viewpoint of other experts and/or the user) to fill in missing gaps. One major concern is that uncertainties (model, scenario and parameter) may be extremely high beyond well-characterized midpoints, resulting in a misleading sense of accuracy and improvement over the midpoint indicators when presented to weighting panels and decision makers. Many modelers believe that the additional complexity and detail is only warranted if it can be demonstrated to provide an improvement in the decision-making basis.

The Brighton workshop was conceived to present both sides of the midpoint versus endpoint argument to an international group of approximately 50 experts and to allow these participants adequate time to discuss the relative merits and limitations

of the approaches. A summary of the presentations, discussions and the outcome is presented below.

## 1 Presentations

This section provides short summaries of each platform presentation. Extended abstracts and slides will be available later in a full report.

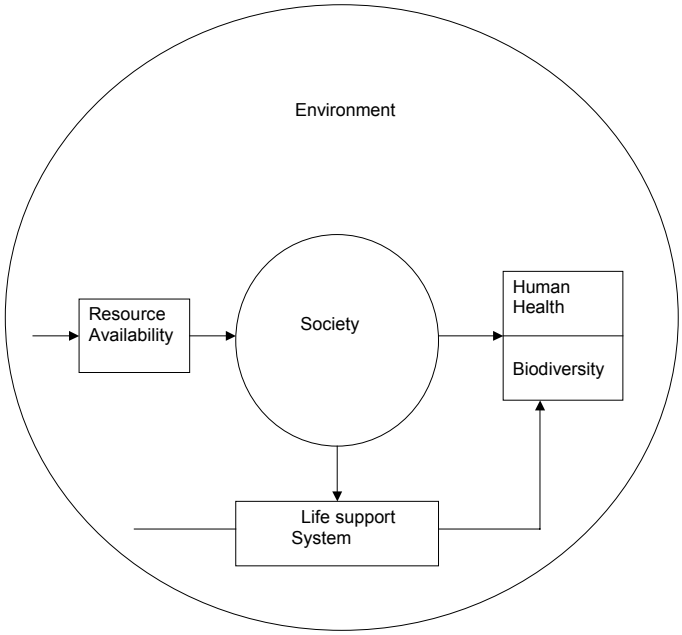
**Jane Bare** of the U.S. Environmental Protection Agency (EPA) opened the workshop with the presentation entitled: Midpoints vs. Endpoints – How Do We Decide? She pointed out that there are several reasons for conducting LCIAs, including LCIAs for enlightenment (which she defined as LCIAs which are used within a larger decision making framework and do not require impact category consolidation) and comparative LCIAs (which may be presented with the desire to determine which of two or more options is more environmentally friendly). Within LCIAs for enlightenment there may be no desire to consolidate the information of the LCIA into a single score. Decision makers may select the LCIA impact categories that are most closely related to their environmental values or ethics, and/or LCIA impact categories they wish to use for communication. In this case, a midpoint and an endpoint approach may be equally desirable. In comparative LCIAs consistency is important and to provide a consistent decision making framework in situations where trade-offs are necessary, a single score or weighted result may be the goal of the study. Bare then outlined some of the issues with midpoint and endpoint modeling. She proposed that endpoint modeling may facilitate a more structured and informed weighting process, which may include economic techniques, but she also stated that a high level of knowledge, data quality, and expert involvement was LCIA, are not transparent to the user and may conflict with the values necessary in forecasting specific endpoint effects. She used the example of ozone depletion. While the midpoint modeling of ozone depletion characterization factors may in principle encompass the consideration of crop damage, immune system suppression, marine life damage, and damage to materials, currently, these endpoints are not included in popular endpoint methodologies such as EcoIndicator'99. She also noted that endpoint modeling may introduce assumptions that are not always compatible with and/or wishes of the decision maker (e.g., human health may not include all possible endpoints.) Bare concluded her talk by suggesting that there are advantages and disadvantages to each approach and suggested that both midpoint and endpoint approaches might be used together to provide more information.

**Bas de Leeuw** of the United Nations Environment Programme (UNEP) presented "LCA: Untapped Potential for Sustainable Consumption and Production Policies." Within this talk he presented the analogy of a car and driver - challenging researchers to determine the "best science" and build software that would enable practitioners to use these models with a very low level of knowledge. He presented the role of UNEP in the LCA process, including: encouraging the use of LCA, helping to build consensus, and bringing LCA to developing countries. He stated that he believed that the production side has embraced LCA application, but the application of LCA to the consumption side of the problem has not been well studied despite the growing awareness among the public (and hence policy makers) about the "world behind the product".

**Mark Goedkoop** of Pré Consulting presented "The Benefit of Endpoints." Instead of discussing what is best, he stressed the focus on what is the most appropriate level of aggregation to communicate with the audiences in a company. As many audiences, especially decision makers, cannot relate to rather abstract midpoints, endpoint modeling is required, as well as midpoint modeling. He noted that an

attempt had been made to incorporate all possible value perspectives in the models by allowing endpoint calculation based on Hierarchist, Individualist, and Egalitarian viewpoints. He stated that the weighting process is difficult enough without expecting the panelists to model endpoints. He discussed some of the issues with the weighting process including panelists' incorporation of observed, perceived, and predicted damages. He suggested that fewer endpoints were better than too many. EcoIndicators '99 has human health, ecosystem quality, and resources. He suggested that the weighting process may take a different form if panelists are able to use the weighting triangle instead of estimating deterministic weighting factors. Goedkoop acknowledged the many assumptions and large data uncertainty in endpoint modeling and acknowledged the incomprehensive nature of the endpoints at this time. Goedkoop concluded by answering some of the questions written by the workshop chairs prior to the workshop. He believed there are gaps in endpoint modeling, but that these gaps are not a fundamental problem. He also felt that there is a need to avoid bias within all types of models. He recommended more weighting panels using both endpoint and midpoint modeling, and recommended that research continue for both approaches, preferably as one consistent system that can supply data at both midpoint and endpoint level.

**Helias Udo de Haes** of the Centre of Environmental Science (CML) presented "The Advantages of Midpoint Modeling." He considered endpoint modeling to be scientifically challenging, but with a much smaller reach, (i.e., much less encompassing) and much higher uncertainty compared with midpoint modeling. He referred to midpoint modeling as the traditional approach with a relatively good level of (model parameter) certainty at the level of characterization modeling, and quite encompassing with respect to the reach of the endpoints involved. However, in midpoint models a lot of the uncertainty is not included in the characterization modeling but is in the environmental relevance of the category indicators providing information about the links between the midpoint indicators and the respective endpoints (e.g. uncertainty associated with missing pathways in the cause-effect chain and not taking the indicator to an endpoint measure). Udo de Haes then proposed a new framework (Figure 2) for the areas of protection in LCIA, which distinguishes four areas of protection: resources, human health, biodiversity, and life support system. Individual impact categories are related to one or more of these areas of protection. The newly included area of protection, the life support system, deals with the supporting role of processes in the environment that enable sustainable life on earth. The use of characterization factors at the midpoint level is desirable for this category, not as a second best option as long as endpoint modeling is not yet feasible, but because these midpoint indicators reflect the impacts on the life support system itself. Categories for which this is pertinent include: climate change, ozone depletion, acidification and eutrophication.




| Resource Availability | Life Support System | Human Health |
|---|---|---|
| abiotic resources | climate change | trop.oxidant form |
| biotic resources | strat. ozone depletion | human toxicity |
| land competition | acidification | radiation |
| nutrification | noise, odour | |
| soil erosion | work environment | |
| hydrological change | Biodiversity | |
| | land productivity | ecotoxicity |
| | hunting | |
| | introd. new species | |
| | land use: species loss | |

FIGURE 2. PROPOSED FRAMEWORK FOR FOUR AREAS OF PROTECTION BASED ON BOTH MIDPOINT AND ENDPOINT INDICATORS.

**Patrick Hofstetter** of the U.S. EPA presented "Looking at the Full Picture – Implications Associated with Valuation." He restricted his presentations to cases where trade-offs between category indicators are needed and focused on methods that use stated preferences to do so (panel methods, WTP etc.). Based on descriptive decision analysis literature, he explained how important the selection of impact categories is on the final weighting step. Confronted with the question of how to allocate 100 importance points to a number of impact categories human beings tend to anchor their answers around 100 points divided by the number of impact categories. A review of recent panel studies in LCA confirmed that anchoring may have biased the studies. One step (among others) to avoid anchoring is to present category indicators that are perceivable and have a meaning, i.e., preferences may exist. Although endpoint approaches can potentially fulfill this requirement better than midpoint-based methods this is not yet the actual case. Both, midpoint and endpoint indicators are presently not based on a careful selection procedure that reflects societal consensus or the involvement of decision makers. Further research may well show that the way mass media and communication deals with environmental problems is finally decisive for the selection of the modeling level. Based on criteria like the 'perceivability of

indicators' and the 'possibility to provide more detailed information' Hofstetter also showed how the level of modeling influences the type of weighting methods that can be used. He concluded this evaluation with the finding that midpoint approaches appear not to fit with stated preference methods that elicit societal preferences.

In contradiction to Udo de Haes, Hofstetter claimed that from a decision support perspective the modeling at the endpoint level does not have more gaps than midpoint approaches. He suggested that true gaps in knowledge and understanding should rather be captured by a parallel precautionary index than by unstructured lists of suspected effects due to environmental mechanisms captured by midpoint indicators.

**Dik van de Meent** of RIVM (National Institute of Public Health and the Environment) presented "Ecological Impact Assessment of Toxic Substances: All the Way to the Endpoint?" He discussed the four steps to endpoint modeling as follows: 1) from functional unit to release inventory, 2) from emissions to concentrations, 3) from concentrations to "toxic pressure," and 4) from "toxic pressure" to "environment stress." He discussed ways to deal with unavailable data through estimation techniques, and the high level of correlation among chemicals with the same toxic mode of action. He provided greater detail in the fourth step for specific circumstances within the Dutch environment. He concluded by answering the chair's questions. He stated that some of the key assumptions included are: 1) Is vegetation representative of the ecosystems? 2) Are heavy metals representative of toxic environment stress? 3) And was a proper extension made to specific midpoint categories such as ozone depletion and climate change? Finally, he listed the primary uncertainties involved in the extension from midpoint to endpoint in this case.

**David Pennington** of the U.S. EPA presented "Midpoint vs. Endpoint Issues: Toxicological Burden on Aquatic Ecosystems." He opened with a discussion that some straightforward approaches based on indicators of implicit concern (usually midpoint indicators such as persistence, bioaccumulation and toxic potency scores) can be used to double check the results of models in LCA that attempt to more explicitly represent the fate and exposure mechanisms of a chemical in the environment (similar to Hofstetter's parallel precautionary index used to check for gaps). In one cited case study, the limited representation of the aquatic food web in a multimedia model had resulted in misleadingly low characterization factors for some chemicals. The error was spotted through such a crosscheck. Moving from this methodological overview, he then discussed the relative merits and complexities of the linear versus the tangential gradient as the measure of toxicological potency used in the calculation of characterization factors. It was stressed that both gradients are endpoint measures (change in percentage of stressed species in the case of ecosystems; the percentage of individuals in the case of human health), that there are limitations associated with this endpoint basis (e.g., increases in stress on an already stressed group of species and for the potential extinction are not measured), and that a common midpoint in the cause-effect chain of toxicological impacts does not exist to support comparisons in LCA. He concluded that uncertainties (parameter, model and scenario) must be stated before distinctions amongst alternatives can be expressed and that extreme caution is required when adopting complex LCIA methodologies, as they may not be scientifically robust and can be built on assumptions that add little additional information, or even increase uncertainty.

**Tom McKone** of the University of California Berkeley presented "Midpoint vs. Endpoint Modeling of Human Health." McKone compared the two levels by

saying that one represented greater relevancy (endpoints) while the other represented greater reliability (midpoints). He pointed out that the field of human health modeling is much more complex than most LCA researchers might realize. Human effects can be deterministic (i.e., effect and severity directly related to exposure, as in a sunburn) or stochastic (i.e., effect, but not severity related to exposure, as in cancerous effects). He stated that there is a dearth of information in this area - fewer than 30 chemicals have human carcinogenic data available, while only approximately 200 chemicals have animal carcinogenic test data. For other chemicals and other types of health effects we have to make highly uncertain estimates of dose-response relationships. He concluded that midpoint models provide more opportunities for scientific validation than endpoint models (e.g., for acidification it is easier to measure pH than to measure affected species) and eventually, midpoint models could be extrapolated into endpoint approaches so long as the resulting loss of reliability is addressed.

**Wolfram Krewitt** of the University of Stuttgart, presented ”Advantages and Limitations of Endpoint Modeling – Experiences from ExternE.” Krewitt pointed out that all models should fit the goal and scope of the study, and in the case of ExternE the context was presented. He gave an example of ExternE endpoint modeling to the Years of Life Lost (YOLL) due to ozone formation per 1000 tons of NOx and pointed out that it is possible to have both negative and positive effects in this example. He discussed uncertainty in many different categories including those of a scientific nature which can be quantified with statistical methods including some data and model uncertainty. He also noted that there were uncertainties related to policy and ethical choices, uncertainty about the future, and idiosyncrasies of the analysis (e.g., interpretation of ambiguous information). For impacts that currently cannot be quantified on the endpoint level (e.g. global warming, impacts on biodiversity), Krewitt suggested to use the costs for achieving environmental targets (‘standard-price approach’) as a measure of society’s preferences towards the expected, but unknown impacts. He concluded his talk by supporting endpoint modeling to enhance weighting and increase the understanding of the environmental mechanisms.

**José Potting** of Institute for Product Development at the Danish Technical University presented “Acidification and Terrestrial Eutrophication – Comparison of Different Levels of Sophistication.” She compared a number of midpoint approaches, all based on spatially resolved modeling with the RAINS model, but defined increasingly closer towards the endpoint. She showed that spatial differentiation into source regions (and subsequent effects) becomes more important as modeling comes closer to the endpoint. In other words, the uncertainties posed by refraining from spatial differentiation increase by orders of magnitude as modeling comes closer to the endpoint. She identified the lack of differentiation in source regions as a main drawback of the endpoint-approach in Ecoindicator’99 that is based on a model confined to the – relatively small – Dutch territory. Aggregation of acidification and terrestrial eutrophication (already implemented) together with ecosystem effects (not yet fully implemented) was on the other hand appreciated by Potting as one of the strong features of Ecoindicator’99. She therefore suggested a combination of the spatial differentiated or site-dependent midpoint modeling with the site-generic endpoint modeling (for instance by extrapolating the midpoint modeling with RAINS to endpoint by calibrating on Ecoindicator’99). Potting stressed that the state-of-the-art modeling is for some regions (like Europe) closer towards endpoint than in other regions (like North America). She therefore recommended, in line with ISO14042, to limit characterization to modeling at the point for which accurate – spatially resolved –

modeling is available (often midpoint modeling), and to consider the extrapolation to endpoint as a part of weighting.

**Greg Norris** of Sylvatica presented "Midpoint -> Endpoint: Changes in Relative Importance of Pollutant, Location, and Source." He pointed out the rapidly changing nature of modeling in LCIA, noting how quickly we have moved from potentials to models, and he predicted we would soon be using more sophisticated estimates of uncertainty within our models. He stressed the importance and decision support value of calculating and maintaining uncertainty information at each stage in the impact assessment, and suggested iterative tests for dominance at each impact assessment modeling stage. In the second portion of Norris's talk he stressed that location is important for some impact categories and should be considered during the inventory stage. Using acidification as an example he pointed out analyses in which location was even more important than pollutant. He pointed to source class as a possible indicator of location and noted that source class correlated with other important factors including exposure efficiency. He suggested that source class related information may be used to fill in some of the existing holes in LCA.

**Edgar Hertwich** of the LCA Laboratory presented "Judging Environmental Harm: What Evidence should be Included?" Edgar began his presentation by stating that all "Environmental concerns are public." And "There is no satisfactory way to determine social preferences from individual preferences." He also stated that he thought some expression of uncertainty was imperative, perhaps including uncertainties about mechanisms, magnitudes, and relevance. He stated that within midpoints analysis we know things with more certainty, but within endpoints analysis we know things with more relevance. Hertwich warned against compounding uncertainty, i.e., introducing the same uncertainty in additional steps of impact assessment that change a clear preference order of a comparative LCA to overlapping indicator results. Instead he recommended that to maximize the differentiability, one should operate with differences at the inventory level, and again operate with differences at the midpoint level. He recommended keeping both midpoint and endpoint analysis for a number of reasons. He noted that endpoint modeling allows for an easier evaluation of the magnitude of effects, while midpoint modeling allowed higher confidence and lower uncertainty.

## 2 Group Discussions

A summary of the issues discussed within the small break-out groups and then during a moderated discussion session is presented below.

### 2.1 Definition of the terms Midpoint and Endpoint

A midpoint indicator can be defined as a parameter in a cause-effect chain or network (environmental mechanism) for a particular impact category that is between the inventory data and the category endpoints. Although in general this definition will hold true, such as in categories like climate change and acidification, it may not be fully adequate in others. In particular, this definition was questioned in relation to many impact categories (e.g., human health and some ecosystem effects) that were considered to have no common midpoint in the cause-effect chain at which characterization factors could be adequately defined. The parallel role of midpoint measures, such as the overall persistence of a chemical, as a check of endpoint characterization factors was however stated.

Endpoint characterization factors (or indicators) are calculated to reflect differences between stressors at an endpoint in a cause-effect chain and may be of direct relevance to society's understanding of the final effect, such as measures of

biodiversity change. In some impact categories, more than one endpoint measure exists. For example, in the context of ecosystem effects, measures include the Potentially Affected Fraction (PAF) of species and the Potentially Disappeared Fraction (PDF) of species.

## 2.2 Uncertainty, Comprehensiveness and Environmental Relevance

Uncertainties in LCIA remain high. There was a recognition that at least two types of uncertainty exist: model uncertainty and parameter uncertainty. Model uncertainty is reflects the accuracy of the model, as determined through evaluation studies. Parameter uncertainty is the uncertainty associated with the input data, as commonly determined using tools like Monte-Carlo analysis. Many participants expressed concern that model uncertainties are often ignored in LCA, and the limited efforts to date have only focused on parameter uncertainty.

There was a recognition that there is also uncertainty regarding the relevance of the results. This is referred to as scenario or decision rule uncertainty by some researchers. (This was also presented as “What we know” vs. “What we want”.) There was an overall belief that endpoint models may be more relevant, but less certain (i.e., higher model and parameter uncertainty) but that midpoint modeling may be more certain (i.e., lower model and parameter uncertainty), but less relevant to what the decision makers really want to know.

In the context of relevance, Udo de Haes suggested, "Life Support Systems" may be seen as having intrinsic value in their own right. For example, GWPs are a midpoint measure in the context of impacts to humans and ecosystems in the event of global warming. The GWPs also relate to the integrity of the global climate as a LSS - an area of protection in its own right, being supportive to life on earth in a broad sense; hence, the GWPs in this context may still be regarded as midpoint indicators, but now with a high environmental relevance.

One group stated that the inventory was truly the “starting point” in the model and that one could make some decisions at this level, but the hidden uncertainty would be very high, in fact maximal. In some cases it makes sense to stop at the midpoint level from an uncertainty standpoint (no additional differentiation is added by modeling further along the cause-effect chain and, in general, the uncertainty will be increased). A dissenting opinion stressed that some endpoint models may include additional information, which is generally left out of consideration at the midpoint (e.g., endpoint models may more easily include the precise time pattern of the emission of ozone depleting gases).

The relative comprehensiveness of the midpoint and endpoint indicators was discussed. In general, midpoint indicators will be more comprehensive because they will be relevant for a wider variety of impacts at endpoint level, although these impacts are not modeled and may not be specified or known. Generally, endpoint models will focus on a smaller number of pathways because of the requirement to model them quantitatively. Although some “gaps” are qualitatively "known", the experts in the associated domains may not be confident about assessment beyond well-characterized midpoints up to endpoint effects. Pathways that carry significant knowledge gaps prohibiting quantification can be considered within endpoint modeling by making assumptions within the cause-effect chain modeling itself, by leaving pathways out of consideration, or by using parallel precautionary indices. In contrast, midpoint approaches do not address these knowledge gaps, but allow their consideration within the weighting and decision making phases. It was also noted that for both midpoint and endpoint approaches, participants in a weighting process may not even be qualitatively aware of all of the primary or secondary effects associated with each impact category.

Faced with the benefits and limitations of midpoint and endpoint approaches, it was suggested that both sets of results should be presented, either in parallel or in a tiered approach, within one consistent framework. The user could then see the comparative results at the midpoint level, as well as at the endpoint level. It was noted that this is analogous to the use of endpoint methodologies to provide a default basis for cross-comparison amongst midpoint category indicators.

### 2.3 Transparency

The more complex the model, the harder it is to maintain transparency and the greater the level of required documentation. For example, it is not always obvious which toxicological effects are taken into consideration in some endpoint methodologies or which assumptions and value-choices are made in the associated chemical fate and exposure models. It may be clarifying to learn that human health effects on endpoint level due to climate change are considered to be mainly due to the expected increase of malaria. A specific problem may be that the value choices encoded into the methodology may not reflect those of the decision-maker. Similar arguments may exist in the context of midpoint indicators, including ozone depletion potentials and global warming potentials, but are probably less abundant. It was suggested that methodologies should be as transparent as possible whilst still providing the desired level of accuracy. In the case of complex models, there has to be sufficient consensus within the scientific community that the approaches are acceptable and that detailed documentation is not required by the general user. De Leeuw stated, “It is not necessary to know how the engine works to drive a car”.

Based on the level of modeling alone, the level of transparency associated with midpoint indicators can be considered higher than in endpoint approaches. However, when weighting is required to compare and aggregate across impact categories, the implicit links between the midpoint indicators and the endpoint effects may not always be expressed clearly or represented in a structured fashion. This may impact the robustness of the weighting exercise and the final result. This is another reason to support the use of midpoint and endpoint indicators in one consistent framework, where the endpoint indicators provide structured insights to be used at the midpoint level.

### 2.4 Relationship with decision support

Many of the issues addressed in the Brighton workshop were related to the decision support process.

Communication of the results was recognized as an important factor. For example, indicators at a midpoint level may be preferred for specific communication purposes (e.g. it may be politically preferable to speak in terms of global warming potentials rather than in terms of DALYs.). In general, indicators at endpoint level are sometimes considered to lead to more understandable results; in fact this is connected with the environmental relevance of the indicators, already discussed above. However, indicators at a midpoint level may be more readily communicated in the sense that they will less readily lead to unwarranted conclusions. (For instance, global warming potentials will not lead to an unproven suggestion that malaria indeed will increase in certain regions, in contrast to results in DALYs which indeed give such a suggestion.) In contrast, other practitioners liked the idea of increased specificity of the modeling of associated effects, stating that it may result in increased awareness of the implications of consumption.

As endpoint approaches were seen to be most valuable in those cases where aggregation was desired, there was a considerable discussion about the value of aggregating results. Some participants pointed out that the degree of aggregation

across categories may be dependent upon the point at which one alternative can be demonstrated to be an improvement over the other. Other participants suggested that it can be desirable to determine the relative importance of an indicator in one impact category compared to another (e.g., global warming compared to ozone depletion), or even to fully aggregate all impact categories into a single number. Still other participants questioned whether it was necessary to strive for a single number; they argued that it would be sufficient to compare options within categories like human health, ecosystem health, and resources, without aggregating these disparate measures. Related to the "single number approach" some participants cautioned others to spend significant time analyzing the value of the LCIA within the decision making process. They pointed out that these decisions are often not independent of other information, but are simply informative within a larger picture. Similar to the ISO 14042 admonition not to use LCIA as the sole basis for comparative assertions, these participants warned against isolating the results of the LCIA in the single number approach and advocated using specific environmental impact categories as independent indicators along with other types of information, such as economic and social considerations.

When aggregation was considered desirable, there was a recognition that conducting comparisons across categories is difficult. Three examples of weighting strategies were discussed: 1) using normalized midpoint indicators, 2) the same, but in addition using endpoint measures to provide default insights into the relative importance of certain midpoint categories, or 3) using endpoint indicators. Many supported the use of both midpoint and endpoint approaches when conducting a weighting exercise.

Hofstetter in his presentation, summarized earlier, pointed to the complications associated with panel methods and the severe limitations in current LCA practices related to their use with both midpoint and endpoint factors. Consequently, during the larger group discussions, the present quality of default weighting factors between impact categories was questioned. Participants were challenged to come up with a single example of well conducted, well documented, and bias-free panel results available within the literature. The general conclusion that midpoint results can only be weighted by experts, whereas endpoint results can also be evaluated (or weighted) by non-expert stakeholders, was further questioned by a number of experts. Hofstetter stated that more important than the modeling level is the way environmental issues are covered in mass media because mass media information will influence at which levels individuals develop preferences. In that respect both present midpoint and endpoint approaches may need to be adjusted to the level of actual perception by the public. If non-perceivable indicators are offered in a weighting exercise it is likely that preferences do not exist and answers will be biased by the provided information and the question format. Therefore, both midpoint and endpoint results can in principle be useful by non-experts, depending on attention they obtain in the mass media.

A far reaching remark by Hofstetter was that in the weighting stage quantitative and readily available information will have much more influence than qualitative or not presented information. This would affect both midpoint and endpoint modeling in the moment that they provide qualitative information on environmental relevance (with the midpoint models) or on the gaps (in the endpoint models). Norris went even one step further, arguing that non-quantified information cannot and should not be included in a weighting process because it will influence the decision in an uncontrollable way. In order to get clarity on this important issue there is a high need to learn more from experiences in related science fields.

## 2.5 Using both midpoint and endpoint indicators

Theoretically, providing they are developed using a consistent framework, midpoint and endpoint characterization factors within some impact categories may display linear proportionality (e.g., the midpoint measure "ozone depletion potentials" and the endpoint measure of "DALYs" related to ozone depletion may be linearly proportional). In cases in which there is essentially just a multiplication factor between the midpoint and endpoint measures there is still value in communicating, and perhaps utilizing both approaches because different endpoint impacts will use different factors (and also evidenced in the arguments for Life Support Systems, and the issue of communication needs). This remained a presupposition, however, since there are currently no examples of models which allow consistent analyses to occur at both levels.

To use current midpoint and endpoint approaches together would require the use of models that have incompatible data sets, impact assessment methodologies, and modeling assumptions. Analogous to the idea of using midpoint and endpoint approaches in parallel, some practitioners suggested conducting studies using available, multiple methodologies (and even inventory databases) to determine whether this affected the results. Others voiced frustration with available software and warned that decision makers will not accept conflicting models next to each other. Further investigation would then be required to resolve contradictory results.

In order to overcome the above stated problems, the aim may well be to develop one framework which includes both midpoint and endpoint approaches in a consistent way. Then for a particular study a choice can be made which level or levels to use for the modeling, depending on the requirements set by the given application. Such a perspective could be considered within the presently envisaged SETAC/UNEP program, aiming at the identification of best available practice.

## 3 Conclusions

A consensus was reached by the LCIA experts at the Brighton workshop that both midpoint and endpoint level indicators have complementary merits and limitations. Decisions can be made using the midpoint indicators, which are more certain but can have a lower relevance for decision support in some cases, or using the endpoint indicators, which were argued to often have a higher relevance but lower certainty.

Some practitioners suggested that the midpoint and endpoint indicators should be available in parallel. An interesting perspective would be to provide both sets of information to decision makers within a consistent framework (midpoint and endpoint indicators provided from a given model of the cause-effect network). In line with this, strong support was expressed for the use of tiered approaches within LCA, where, for example, preliminary comparisons using midpoint approaches are followed by more detailed approaches at endpoint level. However, the form of such a tiered approach was not identified.

The present workshop has played an important role in clarifying the difference between the two approaches regarding comprehensiveness and gaps, uncertainty (model and parameter), relevance (or scenario uncertainty), the degree of transparency, value-choices, and an improved understanding of the limitations of panel-based weighting methods for comparing across impact categories. However, this can only be seen as a step in a process, because on all these issues further information and discussion is needed.

Participants finally expressed a desire to hold future workshops on these and on related issues in the field of LCIA, such as the treatment of ecosystem effects and environmental quality as it relates to land use issues, the different forms of uncertainty, issues in weighting, and the interaction between risk assessment and LCIA.

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Appendix 6: Workshop Participants

# Participants in the UNEP Workshop in Brussels, 29-30 November 1998


**Aistars, Guntra**
University of Michigan
Dana Building 430 E. University
Ann Arbor, MI 48109-1115
Tel: 734-764-1412
Fax: 734-647-5841
e-mail: guntra@umich.edu

**Anderson, Jane**
BRE
Watford, Herts, WD2 7JR
United Kingdom
Fax: 44-1923-664 084
e-mail: andersonj@bre.co.uk

**Bare, Jane**
U.S. EPA (MS-466)
Cincinnati, OH 45268
Tel: 513-569-7513
Fax: 513-569-7111
e-mail: bare.jane@epa.gov

**Beaufort-Langeveld, Angeline de**
FEFCO-GO-KI
Groeterweg 13
6071 ND Swalmen
Tel: 0475 - 501 014
Fax: 0475 - 504 478
e-mail: beulang@wxs.nl

**Buridard, Mark**
International Iron & Steel
Rue Colonnel Boury 120
1140 Brussels
Belgium
e-mail: lcaletter@iisi.be

**Butterworth, Paul**
International Iron & Steel Institute
e-mail: butterworth@iisi.be

**Ciroth, Andreas**
Technische Universität Berlin
Abfallvermeidung und Sekundärrohstoffwirtschaft
Strasse des 17. Juni 135
D-10623 Berlin
Tel: 49-30-314 79564
Fax: 49-30-314 21720
e-mail: ciroth@itu302.ut.tu-berlin.de

**Clark, Garrette**
UNEP DTIE
Tour Mirabeau – 39-43,
Quai André Citroen
75739 Paris Cedex 15
France
Tel: +33-1-4437 1441
Fax: +33-1-4437 1474
e-mail: garrette.clark@unep.fr

**Crettaz, Pierre**
Ecole Polytechnique Federale de Lausanne
DGR-IATE-HYDRAM
CH-1015 Lausanne
Switerland
Tel: 41-21-693 3729
Fax: 41-21-693 3739
e-mail: pierre.crettaz@epfl.ch

**Curran, Mary Ann**
U.S. EPA (MS-466)
Cincinnati, OH 45268
Tel: 513-569-7513
Fax: 513-569-7111
e-mail: curran.maryann@epamail.epa.gov

**Edwards, Suzy**
BRE
Watford, Herts, WD2 7JR
United Kingdom
Fax: 44-1923-664 084
e-mail: edwardss@bre.co.uk

**Ekvall, Tomas**
Chalmers Industriteknik
Chalmers Teknikpark
S-41288 Göteborg
Sweden
Tel: 46-31-772 4336
Fax: 46-31-827 421
e-mail: tomas.ekvall@cit.chalmers.se

**Finnveden, Göran**
Fmw and Department of Systems Ecology
Box 2142
SE-103 14 Stockholm
Sweden
Tel: 46-8-402 3827
Fax: 46-8-402 3801
e-mail: finnveden@fms.ecology.su.se

**Franke, Marina**
Proctor & Gamble
Global Technical Policy/Environmental Management
Postfach 5825, Industriestrafe 30-34
D-65733 Eschborn, Tanus
Tel: +49-6196 89-4723
Fax: +49-6196 89-6648
e-mail: franke.m@pg.com

**Fretiere, Jean-Paul**
European Product Responsibility Manager
3M France
Boulevard de l'Oise
95006 Cergy Pontoise Cedex
Tel: 33-130318107
Fax: 33-130318192
e-mail: jfretiere@mmm.com

# Appendix 6: Workshop Participants

**Gonzales, Bernard**
3M
U.S.A.
e-mail: bagonzales@mmm.com

**Goedkoop, Mark**
PRé Consultants B.V.
Plotterweg 12
NL-3821 BB Amersfoort
Netherlands
Tel: 31-33-455 5022
Fax: 31-33-455 5024
e-mail: goedkoop@pre.nl

**Guinée, Jeroen**
Centre of Environmental Science
P.O. Box 9518
NL-2300 RA Leiden
Netherlands
Tel.: 31-71-527 7477
Fax: 31-71-527 7434
e-mail: guinee@rulcml.leidenuniv.nl

**Hauschild, Michael**
Department of Manufacturing Engineering
Technical University of Denmark
Building 424
DK-2800 Lyngby
Denmark
Tel: 45-45-254 664
Fax: 45-45-935 556
e-mail: mic@ipt.dtu.dk

**Heath, David**
ICI
e-mail: david_heath@ici.co.uk

**Hertwich, Edgar**
University of California, Berkeley
310 Barrows Hall #3050
Berkeley, CA 94720-3050
Tel: 510-642-8853
Fax: 510-642-5815
U.S.A.
e-mail: hertwich@socrates.berkeley.edu

**Hofstetter, Patrick**
Umweltnatur- und Umweltsozialwissenschaften (UNS)
ETH-Zentrum HAD F1
8092 Zuerich
Switzerland
Tel: +41-1-632 49 78
Fax: +41-1-632 10 29
e-mail: hofstetter@uns.umnw.ethz.ch

**Houten, Maarten ten**
TNO-Institute of Industrial Technology
P.O. Box 5073
2600 GB Delft
Netherlands
Tel: 31-15-260 8828
Fax: 31-15-260 8756
e-mail: m.tenhouten@ind.tno.nl

**Huijbregts, Mark**
IVAM, University of Amsterdam
Nieuwe Prinsengracht 130
1018 VZ Amsterdam
Netherlands
Tel: 31-20-525 6263
Fax: 31-20-525 6272
email: m.huijbregts@frw.uva.nl

**Itsubo, Norihiro**
Japan Environmental Management Association for Industry
Hirokohji Bldg. Ueno 1-17-6, Taitoh-ku
Tokyo
Japan 110-8535
Tel: 81-3-3832 0515
Fax: 81-3-3832 2774
e-mail: itsubo@jemai.or.jp

**Jolliet, Olivier**
Institute of Soil and Water Management
EPFL-IATE-HYDRAM
CH-1015 Lausanne
Switzerland
Tel: 41-21-693 7011
Fax: 41-21-693 7084
e-mail: olivier.jolliet@epfl.ch

**King, Henry**
Unilever
e-mail: henry.king@unilever.com

**Klöpffer, Walter**
C.A.U. GmbH
Daimlerstraße 23
D-63303 Dreieich
Germany
Tel: +49-6103-983 28
Fax: +49-6103-983 10
e-mail: C.A.U.@t-online.de

**Mälkki, Helena**
VTT Chemical Technology
P.O. Box 14031
FIN-02044 VTT Espoo
Finland
Tel: 358-9-4566442
Fax: 358-9-4567043
e-mail: helena.malkki@vtt.fi

**Milà i Canals, Llorenç**
Universitat Autònoma de Barcelona
Unitat de Química Física, Edifici Cn,
Bellaterra
Barcelona 08193
Spain
Tel: +34-3-581 21 64
Fax: +34-3-581 29 20
e-mail: llorenc@klingon.uab.es

**Nigge, Karl-Michael**
Rheinweg 27
D-53113 Bonn
Germane
Tel: +49-228-233 763
Fax: +49-228-233 763
e-mail: karl-michael.nigge@dir.de

# Appendix 6: Workshop Participants

**Nocker, Leo De**
VITO
Boeratang 200
B-2400 Mol
Belgium
Tel: +32-14-334 885
Fax: +32-14-321 185
e-mail: denockel@vito.be

**Norris, Gregory**
Sylvatica
147 Bauneg Beg Hill Rd.
Suite 200
North Berwick, ME 03906
U.S.A.
Tel: 207-676-7640
Fax: 207-676-7647
e-mail: norris@sylvatica.com

**Olsen, Stig Irving**
Institute for Product Development
Technical University of Denmark
Building 424
DK-2800 Lyngby
Denmark
Tel: +45-45-254 611
Fax: +45-45-935 556
e-mail: sio@ipt.dtu.dk

**Owens, Willie**
Proctor & Gamble
5299 Spring Grove Ave.
Cincinnati, Ohio 45214
U.S.A.
Tel: 513-627-8183
Fax: 513-627-8198
e-mail: owens.jw@pg.com

**Pennington, David**
ORISE Post Doctoral Researcher
U.S. EPA (MS-466)
Cinncinnati, OH 45268
Tel: 513-569-7618
Fax: 513-569-7111
e-mail: pennington.david@epamail.epa.gov

**Potting, Jose**
Technical University of Denmark
c/o Bo Pedersen Weidema
IPU, Life Cycle Engineering Group
Building 40311
DK-2800 Lyngby Denmark
Tel: +4545254677
Fax: +4545935556
e-mail: jp@ipt.dtu.dk

**Rolander, Steven**
SAIC
11251 Roger Bacon Dr.
Reston, VA 20190
Tel: 703-318-4605
Fax: 703-736-0826
U.S.A.
e-mail: rolanders@saic.com

**Saouter, Erwan**
Procter & Gamble, Environmental Science Department
100 Temselaan
B-1853 Strombeek Bever
Belgium
Tel: +32-2-4562491
Fax: +32-2-4562845
e-mail: saouter.e@pg.com

**Sonnemann, Guido**
Chemical Engineering Department
Universitat Rovira i Virgili
Carretera de Salou s/n
E-43006 Tarragona, Spain
Tel: +34-977-559 618
Fax: +34-977-559 667
e-mail: gsonnema@etseq.urv.es

**Steen, Bengt**
CPM
Chalmers University of Technology
SE-412 96 Gothenburg
Sweden
Tel: 46-31-772 2177
Fax: 46-31-772 2172
e-mail: bengts@vsect.chalmers.se

**Tolle, Duane**
Battelle Columbus Division
Columbus, OH 43201
U.S.A.
Tel: 614-424-7591
Fax: 614-424-3404
e-mail: tolled@battelle.org

**Tukker, Arnold**
TNO-STB
P.O. Box 541
NL-7300 AM Apeldoorn
Netherlands
Tel: 31-55-5493907
Fax: 31-55-5421458
e-mail: tukker@stb.tno.nl

**Udo de Haes, Helias A.**
Centre of Environmental Science
P.O. Box 9518
NL-2300 RA Leiden
Netherlands
Tel: 31-71-527 7488
Fax: 31-71-527 5587
e-mail: udodehaes@rulcml.leidenuniv.nl

**Weidema, Bo**
Technical University of Denmark
Inst. for Product Development
Building 424
2800 Lyngby
Denmark
e-mail: bow@ipt.dtu.dk

**Weitz, Keith**
Research Triangle Institute
3040 Cornwallis Rd.
P.O. Box 12194
RTP, NC 27709
U.S.A
Tel: 919-541-6973
Fax: 919-541-7155
e-mail: kaw@rti.org

**Wenzel, Henrik**
IPU-DTU
Technical University Denmark
Building 424
D-2800 Denmark
Denmark
Tel: 45-45-254 663
Fax: 45-45-935 556
e-mail: hwc@ipt.dtu.dk

# Appendix 6: Workshop Participants

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# Participants in the UNEP Workshop in Brighton, 25-26 May 2000


**Braunschweig, Arthur**
University of St.Gallen, Institute for Economy and the Environment IWÖ-HSG
E2 Management Consulting AG
Tigerbergstr. 2, CH-9000 St.Gallen Switzerland
Tel: +41 1 362 8572
Fax: +41 1 361 8601
e-mail: abraunschweig@e2mc.com

**Brekke, Andreas**
Research assistant
The LCA Laboratory, IPD
Kolbjorn Hejes vei 2b
N-7491 Trondheim
Norway
Tel: +47 73 55 06 34
Fax: +47 73 59 01 10
e-mail: andreasb@design.ntnu.no

**Cunningham, Virginia L.**
SmithKline Beecham
2200 Renaissance Blvd. -Suite 105
King of Prussia, PA 19406
USA
Tel: +610 239 5262
Fax: +610 239 5250
e-mail: virginia.l.cunningham@sb.com

**Caluwe Nils de**
Eco Design Consultant
Plilips Environmental Services
Building SAN-5
P.O. BOX 218/Glaslaaan 2
5600 MD Eindhoven
The Netherlands

**Groot, Adrie de van Dam**
TNO Building and Construction Research
Division BKR
P.O. Box 49
2600 AA DELFT
The Netherlands
Tel: +31 152 69 5235
Fax: +31 152 69 5335
e-mail: a.degroot@bouw.tno.nl

**Driver, Alex**
BICC Compounds General , Technology,
WreExham Instustia Estate
Wrexham
UK

**Edwards, Suzy**
Centre for Sustainable Construction
Building Research Establishment
Garston, Watford
Herts, WD2 7JR
UK
Tel: +01923 664390
Fax: +01923 664084
e-mail: edwardss@bre.co.uk

**Eggers, Hans-Hermann**
German Federal Environmental Protection Agency,
PO Box 33 00 22
14191 Berlin
Gemany
Tel: +49 30 8903 3831
Fax: +49 30 8903 3232
e-mail: hans-hermann.eggers@uba.de

**Eik, Arne**
The Industrial Ecology Programmec
Norwegian Technical University
Paviljong B, Dragvoll
N-7491 Trondheim
Norway
Tel: +47 73 59 89 57
Fax: +47 73 59 89 41
e-mail: arne.eik@indecol.ntnu.no

**Finnveden, Göran**
FMS Environmental Strategies Research Group
National Defence Research Establishment
Box 2142
103 14 Stockholm
Sweden
Tel: +46 8 402 38 27
Fax: +46 8 402 38 01
e-mail: finnveden@fms.ecology.su.se

**Goedkoop, Mark J.**
Plotterweg 12 3821 BB Amesfoort
The Netherlands
Tel: +33 4555022
Fax: +33 4555024
e-mail:goedkoop@pre.nl

**Gouda, Hazem**
UWRC Bell Street
University of Albertay Dundee
Dundee, DD1 1HG
UK
e-mail: serhmeg@tay.ac.uk

**Hauschild, Michael**
Technical University of Denmark
Department of Manufacturing Engineering
Building 424
DK-2800 Lyngby
Denmark
Tel: +45 45 25 46 64
Fax: +45 45 93 55 56
e-mail: mic@ipt.dtu.dk

# Appendix 6: Workshop Participants

**Henshaw, Carole**
Unilever Research Port Sunlight
Quarry Road East
Bebington, Wirral
L63 3JW
UK
Tel: +44 0151 6413373
Fax: +44 0151 6411816
e-mail: carole.henshaw@unilever.com

**Hischier, Roland**
Swiss Federal Laboratories for Materials Testing and Research
EMPA St.Gallen
Ecology Section 245
Lerchenfeldstrasse 5
9014 St.Gallen
Switzerland
Tel: +41 (0)71 - 274 78 47
Fax: +41 (0)71 - 274 78 62
e-mail: roland.hischier@empa.ch

**Hofstetter, Patrick**
ORISE Research Fellow
US Environmental Protection Agency (MS-466)
26 W. Martin Luther King Dr.
Cincinnati, OH 45268
USA
Tel: +513 569 73 26
Fax: +513 569 71 11
e-mail: hofstetter.patrick@epa.gov

**Itsubo, Norihiro**
Japan Environmental Management Association for Industry
Hirokohji Bldg.
Ueno 1-17-6, Taitohku
Tokyo, 110-8535
Japan
Tel: +81 3 3832 0515
Fax: +81 3 3832 2774
e-mail: itsubo@jemai.or.jp

**James, Karli L**
Centre for Packaging, Transportation & Storage
Victoria University of Technology
PO Box 14428
Melbourne City, MC, Victoria 8001
Australia
Tel: +61 0 3 9216 8050
Fax: +61 0 3 9216 8074
e-mail: Karli.James@vu.edu.au

**Jensen, Allan Astrup**
dk-TEKNIK ENERGY & ENVIRONMENT
15, Gladsaxe Møllevej
DK-2860 Søborg, Denmark
Tel: +45 39 555 904
Fax: +45 39 696 002
e-mail: aajensen@dk-teknik.

**Jimenez-Gonzalez, Concepcion**
North Carolina State University, USA
USA: 721 Ryan Ct., Raleigh NC 27606, USA
Tel: +919 821 5236
Fax: +919 515 1975
e-mail: jconchita@hotmail.com

**Mälkki, Helena**
VTT CHEMICAL TECHNOLOGY
Environmental Technology/Industrial Environmental Economics
P.O.Box 14031, FIN - 02044 VTT
Finland
Tel: +358 9 456 6442
Fax: +358 9 456 7043
e-mail: helena.malkki@vtt.fi

**Margni, Manuele**
IATE/GECOS
Ecole Polytechnique Fédérale de Lausanne
CH-1015 Lausanne
Switzerland
Tel: +41.21.6933729
Fax: +41.21.6935760
e-mail: manuele.margni@epfl.ch

**McKone, Tom**
University of California
Lawrence Berkeley National Laboratory and School of Public Health
140 Warren Hall #7360
Berkeley, CA 94720-7360
USA
Tel: +510 642 8771
Fax: +510 642 5815
e-mail: temckone@LBL.gov

**Milà i Canals, Llorenç**
Unitat de Química Física
Edifici C, Universitat Autónoma de Barcelona
E-08193-Bellaterra (Barcelona)
Spain
Tel: +34 93 581 21 64
Fax: +34 93 581 29 20
e-mail: llorenc@klingon.uab.es

**Mueller-Wenk, Ruedi**
Institut fuer Wirtschaft und Oekologie
Universitaet St.Gallen (IWOE-HSG)
Tigerbergstr. 2, CH-9000 St.Gallen
Switzerland
Tel: +41 71 224 2718
Fax: +41 71 224 2722
e-mail: ruedi.mueller-wenk@unisg.ch

**Payet, Jérôme**
DGR – GECOS
Ecole Polytechnique Federale de Lausanne
CH - 1015 Lausanne
Switzerland
Tel: +41 21 693 57 93
Fax: +41 21 693 57 60
e-mail: jerome.payet@epfl.ch

**Pennington, David W**
ORISE Research Fellow
US Environmental Protection Agency (MS 466)
26 W. Martin Luther King Dr.
Cincinnati, OH 45268
USA
Tel: +513 569 7618
Fax: +513 569 7111
e-mail: pennington.david@epa.gov

# Appendix 6: Workshop Participants


**Schulze, Carsten**
Dipl. Systemwissenschaftler Carsten Schulze
Institute of Environmental Systems Research,
University of Osnabrück
49069 Osnabrück
Germany
Tel: +49 541 969 2520
Fax: +49 541 969 2599
e-mail: carsten.schulze@usf.uni-osnabrueck.de

**Seppälä, Jyri**
Environmental Management Group, Pollution Prevention Division
Finnish Enviornment Insititute
Kesäkatu 6, P.O. Box 140
FIN-00251 Helsinki
Finland
Tel: +358 9 4040 0406
Fax: +358 9 4030 0490
e-mail: www.seppala@vyh.fi

**Steen, Bengt**
Dept of Environmental System Analysis and CPM
Chalmers University of Technology
SE-412 96 Göteborg
Sweden
Tel: +46 31 772 2177
Fax: +46 31 772 2172
e-mail: bengt.steen@esa.chalmers.se

**Sullivan, John**
Ford Motor Company
686 Wembly Court
An Arbor, MI 48103
USA

**Tørsløv, Jens**
DHI - Institute of Water and Environment
Agern Allé 11
2970 Hørsholm
Denmark
Tel: +45 45 16 90 22
Fax: +45 45 16 92 92
e-mail: jet@dhi.dk

**Udo de Haes, Helias A.**
Centre of Environmental Science (CML)
Leiden University
P.O. Box 9518
2300 RA Leiden
Netherlands
Tel: +31 71 527 74 88
Fax: +31 71 527 55 87
e-mail: udodehaes@cml.leidenuniv.nl

**Meent, Dik van de**
RIVM
P.O. BOX 1
3720 BA Bilthoven,
The Netherlands

**Olivier Jolliet**
Laboratory of ecosystem management
Ecole polytechnique fédérale de Lausanne
EPFL-GECOS
CH-1015 Lausanne
Tel: +41 21 693 57 68
Fax: +41 21 693 57 60
e-mail: olivier.jolliet@epfl.ch

**Klöpffer, Walter**
C.A.U. GmbH
Daimlerstrasse 23
63303 Dreieich
Tel: +49 61 03 983 17
Fax: +49 61 03 983 10
e-mail: C.A.U.@t-online.de

**Erwin Lindeijer**
Sustainable product innovation
TNO Industry
PO Box 5073
2600 GB Delft
The Netherlands
Tel: +31-15-2608.897
Fax: +31-15-2608.846
e-mail: e.lindeijer@ind.tno.nl

**Mettier, Thomas**
Umweltnatur- und Umweltsozialwissenschaften (UNS)
ETH Zuerich -Zentrum, HAD F1
8092 Zurich
Switzerland
Tel: +41 1 632 63 14
Fax: +41 1 632 10 29
e-mail: mettier@uns.umnw.ethz.ch

**Nishioka, Yurika**
Harvard School of Public Health
Department of Environmental Health
400 Brookline Ave. Rm 11C
Boston, MA 02215
USA
Tel: +617-277-3319
Fax: +617-432-4122
e-mail: ynishiok@hsph.harvard.edu

**Norris, Greg**
Sylvatica, Inc
147 Bauneg Hill Rd, Suite 200
North Berwick, ME 03906
Tel: +1-207-676-7640
Fax: +1-207-676-7647
e-mail: norris@sylvatica.com

**Olsen, Stig Irving**
Institute for Product Development, IPU
Technical University of Denmark
Building 424
2800 Lyngby
Denmark
Tel: +45 45 25 46 11
Fax: +45 45 93 55 56
e-mail: sio@ipt.dtu.dk

# Appendix 6: Workshop Participants

**Romach, George**
IME Die Metallurgen
Department of Nonferrous
Intzestra 3,
D-52056 Aachen
Germany

**Shonnard, David R.**
Department of Chemical Engineering
Michigan Technological University
1400 Townsend Drive
Houghton, MI 49931
USA
Tel: +906 487 3468
Fax: +906 487 3213
e-mail: drshonna@mtu.edu

**Sliwka, Peter**
Department of Engineering Geology and
Hydrogeology
University of Technology
Lochnerstr. 4-20
52064 Aachen
Germany
Tel: +49 241 806776
Fax: +49 241 8888280
e-mail: sliwka@adler.lih.rwth-aachen.de

**Sonnemann, Guido**
Chemical Engineering Department
Universitat Rovira i Virgili
Carretera de Salou s/n
E-43006 Tarragona - Spain
Tel: +34 977 559618
Fax: +34 977 559667
e-mail: gsonnema@etseq.urv.es

**Vidal, Nuria**
Departament d'Enginyeria Química Ambiental i
Tecnologies Agroalimentaries
Universitat de Girona
C/ Montilivi, s/n
17071Girona
Spain
Tel: +34 972418355
e-mail: nvidal@lequia.udg.es

**Volkwein, Stephan**
C.A.U. GmbH
Daimlestr. 23
63303 Dreieich
Germany
Tel: +49-61 03-983-25
Fax: +49-61 03-983-10
e-mail: info@cau-online.de

**Zapp, Petra**
Forschungszentrum Juelich
52425 Juelich
Germany
Tel: +49 2461 615942
Fax: +49 2461 612540
e-mail: p.zapp@fz-juelich.de

About UNEP DTIE

# UNEP - Division of Technology, Industry and Economics

The mission of UNEP's Division of Technology, Industry and Economics (DTIE) is to help decision-makers in government, industry and local authorities develop and adopt policies and practices that:

- Are cleaner and safer;
- Make efficient use of natural resources;
- Ensure adequate management of chemicals;
- Incorporate environmental costs;
- Reduce pollution, and risks to humans and the environment

The Division is based in Paris and comprises one center and four units.

- **The International Environmental Technology Centre (Osaka**), which promotes the adoption and use of environmentally sound technologies which focus on the environmental management of cities and freshwater basins in developing countries and countries in transition.
- **Production and Consumption Unit (Paris),** which fosters the development of cleaner and safer production and consumption patterns that lead to increase efficiency in the use of natural resources, and reduction in pollution.
- **Chemicals Unit (Geneva)**, which promotes sustainable development by catalyzing global actions and building national capacities for the sound management of chemicals and the improvement of chemical safety world-wide, with a priority on Persistent Organic Pollutants (POPs) and Prior Informed Consent (PIC, jointly with FAO).
- **Energy and Ozone Action Unit (Paris),** which supports the phase-out of ozone-depleting substances in developing countries and countries with economies in transition, and promotes good management practices and use of energy, with a focus on atmospheric impacts. The UNEP/RISØ Collaborating Centre of Energy and Environment supports the work of the Unit.
- **Economics and Trade Unit (Geneva)**, which promotes the use and application of assessment and incentive tools for environmental policy, and helps improve the understanding of linkages between trade and environment and the role of financial institutions in promoting sustainable development.

UNEP DTIE activities focus on raising awareness, improving the transfer of information, building capacity, fostering technology co-operation, partnerships and transfer, improving understanding of environmental impacts of trade issues, promoting integration of environmental considerations into economic policies, and catalyzing global chemical safety.

For more information contact:


UNEP, Division of Technology, Industry and Economics
39-43, Quai André Citroën
75739 Paris Cedex 15, France

Tel: +33 1 44 37 14 50
Fax: +33 1 44 37 14 74
E-mail: unep.tie@unep.fr
URL: http://www.uneptie.org

# About EPA, CML & AGA

**The U.S. Environmental Protection Agency** was established in 1970 to consolidate in one agency a variety of federal research, monitoring, standard-setting and enforcement activities to ensure environmental protection. EPA's mission is to protect human health and to safeguard the natural environment - air, water, and land - upon which life depends. For 30 years, the EPA has been working for a cleaner, healthier environment for the American people.

United States
Environmental Protection Agency
MS-466
Cincinnati, OH 45268
USA

Tel: 513-569-7513
Fax: 513-569-7111

**The Centre of Environmental Science** (CML) is an inter-faculty department of Leiden University, providing education and research on social and environmental processes relevant to progress towards a sustainable society. Its four sections deal with Substances and Products, Ecosystems and Environmental Quality, Environment and Development, and Education. The center has a staff of 40.

Center of Environmental Science
Leiden University
P.O. Box 9518
2300 RA Leiden
The Netherlands

Tel: +31 71 5277477
Fax: +31 71 5277434

**The Environmental Management and Analysis Group AGA** (Grup d'Anàlisi i Gestió Ambiental) of the University Rovira i Virgili URV has the mission to carry out environmental research on a European level and to satisfy, from the university background, technology and outsourcing requirements of industry and public administration by means of technology and knowledge transfer actions. The group is located in the Technology Transfer Service STQ and the Chemical Engineering Department of the School for Chemical Engineering ETSEQ. Since 1994 AGA's research group has developed different projects and courses, has participated in several national and international meetings and has published more than 50 reports as well as publications related to the subjects mentioned above.

Environmental Analysis and
Management Group
University Rovira i Virgili
Av. dels Països Catalans s/n
43007 Tarragona
Spain

Tel: +31 71 5277477
Fax: +31 71 5277434

## Why use Life Cycle Assessment? (UNEP, 1996)

There are three reasons for using LCA:
It is **product and service** oriented; it is **integrative**; and it is **scientific and quantitative**.
LCA thus has a unique role to play in furthering the environmental aspects of sustainable development.

**Products and services** are extremely important in an industrial society. All economic activities depend on the use and consumption of products and services. Products and services are the axis around which industrial activity turns. Policies on products and services in business and governments are an important means of making economic activities environmentally more sustainable.

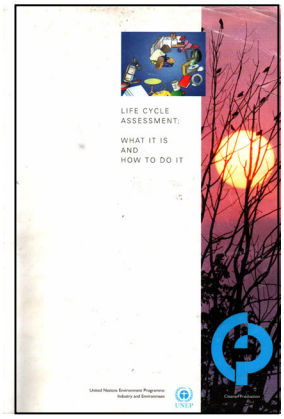
By its **integrative** approach, LCA can be used to prevent three common forms of pollution problem shifting:

- from one stage of the life cycle to another;
- from one environmental medium to another; and
- from one location to another.

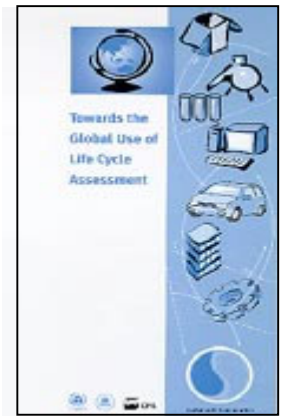
LCA is designed to provide the most **scientific and quantitative** information possible to support decision-making. Other types of criteria – economic, social and political – enter the discussion when decision-makers use the overall information furnished by LCA to analyze the information at stake.

### PREVIOUS UNEP REPORTS ON LIFE CYCLE ASSESSMENT

UNEP Industry and Environment, 1996.
*Life cycle assessment: what is it and how to do it.*
United Nations Publication Sales No. 9C-III-D.2, Paris.




UNEP Division of Technology, Industry and Economics, 1999. *Towards the Global Use of Life Cycle Assessment*. United Nations Publication, ISBN 82-807-1704-5, Paris.



# Life Cycle Initiative

## UNEP/ SETAC cooperation
## on approaches and best practice for a Life Cycle Economy

### Objectives and Deliverables

The Life Cycle Initiative builds on the ISO 14040 standards and intends to establish approaches and best practice for a Life Cycle Economy. The overall objective is to ***develop and disseminate practical tools for evaluating the opportunities, risks, and trade-offs associated with products over their entire life cycle to achieve sustainable development***. This includes the sharing of information between existing bodies of life cycle knowledge and the stimulation of multidisciplinary work.

An important tool concerns Life Cycle Assessment (LCA); to establish ***best practice in LCA*** the following deliverables have been identified:

- **Information system with Life Cycle Inventory databases** peer reviewed and regularly updated.
- **Set of rules for the setting of system boundaries and for allocation** as a basis for the elaboration of consistent data.
- **Set of best available Life Cycle Impact Assessment methods,** models and factors.

To facilitate a framework ***for incorporating Life Cycle Thinking and the social, economical and environmental aspects of sustainability in management systems*** the following elements have been proposed:

- **Integration of various existing tools and concepts** for decision-making on sustainable products and services.
- **Set of adequate indicators** for benchmarking.
- **Strategies for the communication** with relevant stakeholders about life cycle information.

The ***initiative will be driven by*** the implementation and dissemination of life cycle thinking with:

- **Demonstration studies** on life cycle approaches and best practice in different industry sectors and world regions.
- **Training modules** for SMEs and developing countries.

### Expected benefits

Expected benefits concern the development of practical tools for governments, industry and consumers that ***translate life cycle thinking into practice*** with:

- **Avoiding duplication of work and arbitrariness**
- **Providing reliable information in accessible format**
- **Preparing industry for increasingly aware consumers**
- **Supporting good business practices**
- **Contributing to continuous improvement**
- **Ensuring global applicability and dissemination**

For more information contact the Sustainable Consumption Group of UNEP DTIE at sc@unep.fr.

**www.unep.org**

United Nations Environment Programme
P.O. Box 30552 Nairobi, Kenya
Tel: (254 2) 621234
Fax: (254 2) 623927
E-mail: cpiinfo@unep.org
web: www.unep.org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INTERNATIONAL STANDARD

**ISO 14040**

Second edition
2006-07-01

# Environmental management — Life cycle assessment — Principles and framework

*Management environnemental — Analyse du cycle de vie — Principes et cadre*

Reference number
ISO 14040:2006(E)

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# Contents

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# Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 14040 was prepared by Technical Committee ISO/TC 207, *Environmental management*, Subcommittee SC 5, *Life cycle assessment*.

This second edition of ISO 14040, together with ISO 14044:2006, cancels and replaces ISO 14040:1997, ISO 14041:1998, ISO 14042:2000 and ISO 14043:2000, which have been technically revised.

# Introduction

The increased awareness of the importance of environmental protection, and the possible impacts associated with products [1)], both manufactured and consumed, has increased interest in the development of methods to better understand and address these impacts. One of the techniques being developed for this purpose is life cycle assessment (LCA).

LCA can assist in

— identifying opportunities to improve the environmental performance of products at various points in their life cycle,

— informing decision-makers in industry, government or non-government organizations (e.g. for the purpose of strategic planning, priority setting, product or process design or redesign),

— the selection of relevant indicators of environmental performance, including measurement techniques, and

— marketing (e.g. implementing an ecolabelling scheme, making an environmental claim, or producing an environmental product declaration).

For practitioners of LCA, ISO 14044 details the requirements for conducting an LCA.

LCA addresses the environmental aspects and potential environmental impacts [2)] (e.g. use of resources and the environmental consequences of releases) throughout a product's life cycle from raw material acquisition through production, use, end-of-life treatment, recycling and final disposal (i.e. cradle-to-grave).

There are four phases in an LCA study:

a) the goal and scope definition phase,

b) the inventory analysis phase,

c) the impact assessment phase, and

d) the interpretation phase.

The scope, including the system boundary and level of detail, of an LCA depends on the subject and the intended use of the study. The depth and the breadth of LCA can differ considerably depending on the goal of a particular LCA.

The life cycle inventory analysis phase (LCI phase) is the second phase of LCA. It is an inventory of input/output data with regard to the system being studied. It involves collection of the data necessary to meet the goals of the defined study

The life cycle impact assessment phase (LCIA) is the third phase of the LCA. The purpose of LCIA is to provide additional information to help assess a product system’s LCI results so as to better understand their environmental significance.

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1) In this International Standard, the term “product” includes services.

2) The “potential environmental impacts” are relative expressions, as they are related to the functional unit of a product system.

Life cycle interpretation is the final phase of the LCA procedure, in which the results of an LCI or an LCIA, or both, are summarized and discussed as a basis for conclusions, recommendations and decision-making in accordance with the goal and scope definition.

There are cases where the goal of an LCA can be satisfied by performing only an inventory analysis and an interpretation. This is usually referred to as an LCI study.

This International Standard covers two types of studies: life cycle assessment studies (LCA studies) and life cycle inventory studies (LCI studies). LCI studies are similar to LCA studies but exclude the LCIA phase. LCI studies are not to be confused with the LCI phase of an LCA study.

Generally, the information developed in an LCA or LCI study can be used as part of a much more comprehensive decision process. Comparing the results of different LCA or LCI studies is only possible if the assumptions and context of each study are equivalent. Therefore this International Standard contains several requirements and recommendations to ensure transparency on these issues.

LCA is one of several environmental management techniques (e.g. risk assessment, environmental performance evaluation, environmental auditing, and environmental impact assessment) and might not be the most appropriate technique to use in all situations. LCA typically does not address the economic or social aspects of a product, but the life cycle approach and methodologies described in this International Standard can be applied to these other aspects.

This International Standard, like other International Standards, is not intended to be used to create non-tariff trade barriers or to increase or change an organization's legal obligations.

# Environmental management — Life cycle assessment — Principles and framework

## 1 Scope

This International Standard describes the principles and framework for life cycle assessment (LCA) including

a) the goal and scope definition of the LCA,

b) the life cycle inventory analysis (LCI) phase,

c) the life cycle impact assessment (LCIA) phase,

d) the life cycle interpretation phase,

e) reporting and critical review of the LCA,

f) limitations of the LCA,

g) relationship between the LCA phases, and

h) conditions for use of value choices and optional elements.

This International Standard covers life cycle assessment (LCA) studies and life cycle inventory (LCI) studies. It does not describe the LCA technique in detail, nor does it specify methodologies for the individual phases of the LCA.

The intended application of LCA or LCI results is considered during the goal and scope definition, but the application itself is outside the scope of this International Standard.

This International Standard is not intended for contractual or regulatory purposes or registration and certification.

## 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14044, *Environmental management — Life cycle assessment — Requirements and guidelines*

## 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

**3.1**
**life cycle**
consecutive and interlinked stages of a product system, from raw material acquisition or generation from natural resources to final disposal

**3.2**
**life cycle assessment**
**LCA**
compilation and evaluation of the inputs, outputs and the potential environmental impacts of a product system throughout its life cycle

**3.3**
**life cycle inventory analysis**
**LCI**
phase of life cycle assessment involving the compilation and quantification of inputs and outputs for a product throughout its life cycle

**3.4**
**life cycle impact assessment**
**LCIA**
phase of life cycle assessment aimed at understanding and evaluating the magnitude and significance of the potential environmental impacts for a product system throughout the life cycle of the product

**3.5**
**life cycle interpretation**
phase of life cycle assessment in which the findings of either the inventory analysis or the impact assessment, or both, are evaluated in relation to the defined goal and scope in order to reach conclusions and recommendations

**3.6**
**comparative assertion**
environmental claim regarding the superiority or equivalence of one product versus a competing product that performs the same function

**3.7**
**transparency**
open, comprehensive and understandable presentation of information

**3.8**
**environmental aspect**
element of an organization's activities, products or services that can interact with the environment

[ISO 14001:2004, definition 3.6]

**3.9**
**product**
any goods or service

NOTE 1 The product can be categorized as follows:

— services (e.g. transport);

— software (e.g. computer program, dictionary);

— hardware (e.g. engine mechanical part);

— processed materials (e.g. lubricant).

NOTE 2 Services have tangible and intangible elements. Provision of a service can involve, for example, the following:

— an activity performed on a customer-supplied tangible product (e.g. automobile to be repaired);

— an activity performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a tax return);

— the delivery of an intangible product (e.g. the delivery of information in the context of knowledge transmission);

— the creation of ambience for the customer (e.g. in hotels and restaurants).

Software consists of information and is generally intangible and can be in the form of approaches, transactions or procedures.

Hardware is generally tangible and its amount is a countable characteristic. Processed materials are generally tangible and their amount is a continuous characteristic.

NOTE 3 Adapted from ISO 14021:1999 and ISO 9000:2005.

**3.10**
**co-product**
any of two or more products coming from the same unit process or product system

**3.11**
**process**
set of interrelated or interacting activities that transforms inputs into outputs

[ISO 9000:2005, definition 3.4.1 (without notes)]

**3.12**
**elementary flow**
material or energy entering the system being studied that has been drawn from the environment without previous human transformation, or material or energy leaving the system being studied that is released into the environment without subsequent human transformation

**3.13**
**energy flow**
input to or output from a unit process or product system, quantified in energy units

NOTE Energy flow that is an input can be called an energy input; energy flow that is an output can be called an energy output.

**3.14**
**feedstock energy**
heat of combustion of a raw material input that is not used as an energy source to a product system, expressed in terms of higher heating value or lower heating value

NOTE Care is necessary to ensure that the energy content of raw materials is not counted twice.

**3.15**
**raw material**
primary or secondary material that is used to produce a product

NOTE Secondary material includes recycled material.

**3.16**
**ancillary input**
material input that is used by the unit process producing the product, but which does not constitute part of the product

**3.17**
**allocation**
partitioning the input or output flows of a process or a product system between the product system under study and one or more other product systems

**3.18**
**cut-off criteria**
specification of the amount of material or energy flow or the level of environmental significance associated with unit processes or product system to be excluded from a study

**3.19**
**data quality**
characteristics of data that relate to their ability to satisfy stated requirements

**3.20**
**functional unit**
quantified performance of a product system for use as a reference unit

**3.21**
**input**
product, material or energy flow that enters a unit process

NOTE Products and materials include raw materials, intermediate products and co-products.

**3.22**
**intermediate flow**
product, material or energy flow occurring between unit processes of the product system being studied

**3.23**
**intermediate product**
output from a unit process that is input to other unit processes that require further transformation within the system

**3.24**
**life cycle inventory analysis result**
**LCI result**
outcome of a life cycle inventory analysis that catalogues the flows crossing the system boundary and provides the starting point for life cycle impact assessment

**3.25**
**output**
product, material or energy flow that leaves a unit process

NOTE Products and materials include raw materials, intermediate products, co-products and releases.

**3.26**
**process energy**
energy input required for operating the process or equipment within a unit process, excluding energy inputs for production and delivery of the energy itself

**3.27**
**product flow**
products entering from or leaving to another product system

**3.28**
**product system**
collection of unit processes with elementary and product flows, performing one or more defined functions, and which models the life cycle of a product

**3.29**
**reference flow**
measure of the outputs from processes in a given product system required to fulfil the function expressed by the functional unit

**3.30**
**releases**
emissions to air and discharges to water and soil

**3.31**
**sensitivity analysis**
systematic procedures for estimating the effects of the choices made regarding methods and data on the outcome of a study

**3.32**
**system boundary**
set of criteria specifying which unit processes are part of a product system

NOTE The term "system boundary" is not used in this International Standard in relation to LCIA.

**3.33**
**uncertainty analysis**
systematic procedure to quantify the uncertainty introduced in the results of a life cycle inventory analysis due to the cumulative effects of model imprecision, input uncertainty and data variability

NOTE Either ranges or probability distributions are used to determine uncertainty in the results.

**3.34**
**unit process**
smallest element considered in the life cycle inventory analysis for which input and output data are quantified

**3.35**
**waste**
substances or objects which the holder intends or is required to dispose of

NOTE This definition is taken from the *Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal* (22 March 1989), but is not confined in this International Standard to hazardous waste.

**3.36**
**category endpoint**
attribute or aspect of natural environment, human health, or resources, identifying an environmental issue giving cause for concern

**3.37**
**characterization factor**
factor derived from a characterization model which is applied to convert an assigned life cycle inventory analysis result to the common unit of the category indicator

NOTE The common unit allows calculation of the category indicator result.

**3.38**
**environmental mechanism**
system of physical, chemical and biological processes for a given impact category, linking the life cycle inventory analysis results to category indicators and to category endpoints

**3.39**
**impact category**
class representing environmental issues of concern to which life cycle inventory analysis results may be assigned

**3.40**
**impact category indicator**
quantifiable representation of an impact category

NOTE The shorter expression "category indicator" is used in this International Standard for improved readability.

**3.41**
**completeness check**
process of verifying whether information from the phases of a life cycle assessment is sufficient for reaching conclusions in accordance with the goal and scope definition

**3.42**
**consistency check**
process of verifying that the assumptions, methods and data are consistently applied throughout the study and are in accordance with the goal and scope definition performed before conclusions are reached

**3.43**
**sensitivity check**
process of verifying that the information obtained from a sensitivity analysis is relevant for reaching the conclusions and for giving recommendations

**3.44**
**evaluation**
element within the life cycle interpretation phase intended to establish confidence in the results of the life cycle assessment

NOTE Evaluation includes completeness check, sensitivity check, consistency check, and any other validation that may be required according to the goal and scope definition of the study

**3.45**
**critical review**
process intended to ensure consistency between a life cycle assessment and the principles and requirements of the International Standards on life cycle assessment

NOTE 1 The principles are described in this International Standard (see 4.1).

NOTE 2 The requirements are described in ISO 14044.

**3.46**
**interested party**
individual or group concerned with or affected by the environmental performance of a product system, or by the results of the life cycle assessment

# 4 General description of life cycle assessment (LCA)

## 4.1 Principles of LCA

### 4.1.1 General

These principles are fundamental and should be used as guidance for decisions relating to both the planning and the conducting of an LCA.

### 4.1.2 Life cycle perspective

LCA considers the entire life cycle of a product, from raw material extraction and acquisition, through energy and material production and manufacturing, to use and end of life treatment and final disposal. Through such

 

a systematic overview and perspective, the shifting of a potential environmental burden between life cycle stages or individual processes can be identified and possibly avoided.

#### 4.1.3 Environmental focus

LCA addresses the environmental aspects and impacts of a product system. Economic and social aspects and impacts are, typically, outside the scope of the LCA. Other tools may be combined with LCA for more extensive assessments.

#### 4.1.4 Relative approach and functional unit

LCA is a relative approach, which is structured around a functional unit. This functional unit defines what is being studied. All subsequent analyses are then relative to that functional unit, as all inputs and outputs in the LCI and consequently the LCIA profile are related to the functional unit.

#### 4.1.5 Iterative approach

LCA is an iterative technique. The individual phases of an LCA use results of the other phases. The iterative approach within and between the phases contributes to the comprehensiveness and consistency of the study and the reported results.

#### 4.1.6 Transparency

Due to the inherent complexity in LCA, transparency is an important guiding principle in executing LCAs, in order to ensure a proper interpretation of the results.

#### 4.1.7 Comprehensiveness

LCA considers all attributes or aspects of natural environment, human health and resources. By considering all attributes and aspects within one study in a cross-media perspective, potential trade-offs can be identified and assessed.

#### 4.1.8 Priority of scientific approach

Decisions within an LCA are preferably based on natural science. If this is not possible, other scientific approaches (e.g. from social and economic sciences) may be used or international conventions may be referred to. If neither a scientific basis exists nor a justification based on other scientific approaches or international conventions is possible, then, as appropriate, decisions may be based on value choices.

### 4.2 Phases of an LCA

**4.2.1** LCA studies comprise four phases. The relationship between the phases is illustrated in Figure 1. These are

— the goal and scope definition,

— inventory analysis,

— impact assessment, and

— interpretation.

**4.2.2** LCI studies comprise three phases:

— the goal and scope definition,

— inventory analysis, and

— interpretation.

**4.2.3** LCA results may be useful inputs to a variety of decision-making processes. Direct applications of the results of LCA or LCI studies, i.e. the applications intended in the goal and scope definition of the LCA or LCI study, are depicted in Figure 1. More information on application areas for LCA can be found in Annex A.

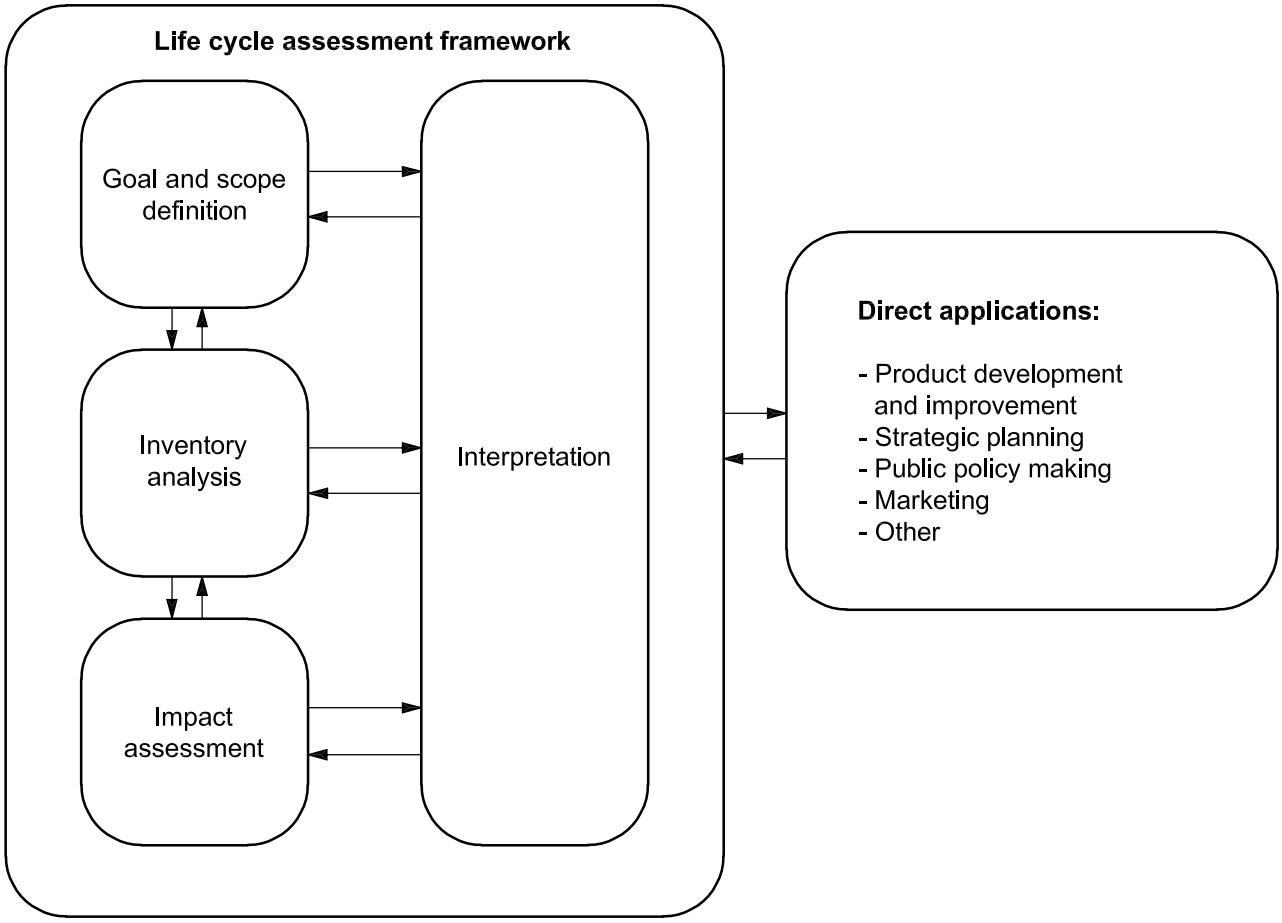


**Figure 1 — Stages of an LCA**

## 4.3 Key features of an LCA

The following list summarizes some of the key features of the LCA methodology:

a) LCA assesses, in a systematic way, the environmental aspects and impacts of product systems, from raw material acquisition to final disposal, in accordance with the stated goal and scope;

b) the relative nature of LCA is due to the functional unit feature of the methodology;

c) the depth of detail and time frame of an LCA may vary to a large extent, depending on the goal and scope definition;

d) provisions are made, depending on the intended application of the LCA, to respect confidentiality and proprietary matters;

e) LCA methodology is open to the inclusion of new scientific findings and improvements in the state-of-the-art of the technique;

f) specific requirements are applied to LCA that are intended to be used in comparative assertions intended to be disclosed to the public;

g) there is no single method for conducting LCA. Organizations have the flexibility to implement LCA as established in this International Standard, in accordance with the intended application and the requirements of the organization;

h) LCA is different from many other techniques (such as environmental performance evaluation, environmental impact assessment and risk assessment) as it is a relative approach based on a functional unit; LCA may, however, use information gathered by these other techniques;

i) LCA addresses potential environmental impacts; LCA does not predict absolute or precise environmental impacts due to

   — the relative expression of potential environmental impacts to a reference unit,

   — the integration of environmental data over space and time,

   — the inherent uncertainty in modelling of environmental impacts, and

   — the fact that some possible environmental impacts are clearly future impacts;

j) the LCIA phase, in conjunction with other LCA phases, provides a system-wide perspective of environmental and resource issues for one or more product system(s);

k) LCIA assigns LCI results to impact categories; for each impact category, a life cycle impact category indicator is selected and the category indicator result (indicator result) is calculated; the collection of indicator results (LCIA results) or the LCIA profile provides information on the environmental issues associated with the inputs and outputs of the product system;

l) there is no scientific basis for reducing LCA results to a single overall score or number, since weighting requires value choices;

m) life cycle interpretation uses a systematic procedure to identify, qualify, check, evaluate and present the conclusions based on the findings of an LCA, in order to meet the requirements of the application as described in the goal and scope of the study;

n) life cycle interpretation uses an iterative procedure both within the interpretation phase and with the other phases of an LCA;

o) life cycle interpretation makes provisions for links between LCA and other techniques for environmental management by emphasizing the strengths and limits of an LCA in relation to its goal and scope definition.

## 4.4 General concepts of product systems

LCA models the life cycle of a product as its product system, which performs one or more defined functions.

The essential property of a product system is characterized by its function and cannot be defined solely in terms of the final products. Figure 2 shows an example of a product system.

Product systems are subdivided into a set of unit processes (see Figure 3). Unit processes are linked to one another by flows of intermediate products and/or waste for treatment, to other product systems by product flows, and to the environment by elementary flows.

Dividing a product system into its component unit processes facilitates identification of the inputs and outputs of the product system. In many cases, some of the inputs are used as a component of the output product, while others (ancillary inputs) are used within a unit process but are not part of the output product. A unit process also generates other outputs (elementary flows and/or products) as a result of its activities. The level of modelling detail that is required to satisfy the goal of the study determines the boundary of a unit process.

The elementary flows include the use of resources and releases to air, water and land associated with the system. Interpretations may be drawn from these data, depending on the goal and scope of the LCA. These data are the LCI results and constitute the input for LCIA.

EXAMPLES

| | |
|---|---|
| Elementary flows entering the unit process: | crude oil from the ground and solar radiation. |
| Elementary flows leaving the unit process: | emissions to air, discharges to water or soil and radiation. |
| Intermediate product flows: | basic materials and subassemblies. |
| Product flows entering or leaving the system: | recycled materials and components for reuse. |

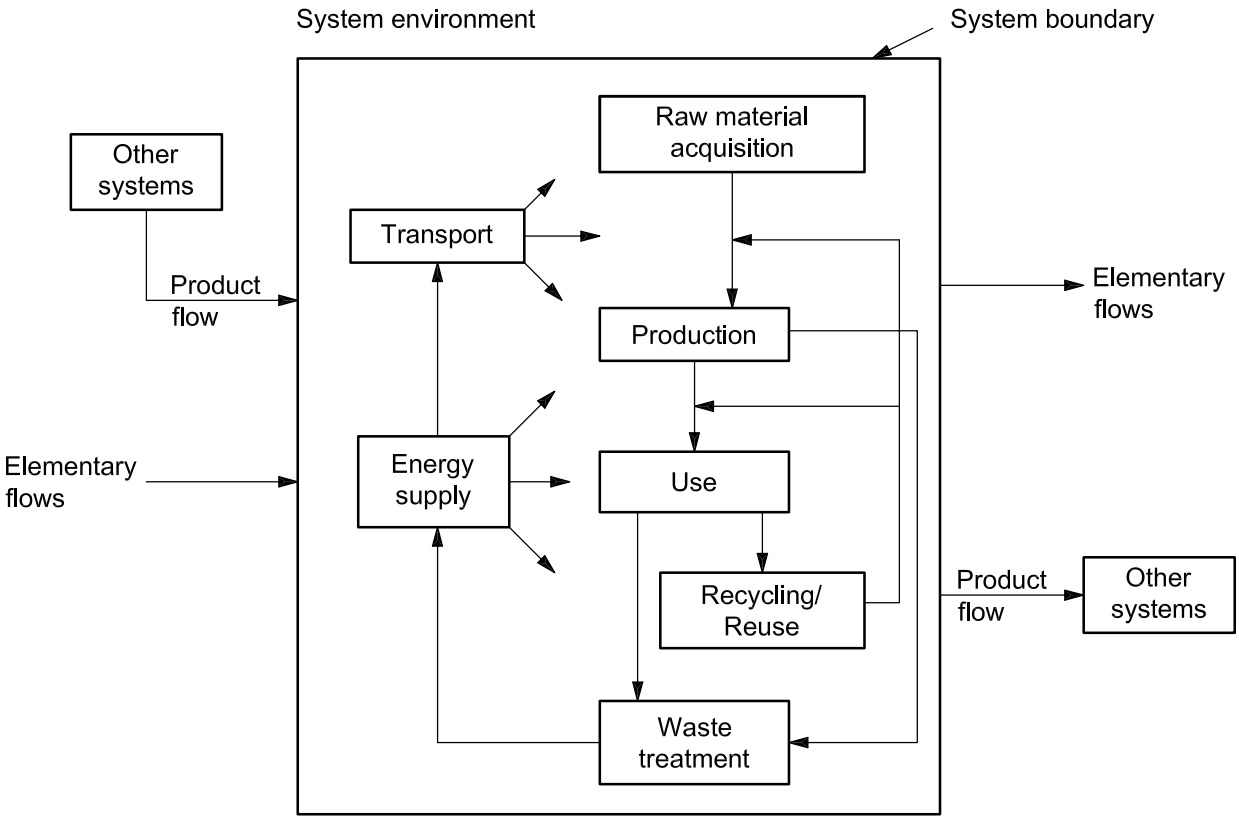


**Figure 2 — Example of a product system for LCA**

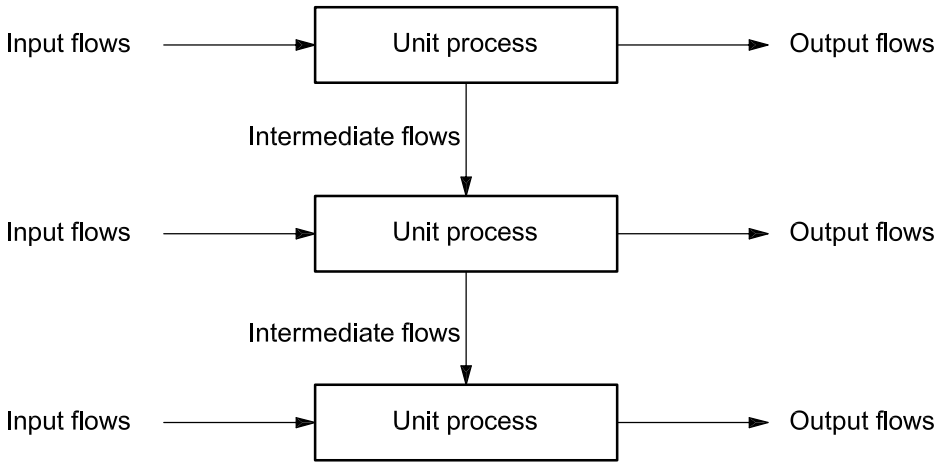


**Figure 3 — Example of a set of unit processes within a product system**

# 5 Methodological framework

## 5.1 General requirements

When performing an LCA, the requirements of ISO 14044 shall apply.

## 5.2 Goal and scope definition

### 5.2.1 General

**5.2.1.1** The goal of an LCA states

— the intended application,

— the reasons for carrying out the study,

— the intended audience, i.e. to whom the results of the study are intended to be communicated, and

— whether the results are intended to be used in comparative assertions intended to be disclosed to the public.

The scope should be sufficiently well defined to ensure that the breadth, depth and detail of the study are compatible and sufficient to address the stated goal.

**5.2.1.2** The scope includes the following items:

— the product system to be studied;

— the functions of the product system or, in the case of comparative studies, the systems;

— the functional unit;

— the system boundary;

— allocation procedures;

— impact categories selected and methodology of impact assessment, and subsequent interpretation to be used;

— data requirements;

— assumptions;

— limitations;

— initial data quality requirements;

— type of critical review, if any;

— type and format of the report required for the study.

LCA is an iterative technique, and as data and information are collected, various aspects of the scope may require modification in order to meet the original goal of the study.

### 5.2.2 Function, functional unit and reference flows

A system may have a number of possible functions and the one(s) selected for a study depend(s) on the goal and scope of the LCA.

The functional unit defines the quantification of the identified functions (performance characteristics) of the product. The primary purpose of a functional unit is to provide a reference to which the inputs and outputs are related. This reference is necessary to ensure comparability of LCA results. Comparability of LCA results is particularly critical when different systems are being assessed, to ensure that such comparisons are made on a common basis.

It is important to determine the reference flow in each product system, in order to fulfil the intended function, i.e. the amount of products needed to fulfil the function.

EXAMPLE In the function of drying hands, both a paper towel and an air-dryer system are studied. The selected functional unit may be expressed in terms of the identical number of pairs of hands dried for both systems. For each system, it is possible to determine the reference flow, e.g. the average mass of paper or the average volume of hot air required for one pair of hand-dry, respectively. For both systems, it is possible to compile an inventory of inputs and outputs on the basis of the reference flows. At its simplest level, in the case of paper towel, this would be related to the paper consumed. In the case of the air-dryer, this would be related to the mass of hot air needed to dry the hands.

### 5.2.3 System boundary

LCA is conducted by defining product systems as models that describe the key elements of physical systems. The system boundary defines the unit processes to be included in the system. Ideally, the product system should be modelled in such a manner that inputs and outputs at its boundary are elementary flows. However, resources need not be expended on the quantification of such inputs and outputs that will not significantly change the overall conclusions of the study.

The choice of elements of the physical system to be modelled depends on the goal and scope definition of the study, its intended application and audience, the assumptions made, data and cost constraints, and cut-off criteria. The models used should be described and the assumptions underlying those choices should be identified. The cut-off criteria used within a study should be clearly understood and described.

The criteria used in setting the system boundary are important for the degree of confidence in the results of a study and the possibility of reaching its goal.

When setting the system boundary, several life cycle stages, unit processes and flows should be taken into consideration, for example, the following:

— acquisition of raw materials;

— inputs and outputs in the main manufacturing/processing sequence;

— distribution/transportation;

— production and use of fuels, electricity and heat;

— use and maintenance of products;

— disposal of process wastes and products;

— recovery of used products (including reuse, recycling and energy recovery);

— manufacture of ancillary materials;

— manufacture, maintenance and decommissioning of capital equipment;

— additional operations, such as lighting and heating.

In many instances, the initially defined system boundary defined will subsequently need to be refined.

### 5.2.4 Data quality requirements

Data quality requirements specify in general terms the characteristics of the data needed for the study.

Descriptions of data quality are important to understand the reliability of the study results and properly interpret the outcome of the study.

## 5.3 Life cycle inventory analysis (LCI)

### 5.3.1 General

Inventory analysis involves data collection and calculation procedures to quantify relevant inputs and outputs of a product system.

The process of conducting an inventory analysis is iterative. As data are collected and more is learned about the system, new data requirements or limitations may be identified that require a change in the data collection procedures so that the goals of the study will still be met. Sometimes, issues may be identified that require revisions to the goal or scope of the study.

### 5.3.2 Data collection

Data for each unit process within the systems boundary can be classified under major headings, including

— energy inputs, raw material inputs, ancillary inputs, other physical inputs,

— products, co-products and waste,

— emissions to air, discharges to water and soil, and

— other environmental aspects.

Data collection can be a resource-intensive process. Practical constraints on data collection should be considered in the scope and documented in the study report.

### 5.3.3 Data calculation

Following the data collection, calculation procedures, including

— validation of data collected,

— the relating of data to unit processes, and

— the relating of data to the reference flow of the functional unit,

are needed to generate the results of the inventory of the defined system for each unit process and for the defined functional unit of the product system that is to be modelled.

The calculation of energy flows should take into account the different fuels and electricity sources used, the efficiency of conversion and distribution of energy flow, as well as the inputs and outputs associated with the generation and use of that energy flow.

### 5.3.4 Allocation of flows and releases

Few industrial processes yield a single output or are based on a linearity of raw material inputs and outputs. In fact, most industrial processes yield more than one product, and they recycle intermediate or discarded products as raw materials.

Consideration should be given to the need for allocation procedures when dealing with systems involving multiple products and recycling systems.

## 5.4 Life cycle impact assessment (LCIA)

### 5.4.1 General

The impact assessment phase of LCA is aimed at evaluating the significance of potential environmental impacts using the LCI results. In general, this process involves associating inventory data with specific environmental impact categories and category indicators, thereby attempting to understand these impacts. The LCIA phase also provides information for the life cycle interpretation phase.

The impact assessment may include the iterative process of reviewing the goal and scope of the LCA study to determine if the objectives of the study have been met, or to modify the goal and scope if the assessment indicates that they cannot be achieved.

Issues such as choice, modelling and evaluation of impact categories can introduce subjectivity into the LCIA phase. Therefore, transparency is critical to the impact assessment to ensure that assumptions are clearly described and reported.

### 5.4.2 Elements of LCIA

The elements of the LCIA phase are illustrated in Figure 4.

NOTE Further explanation of LCIA terminology can be found in ISO 14044.

Separation of the LCIA phase into different elements is helpful and necessary for several reasons, as follows:

a) each LCIA element is distinct and can be clearly defined;

b) the goal and scope definition phase of an LCA can consider each LCIA element separately;

c) a quality assessment of the LCIA methods, assumptions and other decisions can be conducted for each LCIA element;

d) LCIA procedures, assumptions and other operations within each element can be made transparent for critical review and reporting;

e) the use of values and subjectivity (hereafter referred to as value-choices), within each element, can be made transparent for critical review and reporting.

The level of detail, choice of impacts evaluated and methodologies used depend on the goal and scope of the study.

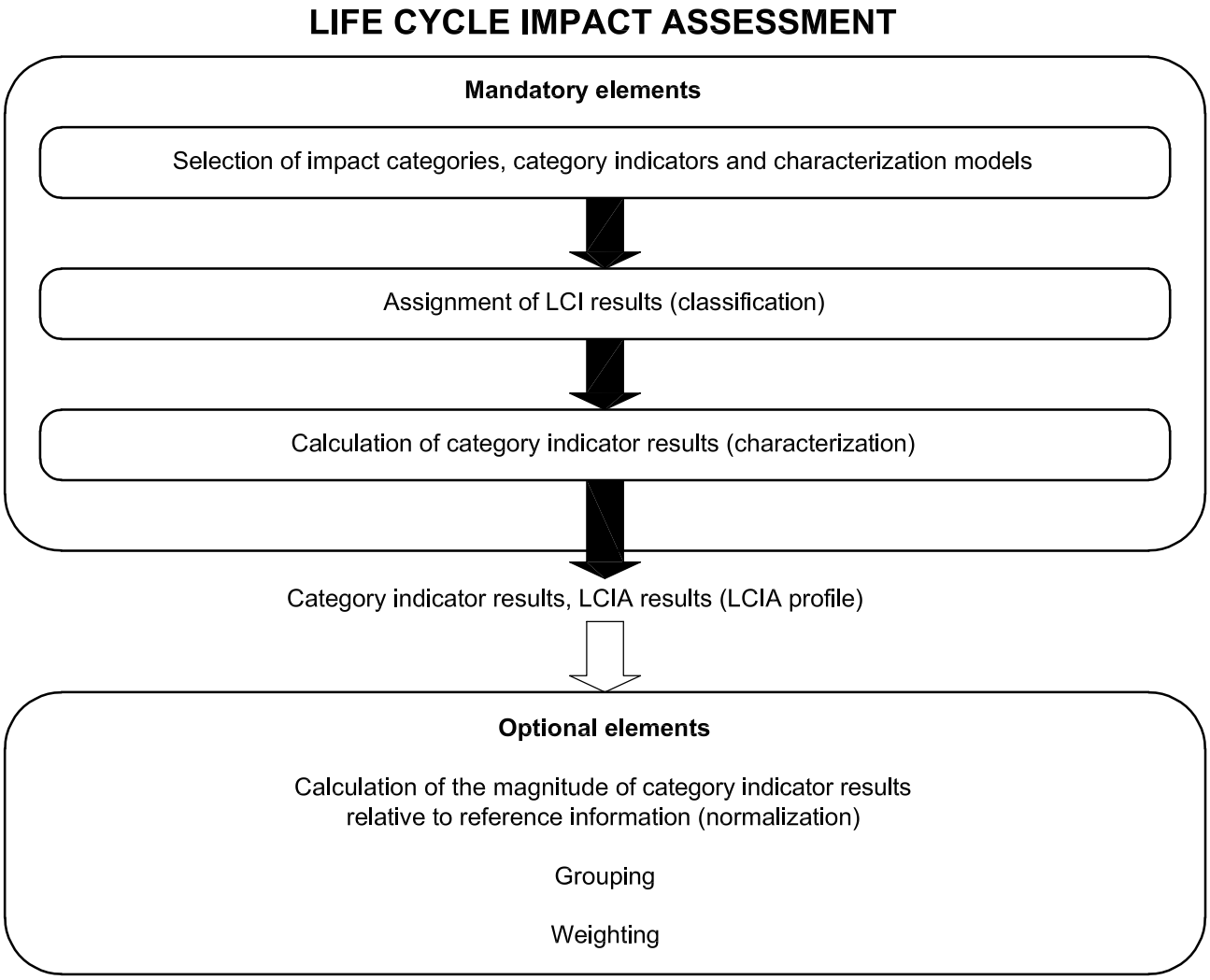


**Figure 4 — Elements of the LCIA phase**

### 5.4.3 Limitations of LCIA

The LCIA addresses only the environmental issues that are specified in the goal and scope. Therefore, LCIA is not a complete assessment of all environmental issues of the product system under study.

LCIA cannot always demonstrate significant differences between impact categories and the related indicator results of alternative product systems. This may be due to

— limited development of the characterization models, sensitivity analysis and uncertainty analysis for the LCIA phase,

— limitations of the LCI phase, such as setting the system boundary, that do not encompass all possible unit processes for a product system or do not include all inputs and outputs of every unit process, since there are cut-offs and data gaps,

— limitations of the LCI phase, such as inadequate LCI data quality which may, for instance, be caused by uncertainties or differences in allocation and aggregation procedures, and

— limitations in the collection of inventory data appropriate and representative for each impact category.

The lack of spatial and temporal dimensions in the LCI results introduces uncertainty in the LCIA results. The uncertainty varies with the spatial and temporal characteristics of each impact category.

There are no generally accepted methodologies for consistently and accurately associating inventory data with specific potential environmental impacts. Models for impact categories are in different stages of development.

### 5.5 Life cycle interpretation

Interpretation is the phase of LCA in which the findings from the inventory analysis and the impact assessment are considered together or, in the case of LCI studies, the findings of the inventory analysis only. The interpretation phase should deliver results that are consistent with the defined goal and scope and which reach conclusions, explain limitations and provide recommendations.

The interpretation should reflect the fact that the LCIA results are based on a relative approach, that they indicate potential environmental effects, and that they do not predict actual impacts on category endpoints, the exceeding of thresholds or safety margins or risks.

The findings of this interpretation may take the form of conclusions and recommendations to decision-makers, consistent with the goal and scope of the study.

Life cycle interpretation is also intended to provide a readily understandable, complete and consistent presentation of the results of an LCA, in accordance with the goal and scope definition of the study.

The interpretation phase may involve the iterative process of reviewing and revising the scope of the LCA, as well as the nature and quality of the data collected in a way which is consistent with the defined goal.

The findings of the life cycle interpretation should reflect the results of the evaluation element.

## 6 Reporting

A reporting strategy is an integral part of an LCA. An effective report should address the different phases of the study under consideration.

Report the results and conclusions of the LCA in an adequate form to the intended audience, addressing the data, methods and assumptions applied in the study, and the limitations thereof.

If the study extends to the LCIA phase and is reported to a third-party, the following issues should be reported:

— the relationship with the LCI results;

— a description of the data quality;

— the category endpoints to be protected;

— the selection of impact categories;

— the characterization models;

— the factors and environmental mechanisms;

— the indicator results profile.

The relative nature of the LCIA results and their inadequacy to predict impacts on category endpoints should also be addressed in the report. Include reference and description of value choices used in the LCIA phase of the study in relation to characterization models, normalization, weighting, etc.

Include other requirements given in ISO 14044 whenever the study results are intended to be used in comparative assertions intended to be disclosed to the public. Furthermore, in reporting the interpretation phase, ISO 14044 requires full transparency in terms of value choices, rationales and expert judgements.

# 7 Critical review

## 7.1 General

Critical review is a process to verify whether an LCA has met the requirements for methodology, data, interpretation and reporting and whether it is consistent with the principles.

In general, critical reviews of an LCA may utilize any of the review options outlined in 7.3. A critical review can neither verify nor validate the goals that are chosen for an LCA by the study commissioner, nor the ways in which the LCA results are used.

## 7.2 Need for critical review

A critical review may facilitate understanding and enhance the credibility of LCA, for example by involving interested parties.

The use of LCA results to support comparative assertions raises special concerns and requires critical review, since this application is likely to affect interested parties that are external to the LCA. However, the fact that a critical review has been conducted should in no way imply an endorsement of any comparative assertion that is based on an LCA study.

## 7.3 Critical review processes

### 7.3.1 General

The scope and type of critical review desired is defined in the scope phase of an LCA. The scope should identify why the critical review is being undertaken, what will be covered and to what level of detail, and who needs to be involved in the process.

The review should ensure that the classification, characterization, normalization, grouping and weighting elements are sufficient and are documented in such a way that enables the life cycle interpretation phase of the LCA to be carried out.

Confidentiality agreements regarding the content of the LCA should be entered into as needed.

### 7.3.2 Critical review by internal or external expert

The internal or external expert should be familiar with the requirements of LCA and should have the appropriate scientific and technical expertise.

### 7.3.3 Critical review by a panel of interested parties

An external independent expert should be selected by the original study commissioner to act as chairperson of a review panel of at least three members. Based on the goal, scope and budget available for the review, the chairperson should select other independent qualified reviewers.

This panel may also include other interested parties affected by the conclusions drawn from the LCA, such as government agencies, non-governmental groups, competitors and affected industries.

# Annex A
(informative)

# Application of LCA

## A.1 Application areas

**A.1.1** The intended applications of LCA are addressed in 4.2 (Figure 1) in a non-exclusive, exemplary manner. The applications of LCA as such are outside the scope of this International Standard.

Further applications in the field of environmental management systems and tools include, among others:

a) environmental management systems and environmental performance evaluation (ISO 14001, ISO 14004, ISO 14031 and ISO/TR 14032), for example, identification of significant environmental aspects of the products and services of an organization;

b) environmental labels and declarations (ISO 14020, ISO 14021 and ISO 14025);

c) integration of environmental aspects into product design and development (design for environment) (ISO/TR 14062);

d) inclusion of environmental aspects in product standards (ISO Guide 64);

e) environmental communication (ISO 14063);

f) quantification, monitoring and reporting of entity and project emissions and removals, and validation, verification and certification of greenhouse gas emissions [ISO 14064 (all parts)].

There are a variety of potential further applications in private and public organizations. The list of techniques, methods and tools below does not indicate that they are based on the LCA technique as such, but that the life cycle approach, principles and framework can be beneficially applied. These are, amongst others:

— environmental impact assessment (EIA);

— environmental management accounting (EMA);

— assessment of policies (models for recycling, etc.);

— sustainability assessment; economic and social aspects are not included in LCA, but the procedures and guidelines could be applied by appropriate competent parties;

— substance and material flow analysis (SFA and MFA);

— hazard and risk assessment of chemicals;

— risk analysis and risk management of facilities and plants;

— product stewardship, supply chain management;

— life cycle management (LCM);

— design briefs, life cycle thinking;

— life cycle costing (LCC).

Clarifications, considerations, practices, simplifications and options for the different applications are also beyond the scope of this International Standard.

**A.1.2** There is no single solution as to how LCA can best be applied within the decision-making context. Each organization has to solve and decide that case by case depending (amongst others) on the size and culture of the organization, its products, the strategy, the internal systems, tools and procedures and the external drivers.

LCA may be used for a broad spectrum of applications. The individual use, adaptation and practice of LCA for all potential applications are based on this International Standard and on ISO 14044.

In addition, the LCA technique with proper justification could be applied in studies that are not LCA or LCI studies. Examples are

— cradle-to-gate studies,

— gate-to-gate studies, and

— specific parts of the life cycle (e.g. waste management, components of a product).

For those studies most requirements of this International Standard and ISO 14044 are applicable (e.g. data quality, collection and calculation as well as allocation and critical review), but not all the requirements for the system boundary.

**A.1.3** For specific applications, it can be appropriate, as part of the LCIA, to determine the indicator results of each unit process or of each stage of a life cycle individually and to calculate the indicator results of the whole product system by adding up the indicator results of the different unit processes or stages.

This procedure is within the framework of this International Standard, provided that

— it has been defined within the goal and scope definition phase, and

— it is shown that the results of such an approach are identical with the results of an LCA which applies the sequence of steps according to the guidance of this International Standard and ISO 14044.

## A.2 Application approach

It is necessary to consider the decision-making context when defining the scope of an LCA; i.e. the product systems studied should adequately address the products and processes affected by the intended application.

The examples of applications relate to decisions that aim for environmental improvements, which is also the overall focus of the ISO 14000 series. Therefore, the products and processes studied in an LCA are those affected by the decision that the LCA intends to support.

Some applications may not appear to immediately address improvements, such as LCA to be used for education or information about the product life cycle. However, as soon as such information is applied in practice, it is used in an improvement context. Therefore, special care is necessary to ensure that the information is applicable to the context in which it is likely to be applied.

Two possible different approaches to LCA have developed during the recent years. These are

a) one which assigns elementary flows and potential environmental impacts to a specific product system typically as an account of the history of the product, and

b) one which studies the environmental consequences of possible (future) changes between alternative product systems.

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[11] ISO/TR 14049, *Environmental management — Life cycle assessment — Examples of application of ISO 14041 to goal and scope definition and inventory analysis*

[12] ISO 14050, *Environmental management — Vocabulary*

[13] ISO/TR 14062, *Environmental management — Integrating environmental aspects into product design and development*

[14] ISO 14063, *Environmental management — Environmental communication — Guidelines and examples*

[15] ISO 14064-1, *Greenhouse gases — Part 1: Specification with guidance at the organization level for quantification and reporting of greenhouse gas emissions and removals*

[16] ISO 14064-2, *Greenhouse gases — Part 2: Specification with guidance at the project level for quantification, monitoring and reporting of greenhouse gas emission reductions or removal enhancements*

[17] ISO 14064-3, *Greenhouse gases — Part 3: Specification with guidance for the validation and verification of greenhouse gas assertions*

[18] ISO Guide 64, *Guide for the inclusion of environmental aspects in product standards*

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INTERNATIONAL STANDARD

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# Environmental management — Life cycle assessment — Requirements and guidelines

*Management environnemental — Analyse du cycle de vie — Exigences et lignes directrices*

Reference number
ISO 14044:2006(E)

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# Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 14044 was prepared by Technical Committee ISO/TC 207, *Environmental management*, Subcommittee SC 5, *Life cycle assessment*.

This first edition of ISO 14044, together with ISO 14040:2006, cancels and replaces ISO 14040:1997, ISO 14041:1998, ISO 14042:2000 and ISO 14043:2000, which have been technically revised.

# Introduction

The increased awareness of the importance of environmental protection, and the possible impacts associated with products[1)], both manufactured and consumed, has increased interest in the development of methods to better understand and address these impacts. One of the techniques being developed for this purpose is life cycle assessment (LCA).

LCA can assist in

— identifying opportunities to improve the environmental performance of products at various points in their life cycle,

— informing decision-makers in industry, government or non-government organizations (e.g. for the purpose of strategic planning, priority setting, product or process design or redesign),

— the selection of relevant indicators of environmental performance, including measurement techniques, and

— marketing (e.g. implementing an ecolabelling scheme, making an environmental claim, or producing an environmental product declaration).

LCA addresses the environmental aspects and potential environmental impacts[2)] (e.g. use of resources and environmental consequences of releases) throughout a product's life cycle from raw material acquisition through production, use, end-of-life treatment, recycling and final disposal (i.e. cradle-to-grave).

There are four phases in an LCA study:

a) the goal and scope definition phase,

b) the inventory analysis phase,

c) the impact assessment phase, and

d) the interpretation phase.

The scope, including system boundary and level of detail, of an LCA depends on the subject and the intended use of the study. The depth and the breadth of LCA can differ considerably depending on the goal of a particular LCA.

The life cycle inventory analysis phase (LCI phase) is the second phase of LCA. It is an inventory of input/output data with regard to the system being studied. It involves the collection of the data necessary to meet the goals of the defined study.

The life cycle impact assessment phase (LCIA) is the third phase of the LCA. The purpose of LCIA is to provide additional information to help assess a product system's LCI results so as to better understand their environmental significance.

1) In this International Standard, the term "product" includes services.

2) The "potential environmental impacts" are relative expressions, as they are related to the functional unit of a product system.

Life cycle interpretation is the final phase of the LCA procedure, in which the results of an LCI or an LCIA, or both, are summarized and discussed as a basis for conclusions, recommendations and decision-making in accordance with the goal and scope definition.

There are cases where the goal of an LCA may be satisfied by performing only an inventory analysis and an interpretation. This is usually referred to as an LCI study.

This International Standard covers two types of studies: life cycle assessment studies (LCA studies) and life cycle inventory studies (LCI studies). LCI studies are similar to LCA studies but exclude the LCIA phase. LCI are not to be confused with the LCI phase of an LCA study.

Generally, the information developed in an LCA or LCI study can be used as part of a much more comprehensive decision process. Comparing the results of different LCA or LCI studies is only possible if the assumptions and context of each study are equivalent. Therefore this International Standard contains several requirements and recommendations to ensure transparency on these issues.

LCA is one of several environmental management techniques (e.g. risk assessment, environmental performance evaluation, environmental auditing, and environmental impact assessment) and might not be the most appropriate technique to use in all situations. LCA typically does not address the economic or social aspects of a product, but the life cycle approach and methodologies described in this International Standard may be applied to these other aspects.

This International Standard, like other International Standards, is not intended to be used to create non-tariff trade barriers or to increase or change an organization's legal obligations.

# Environmental management — Life cycle assessment — Requirements and guidelines

## 1 Scope

This International Standard specifies requirements and provides guidelines for life cycle assessment (LCA) including

a) the goal and scope definition of the LCA,

b) the life cycle inventory analysis (LCI) phase,

c) the life cycle impact assessment (LCIA) phase,

d) the life cycle interpretation phase,

e) reporting and critical review of the LCA,

f) limitations of the LCA,

g) relationship between the LCA phases, and

h) conditions for use of value choices and optional elements.

This International Standard covers life cycle assessment (LCA) studies and life cycle inventory (LCI) studies.

The intended application of LCA or LCI results is considered during the goal and scope definition, but the application itself is outside the scope of this International Standard.

This International Standard is not intended for contractual or regulatory purposes or registration and certification.

## 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14040:2006, *Environmental management — Life cycle assessment — Principles and framework*

## 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

NOTE These terms and definitions are taken from ISO 14040:2006 and are repeated for the convenience of users of this International Standard.

**3.1**
**life cycle**
consecutive and interlinked stages of a product system, from raw material acquisition or generation from natural resources to final disposal

**3.2**
**life cycle assessment**
**LCA**
compilation and evaluation of the inputs, outputs and the potential environmental impacts of a product system throughout its life cycle

**3.3**
**life cycle inventory analysis**
**LCI**
phase of life cycle assessment involving the compilation and quantification of inputs and outputs for a product throughout its life cycle

**3.4**
**life cycle impact assessment**
**LCIA**
phase of life cycle assessment aimed at understanding and evaluating the magnitude and significance of the potential environmental impacts for a product system throughout the life cycle of the product

**3.5**
**life cycle interpretation**
phase of life cycle assessment in which the findings of either the inventory analysis or the impact assessment, or both, are evaluated in relation to the defined goal and scope in order to reach conclusions and recommendations

**3.6**
**comparative assertion**
environmental claim regarding the superiority or equivalence of one product versus a competing product that performs the same function

**3.7**
**transparency**
open, comprehensive and understandable presentation of information

**3.8**
**environmental aspect**
element of an organization's activities, products or services that can interact with the environment

[ISO 14001:2004; definition 3.6]

**3.9**
**product**
any goods or service

NOTE 1 The product can be categorized as follows:

— services (e.g. transport);

— software (e.g. computer program, dictionary);

— hardware (e.g. engine mechanical part);

— processed materials (e.g. lubricant);

NOTE 2 Services have tangible and intangible elements. Provision of a service can involve, for example, the following:

— an activity performed on a customer-supplied tangible product (e.g. automobile to be repaired);

— an activity performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a tax return);

— the delivery of an intangible product (e.g. the delivery of information in the context of knowledge transmission);

— the creation of ambience for the customer (e.g. in hotels and restaurants).

Software consists of information and is generally intangible and can be in the form of approaches, transactions or procedures.

Hardware is generally tangible and its amount is a countable characteristic. Processed materials are generally tangible and their amount is a continuous characteristic.

NOTE 3 Adapted from ISO 14021:1999 and ISO 9000:2005.

**3.10**
**co-product**
any of two or more products coming from the same unit process or product system

**3.11**
**process**
set of interrelated or interacting activities that transforms inputs into outputs

[ISO 9000:2005, definition 3.4.1 (without notes)]

**3.12**
**elementary flow**
material or energy entering the system being studied that has been drawn from the environment without previous human transformation, or material or energy leaving the system being studied that is released into the environment without subsequent human transformation

**3.13**
**energy flow**
input to or output from a unit process or product system, quantified in energy units

NOTE Energy flow that is an input may be called an energy input; energy flow that is an output may be called an energy output.

**3.14**
**feedstock energy**
heat of combustion of a raw material input that is not used as an energy source to a product system, expressed in terms of higher heating value or lower heating value

NOTE Care is necessary to ensure that the energy content of raw materials is not counted twice.

**3.15**
**raw material**
primary or secondary material that is used to produce a product

NOTE Secondary material includes recycled material.

**3.16**
**ancillary input**
material input that is used by the unit process producing the product, but does not constitute part of the product

**3.17**
**allocation**
partitioning the input or output flows of a process or a product system between the product system under study and one or more other product systems

**3.18**
**cut-off criteria**
specification of the amount of material or energy flow or the level of environmental significance associated with unit processes or product system to be excluded from a study

**3.19**
**data quality**
characteristics of data that relate to their ability to satisfy stated requirements

**3.20**
**functional unit**
quantified performance of a product system for use as a reference unit

**3.21**
**input**
product, material or energy flow that enters a unit process

NOTE Products and materials include raw materials, intermediate products and co-products.

**3.22**
**intermediate flow**
product, material or energy flow occurring between unit processes of the product system being studied

**3.23**
**intermediate product**
output from a unit process that is input to other unit processes that require further transformation within the system

**3.24**
**life cycle inventory analysis result**
**LCI result**
outcome of a life cycle inventory analysis that catalogues the flows crossing the system boundary and provides the starting point for life cycle impact assessment

**3.25**
**output**
product, material or energy flow that leaves a unit process

NOTE Products and materials include raw materials, intermediate products, co-products, and releases.

**3.26**
**process energy**
energy input required for operating the process or equipment within a unit process, excluding energy inputs for production and delivery of the energy itself

**3.27**
**product flow**
products entering from or leaving to another product system

**3.28**
**product system**
collection of unit processes with elementary and product flows, performing one or more defined functions, and which models the life cycle of a product

**3.29**
**reference flow**
measure of the outputs from processes in a given product system required to fulfil the function expressed by the functional unit

**3.30**
**releases**
emissions to air and discharges to water and soil

**3.31**
**sensitivity analysis**
systematic procedures for estimating the effects of the choices made regarding methods and data on the outcome of a study

**3.32**
**system boundary**
set of criteria specifying which unit processes are part of a product system

NOTE The term “system boundary” is not used in this International Standard in relation to LCIA.

**3.33**
**uncertainty analysis**
systematic procedure to quantify the uncertainty introduced in the results of a life cycle inventory analysis due to the cumulative effects of model imprecision, input uncertainty and data variability

NOTE Either ranges or probability distributions are used to determine uncertainty in the results.

**3.34**
**unit process**
smallest element considered in the life cycle inventory analysis for which input and output data are quantified

**3.35**
**waste**
substances or objects which the holder intends or is required to dispose of

NOTE The definition is taken from the *Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal* (22 March 1989) but is not confined in this International Standard to hazardous waste.

**3.36**
**category endpoint**
attribute or aspect of natural environment, human health, or resources, identifying an environmental issue giving cause for concern

**3.37**
**characterization factor**
factor derived from a characterization model which is applied to convert an assigned life cycle inventory analysis result to the common unit of the category indicator

NOTE The common unit allows calculation of the category indicator result.

**3.38**
**environmental mechanism**
system of physical, chemical and biological processes for a given impact category, linking the life cycle inventory analysis results to category indicators and to category endpoints

**3.39**
**impact category**
class representing environmental issues of concern to which life cycle inventory analysis results may be assigned

**3.40**
**impact category indicator**
quantifiable representation of an impact category

NOTE The shorter expression “category indicator” is used in this International Standard for improved readability.

**3.41**
**completeness check**
process of verifying whether information from the phases of a life cycle assessment is sufficient for reaching conclusions in accordance with the goal and scope definition

**3.42**
**consistency check**
process of verifying that the assumptions, methods and data are consistently applied throughout the study and are in accordance with the goal and scope definition performed before conclusions are reached

**3.43**
**sensitivity check**
process of verifying that the information obtained from a sensitivity analysis is relevant for reaching the conclusions and giving recommendations

**3.44**
**evaluation**
element within the life cycle interpretation phase intended to establish confidence in the results of the life cycle assessment

NOTE Evaluation includes completeness check, sensitivity check, consistency check, and any other validation that may be required according to the goal and scope definition of the study

**3.45**
**critical review**
process intended to ensure consistency between a life cycle assessment and the principles and requirements of the International Standards on life cycle assessment

NOTE 1 The principles are described in ISO 14040:2006, 4.1.

NOTE 2 The requirements are described in this International Standard.

**3.46**
**interested party**
individual or group concerned with or affected by the environmental performance of a product system, or by the results of the life cycle assessment

# 4 Methodological framework for LCA

## 4.1 General requirements

See ISO 14040 for the principles and framework to be used to conduct an LCA.

LCA studies shall include the goal and scope definition, inventory analysis, impact assessment and interpretation of results.

LCI studies shall include definition of the goal and scope, inventory analysis and interpretation of results. The requirements and recommendations of this International Standard, with the exception of those provisions regarding impact assessment, also apply to life cycle inventory studies.

An LCI study alone shall not be used for comparisons intended to be used in comparative assertions intended to be disclosed to the public.

It should be recognized that there is no scientific basis for reducing LCA results to a single overall score or number.

## 4.2 Goal and scope definition

### 4.2.1 General

The goal and scope of an LCA shall be clearly defined and shall be consistent with the intended application. Due to the iterative nature of LCA, the scope may have to be refined during the study.

### 4.2.2 Goal of the study

In defining the goal of an LCA, the following items shall be unambiguously stated:

— the intended application;

— the reasons for carrying out the study:

— the intended audience, i.e. to whom the results of the study are intended to be communicated:

— whether the results are intended to be used in comparative assertions intended to be disclosed to the public.

### 4.2.3 Scope of the study

#### 4.2.3.1 General

In defining the scope of an LCA, the following items shall be considered and clearly described:

— the product system to be studied;

— the functions of the product system or, in the case of comparative studies, the systems;

— the functional unit;

— the system boundary;

— allocation procedures;

— LCIA methodology and types of impacts;

— interpretation to be used;

— data requirements;

— assumptions;

— value choices and optional elements;

— limitations;

— data quality requirements;

— type of critical review, if any;

— type and format of the report required for the study.

In some cases, the goal and scope of the study may be revised due to unforeseen limitations, constraints or as a result of additional information. Such modifications, together with their justification, should be documented.

Some of the items above are specified in detail in 4.2.3.2 to 4.2.3.8.

#### 4.2.3.2 Function and functional unit

The scope of an LCA shall clearly specify the functions (performance characteristics) of the system being studied. The functional unit shall be consistent with the goal and scope of the study. One of the primary purposes of a functional unit is to provide a reference to which the input and output data are normalized (in a mathematical sense). Therefore the functional unit shall be clearly defined and measurable.

Having chosen the functional unit, the reference flow shall be defined. Comparisons between systems shall be made on the basis of the same function(s), quantified by the same functional unit(s) in the form of their reference flows. If additional functions of any of the systems are not taken into account in the comparison of functional units, then these omissions shall be explained and documented. As an alternative, systems associated with the delivery of this function may be added to the boundary of the other system to make the systems more comparable. In these cases, the processes selected shall be explained and documented.

#### 4.2.3.3 System boundary

**4.2.3.3.1** The system boundary determines which unit processes shall be included within the LCA. The selection of the system boundary shall be consistent with the goal of the study. The criteria used in establishing the system boundary shall be identified and explained.

Decisions shall be made regarding which unit processes to include in the study and the level of detail to which these unit processes shall be studied.

The deletion of life cycle stages, processes, inputs or outputs is only permitted if it does not significantly change the overall conclusions of the study. Any decisions to omit life cycle stages, processes, inputs or outputs shall be clearly stated, and the reasons and implications for their omission shall be explained.

Decisions shall also be made regarding which inputs and outputs shall be included and the level of detail of the LCA shall be clearly stated.

**4.2.3.3.2** It is helpful to describe the system using a process flow diagram showing the unit processes and their inter-relationships. Each of the unit processes should be initially described to define

— where the unit process begins, in terms of the receipt of raw materials or intermediate products,

— the nature of the transformations and operations that occur as part of the unit process, and

— where the unit process ends, in terms of the destination of the intermediate or final products.

Ideally, the product system should be modelled in such a manner that inputs and outputs at its boundary are elementary and product flows. It is an iterative process to identify the inputs and outputs that should be traced to the environment, i.e. to identify which unit processes producing the inputs (or which unit processes receiving the outputs) should be included in the product system under study. The initial identification is made using available data. Inputs and outputs should be more fully identified after additional data are collected during the course of the study, and then subjected to a sensitivity analysis (see 4.3.3.4).

For material inputs, the analysis begins with an initial selection of inputs to be studied. This selection should be based on an identification of the inputs associated with each of the unit processes to be modelled. This effort may be undertaken with data collected from specific sites or from published sources. The goal is to identify the significant inputs associated with each of the unit processes.

Energy inputs and outputs shall be treated as any other input or output to an LCA. The various types of energy inputs and outputs shall include inputs and outputs relevant for the production and delivery of fuels, feedstock energy and process energy used within the system being modelled.

**4.2.3.3.3** The cut-off criteria for initial inclusion of inputs and outputs and the assumptions on which the cut-off criteria are established shall be clearly described. The effect on the outcome of the study of the cut-off criteria selected shall also be assessed and described in the final report.

Several cut-off criteria are used in LCA practice to decide which inputs are to be included in the assessment, such as mass, energy and environmental significance. Making the initial identification of inputs based on mass contribution alone may result in important inputs being omitted from the study. Accordingly, energy and environmental significance should also be used as cut-off criteria in this process.

a) **Mass**: an appropriate decision, when using mass as a criterion, would require the inclusion in the study of all inputs that cumulatively contribute more than a defined percentage to the mass input of the product system being modelled.

b) **Energy**: similarly, an appropriate decision, when using energy as a criterion, would require the inclusion in the study of those inputs that cumulatively contribute more than a defined percentage of the product system's energy inputs.

c) **Environmental significance**: decisions on cut-off criteria should be made to include inputs that contribute more than an additional defined amount of the estimated quantity of individual data of the product system that are specially selected because of environmental relevance.

Similar cut-off criteria may also be used to identify which outputs should be traced to the environment, e.g. by including final waste treatment processes.

Where the study is intended to be used in comparative assertions intended to be disclosed to the public, the final sensitivity analysis of the inputs and outputs data shall include the mass, energy and environmental significance criteria so that all inputs that cumulatively contribute more than a defined amount (e.g. percentage) to the total are included in the study.

All of the selected inputs identified through this process should be modelled as elementary flows.

It should be decided which inputs and outputs data have to be traced to other product systems, including flows subject to allocation. The system should be described in sufficient detail and clarity to allow another practitioner to duplicate the inventory analysis.

#### 4.2.3.4 LCIA methodology and types of impacts

It shall be determined which impact categories, category indicators and characterization models are included within the LCA study. The selection of impact categories, category indicators and characterization models used in the LCIA methodology shall be consistent with the goal of the study and considered as described in 4.4.2.2.

#### 4.2.3.5 Types and sources of data

Data selected for an LCA depend on the goal and scope of the study. Such data may be collected from the production sites associated with the unit processes within the system boundary, or they may be obtained or calculated from other sources. In practice, all data may include a mixture of measured, calculated or estimated data.

Inputs may include, but are not limited to, use of mineral resources (e.g. metals from ores or recycling, services like transportation or energy supply, and use of ancillary materials like lubricants or fertilisers).

As part of emissions to air, emissions of carbon monoxide, carbon dioxide, sulfur oxides, nitrogen oxides, etc. may be separately identified.

Emissions to air, and discharges to water and soil, often represent releases from point or diffuse sources, after passing through pollution control devices. These data should also include fugitive emissions, when significant. Indicator parameters may include, but are not limited to,

— biochemical oxygen demand (BOD),

— chemical oxygen demand (COD),

— absorbable organic halogen compounds (AOX),

— total halogen content (TOX), and

— volatile organic chemicals (VOC).

In addition, data representing noise and vibration, land use, radiation, odour and waste heat may be collected.

#### 4.2.3.6 Data quality requirements

**4.2.3.6.1** Data quality requirements shall be specified to enable the goal and scope of the LCA to be met.

**4.2.3.6.2** The data quality requirements should address the following:

a) time-related coverage: age of data and the minimum length of time over which data should be collected;

b) geographical coverage: geographical area from which data for unit processes should be collected to satisfy the goal of the study;

c) technology coverage: specific technology or technology mix;

d) precision: measure of the variability of the data values for each data expressed (e.g. variance);

e) completeness: percentage of flow that is measured or estimated;

f) representativeness: qualitative assessment of the degree to which the data set reflects the true population of interest (i.e. geographical coverage, time period and technology coverage);

g) consistency: qualitative assessment of whether the study methodology is applied uniformly to the various components of the analysis;

h) reproducibility: qualitative assessment of the extent to which information about the methodology and data values would allow an independent practitioner to reproduce the results reported in the study;

i) sources of the data;

j) uncertainty of the information (e.g. data, models and assumptions).

Where a study is intended to be used in comparative assertions intended to be disclosed to the public, the data quality requirements stated in a) to j) above shall be addressed.

**4.2.3.6.3** The treatment of missing data shall be documented. For each unit process and for each reporting location where missing data are identified, the treatment of the missing data and data gaps should result in

— a “non-zero” data value that is explained,

— a “zero” data value if explained, or

— a calculated value based on the reported values from unit processes employing similar technology.

Data quality should be characterized by both quantitative and qualitative aspects as well as by the methods used to collect and integrate those data.

Data from specific sites or representative averages should be used for those unit processes that contribute the majority of the mass and energy flows in the systems being studied, as determined in the sensitivity analysis performed in 4.3.3.4. Where possible, data from specific sites should also be used for unit processes that are considered to have environmentally relevant inputs and outputs.

#### 4.2.3.7 Comparisons between systems

In a comparative study, the equivalence of the systems being compared shall be evaluated before interpreting the results. Consequently, the scope of the study shall be defined in such a way that the systems can be compared. Systems shall be compared using the same functional unit and equivalent methodological considerations, such as performance, system boundary, data quality, allocation procedures, decision rules on evaluating inputs, and outputs and impact assessment. Any differences between systems regarding these parameters shall be identified and reported. If the study is intended to be used for a comparative assertion intended to be disclosed to the public, interested parties shall conduct this evaluation as a critical review.

A life cycle impact assessment shall be performed for studies intended to be used in comparative assertions intended to be disclosed to the public.

#### 4.2.3.8 Critical review considerations

The scope of the study shall define

— whether a critical review is necessary and, if so, how to conduct it,

— the type of critical review needed (see Clause 6), and

— who would conduct the review, and their level of expertise.

### 4.3 Life cycle inventory analysis (LCI)

#### 4.3.1 General

The definition of the goal and scope of a study provides the initial plan for conducting the life cycle inventory phase of an LCA. When executing the plan for the life cycle inventory analysis, the operational steps outlined in Figure 1 should be performed. (It should be noted that some iterative steps are not shown in Figure 1.)

#### 4.3.2 Collecting data

**4.3.2.1** The qualitative and quantitative data for inclusion in the inventory shall be collected for each unit process that is included within the system boundary. The collected data, whether measured, calculated or estimated, are utilized to quantify the inputs and outputs of a unit process.

When data have been collected from public sources, the source shall be referenced. For those data that may be significant for the conclusions of the study, details about the relevant data collection process, the time when data have been collected, and further information about data quality indicators shall be referenced. If such data do not meet the data quality requirements, this shall be stated.

To decrease the risk of misunderstandings (e.g. resulting in double counting when validating or reusing the data collected), a description of each unit process shall be recorded.

Since data collection may span several reporting locations and published references, measures should be taken to reach uniform and consistent understanding of the product systems to be modelled.

**4.3.2.2** These measures should include the following:

— drawing unspecific process flow diagrams that outline all the unit processes to be modelled, including their interrelationships;

— describing each unit process in detail with respect to factors influencing inputs and outputs;

— listing of flows and relevant data for operating conditions associated with each unit process;

— developing a list that specifies the units used;

— describing the data collection and calculation techniques needed for all data;

— providing instructions to document clearly any special cases, irregularities or other items associated with the data provided.

Examples of data collection sheets are provided in Annex A.

**4.3.2.3** The major headings under which data may be classified include

— energy inputs, raw material inputs, ancillary inputs, other physical inputs,

— products, co-products and waste,

— releases to air, water and soil, and

— other environmental aspects.

Within these headings, individual data shall be further detailed to satisfy the goal of the study.

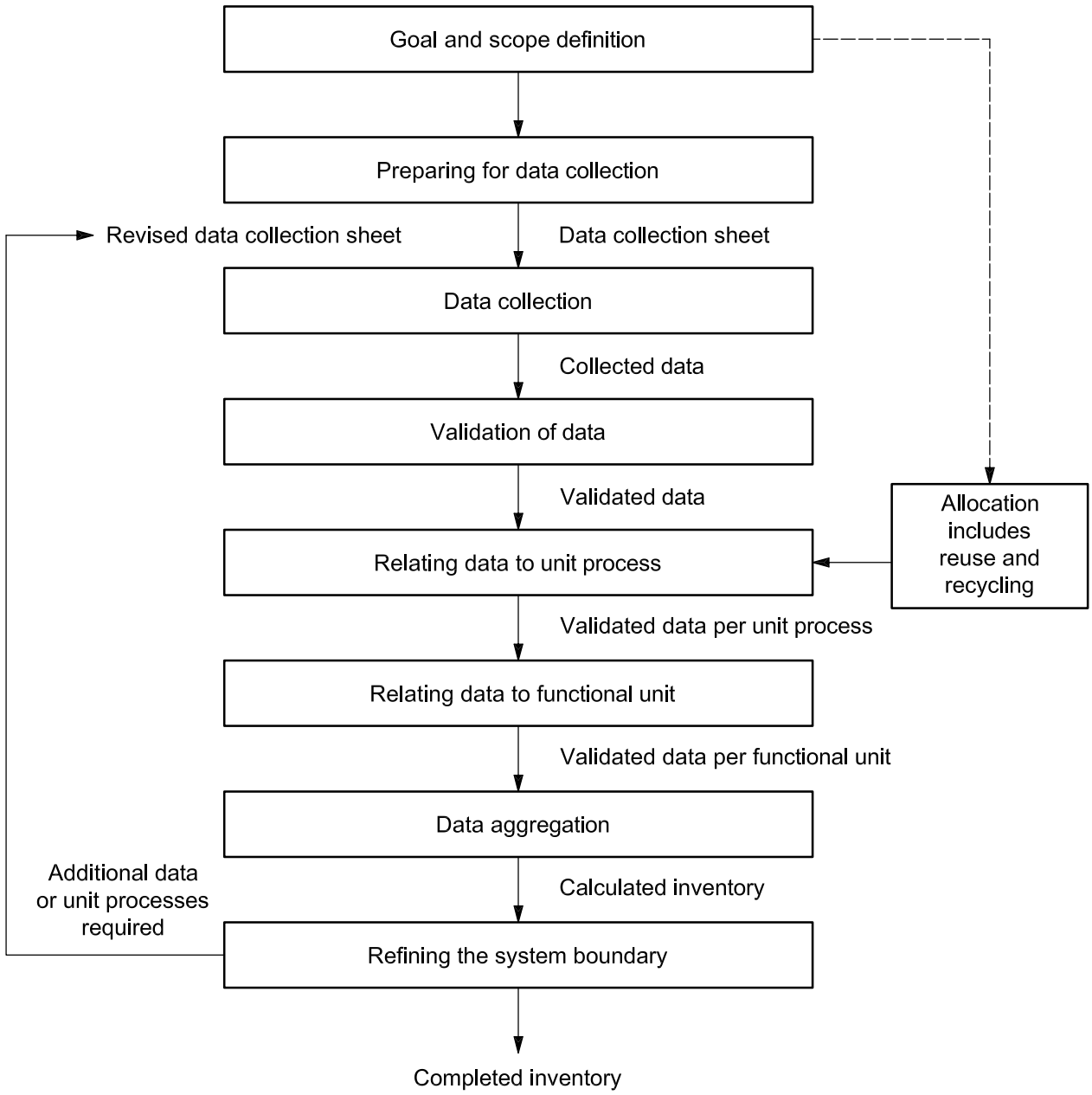


**Figure 1 — Simplified procedures for inventory analysis**

### 4.3.3 Calculating data

#### 4.3.3.1 General

All calculation procedures shall be explicitly documented and the assumptions made shall be clearly stated and explained. The same calculation procedures should be consistently applied throughout the study.

When determining the elementary flows associated with production, the actual production mix should be used whenever possible, in order to reflect the various types of resources that are consumed. As an example, for the production and delivery of electricity, account shall be taken of the electricity mix, the efficiencies of fuel combustion, conversion, transmission and distribution losses.

Inputs and outputs related to a combustible material (e.g. oil, gas or coal) can be transformed into an energy input or output by multiplying them by the relevant heat of combustion. In this case, it shall be reported whether the higher heating value or the lower heating value is used.

Several operational steps are needed for data calculation. These are described in 4.3.3.2 to 4.3.3.4 and 4.3.4.

#### 4.3.3.2 Validation of data

A check on data validity shall be conducted during the process of data collection to confirm and provide evidence that the data quality requirements for the intended application have been fulfilled.

Validation may involve establishing, for example, mass balances, energy balances and/or comparative analyses of release factors. As each unit process obeys the laws of conservation of mass and energy, mass and energy balances provide a useful check on the validity of a unit process description. Obvious anomalies in the data resulting from such validation procedures require alternative data that comply with the data selection as established according to 4.2.3.5.

#### 4.3.3.3 Relating data to unit process and functional unit

An appropriate flow shall be determined for each unit process. The quantitative input and output data of the unit process shall be calculated in relation to this flow.

Based on the flow chart and the flows between unit processes, the flows of all unit processes are related to the reference flow. The calculation should result in all system input and output data being referenced to the functional unit.

Care should be taken when aggregating the inputs and outputs in the product system. The level of aggregation shall be consistent with the goal of the study. Data should only be aggregated if they are related to equivalent substances and to similar environmental impacts. If more detailed aggregation rules are required, they should be explained in the goal and scope definition phase of the study or should be left to a subsequent impact assessment phase.

#### 4.3.3.4 Refining the system boundary

Reflecting the iterative nature of LCA, decisions regarding the data to be included shall be based on a sensitivity analysis to determine their significance, thereby verifying the initial analysis outlined in 4.2.3.3. The initial system boundary shall be revised, as appropriate, in accordance with the cut-off criteria established in the definition of the scope. The results of this refining process and the sensitivity analysis shall be documented.

The sensitivity analysis may result in

— exclusion of life cycle stages or unit processes when lack of significance can be shown by the sensitivity analysis,

— exclusion of inputs and outputs that lack significance to the results of the study, or

— inclusion of new unit processes, inputs and outputs that are shown to be significant in the sensitivity analysis.

This analysis serves to limit the subsequent data handling to those input and output data that are determined to be significant to the goal of the LCA.

### 4.3.4 Allocation

#### 4.3.4.1 General

The inputs and outputs shall be allocated to the different products according to clearly stated procedures that shall be documented and explained together with the allocation procedure.

The sum of the allocated inputs and outputs of a unit process shall be equal to the inputs and outputs of the unit process before allocation.

Whenever several alternative allocation procedures seem applicable, a sensitivity analysis shall be conducted to illustrate the consequences of the departure from the selected approach.

#### 4.3.4.2 Allocation procedure

The study shall identify the processes shared with other product systems and deal with them according to the stepwise procedure [3] presented below.

a) **Step 1**: Wherever possible, allocation should be avoided by

   1) dividing the unit process to be allocated into two or more sub-processes and collecting the input and output data related to these sub-processes, or

   2) expanding the product system to include the additional functions related to the co-products, taking into account the requirements of 4.2.3.3.

b) **Step 2**: Where allocation cannot be avoided, the inputs and outputs of the system should be partitioned between its different products or functions in a way that reflects the underlying physical relationships between them; i.e. they should reflect the way in which the inputs and outputs are changed by quantitative changes in the products or functions delivered by the system.

c) **Step 3**: Where physical relationship alone cannot be established or used as the basis for allocation, the inputs should be allocated between the products and functions in a way that reflects other relationships between them. For example, input and output data might be allocated between co-products in proportion to the economic value of the products.

Some outputs may be partly co-products and partly waste. In such cases, it is necessary to identify the ratio between co-products and waste since the inputs and outputs shall be allocated to the co-products part only.

Allocation procedures shall be uniformly applied to similar inputs and outputs of the system under consideration. For example, if allocation is made to usable products (e.g. intermediate or discarded products) leaving the system, then the allocation procedure shall be similar to the allocation procedure used for such products entering the system.

The inventory is based on material balances between input and output. Allocation procedures should therefore approximate as much as possible such fundamental input/output relationships and characteristics.

#### 4.3.4.3 Allocation procedures for reuse and recycling [4]

**4.3.4.3.1** The allocation principles and procedures in 4.3.4.1 and 4.3.4.2 also apply to reuse and recycling situations.

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3) Formally, Step 1 is not part of the allocation procedure.

4) In some countries and regions, recycling encompasses re-use, material recovery and energy recovery.

Changes in the inherent properties of materials shall be taken into account. In addition, particularly for the recovery processes between the original and subsequent product system, the system boundary shall be identified and explained, ensuring that the allocation principles are observed as described in 4.3.4.2.

**4.3.4.3.2** However, in these situations, additional elaboration is needed for the following reasons:

— reuse and recycling (as well as composting, energy recovery and other processes that can be assimilated to reuse/recycling) may imply that the inputs and outputs associated with unit processes for extraction and processing of raw materials and final disposal of products are to be shared by more than one product system;

— reuse and recycling may change the inherent properties of materials in subsequent use;

— specific care should be taken when defining system boundary with regard to recovery processes.

**4.3.4.3.3** Several allocation procedures are applicable for reuse and recycling. The application of some procedures is outlined conceptually in Figure 2 and is distinguished in the following to illustrate how the above constraints can be addressed.

a) A closed-loop allocation procedure applies to closed-loop product systems. It also applies to open-loop product systems where no changes occur in the inherent properties of the recycled material. In such cases, the need for allocation is avoided since the use of secondary material displaces the use of virgin (primary) materials. However, the first use of virgin materials in applicable open-loop product systems may follow an open-loop allocation procedure outlined in b).

b) An open-loop allocation procedure applies to open-loop product systems where the material is recycled into other product systems and the material undergoes a change to its inherent properties.

**4.3.4.3.4** The allocation procedures for the shared unit processes mentioned in 4.3.4.3 should use, as the basis for allocation, if feasible, the following order:

— physical properties (e.g. mass);

— economic value (e.g. market value of the scrap material or recycled material in relation to market value of primary material); or

— the number of subsequent uses of the recycled material (see ISO/TR 14049).

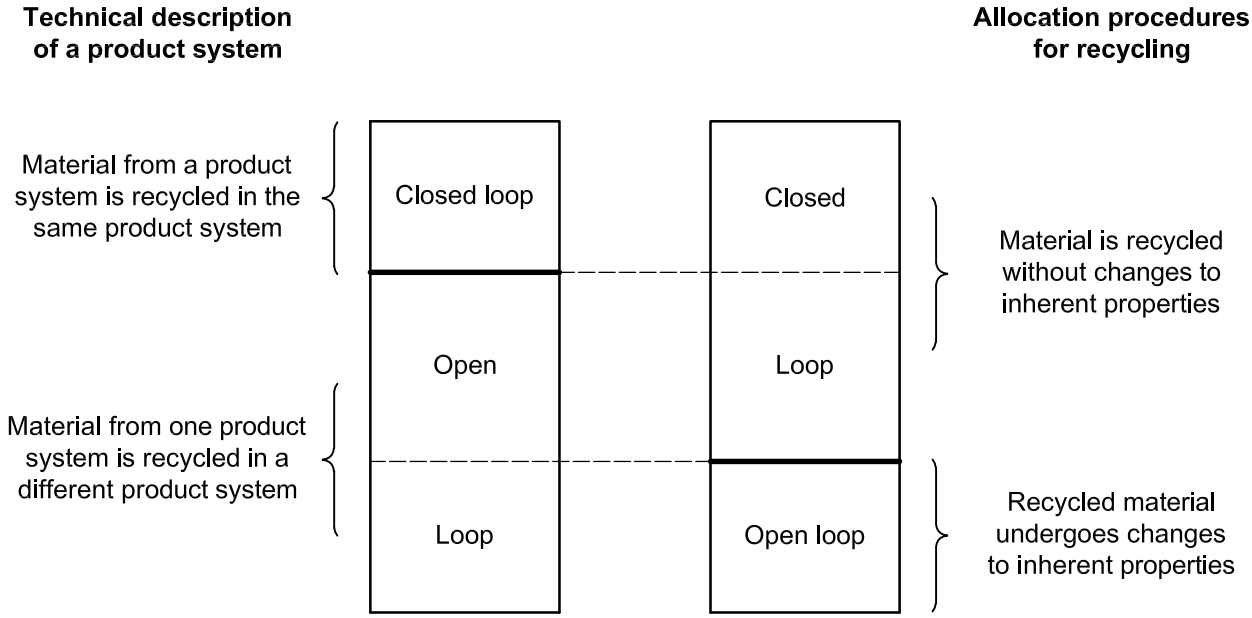


**Figure 2 — Distinction between a technical description of a product system and allocation procedures for recycling**

## 4.4 Life cycle impact assessment (LCIA)

### 4.4.1 General

LCIA is different from other techniques, such as environmental performance evaluation, environmental impact assessment and risk assessment, since it is a relative approach based on a functional unit. LCIA may use information gathered by these other techniques.

The LCIA phase shall be carefully planned to achieve the goal and scope of an LCA study. The LCIA phase shall be coordinated with other phases of the LCA to take into account the following possible omissions and sources of uncertainty:

a) whether the quality of the LCI data and results is sufficient to conduct the LCIA in accordance with the study goal and scope definition;

b) whether the system boundary and data cut-off decisions have been sufficiently reviewed to ensure the availability of LCI results necessary to calculate indicator results for the LCIA;

c) whether the environmental relevance of the LCIA results is decreased due to the LCI functional unit calculation, system wide averaging, aggregation and allocation.

The LCIA phase includes the collection of indicator results for the different impact categories, which together represent the LCIA profile for the product system.

The LCIA consists of mandatory and optional elements.

### 4.4.2 Mandatory elements of LCIA

#### 4.4.2.1 General

The LCIA phase shall include the following mandatory elements:

— selection of impact categories, category indicators and characterization models;

— assignment of LCI results to the selected impact categories (classification);

— calculation of category indicator results (characterization).

#### 4.4.2.2 Selection of impact categories, category indicators and characterization models

**4.4.2.2.1** Whenever impact categories, category indicators and characterization models are selected in an LCA, the related information and sources shall be referenced. This also applies when new impact categories, category indicators or characterization models are defined.

NOTE Examples of impact categories are described in ISO/TR 14047.

Accurate and descriptive names shall be provided for the impact categories and category indicators.

The selection of impact categories, category indicators and characterization models shall be both justified and consistent with the goal and scope of the LCA.

The selection of impact categories shall reflect a comprehensive set of environmental issues related to the product system being studied, taking the goal and scope into consideration.

The environmental mechanism and characterization model that relate the LCI results to the category indicator and provide a basis for characterization factors shall be described.

The appropriateness of the characterization model used for deriving the category indicator in the context of the goal and scope of the study shall be described.

LCI results other than mass and energy flow data included in an LCA (e.g. land use) shall be identified and their relationship to corresponding category indicators shall be determined.

For most LCA studies, existing impact categories, category indicators or characterization models will be selected. However, in some cases existing impact categories, category indicators or characterization models are not sufficient to fulfil the defined goal and scope of the LCA, and new ones have to be defined. When new impact categories, category indicators or characterization models are defined, the recommendations in this sub-clause also apply.

Figure 3 illustrates the concept of category indicators based on an environmental mechanism. The impact category “acidification” is used in Figure 3 as an example. Every impact category has its own environmental mechanism.

Characterization models reflect the environmental mechanism by describing the relationship between the LCI results, category indicators and, in some cases, category endpoint(s). The characterization model is used to derive the characterization factors. The environmental mechanism is the total of environmental processes related to the characterization of the impacts.

**4.4.2.2.2** For each impact category, the necessary components of the LCIA include

— identification of the category endpoint(s),

— definition of the category indicator for given category endpoint(s),

— identification of appropriate LCI results that can be assigned to the impact category, taking into account the chosen category indicator and identified category endpoint(s), and

— identification of the characterization model and the characterization factors.

This procedure facilitates the collection, assignment and characterization modelling of appropriate LCI results. This also helps to highlight the scientific and technical validity, assumptions, value-choices and degree of accuracy in the characterization model.

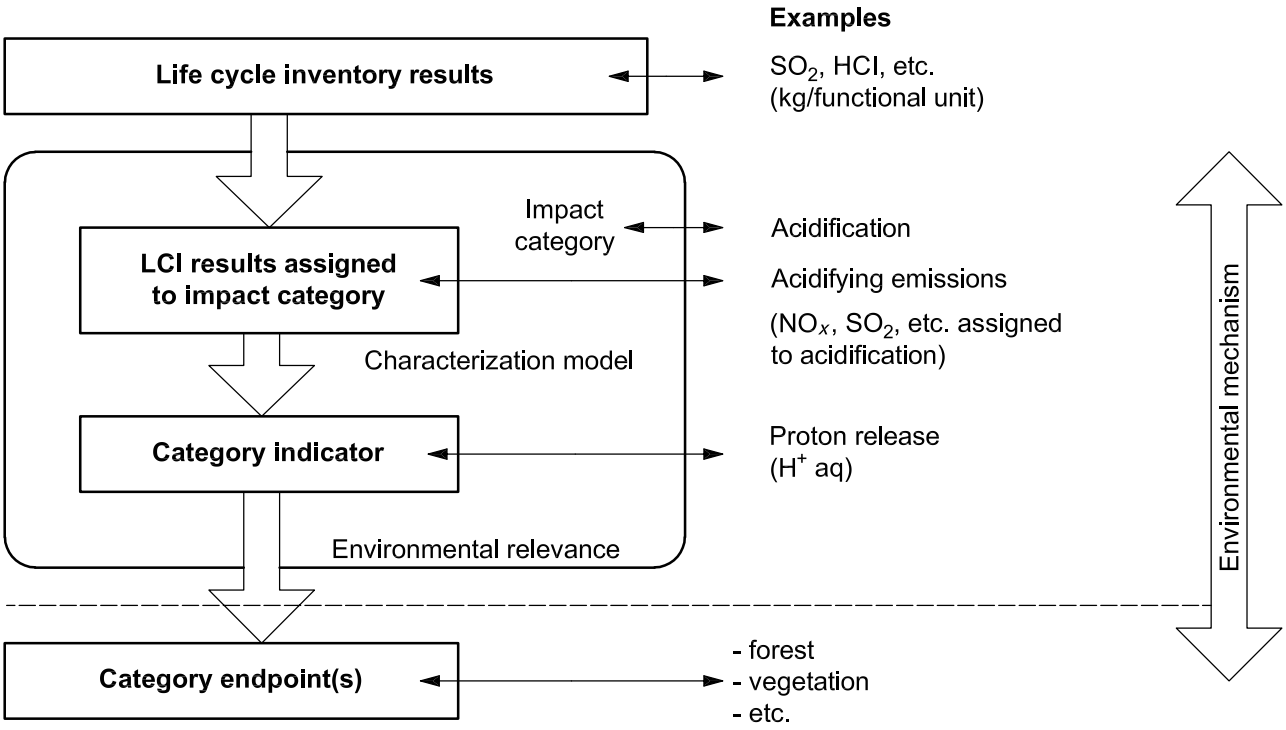


**Figure 3 — Concept of category indicators**

The category indicator can be chosen anywhere along the environmental mechanism between the LCI results and the category endpoint(s) (see Figure 3). Table 1 provides examples of terms used in this International Standard.

NOTE Further examples are provided in ISO/TR 14047.

Environmental relevance encompasses a qualitative assessment of the degree of linkage between category indicator result and category endpoints; for example high, moderate or low linkage.

**Table 1 — Examples of terms**

| Term | Example |
|---|---|
| Impact category | Climate change |
| LCI results | Amount of a greenhouse gas per functional unit |
| Characterization model | Baseline model of 100 years of the Intergovernmental Panel on Climate Change |
| Category indicator | Infrared radiative forcing ($W/m^2$) |
| Characterization factor | Global warming potential ($GWP_{100}$) for each greenhouse gas (kg $CO_2$-equivalents/kg gas) |
| Category indicator result | Kilograms of $CO_2$-equivalents per functional unit |
| Category endpoints | Coral reefs, forests, crops |
| Environmental relevance | Infrared radiative forcing is a proxy for potential effects on the climate, depending on the integrated atmospheric heat adsorption caused by emissions and the distribution over time of the heat absorption |

**4.4.2.2.3** In addition to the requirements in 4.4.2.2.1, the following recommendations apply to the selection of impact categories, category indicators and characterization models:

a) the impact categories, category indicators and characterization models should be internationally accepted, i.e. based on an international agreement or approved by a competent international body;

b) the impact categories should represent the aggregated impacts of inputs and outputs of the product system on the category endpoint(s) through the category indicators;

c) value-choices and assumptions made during the selection of impact categories, category indicators and characterization models should be minimized;

d) the impact categories, category indicators and characterization models should avoid double counting unless required by the goal and scope definition, for example when the study includes both human health and carcinogenicity;

e) the characterization model for each category indicator should be scientifically and technically valid, and based upon a distinct identifiable environmental mechanism and reproducible empirical observation;

f) the extent to which the characterization model and the characterization factors are scientifically and technically valid should be identified;

g) the category indicators should be environmentally relevant.

Depending on the environmental mechanism and the goal and scope, spatial and temporal differentiation of the characterization model relating the LCI results to the category indicator should be considered. The fate and transport of the substances should be part of the characterization model.

**4.4.2.2.4** The environmental relevance of the category indicator or characterization model should be clearly stated in the following terms:

a) the ability of the category indicator to reflect the consequences of the LCI results on the category endpoint(s), at least qualitatively;

b) the addition of environmental data or information to the characterization model with respect to the category endpoint(s), including

   — the condition of the category endpoint(s),

   — the relative magnitude of the assessed change in the category endpoints,

   — the spatial aspects, such as area and scale,

   — the temporal aspects, such as duration, residence time, persistence, timing, etc.,

   — the reversibility of the environmental mechanism, and

   — the uncertainty of the linkages between the category indicators and the category endpoints.

### 4.4.2.3 Assignment of LCI results to the selected impact categories (classification)

Assignment of LCI results to impact categories should consider the following, unless otherwise required by the goal and scope:

a) assignment of LCI results that are exclusive to one impact category;

b) identification of LCI results that relate to more than one impact category, including

— distinction between parallel mechanisms (e.g. $SO_2$ is apportioned between the impact categories of human health and acidification), and

— assignment to serial mechanisms (e.g. $NO_x$ can be classified to contribute to both ground-level ozone formation and acidification).

#### 4.4.2.4 Calculation of category indicator results (characterization)

The calculation of indicator results (characterization) involves the conversion of LCI results to common units and the aggregation of the converted results within the same impact category. This conversion uses characterization factors. The outcome of the calculation is a numerical indicator result.

The method of calculating indicator results shall be identified and documented, including the value-choices and assumptions used.

If LCI results are unavailable or if data are of insufficient quality for the LCIA to achieve the goal and scope of the study, either an iterative data collection or an adjustment of the goal and scope is required.

The usefulness of the indicator results for a given goal and scope depends on the accuracy, validity and characteristics of the characterization models and characterization factors. The number and kind of simplifying assumptions and value-choices used in the characterization model for the category indicator also vary between impact categories and can depend on the geographical region. A trade-off often exists between the simplicity and accuracy of the characterization model. Variation in the quality of category indicators among impact categories can influence the overall accuracy of the LCA, because of, for example, differences in

— the complexity of the environmental mechanisms between the system boundary and the category endpoint,

— the spatial and temporal characteristics, for example the persistence of a substance in the environment, and

— the dose-response characteristics.

Additional data about the environmental condition can enhance the meaning and usability of the indicator results. This issue may also be dealt with in the data quality analysis.

#### 4.4.2.5 Resulting data after characterization

After characterization and before the optional elements described in 4.4.3, the inputs and outputs of the product system are represented, for example, by

— a discrete compilation of the LCIA category indicator results for the different impact categories referred to as an LCIA profile,

— a set of inventory results that are elementary flows but have not been assigned to impact categories e.g. due to lack of environmental relevance, and

— a set of data that does not represent elementary flows.

### 4.4.3 Optional elements of LCIA

#### 4.4.3.1 General

In addition to the elements of LCIA listed in 4.4.2.2, there could be optional elements and information as listed below which can be used depending on the goal and scope of the LCA:

a) **normalization**: calculating the magnitude of category indicator results relative to reference information;

b) **grouping**: sorting and possibly ranking of the impact categories;

c) **weighting**: converting and possibly aggregating indicator results across impact categories using numerical factors based on value-choices; data prior to weighting should remain available;

d) **data quality analysis**: better understanding the reliability of the collection of indicator results, the LCIA profile.

The optional LCIA elements may use information from outside the LCIA framework. The use of such information should be explained and the explanation should be reported.

The application and use of normalization, grouping and weighting methods shall be consistent with the goal and scope of the LCA and it shall be fully transparent. All methods and calculations used shall be documented to provide transparency.

#### 4.4.3.2 Normalization

**4.4.3.2.1** Normalization is the calculation of the magnitude of the category indicator results relative to some reference information. The aim of the normalization is to understand better the relative magnitude for each indicator result of the product system under study. It is an optional element that may be helpful in, for example,

— checking for inconsistencies,

— providing and communicating information on the relative significance of the indicator results, and

— preparing for additional procedures, such as grouping, weighting or life cycle interpretation.

**4.4.3.2.2** Normalization transforms an indicator result by dividing it by a selected reference value. Some examples of reference values are

— the total inputs and outputs for a given area that may be global, regional, national or local,

— the total inputs and outputs for a given area on a *per capita* basis or similar measurement, and

— inputs and outputs in a baseline scenario, such as a given alternative product system.

The selection of the reference system should consider the consistency of the spatial and temporal scales of the environmental mechanism and the reference value.

The normalization of the indicator results can change the conclusions drawn from the LCIA phase. It may be desirable to use several reference systems to show the consequence on the outcome of mandatory elements of the LCIA phase. A sensitivity analysis may provide additional information about the choice of reference data. The collection of normalized category indicator results represents a normalized LCIA profile.

#### 4.4.3.3 Grouping

Grouping is the assignment of impact categories into one or more sets as predefined in the goal and scope definition, and it may involve sorting and/or ranking. Grouping is an optional element with two different possible procedures, either

— to sort the impact categories on a nominal basis (e.g. by characteristics such as inputs and outputs or global regional and local spatial scales), or

— to rank the impact categories in a given hierarchy (e.g. high, medium, and low priority).

Ranking is based on value-choices. Different individuals, organizations and societies may have different preferences; therefore it is possible that different parties will reach different ranking results based on the same indicator results or normalized indicator results.

#### 4.4.3.4 Weighting

**4.4.3.4.1** Weighting is the process of converting indicator results of different impact categories by using numerical factors based on value-choices. It may include aggregation of the weighted indicator results.

**4.4.3.4.2** Weighting is an optional element with two possible procedures, either

— to convert the indicator results or normalized results with selected weighting factors, or

— to aggregate these converted indicator results or normalized results across impact categories.

Weighting steps are based on value-choices and are not scientifically based. Different individuals, organizations and societies may have different preferences; therefore it is possible that different parties will reach different weighting results based on the same indicator results or normalized indicator results. In an LCA it may be desirable to use several different weighting factors and weighting methods, and to conduct sensitivity analysis to assess the consequences on the LCIA results of different value-choices and weighting methods.

**4.4.3.4.3** Data and indicator results or normalized indicator results reached prior to weighting should be made available together with the weighting results. This ensures that

— trade-offs and other information remain available to decision-makers and to others, and

— users can appreciate the full extent and ramifications of the results.

### 4.4.4 Additional LCIA data quality analysis

**4.4.4.1** Additional techniques and information may be needed to understand better the significance, uncertainty and sensitivity of the LCIA results in order

— to help distinguish if significant differences are or are not present,

— to identify negligible LCI results, or

— to guide the iterative LCIA process.

The need for and choice of techniques depend upon the accuracy and detail needed to fulfil the goal and scope of the LCA.

**4.4.4.2** The specific techniques and their purposes are described below.

a) **Gravity analysis** (e.g. Pareto analysis) is a statistical procedure that identifies those data having the greatest contribution to the indicator result. These items may then be investigated with increased priority to ensure that sound decisions are made.

b) **Uncertainty analysis** is a procedure to determine how uncertainties in data and assumptions progress in the calculations and how they affect the reliability of the results of the LCIA.

c) **Sensitivity analysis** is a procedure to determine how changes in data and methodological choices affect the results of the LCIA.

In accordance with the iterative nature of LCA, the result of this LCIA data quality analysis may lead to revision of the LCI phase.

#### 4.4.5 LCIA intended to be used in comparative assertions intended to be disclosed to the public

An LCIA that is intended to be used in comparative assertions intended to be disclosed to the public shall employ a sufficiently comprehensive set of category indicators. The comparison shall be conducted category indicator by category indicator.

An LCIA shall not provide the sole basis of comparative assertion intended to be disclosed to the public of overall environmental superiority or equivalence, as additional information will be necessary to overcome some of the inherent limitations in the LCIA. Value-choices, exclusion of spatial and temporal, threshold and dose-response information, relative approach, and the variation in precision among impact categories are examples of such limitations. LCIA results do not predict impacts on category endpoints, exceeding thresholds, safety margins or risks.

Category indicators intended to be used in comparative assertions intended to be disclosed to the public shall, as a minimum, be

— scientifically and technically valid, i.e. using a distinct identifiable environmental mechanism and/or reproducible empirical observation, and

— environmentally relevant, i.e. have sufficiently clear links to the category endpoint(s) including, but not limited to, spatial and temporal characteristics.

Category indicators intended to be used in comparative assertions intended to be disclosed to the public should be internationally accepted.

Weighting, as described in 4.4.3.4, shall not be used in LCA studies intended to be used in comparative assertions intended to be disclosed to the public.

An analysis of results for sensitivity and uncertainty shall be conducted for studies intended to be used in comparative assertions intended to be disclosed to the public.

### 4.5 Life cycle interpretation

#### 4.5.1 General

**4.5.1.1** The life cycle interpretation phase of an LCA or an LCI study comprises several elements as depicted in Figure 4, as follows:

— identification of the significant issues based on the results of the LCI and LCIA phases of LCA;

— an evaluation that considers completeness, sensitivity and consistency checks;

— conclusions, limitations, and recommendations.

The relationship of the interpretation phase to other phases of LCA is shown in Figure 4.

The goal and scope definition and interpretation phases of life cycle assessment frame the study, whereas the other phases of LCA (LCI and LCIA) produce information on the product system.

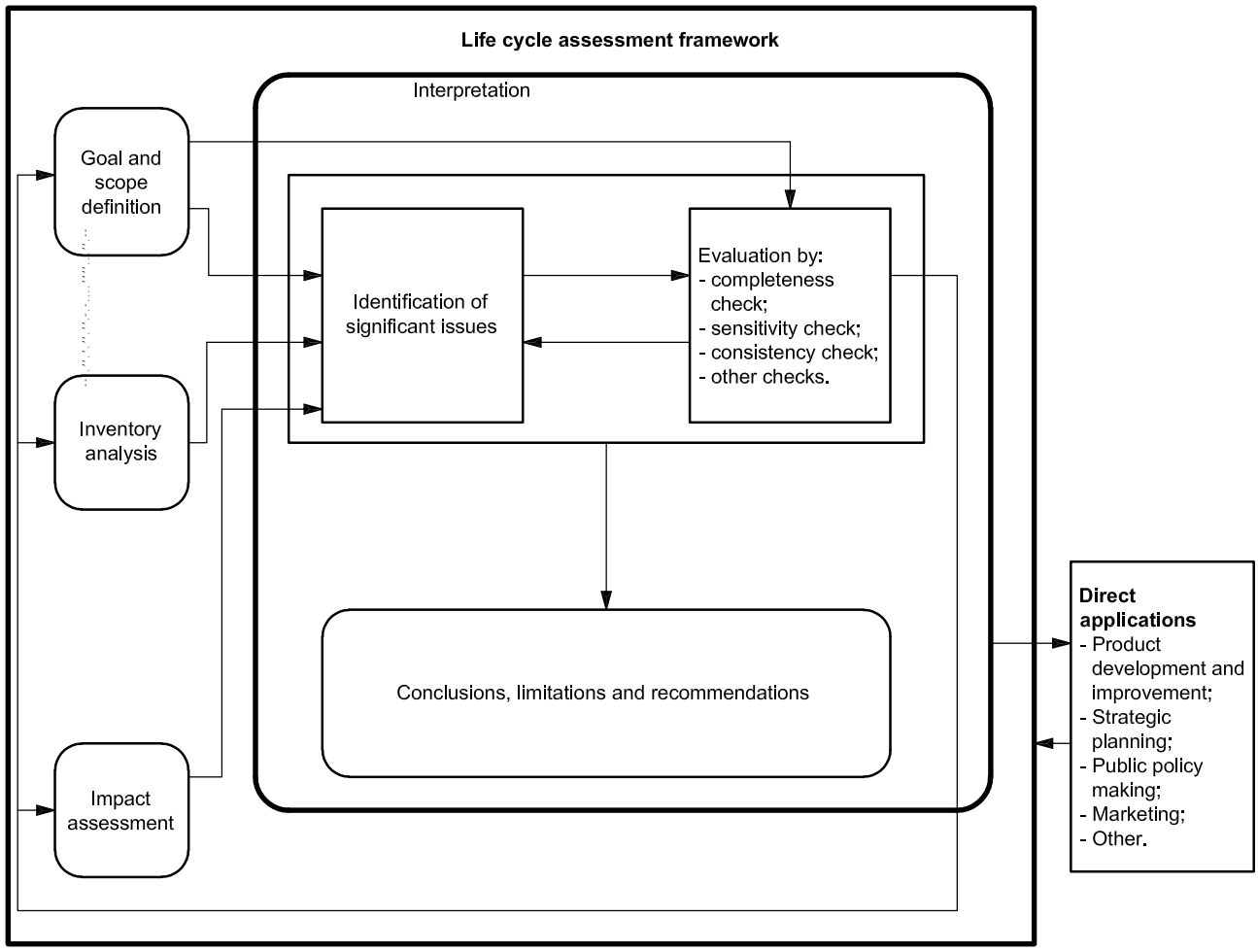


**Figure 4 — Relationships between elements within the interpretation phase with the other phases of LCA**

The results of the LCI or LCIA phases shall be interpreted according to the goal and scope of the study, and the interpretation shall include an assessment and a sensitivity check of the significant inputs, outputs and methodological choices in order to understand the uncertainty of the results.

**4.5.1.2** The interpretation shall also consider the following in relation to the goal of the study:

— the appropriateness of the definitions of the system functions, the functional unit and system boundary;

— limitations identified by the data quality assessment and the sensitivity analysis.

The documentation of the data quality assessment, sensitivity analyses, conclusions and any recommendations from the LCI and LCIA results shall be checked.

The LCI results should be interpreted with caution because they refer to input and output data and not to environmental impacts. In addition, uncertainty is introduced into the results of an LCI due to the compounded effects of input uncertainties and data variability. One approach is to characterize uncertainty in results by ranges and/or probability distributions. Whenever feasible, such analysis should be performed to better explain and support the LCI conclusions.

Further information and examples on the life cycle interpretation phase can be found in informative Annex B.

### 4.5.2 Identification of significant issues

**4.5.2.1** The objective of this element is to structure the results from the LCI or LCIA phases in order to help determine the significant issues, in accordance with the goal and scope definition and interactively with the evaluation element. The purpose of this interaction is to include the implications of the methods used, assumptions made, etc. in the preceding phases, such as allocation rules, cut-off decisions, selection of impact categories, category indicators and models.

**4.5.2.2** Examples of significant issues are

— inventory data, such as energy, emissions, discharges, waste,

— impact categories, such as resource use, climate change, and

— significant contributions from life cycle stages to LCI or LCIA results, such as individual unit processes or groups of processes like transportation and energy production.

A variety of specific approaches, methods and tools are available to identify environmental issues and to determine their significance.

NOTE See B.2 for examples.

**4.5.2.3** There are four types of information required from the preceding phases of the LCA:

a) the findings from the preceding phases (LCI, LCIA) that shall be assembled and structured together with information on data quality;

b) methodological choices, such as allocation rules and system boundary from the LCI and category indicators and models used in LCIA;

c) the value-choices used in the study as found in the goal and scope definition;

d) the role and responsibilities of the different interested parties as found in the goal and scope definition in relation to the application, and also the results from a concurrent critical review process, if conducted.

When the results from the preceding phases (LCI, LCIA) have been found to meet the demands of the goal and scope of the study, the significance of these results shall then be determined.

All relevant results available at the time shall be gathered and consolidated for further analysis, including information on data quality.

### 4.5.3 Evaluation

#### 4.5.3.1 General

The objectives of the evaluation element are to establish and enhance confidence in, and the reliability of, the results of the LCA or the LCI study, including the significant issues identified in the first element of the interpretation. The results of the evaluation should be presented in a manner that gives the commissioner or any other interested party a clear and understandable view of the outcome of the study.

The evaluation shall be undertaken in accordance with the goal and scope of the study.

During the evaluation, the use of the following three techniques shall be considered:

— completeness check (see 4.5.3.2);

— sensitivity check (see 4.5.3.3);

— consistency check (see 4.5.3.4).

The results of uncertainty analysis and data quality analysis should supplement these checks.

The evaluation should take into account the final intended use of the study results.

NOTE See B.3 for examples.

#### 4.5.3.2 Completeness check

The objective of the completeness check is to ensure that all relevant information and data needed for the interpretation are available and complete. If any relevant information is missing or incomplete, the necessity of such information for satisfying the goal and scope of the LCA shall be considered. This finding and its justification shall be recorded.

If any relevant information, considered necessary for determining the significant issues, is missing or incomplete, the preceding phases (LCI, LCIA) should be revisited or, alternatively, the goal and scope definition should be adjusted. If the missing information is considered unnecessary, the reason for this should be recorded.

#### 4.5.3.3 Sensitivity check

The objective of the sensitivity check is to assess the reliability of the final results and conclusions by determining how they are affected by uncertainties in the data, allocation methods or calculation of category indicator results, etc.

The sensitivity check shall include the results of the sensitivity analysis and uncertainty analysis, if performed in the preceding phases (LCI, LCIA).

In a sensitivity check, consideration shall be given to

— the issues predetermined by the goal and scope of the study,

— the results from all other phases of the study, and

— expert judgements and previous experiences.

When an LCA is intended to be used in comparative assertions intended to be disclosed to the public, the evaluation element shall include interpretative statements based on detailed sensitivity analyses.

The level of detail required in the sensitivity check depends mainly upon the findings of the inventory analysis and, if conducted, the impact assessment.

The output of the sensitivity check determines the need for more extensive and/or precise sensitivity analysis as well as shows apparent effects on the study results.

The inability of a sensitivity check to find significant differences between different studied alternatives does not automatically lead to the conclusion that such differences do not exist. The lack of any significant differences may be the end result of the study.

#### 4.5.3.4 Consistency check

The objective of the consistency check is to determine whether the assumptions, methods and data are consistent with the goal and scope.

If relevant to the LCA or LCI study the following questions shall be addressed.

a) Are differences in data quality along a product system life cycle and between different product systems consistent with the goal and scope of the study?

b) Have regional and/or temporal differences, if any, been consistently applied?

c) Have allocation rules and the system boundary been consistently applied to all product systems?

d) Have the elements of impact assessment been consistently applied?

#### 4.5.4 Conclusions, limitations and recommendations

The objective of this part of the life cycle interpretation is to draw conclusions, identify limitations and make recommendations for the intended audience of the LCA.

Conclusions shall be drawn from the study. This should be done iteratively with the other elements in the life cycle interpretation phase. A logical sequence for the process is as follows:

a) identify the significant issues;

b) evaluate the methodology and results for completeness, sensitivity and consistency;

c) draw preliminary conclusions and check that these are consistent with the requirements of the goal and scope of the study, including, in particular, data quality requirements, predefined assumptions and values, methodological and study limitations, and application-oriented requirements;

d) if the conclusions are consistent, report them as full conclusions; otherwise return to previous steps a), b) or c) as appropriate.

Recommendations shall be based on the final conclusions of the study, and shall reflect a logical and reasonable consequence of the conclusions.

Whenever appropriate to the goal and scope of the study, specific recommendations to decision-makers should be explained.

Recommendations should relate to the intended application.

## 5 Reporting

### 5.1 General requirements and considerations

**5.1.1** The type and format of the report shall be defined in the scope phase of the study.

The results and conclusions of the LCA shall be completely and accurately reported without bias to the intended audience. The results, data, methods, assumptions and limitations shall be transparent and presented in sufficient detail to allow the reader to comprehend the complexities and trade-offs inherent in the LCA. The report shall also allow the results and interpretation to be used in a manner consistent with the goals of the study.

**5.1.2** In addition to the items in 5.1.1 and those listed in 5.2 c), the following items should be considered when preparing third-party reports:

a) modifications to the initial scope together with their justification;

b) system boundary, including

- type of inputs and outputs of the system as elementary flows,
- decision criteria;

c) description of the unit processes, including

- decision about allocation;

d) data, including

— decision about data,

— details about individual data, and

— data quality requirements;

e) choice of impact categories and category indicators.

**5.1.3** A graphical presentation of LCI results and LCIA results as part of the report may be useful, but it should be considered that this invites implicit comparisons and conclusions.

## 5.2 Additional requirements and guidance for third-party reports

When results of the LCA are to be communicated to any third party (i.e. interested party other than the commissioner or the practitioner of the study), regardless of the form of communication, a third-party report shall be prepared.

The third-party report can be based on study documentation that contains confidential information that may not be included in the third-party report.

The third-party report constitutes a reference document, and shall be made available to any third party to whom the communication is made. The third-party report shall cover the following aspects.

a) **General aspects**:

1) LCA commissioner, practitioner of LCA (internal or external);

2) date of report;

3) statement that the study has been conducted according to the requirements of this International Standard.

b) **Goal of the study**:

1) reasons for carrying out the study;

2) its intended applications;

3) the target audiences;

4) statement as to whether the study intends to support comparative assertions intended to be disclosed to the public.

c) **Scope of the study**:

1) function, including

i) statement of performance characteristics, and

ii) any omission of additional functions in comparisons;

2) functional unit, including

i) consistency with goal and scope,

ii) definition,

iii) result of performance measurement;

3) system boundary, including

   i) omissions of life cycle stages, processes or data needs,

   ii) quantification of energy and material inputs and outputs, and

   iii) assumptions about electricity production;

4) cut-off criteria for initial inclusion of inputs and output, including

   i) description of cut-off criteria and assumptions,

   ii) effect of selection on results,

   iii) inclusion of mass, energy and environmental cut-off criteria.

d) **Life cycle inventory analysis**:

1) data collection procedures;

2) qualitative and quantitative description of unit processes;

3) sources of published literature;

4) calculation procedures;

5) validation of data, including

   i) data quality assessment, and

   ii) treatment of missing data;

6) sensitivity analysis for refining the system boundary;

7) allocation principles and procedures, including

   i) documentation and justification of allocation procedures, and

   ii) uniform application of allocation procedures.

e) **Life cycle impact assessment**, where applicable:

1) the LCIA procedures, calculations and results of the study;

2) limitations of the LCIA results relative to the defined goal and scope of the LCA;

3) the relationship of LCIA results to the defined goal and scope, see 4.2;

4) the relationship of the LCIA results to the LCI results, see 4.4;

5) impact categories and category indicators considered, including a rationale for their selection and a reference to their source;

6) descriptions of or reference to all characterization models, characterization factors and methods used, including all assumptions and limitations;

7) descriptions of or reference to all value-choices used in relation to impact categories, characterization models, characterization factors, normalization, grouping, weighting and, elsewhere in the LCIA, a justification for their use and their influence on the results, conclusions and recommendations;

8) a statement that the LCIA results are relative expressions and do not predict impacts on category endpoints, the exceeding of thresholds, safety margins or risks.

and, when included as a part of the LCA, also

i) a description and justification of the definition and description of any new impact categories, category indicators or characterization models used for the LCIA,

ii) a statement and justification of any grouping of the impact categories,

iii) any further procedures that transform the indicator results and a justification of the selected references, weighting factors, etc.,

iv) any analysis of the indicator results, for example sensitivity and uncertainty analysis or the use of environmental data, including any implication for the results, and

v) data and indicator results reached prior to any normalization, grouping or weighting shall be made available together with the normalized, grouped or weighted results.

f) **Life cycle interpretation**:

1) the results;

2) assumptions and limitations associated with the interpretation of results, both methodology and data related;

3) data quality assessment;

4) full transparency in terms of value-choices, rationales and expert judgements.

g) **Critical review**, where applicable:

1) name and affiliation of reviewers;

2) critical review reports;

3) responses to recommendations.

## 5.3 Further reporting requirements for comparative assertion intended to be disclosed to the public

**5.3.1** For LCA studies supporting comparative assertions intended to be disclosed to the public, the following issues shall also be addressed by the report in addition to those identified in 5.1 and 5.2:

a) analysis of material and energy flows to justify their inclusion or exclusion;

b) assessment of the precision, completeness and representativeness of data used;

c) description of the equivalence of the systems being compared in accordance with 4.2.3.7;

d) description of the critical review process;

e) an evaluation of the completeness of the LCIA;

f) a statement as to whether or not international acceptance exists for the selected category indicators and a justification for their use;

g) an explanation for the scientific and technical validity and environmental relevance of the category indicators used in the study;

h) the results of the uncertainty and sensitivity analyses;

i) evaluation of the significance of the differences found.

**5.3.2** If grouping is included in the LCA, add the following:

a) the procedures and results used for grouping;

b) a statement that conclusions and recommendations derived from grouping are based on value-choices;

c) a justification of the criteria used for normalization and grouping (these can be personal, organizational or national value-choices);

d) the statement that "ISO 14044 does not specify any specific methodology or support the underlying value-choices used to group the impact categories";

e) the statement that "The value-choices and judgements within the grouping procedures are the sole responsibilities of the commissioner of the study (e.g. government, community, organization, etc.)".

# 6 Critical review

## 6.1 General

The critical review process shall ensure that

— the methods used to carry out the LCA are consistent with this International Standard,

— the methods used to carry out the LCA are scientifically and technically valid,

— the data used are appropriate and reasonable in relation to the goal of the study,

— the interpretations reflect the limitations identified and the goal of the study, and

— the study report is transparent and consistent.

The scope and type of critical review desired shall be defined in the scope phase of an LCA, and the decision on the type of critical review shall be recorded.

In order to decrease the likelihood of misunderstandings or negative effects on external interested parties, a panel of interested parties shall conduct critical reviews on LCA studies where the results are intended to be used to support a comparative assertion intended to be disclosed to the public.

## 6.2 Critical review by internal or external expert

A critical review may be carried out by an internal or external expert. In such a case, an expert independent of the LCA shall perform the review. The review statement, comments of the practitioner and any response to recommendations made by the reviewer shall be included in the LCA report.

## 6.3 Critical review by panel of interested parties

A critical review may be carried out as a review by interested parties. In such a case, an external independent expert should be selected by the original study commissioner to act as chairperson of a review panel of at least three members. Based on the goal and scope of the study, the chairperson should select other

independent qualified reviewers. This panel may include other interested parties affected by the conclusions drawn from the LCA, such as government agencies, non-governmental groups, competitors and affected industries.

For LCIA, the expertise of reviewers in the scientific disciplines relevant to the important impact categories of the study, in addition to other expertise and interest, shall be considered.

The review statement and review panel report, as well as comments of the expert and any responses to recommendations made by the reviewer or by the panel, shall be included in the LCA report.

# Annex A
(informative)

# Examples of data collection sheets

## A.1 General

The data input sheets in this annex are examples that may be used as guidelines. The purpose is to illustrate the nature of the information that can be collected from a reporting location for a unit process.

Care and attention should be given to the selection of data used on the sheets. The data and the level of specification need to be consistent with the goal of the study. As such, the examples of data shown are strictly illustrative. Some studies require highly specific data and, for example, would consider specific compounds to draw up an inventory of the emissions to land, as opposed to the more generic data shown here.

These sample sheets may also be accompanied by specific instructions on collecting the data and completing the input sheets. Questions regarding the inputs may also be included to help further characterize the nature of the inputs as well as the manner in which the amounts reported were derived.

The sample sheets may be modified by adding columns for other factors, such as the quality of the data (uncertainty, measured/calculated/estimated).

## A.2 Example of data sheet for upstream transportation

In this example, the names and tonnages of the intermediate products for which transportation data are required are already recorded in the model of the system to be studied. It is assumed that the transportation mode between the two concerned unit processes is road transport. Equivalent data sheets should be used for rail or water transport.

| Name of intermediate product | Road transport | | | |
|---|---|---|---|---|
| | **Distance** km | **Truck capacity** tonnes | **Actual load** tonnes | **Empty return** (Yes/No) |
| | | | | |
| | | | | |
| | | | | |

The consumption of fuel and the related air emissions are calculated using a transportation model.

## A.3 Example of data sheet for internal transportation

In this example, the inventory is on internal transportation in a plant. The values are collected for a specific period of time and show the actual amounts of fuel used. Additional columns in the data sheet will be required if minimum and maximum values from different time periods are required.

Internal transportation raises allocation issues, as does total electricity consumption for a site, for instance.

Air emissions are calculated using a fuel consumption model.

| | Total amount of input transported | Total consumption of fuel |
|---|---|---|
| Diesel oil | | |
| Gasoline | | |
| LPG [a] | | |

[a] Liquified Petroleum Gas.

## A.4 Example of data sheet for unit process

| **Completed by:** | **Date of completion:** | | | |
|---|---|---|---|---|
| **Unit process identification:** | **Reporting location:** | | | |
| **Time period: Year** | **Starting month:** | **Ending month:** | | |
| **Description of unit process:** (attach additional sheet if required) | | | | |
| **Material inputs** | **Units** | **Quantity** | **Description of sampling procedures** | **Origin** |
| | | | | |
| | | | | |
| | | | | |
| **Water consumption** [a] | **Units** | **Quantity** | | |
| | | | | |
| | | | | |
| | | | | |
| **Energy inputs** [b] | **Units** | **Quantity** | **Description of sampling procedures** | **Origin** |
| | | | | |
| | | | | |
| | | | | |
| **Material outputs** (including products) | **Units** | **Quantity** | **Description of sampling procedures** | **Destination** |
| | | | | |
| | | | | |
| | | | | |

NOTE The data in this data collection sheet refer to all unallocated inputs and outputs during the specified time period.

[a] For example, surface water, drinking water.

[b] For example, heavy fuel oil, medium fuel oil, light fuel oil, kerosene, gasoline, natural gas, propane, coal, biomass, grid electricity.

## A.5 Example of life cycle inventory analysis data collection sheet

| Unit process identification: | | | Reporting location: |
|---|---|---|---|
| **Emissions to air** [a] | **Units** | **Quantity** | **Description of sampling procedures** (attach sheets if necessary) |
| | | | |
| | | | |
| | | | |
| **Emissions to water** [b] | **Units** | **Quantity** | **Description of sampling procedures** (attach sheets if necessary) |
| | | | |
| | | | |
| | | | |
| **Emissions to land** [c] | **Units** | **Quantity** | **Description of sampling procedures** (attach sheets if necessary) |
| | | | |
| | | | |
| | | | |
| **Other releases** [d] | **Units** | **Quantity** | **Description of sampling procedures** (attach sheets if necessary) |
| | | | |
| | | | |
| Describe any unique calculations, data collection, sampling, or variation from description of unit process functions (attach additional sheets if necessary). | | | |

[a] For example inorganics: $Cl_2$, CO, $CO_2$, dust/particulates, $F_2$, $H_2S$, $H_2SO_4$, HCl, HF, $N_2O$, $NH_3$, $NO_x$, $SO_x$; and organics: hydrocarbons, PCB, dioxins, phenols; metals: Hg, Pb, Cr, Fe, Zn, Ni.

[b] For example: BOD, COD, acids, $Cl_2$, $CN_2^-$, detergents/oils, dissolved organics, $F^-$, Fe ions, Hg ions, hydrocarbons, $Na^+$, $NH_4^+$, $NO_3^-$, organochlorides, other metals, other nitrogen compounds, phenols, phosphates, $SO_4^{2-}$, suspended solids.

[c] For example: mineral waste, mixed industrial waste, municipal solid waste, toxic wastes (please list compounds included in this data category).

[d] For example: noise, radiation, vibration, odour, waste heat.

# Annex B
(informative)

# Examples of life cycle interpretation

## B.1 General

This informative annex is intended to provide examples of the elements within the interpretation phase of an LCA or an LCI study, in order to help users understand how life cycle interpretation can be processed.

## B.2 Examples for the identification of significant issues

**B.2.1** The identification element (see 4.5.2) is performed in iteration with the evaluation element (see 4.5.3). It consists of the identification and structuring of information and the subsequent determination of any significant issues. The structuring of the available data and information is an iterative process undertaken in conjunction with the LCI and (if performed) LCIA phases, as well as with the goal and scope definition. This structuring of information may have been completed previously in either the LCI or LCIA, and is intended to provide an overview of the results of these earlier phases. This facilitates determination of important and environmentally relevant issues, as well as the drawing of conclusions and recommendations. On the basis of this structuring process, any subsequent determination is performed using analytical techniques.

**B.2.2** Depending on the goal and scope of the study, different structuring approaches can be useful. Amongst others, the following possible structuring approaches can be recommended for use:

a) differentiation of individual *life cycle stages*; e.g. production of materials, manufacturing of the studied product, use, recycling and waste treatment (see Table B.1);

b) differentiation between *groups of processes*; e.g. transportation, energy supply (see Table B.4);

c) differentiation between processes under different degrees of *management influence*; e.g. own processes where changes and improvements can be controlled, and processes that are determined by external responsibility, such as national energy policy, supplier specific boundary conditions (see Table B.5);

d) differentiation between the individual *unit processes*; this is the highest resolution possible.

The output of this structuring process may be presented as a two-dimensional matrix in which, for example, the above-mentioned differentiation criteria form the columns and the inventory inputs and outputs or individual category indicators results form the rows. It may also be possible to undertake this structuring procedure for individual impact categories for a more detailed examination.

The determination of significant issues is based on structured information.

**B.2.3** Data on the relevance of individual inventory data can be predetermined in the definition of the goal and scope, or may be available from the inventory analysis or from other sources, such as the environmental management system or the environmental policy of the company. Several possible methods exist. Depending on the goal and scope of the study and the level of detail required, the following methods can be recommended for use:

a) *contribution analysis*, in which the contribution of life cycle stages (see Tables B.2 and B.8) or groups of processes (see Table B.4) to the total result are examined by, for example, expressing the contribution as a percent of the total;

b) *dominance analysis*, in which, by means of statistical tools or other techniques such as quantitative or qualitative ranking (e.g. ABC analysis), remarkable or significant contributions are examined (see Table B.3);

c) *influence analysis*, in which the possibility of influencing the environmental issues is examined (see Table B.5);

d) *anomaly assessment*, in which, based on previous experience, unusual or surprising deviations from expected or normal results are observed. This allows a later check and guides improvement assessments (see Table B.6).

The result of this determination process may also be presented as a matrix, in which the above-mentioned differentiation criteria form the columns, and the inventory inputs and outputs or the category indicator results form the rows.

It is also possible to undertake this procedure for any specific inventory inputs and outputs selected from the definition of the goal and scope, or for any single impact category, as a possibility for a more detailed examination. Within this process of identification, no data are changed or recalculated. The only modification made is the conversion into percentages, etc.

In Tables B.1 to B.8, examples are given as to how a structuring process may be performed. The proposed structuring methods are suitable for both LCI results and possible LCIA results.

The structuring criteria are based either on the specific requirements of the definition of the goal and scope or on the findings of the LCI or LCIA.

**B.2.4** Table B.1 gives an example of structuring LCI inputs and outputs by groups of unit processes representing various life cycle stages; these are expressed as percentages in Table B.2.

**Table B.1 — Structuring of LCI inputs and outputs to life cycle stages**

| LCI input/output | Materials production | Manufacturing processes | Use phases | Others | Total |
|---|---|---|---|---|---|
| | kg | kg | kg | kg | kg |
| Hard coal | 1 200 | 25 | 500 | — | 1 725 |
| $CO_2$ | 4 500 | 100 | 2 000 | 150 | 6 750 |
| $NO_x$ | 40 | 10 | 20 | 20 | 90 |
| Phosphates | 2,5 | 25 | 0,5 | — | 28 |
| AOX [a] | 0,05 | 0,5 | 0,01 | 0,05 | 0,61 |
| Municipal waste | 15 | 150 | 2 | 5 | 172 |
| Tailings | 1 500 | — | — | 250 | 1 750 |

[a] AOX = absorbable organic halides.

Analysis of the contributions of the LCI results from Table B.1 identifies the processes or life cycle stages that contribute the most to different inputs and outputs. On this basis, later evaluation can reveal and state the meaning and stability of those findings that then are the bases for conclusions and recommendations. This evaluation may either be qualitative or quantitative.

**Table B.2 — Percentage contribution of LCI inputs and outputs to life cycle stage**

| LCI input/output | Materials production<br>% | Manufacturing processes<br>% | Use phases<br>% | Others<br>% | Total<br>% |
|---|---|---|---|---|---|
| Hard coal | 69,6 | 1,5 | 28,9 | — | 100 |
| $CO_2$ | 66,7 | 1,5 | 29,6 | 2,2 | 100 |
| $NO_x$ | 44,5 | 11,1 | 22,2 | 22,2 | 100 |
| Phosphates | 8,9 | 89,3 | 1,8 | — | 100 |
| AOX | 8,2 | 82,0 | 1,6 | 8,22 | 100 |
| Municipal waste | 8,7 | 87,2 | 1,2 | 2,9 | 100 |
| Tailings | 85,7 | — | — | 14,3 | 100 |

In addition, these results can be ranked and prioritized, either by specific ranking procedures or by predefined rules from the definition of the goal and scope. Table B.3 shows the results of such a ranking procedure, using the following ranking criteria:

A: most important, significant influence, i.e. contribution > 50 %

B: very important, relevant influence, i.e. 25 % < contribution < 50 %

C: fairly important, some influence, i.e. 10 % < contribution < 25 %

D: little importance, minor influence, i.e. 2,5 % < contribution < 10 %

E: not important, negligible influence, i.e. contribution < 2,5 %

**Table B.3 — Ranking of LCI inputs and outputs to life cycle stages**

| LCI input/output | Materials production | Manufacturing processes | Use phases | Others | Total<br>kg |
|---|---|---|---|---|---|
| Hard coal | A | E | B | — | 1 725 |
| $CO_2$ | A | E | B | D | 6 750 |
| $NO_x$ | B | C | C | C | 90 |
| Phosphates | D | A | E | — | 28 |
| AOX | D | A | E | D | 0,61 |
| Municipal waste | D | A | E | D | 172 |
| Tailings | A | — | — | C | 1 750 |

In Table B.4, the same LCI example is used to demonstrate another possible structuring option. This table shows the example of structuring LCI inputs and outputs into different process groups.

**Table B.4 — Structuring matrix sorted into process groups**

| LCI input/output | Energy supply<br>kg | Transport<br>kg | Others<br>kg | Total<br>kg |
|---|---|---|---|---|
| Hard coal | 1 500 | 75 | 150 | 1 725 |
| $CO_2$ | 5 500 | 1 000 | 250 | 6 750 |
| $NO_x$ | 65 | 20 | 5 | 90 |
| Phosphates | 5 | 10 | 13 | 28 |
| AOX | 0,01 | — | 0,6 | 0,61 |
| Municipal waste | 10 | 120 | 42 | 172 |
| Tailings | 1 000 | 250 | 500 | 1 750 |

The other techniques, such as determining the relative contribution and ranking to selected criteria, follow the same procedure as shown in Tables B.2 and B.3.

**B.2.5** Table B.5 shows an example of LCI inputs and outputs ranked as to the degree of influence and structured in groups of unit processes, representing process groups for different LCI inputs and outputs. The degree of influence is indicated here by

A: significant control, large improvement possible,

B: small control, some improvement possible, and

C: no control.

**Table B.5 — Ranking of the degree of influence on the LCI inputs and outputs sorted into process groups**

| LCI input/output | Power grid mix | Site energy supply | Transport | Others | Total<br>kg |
|---|---|---|---|---|---|
| Hard coal | C | A | B | B | 1 725 |
| $CO_2$ | C | A | B | A | 6 750 |
| $NO_x$ | C | A | B | C | 90 |
| Phosphates | C | B | C | A | 28 |
| AOX | C | B | — | A | 0,61 |
| Municipal waste | C | A | C | A | 172 |
| Tailings | C | C | C | C | 1 750 |

**B.2.6** Table B.6 shows an example of an LCI result, assessed with respect to anomalies and unexpected results and structured in groups of unit processes, representing process groups for different LCI inputs and outputs. The anomalies and unexpected results are marked by

- ●: unexpected result, i.e. contribution too high or too low,
- #: anomaly, i.e. certain emissions where no emissions are supposed to occur, and
- ○: no comment.

Anomalies can represent errors in calculations or data transfer. Therefore, they should be considered carefully. Checking of LCI results or LCIA results is recommended before making conclusions.

Unexpected results also should be re-examined and checked.

**Table B.6 — Marking of anomalies and unexpected results of the LCI inputs and outputs of process groups**

| LCI input/output | Power grid mix | Site energy supply | Transport | Others | Total<br>kg |
|---|---|---|---|---|---|
| Hard coal | ○ | ○ | ● | ○ | 1 725 |
| $CO_2$ | ○ | ○ | ● | ○ | 6 750 |
| $NO_x$ | ○ | ○ | ○ | ○ | 90 |
| Phosphates | ○ | ○ | # | ○ | 28 |
| AOX | ○ | ○ | ○ | ○ | 0,61 |
| Municipal waste | ○ | ● | ○ | ● | 172 |
| Tailings | ○ | ○ | ○ | ○ | 1 750 |

**B.2.7** The example in Table B.7 demonstrates a possible structuring process on the basis of LCIA results. It shows a category indicator result, global warming potential ($GWP_{100}$), structured in groups of unit processes.

The analysis of the contributions of specific substances to the category indicator result from Table B.7 identifies the processes or life cycle stages with the highest contributions.

**Table B.7 — Structuring of a category indicator result ($GWP_{100}$) against life cycle stages**

| **Global warming potential** ($GWP_{100}$) from | **Materials production**<br>kg $CO_2$-equiv. | **Manufacturing processes**<br>kg $CO_2$-equiv. | **Use phases**<br>kg $CO_2$-equiv. | **Others**<br>kg $CO_2$-equiv. | **Total GWP**<br>kg $CO_2$-equiv. |
|---|---|---|---|---|---|
| $CO_2$ | 500 | 250 | 1 800 | 200 | 2 750 |
| CO | 25 | 100 | 150 | 25 | 300 |
| $CH_4$ | 750 | 50 | 100 | 150 | 1 050 |
| $N_2O$ | 1 500 | 100 | 150 | 50 | 1 800 |
| $CF_4$ | 1 900 | 250 | — | — | 2 150 |
| Others | 200 | 150 | 120 | 80 | 550 |
| Total | 4 875 | 900 | 2 320 | 505 | 8 600 |

**Table B.8 — Structuring of a category indicator result ($GWP_{100}$) against life cycle stages, expressed as a percentage**

| $GWP_{100}$ from | Materials production | Manufacturing processes | Use phases | Others | Total GWP |
|---|---|---|---|---|---|
| | % | % | % | % | % |
| $CO_2$ | 5,8 | 2 | 20,9 | 2,3 | 31,9 |
| CO | 0,3 | 1,1 | 1,7 | 0,3 | 3,4 |
| $CH_4$ | 8,7 | 0,6 | 1,2 | 1,8 | 12,3 |
| $N_2O$ | 17,4 | 1,2 | 1,8 | 0,6 | 21 |
| $CF_4$ | 22,1 | 2,9 | — | — | 25,0 |
| Others | 2,4 | 1,7 | 1,4 | 0,9 | 6,4 |
| Total | 56,7 | 10,4 | 27 | 5,9 | 100 |

In addition, methodological issues can be considered by, for example, running different options as scenarios. The influence of, for example, allocations rules and cut-off choices can easily be examined by either showing the results in parallel with those for other assumptions, or determining which emissions really occur.

In the same way, the influence of characterization factors for the LCIA (e.g. $GWP_{100}$ vs. $GWP_{500}$) or data set choices for normalization and weighting, if applied, can be illustrated by demonstrating the differences in effect of the various assumptions on the result.

**B.2.8** In summary, the identification elements aim to provide a structured approach for the later evaluation of the study's data, information and findings. Subjects recommended for consideration are, amongst others:

— individual *inventory* data: emissions, energy and material resources, waste, etc.,

— individual *processes*, unit processes or groups thereof,

— individual life cycle stages, and

— individual category indicators.

## B.3 Examples of the evaluation element

### B.3.1 General

The evaluation element and the identification element are procedures that are carried out simultaneously. By means of an iterative procedure, several issues and tasks are discussed in more detail, in order to determine the reliability and stability of the results from the identification element.

### B.3.2 Completeness check

The completeness check attempts to ensure that the full required information and data from all phases have been used and are available for interpretation. In addition, data gaps are identified and the need to complete the data acquisition is evaluated. The identification element is a valuable basis for these considerations. Table B.9 shows an example of the completeness check for a study involving a comparison between two options A and B. Nevertheless, completeness can only be an empirical value, ensuring that no major known aspects have been forgotten.

**Table B.9 — Summary of a completeness check**

| Unit process | Option A | Complete? | Action required | Option B | Complete? | Action required |
|---|---|---|---|---|---|---|
| Material production | X | Yes | | X | Yes | |
| Energy supply | X | Yes | | X | No | Recalculate |
| Transport | X | ? | Check inventory | X | Yes | |
| Processing | X | No | Check inventory | X | Yes | |
| Packaging | X | Yes | | — | No | Compare A |
| Use | X | ? | Compare B | X | Yes | |
| End of life | X | ? | Compare B | X | ? | Compare A |

X: data entry available.
—: no data entry present.

Results from Table B.9 reveal that several tasks need to be done. In the case of recalculation or rechecking of the original inventory, a feedback loop is required.

For example, in the case concerning a product for which the waste management is not known, a comparison between two possible options may be performed. This comparison may lead to an in-depth study of the waste management phase, or to the conclusion that the difference between the two alternatives is not significant or not relevant for the given goal and scope.

The basis for this survey is to use a checklist which includes the required inventory parameters (such as emissions, energy and material resources, waste), required life cycle stages and processes, as well as the required category indicators, etc.

### B.3.3 Sensitivity check

Sensitivity analysis (sensitivity check) tries to determine the influence of variations in assumptions, methods and data on the results. Mainly, the sensitivity of the most significant issues identified is checked. The procedure of sensitivity analysis is a comparison of the results obtained using certain given assumptions, methods or data with the results obtained using altered assumptions, methods or data.

In sensitivity analysis, typically the influence on the results of varying the assumptions and data by some range (e.g. $\pm$ 25 %) is checked. Both results are then compared. Sensitivity can be expressed as the percentage of change or as the absolute deviation of the results. On this basis, significant changes in the results (e.g. larger than 10 %) can be identified.

In addition, carrying out a sensitivity analysis can either be required in the definition of the goal and scope or can be determined during the study based on experience or on assumptions. For the following examples of assumptions, methods or data, sensitivity analysis may be considered valuable:

— rules for allocation;

— cut-off criteria;

— boundary setting and system definition;

— judgements and assumptions concerning data;

— selection of impact category;

— assignment of inventory results (classification);

— calculation of category indicator results (characterization);

— normalized data;

— weighted data;

— weighting method;

— data quality.

Tables B.10, B.11 and B.12 demonstrate how the sensitivity check can be performed on basis of the existing sensitivity analysis results from LCI and LCIA.

**Table B.10 — Sensitivity check on allocation rule**

| Hard coal demand | Option A | Option B | Difference |
|---|---|---|---|
| Allocation by mass, MJ | 1 200 | 800 | 400 |
| Allocation by economic value, MJ | 900 | 900 | 0 |
| Deviation, MJ | – 300 | + 100 | 400 |
| Deviation, % | – 25 | + 12,5 | Significant |
| Sensitivity, % | 25 | 12,5 | |

The conclusions that can be drawn from Table B.10 are that allocation has a significant influence, and that under the circumstances no real difference exists between Options A and B.

**Table B.11 — Sensitivity check on data uncertainty**

| Hard coal demand | Material production | Manufacturing process | Use phases | Total |
|---|---|---|---|---|
| Base case, MJ | 200 | 250 | 350 | 800 |
| Altered assumption, MJ | 200 | 150 | 350 | 700 |
| Deviation, MJ | 0 | – 100 | 0 | – 100 |
| Deviation, % | 0 | – 40 | | – 12,5 |
| Sensitivity, % | 0 | 40 | 0 | 12,5 |

The conclusions that can be drawn from Table B.11 are that significant changes occur, and that variations alter the result. If the uncertainty here has significant influence, a renewed data collection is indicated.

**Table B.12 — Sensitivity check on characterization data**

| GWP data input/effect | Option A | Option B | Difference |
|---|---|---|---|
| Score for GWP = 100 $CO_2$-equiv. | 2 800 | 3 200 | 400 |
| Score for GWP = 500 $CO_2$-equiv. | 3 600 | 3 400 | –200 |
| Deviation | +800 | +200 | 600 |
| Deviation, % | +28,6 | +6,25 | Significant |
| Sensitivity, % | 28,6 | 6,25 | |

The conclusions that can be drawn from Table B.12 are that significant changes occur, that altered assumptions can change or even invert conclusions, and that the difference between Options A and B is smaller than originally expected.

### B.3.4 Consistency check

The consistency check attempts to determine whether the assumptions, methods, models and data are consistent either along a product's life cycle or between several options. Inconsistencies are, for example:

a) differences in *data sources*; e.g. Option A is based on literature, whereas Option B is based on primary data;

b) differences in *data accuracy*; e.g. for Option A a very detailed process tree and process description is available, whereas Option B is described as a cumulated black-box system;

c) differences in *technology coverage*; e.g. data for Option A are based on experimental process (e.g. new catalyst with higher process efficiency on a pilot plant level), whereas data for Option B are based on existing large-scale technology;

d) differences with *time-related coverage*; e.g. data for Option A describe a recently developed technology, whereas Option B is described by a technology mix, including both recently built and old plants;

e) differences in *data age*; e.g. data for Option A are 5-year-old primary data, whereas data for Option B are recently collected;

f) differences in *geographical coverage*; e.g. data for Option A describe a representative European technology mix, whereas Option B describes one European Union member country with a high-level environmental protection policy, or one single plant.

Some of these inconsistencies may be accommodated in line with the definition of the goal and scope. In all other cases, significant differences exist and their validity and influence need to be considered before drawing conclusions and making recommendations.

Table B.13 provides an example of the results of a consistency check for an LCI study.

**Table B.13 — Result of a consistency check**

| Check | Option A | | Option B | | Compare A and B? | Action |
|---|---|---|---|---|---|---|
| Data source | Literature | OK | Primary | OK | Consistent | No action |
| Data accuracy | Good | OK | Weak | Goal and scope not met | Not consistent | Revisit B |
| Data age | 2 years | OK | 3 years | OK | Consistent | No action |
| Technology coverage | State-of-the-art | OK | Pilot plant | OK | Not consistent | Study target = no action |
| Time-related coverage | Recent | OK | Actual | OK | Consistent | No action |
| Geographical coverage | Europe | OK | USA | OK | Consistent | No action |

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# ENVIRONMENTAL LIFE CYCLE ASSESSMENT OF PRODUCTS

## Guide – October 1992

R. Heijungs (final editor)

J.B. Guinée – G. Huppes – R.M. Lankreijer
H.A. Udo de Haes – A. Wegener Sleeswijk

A.M.M. Ansems – P.G. Eggels

R. van Duin – H.P. de Goede

B & G

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- NOVEM (Netherlands Agency for Energy and the Environment)
  St. Jacobsstraat 61, P.O. Box 8242, 3503 RE Utrecht, The Netherlands
  Tel +31 30 363 444
  Coordinator: J. van de Velde.
- RIVM (National Institute of Public Health and Environmental Protection)
  Antonie van Leeuwenhoeklaan 9, P.O. Box 1, 3720 BA Bilthoven, The Netherlands
  Coordinator: G.L. Duvoort.

The NOH cannot guarantee either the correctness or completeness of information, designs, constructions, products or production methods referred to or described in this report nor their suitability for any particular purpose.

The study was carried out jointly by three research groups:

- CML (Centre of Environmental Science)
  Garenmarkt 1, P.O. Box 9518, 2300 RA Leiden, The Netherlands
  Tel. +31 71 277 486, fax +31 71 277 496
- TNO (Netherlands Organisation for Applied Scientific Research)
  Laan van Westenenk 501, P.O. Box 342, 7300 AH Apeldoorn, The Netherlands
  Tel. +31 55 493 493, fax +31 55 419 837
- B&G (Fuels and Raw Materials Bureau)
  G.W. Burgerplein 5, 3021 AS Rotterdam, The Netherlands
  Tel. +31 10 476 6222, fax +31 10 476 6400

The report consists of two related parts, the Guide and the Backgrounds document, which are only available as a set. Further copies of this report can be ordered from the library of the Centre of Environmental Science (tel. +31 71 277 485). The price is NLG 90.00 per set.



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# PREFACE TO THE ENGLISH EDITION

This is a translation of the original report in Dutch, dated October 1992. Only obvious printing errors have been corrected; new developments have not been included. This preface gives an overview of some developments in the state-of-the-art of LCA since the conception of the original report.

The *Society of Environmental Chemistry and Toxicology* (SETAC) is the current leading international organization in the coordination of the methodological development of life cycle assessment. In April 1993, an expert workshop was held in Sesimbra, Portugal, with the aim of establishing an internationally agreed *Code of Practice*. This included the definition of a technical framework for LCA consisting of components (as in Figure 0.1) and a uniform terminology.

The framework and terminology developed in this report differ slightly from that provisionally developed by SETAC. To avoid confusion we have provided an overview of the main differences here. This is followed by a comparison of the framework and terminology used in this report and that in the *Code of Practice*.

The framework in this report consists of five components. The draft *Code of Practice* consists of four components. The main difference concerns the components *classification* and *evaluation* in the present report. These are part of the *impact assessment* in the SETAC framework. Classification as used in this report is subdivided into *classification* and *characterization* in the *Code of Practice*, where the former denotes the labeling of inputs and outputs according to the effect categories they contribute to, and the latter amounts to the weighting and aggregation into scores for these effect categories. The similarities and the differences between the two approaches are summarized in the table below.

| Code of Practice Sesimbra – April 1993 | | Guide + Backgrounds LCA – October 1992 |
|---|---|---|
| goal definition and scoping | | goal definition |
| inventory analysis | | inventory analysis |
| impact assessment | classification | classification |
| | characterization | |
| | valuation | evaluation |
| improvement assessment | | improvement analysis |

In this study the term *impact* has been avoided. *Interventions* indicate human interference in the environment, e.g. resource extraction and emissions (environmental releases). *Effects* indicate the resulting environmental problems, e.g. resource depletion and acidification. Further differences in terminology are minor.

# FOREWORD

The Netherlands National Environmental Policy Plan Plus (NEPP-plus) proposes to accelerate targeted product policy measures. According to the plan this acceleration "is dictated by the need to manage the waste chain as a whole. This covers not only the effects at the waste stage, but also emissions and diffusion of substances." It continues as follows: "Viewed against the background of integrated chain management, it goes without saying that product policy extends over the whole life cycle of a product. Good product policy is not only important to producers. Naturally it also benefits consumers."

The acceleration of the product policy measures has now been implemented in several places in the Netherlands. The concept that good product policy is based on an approach in which the entire life cycle of a product is assessed in relation to all aspects of the environment has been highly significant in gaining broad acceptance in society. The reason for this is that everyone considers it undesirable for environmental effects to be shifted to other stages in the life cycle or other aspects of the environment.

Life cycle assessment is not just an instrument to support the product policy; it is also a philosophy. Consumers in the shops will become aware that there is such a thing as a "life cycle"; a highly polluting process may have been used to manufacture an apparently "environmentally-friendly" (e.g. biodegradable) product. A life cycle assessment provides information about such hidden aspects. As a result the chain concept may become widely accepted.

The method described in this manual for the environmental assessment of product life cycles can be used to implement a product policy as referred to in the NEPP-plus. The method can also be used as a tool for ecological product development and improvement in industry, as a regulatory instrument for government and as an instrument to inform consumers. Hence both the Netherlands Ministry of Environment (VROM) and the Ministry of Economic Affairs have contributed to the funding of this study which was carried out as part of the National Reuse of Waste Research Programme (NOH). It is expected that both the public and private sectors, environmental and consumer organizations will be able to use the results of this method in the next few years.

The ultimate aim of the environmental policy is to bring about sustainable development. The NEPP-plus contains the following statement: "The objective of not leaving environmental problems to be solved by future generations can only be achieved if our present patterns of production and consumption are altered. This requires a departure from the existing trend in our behaviour." This means that the outcome of an environmental life cycle assessment can never legitimize our consumption. There are no environmentally-friendly products, some products however, are more environmentally-friendly than others.

# CONTENTS

# SUMMARY

This chapter provides a summary which can be used in the implementation of environmental life cycle assessments for product studies. It includes a short *document guide* which explains the structure and relationship of the various parts of this report and a *guidelines* section which lists all the guidelines.

## Document guide

The report comprises two integral volumes. Both volumes are entitled *Environmental Product Life Cycle Assessment*. Their subtitles, however, are different: one volume is the *Guide* while the other volume is the *Backgrounds* document. The target groups for these documents and the relationships between them are described below.

*Guide*
The guide describes a method which can be used to carry out an environmental assessment of the life cycle of one or more products. Hence, it is largely aimed at those *who actually undertake environmental product assessments*. These are likely to be consulting engineers, scientific institutes and departments of large companies.

*Backgrounds*
This document discusses the reasoning behind the method described in the guide. The reasons for certain choices are explained and compared to methods used elsewhere. This volume is largely aimed at *scientists in research institutes*.

The guide (i.e. this volume) which is intended for the implementation of life cycle assessments, is divided into three sections:

- the summary which includes all guidelines;
- the report itself;
- the appendices.

The guidelines section gives a concise description of the method, concentrating purely on the procedures. It is clear from the structure that these are guidelines to assist those carrying out an environmental life cycle assessment. Initially, or if in any doubt, a researcher will need more than these guidelines. The number of each step in the summary corresponds with the section numbers and explanations in the document. The report itself explains terms, identifies parallels between actions described in the guide and gives examples. It also gives references to the backgrounds document. The appendices contain information essential to carry out a life cycle assessment but which does not belong in a summary guide.

## Guidelines

This section combines the guidelines for all stages. It cannot be used without practical experience of life cycle assessments. For further information about the guidelines you are referred to the corresponding section of the guide, the backgrounds document and the list of terms on page 91.

### Component 1 - goal definition

#### STEP 1.1 - DETERMINING THE APPLICATION

- The type of application is determined; examples include:
  - information about existing products;
  - innovation of existing products or prototypes;
  - legislation affecting product policies;
  - assessing policy strategies through the use of scenarios;
  - ...
- The application depends on the choice of target group or groups:
  - consumers;
  - producers;
  - government bodies;
  - ...
- List those concerned:
  - those undertaking the study;
  - the client and the funding body;
  - the steering committee;
  - those providing (and possibly verifying) the information required;
  - ...
- Such a full explanation will not be required if the LCA is only to be used internally e.g. to optimise a design.

#### STEP 1.2 - DETERMINING THE DEPTH OF THE STUDY

- A complete LCA should first be considered: covering all processes and environmental effects and at least the following components: goal definition, inventory analysis, classification and evaluation. At this stage it would not be sensible to omit any elements, this can only be done once an inventory analysis has provided sufficient information to justify this.
- Identical elements may be excluded when products are being compared. However, this can only be done after defining the process tree in step 2.1.
- When improving a product it may well be feasible to make recommendations for a redesign at the inventory analysis level. However, the new design will have to undergo a complete LCA to assess any shift to other environmental effects.
- In all cases reliability and validity will have to be assessed (step 4.2).

#### STEP 1.3 - DEFINING THE SUBJECT OF THE STUDY

- Select a functional unit which is clearly defined in detail and covers an activity to the greatest possible extent.
- Provide an accurate specification of the products being assessed. The extent to which the information is representative (in time and space) and the functional properties are particularly important.
- Indicate any product alternatives which meet the specifications fully or almost fully that were not included in the assessment, and the reasons for this.

### Component 2 - inventory analysis

#### STEP 2.1 - DRAWING UP THE PROCESS TREE

- A process tree is drawn up for each alternative under consideration, i.e. the processes which form part of the product life cycles are determined. The process tree is best laid out as a diagram, often

with a summary process tree and separate trees for individual parts of the summary process tree.

- The extraction of raw materials from the environment is considered as the start of the life cycle.
- Although waste processing is considered as the end of the life cycle it is treated as an economic process which affects the environment through the consumption of raw materials, emissions and in other ways. Similarly, waste treatment steps carried out before a substance is introduced into the environment are included as part of the product system.
- The process tree is made up of economic processes.
- Economic processes have at least one economic output – goods (materials, components, products, etc.) or services (transport, energy, waste processing, etc.) – which forms the goal of the process.
- Each economic output of a process is the economic input of another process, with the exception of the service provided by the overall product system which is related to the functional unit.
- There is no need to extend the process tree by following the processes related to associated products and their production or the useful application of residual and waste materials.
- If the life cycle includes open loop recycling extraction and production are fully allocated to the primary application. Collection and upgrading are fully allocated to the secondary application while waste processing is only allocated to the last application in the cascade.
- This allocation system for open loop recycling will result in some of the consequences being shifted elsewhere. In some situations this shift may well be undesirable. In this event the reuse will not be interpreted as recycling in the LCA. The initial proposal for those situations in which there is no open loop recycling but where the rest of the life cycle has to be followed is as follows:
  - reuse of incinerator flue gas scrubbing residue;
  - reuse of incinerator fly ash;
  - application of combustible waste obtained from different, highly varied combustible waste fractions as RDF;
  - reuse of sewage sludge.
- Reuse which is considered to be open loop recycling must be identified.
- All branches of the process tree must be extended to include processes whose inputs are auxiliary environmental sources or whose outputs are emissions, unless they end in processes which are not considered in detail (i.e. indicated as *p.m.* processes).
- When drawing up a process tree the processes which have been excluded should be clearly indicated, where possible with a semi-quantitative estimate of the significance of these processes.

## STEP 2.2 – ENTERING THE PROCESS DATA

- The data for all processes is collected and presented as shown in Table A.1. This includes both the input from and the output into other economic processes: the use and production of goods, materials, energy, services and waste to be processed. Other data includes flows to and from the environment in terms of raw materials, space use, and emissions of substances, noise, heat, etc.
- The nature and quality of the process data will be specified for each process. Data whose quality or representativeness does not match the general standard may have to be identified separately.
- Some processes have non-quantifiable aspects. These should also be included; the format makes special provision for them.
- Preferably, the long-term marginal process data should be collected. In many cases this data will be similar to the average process data during normal operations.
- Whenever possible numerical process data should be specified in SI units.
- Space use is a process parameter which requires a special conversion. It is expressed as a relationship between the area of the plant, its annual production and the consumption of a product or material. For a material whose quantity is expressed in kg this could be calculated as follows:

$$space\ use\,(m^2 \cdot yr) = material\ use\,(kg) \times \frac{area\,(m^2)}{annual\ production\,(kg \cdot yr^{-1})} \qquad (1)$$

  Thus space use is expressed in $m^2 \cdot s$ or $m^2 \cdot yr$.
- Noise is treated similarly:

$$noise\,(Pa^2 \cdot yr) = material\ use\,(kg) \times \frac{4 \cdot 10^{-10}\,(Pa^2) \times 10^{sound\ pressure\ level\,(dB)/10}}{annual\ production\,(kg \cdot yr^{-1})} \quad (2)$$

The unit is $Pa^2 \cdot s$ or $Pa^2 \cdot yr$.

..... STEP 2.3 - APPLICATION OF THE ALLOCATION RULES .....

- Allocations are made to outputs with a positive economic value (or, where there is no external market, which have a useful application). The other flows (flows to and from the environment, economic inputs and economic outputs of zero or negative value) are the items which are allocated.
- Whenever possible the causal links should be determined first in an analysis. In this way part of the allocation problem may be neatly solved.
- The remaining allocation problems are solved by overall apportioned allocation.
- If the outputs to which the allocations are made have different units the allocation has to be made on the basis of economic value.
- For co-production allocation is generally made to the relevant physical unit. Normally this will be the unit in which the outputs, to which the allocation is made, are expressed. Generally, this will be mass, although area is not unusual.
- If the economic values of the outputs differ greatly for each physical unit, the allocation is made on the basis of economic value.
- If the allocation key could be open to dispute, it is advisable to use two or more variations of the allocation and consider the difference between the results as a measure of the reliability (see step 4.2).

..... STEP 2.4 - CREATING THE INVENTORY TABLE .....

- The quantitative occurrence of all processes in the process tree can be determined by drawing up mass and energy balances for each economic input: the sum of all occurrences in each process must be zero for each economic unit, with the exception of the process producing the functional unit.
- Thereafter the inventory table for the functional unit can be determined by calculating, for each environmental intervention, the sum of all the occurrences of these interventions.
- Additionally, all unquantified interventions for each process are combined and included in the inventory table of the functional unit.
- When a number of products are being compared and a conclusion can clearly be drawn by comparing the inventory tables, the classification and evaluation steps will not have to be carried out. However, the reliability and sensitivity of the result (step 4.2) will need to be determined.

## Component 3 - classification

..... STEP 3.1 - SELECTION OF THE PROBLEM TYPES .....

- The provisional classification system is shown in Table 3.1. It indicates the environmental effects under consideration and which are to be used in step 3.2.
- If necessary, a different set may be chosen provided the reasons for this are given.

..... STEP 3.2 - DEFINITION OF THE CLASSIFICATION FACTORS .....

- The depletion of abiotic raw materials is assessed by comparing the nett quantity used of each raw material with the reserves (Table B.1 on page 65) of that raw material. This produces a dimensionless expression:

$$abiotic\ depletion = \sum_i \frac{material\ use_i\,(kg)}{reserves_i\,(kg)} \quad (3)$$

- The depletion of biotic raw materials is assessed by comparing the nett quantity used of each raw material with its reserves and its reserves/production-ratio. These two together provide a *biotic depletion factor* (BDF; Table B.2 on page 65). The result is an expression in $yr^{-1}$:

$$biotic\ depletion\,(yr^{-1}) = \sum_i BDF_i\,(kg^{-1} \cdot yr^{-1}) \times material\ use_i\,(kg) \quad (4)$$

- For some substances which contribute to the enhancement of the greenhouse effect parameters have

been developed in the form of a *global warming potential* (GWP; see Table B.3 on page 66). These parameters can be used to express the potential direct* contribution to the greenhouse effect in a single effect score. The GWP is a relative parameter which uses $CO_2$ as a reference†: the extent to which a mass unit of a given substance can absorb infrared radiation compared with a mass unit of $CO_2$. In this way atmospheric emissions (in kg) can be converted to $CO_2$ emissions (in kg) with an equivalent greenhouse effect:

$$\textit{greenhouse effect}(\text{kg}) = \sum_i \textit{GWP}_i \times \textit{emission}_i \textit{ to the air}(\text{kg}) \quad (5)$$

- For some substances which contribute to the depletion of the ozone layer parameters have been developed in the form of an *ozone depletion potential* (ODP; see Table B.4 on page 67). These parameters can be used to express the potential contribution which these substances make to the depletion of the ozone layer in a single effect score. The ODP is a relative parameter which uses CFC-11 as a reference: the *steady state* ozone depletion per mass unit of gas emitted to the atmosphere per year is calculated relative to that of a mass unit of CFC-11. In this way atmospheric emissions (in kg) can be converted to CFC-11 emissions (in kg) resulting in an equivalent depletion of the ozone layer:

$$\textit{ozone depletion}(\text{kg}) = \sum_i \textit{ODP}_i \times \textit{emission}_i \textit{ to the air}(\text{kg}) \quad (6)$$

- Human toxicity is assessed by relating the emissions‡ to the *tolerable daily intake* (TDI), the *acceptable daily intake* (ADI), the *tolerable concentration in air* (TCL), the *air quality guidelines*, the *maximum tolerable risk level* (MTR) or the *C-value for soil based on human toxicology considerations*. This is data from toxicological experiments about the maximum daily intake or concentration which is considered acceptable. A conversion is made so that emissions to water, the atmosphere and soil can be combined in an acceptable way. This results in the definition of *human toxicological classification factors* which depend on the substance and the environmental medium concerned (see Table B.5 on page 68): for the atmosphere (HCA), for water (HCW) and for soil (HCS). The unit of the effect score is kg: the part of the body weight in kg exposed to the toxicologically acceptable limit. This is calculated as follows:

$$\begin{aligned}\textit{human toxicity}(\text{kg}) = \sum_i & \textit{HCA}_i(\text{kg}\cdot\text{kg}^{-1}) \times \textit{emission}_i \textit{ to the air}(\text{kg}) + \\ & \textit{HCW}_i(\text{kg}\cdot\text{kg}^{-1}) \times \textit{emission}_i \textit{ to water}(\text{kg}) + \\ & \textit{HCS}_i(\text{kg}\cdot\text{kg}^{-1}) \times \textit{emission}_i \textit{ to the soil}(\text{kg})\end{aligned} \quad (7)$$

- The assessment of substances with an ecotoxic effect on species in the ecosystem is based on *maximum tolerable concentrations* (MTCs) determined according to the EPA-method. This results in the definition of two groups of *ecotoxicological classification factors*: one for aquatic ecosystems (ECA) and one for terrestrial ecosystems (ECT); see Table B.6 on page 77. The unit of aquatic ecotoxicity is $m^3$ polluted water:

$$\textit{aquatic ecotoxicity}(\text{m3}) = \sum_i \textit{ECA}_i(\text{m}^3\cdot\text{mg}^{-1}) \times \textit{emission}_i \textit{ to water}(\text{mg}) \quad (8)$$

and for terrestrial ecosystems, it is kg polluted soil:

$$\textit{terrestrial ecotoxicity}(\text{kg}) = \sum_i \textit{ECT}_i(\text{kg}\cdot\text{mg}^{-1}) \times \textit{emission}_i \textit{ to the soil}(\text{mg}) \quad (9)$$

- *Photochemical ozone creation potential* parameters (POCP; see Table B.7 on page 83) have been

* The indirect contribution is included as a qualitative aspect, see §3.3.1.

† In addition to $CO_2$ another reference gas which is commonly used is CFC-12. As CFC-11 is also used occasionally the term GWP should be used with some caution.

‡ In the context of this study it was proposed that the properties of toxic substances in the environment be included in the assessment. This has already been done with some other effect scores; for GWP for example, the degradation of the substance in the environment has also been considered. For human toxicity this results in the definition of a *human toxicity potential* (HTP) and a reference substance. However, HTP has not yet been implemented.

developed* for some substances† which contribute to the formation of photochemical oxidants. These values can be used to express the potential contribution made by these substances to this problem as a single effect score. The POCP is a relative measure which uses ethylene ($C_2H_4$) as a reference: the extent to which a mass unit of a substance forms oxidants compared with a mass unit of ethylene. In this way atmospheric emissions (in kg) can be converted to ethylene emissions (in kg) with equivalent oxidant formation:

$$oxidant\ formation(\text{kg}) = \sum_i POCP_i \times emission_i\ to\ the\ air(\text{kg}) \qquad (10)$$

- The contribution to acidification made by various forms of intervention in the environment can be determined by weighting with *acidification potentials* (AP; see Table B.8 on page 86) which are a measure of the propensity to release $H^+$ compared with sulfur dioxide ($SO_2$). Atmospheric emissions (in kg) are converted, using the AP, to sulfur dioxide emissions (in kg) resulting in equivalent acidification:

$$acidification(\text{kg}) = \sum_i AP_i \times emission_i\ to\ the\ air(\text{kg}) \qquad (11)$$

- The contribution to nutrification made by various forms of intervention in the environment can be determined by weighting with *nutrification potentials* (NP; see Table B.9 on page 87) which are a measure of the capacity to form biomass, compared with phosphate ($PO_4^{3-}$). Emissions to the atmosphere, water or soil (in kg) are converted, using the NP, to an equivalent phosphate emission (in kg) in terms of nutrification:

$$nutrification(\text{kg}) = \sum_i NP_i \times emission_i(\text{kg}) \qquad (12)$$

- Until the consequences of waste heat have been sufficiently determined, the release of heat, as a form of environmental intervention, can only be taken directly from the inventory analysis and aggregated. Only waste heat emissions into water are included:

$$aquatic\ heat(\text{MJ}) = energy\text{-}emissions_{water}(\text{MJ}) \qquad (13)$$

- The odour threshold values in air (OTV; see Table B.10 on page 87) which have been determined for the most important substances can be used to assess odours. Atmospheric emissions are converted to the volume of air polluted up to the odour threshold:

$$malodourous\ air(\text{m}^3) = \sum_i \frac{emission_i\ to\ the\ air(\text{kg})}{OTV_i(\text{kg}\cdot\text{m}^{-3})} \qquad (14)$$

- To assess noise, sound production data from the inventory analysis are aggregated:

$$noise(\text{Pa}^2\cdot\text{s}) = sound(\text{Pa}^2\cdot\text{s}) \qquad (15)$$

- As the exhaustive effects of space use are inextricably bound up with displacement effects, they are combined in a single effect score. A maximum of ten forms of intervention of this nature are collected during the inventory. At present categories I, II and III are considered "natural" and categories IV and V as "unnatural". Thus the ten forms of intervention are combined in a single effect score with the unit $m^2 \cdot s$:

* As the use of the POCP for this purpose is disputed, a further indication could be obtained by adding the quantities of VOC and $NO_x$ without further weighting; see step 4.2.

† No POCP has yet been defined for nitrogen oxides hence the quantity of $NO_x$ emitted is included separately as a "flag", see §3.3.1.

$$\begin{aligned} damage\,(\mathrm{m^2 \cdot s}) = {} & space\ use_{\mathrm{I}\rightarrow\mathrm{IV}}(\mathrm{m^2 \cdot s}) + \\ & space\ use_{\mathrm{I}\rightarrow\mathrm{V}}(\mathrm{m^2 \cdot s}) + \\ & space\ use_{\mathrm{II}\rightarrow\mathrm{IV}}(\mathrm{m^2 \cdot s}) + \\ & space\ use_{\mathrm{II}\rightarrow\mathrm{V}}(\mathrm{m^2 \cdot s}) + \\ & space\ use_{\mathrm{III}\rightarrow\mathrm{IV}}(\mathrm{m^2 \cdot s}) + \\ & space\ use_{\mathrm{III}\rightarrow\mathrm{V}}(\mathrm{m^2 \cdot s}) \end{aligned} \qquad (16)$$

- In the inventory analysis processes hazards were determined as the number of fatalities directly attributable to an accident. This parameter is included in the classification without further weighting:

$$victims = number\ of\ victims \qquad (17)$$

### ..... STEP 3.3 – CREATING THE ENVIRONMENTAL PROFILE .....

- The standard classification model (possibly amended or extended) is applied to the quantitative part of the inventory table.
- Forms of intervention which may contribute to more than one effect (CFC emissions for example contribute to the greenhouse effect as well as to ozone depletion) are included more than once.
- The qualitative aspects of the inventory table appear as a qualitative part of the environmental profile, wherever possible in the form of effects.
- It is preferable not to use graphs at this stage as they may give the wrong impression or depend solely on the choice of scale used in the graphs.
- Caution is advised when discussing the environmental profile, otherwise the classification could include an implicit evaluation.
- When products are being compared it may happen that all effect scores and all qualitative aspects point in the same direction. In such an event there will be no need to take steps 3.4 and 4.1. However, the reliability and validity will have to be considered; see step 4.2.

### ..... STEP 3.4 – NORMALIZATION OF THE EFFECT SCORES .....

- To make the effect scores of the environmental profile more meaningful they can be normalized by relating them to the magnitude of the problem in a given period. For this purpose the same classification model should be used as that used to draw up the environmental profile; the difference being that the magnitude of the environmental intervention in one year, for example, is used as the input data rather than the magnitude of the environmental intervention of a single functional unit. This results in a normalized environmental profile, comprising a number of normalized effect scores all with the unit yr. For an effect score expressed in kg this results in:

$$normalized\ effect\ score\,(\mathrm{yr}) = \frac{effect\ score\,(\mathrm{kg})}{annual\ volume\,(\mathrm{kg \cdot yr^{-1}})} \qquad (18)$$

- Although these normalized effect scores have the same unit they should never be added to each other in the classification.
- While information about the global magnitude of the effect scores is not available, the magnitude in e.g. the Netherlands alone will have to be used.
- As it will continue for some time to be difficult to obtain all the required information for the normalization this step will often have to be dispensed with.

## Component 4 – evaluation

### ..... STEP 4.1 – EVALUATION OF THE ENVIRONMENTAL PROFILE .....

- There are two methods for the evaluation of environmental profiles: quantitative and qualitative multi-criteria analyses. Quantitative multi-criteria analysis is preferable as it provides greater transparency but at present it is only used to a limited extent, if at all.
- As the evaluation will, for the time being, mostly be undertaken through qualitative multi-criteria analysis, the highest possible level of transparency should be aimed for. Hence, the reasons for preferring one product alternative over another will have to be specified in discussion.

STEP 4.2 - EVALUATION OF THE VALIDITY AND RELIABILITY

- The functional unit may be formulated differently in the goal definition. For example, in a comparison of plastic coffee cups and porcelain cups, the calculations could be performed for cups with and without saucers.
- During the inventory analysis the exact definition of the system boundary in step 2.1 should not be relevant, so the inclusion of capital goods, for example, should not change the conclusion.
- In step 2.2 - when the process data are collected - there are generally some uncertainties included in the data. The aim is to provide a clear presentation by using the format and by estimating the quality of the data. However, the data will often be obtained from indefinite sources. In this step the estimate of the quality of individual process data, which in step 2.2 was converted to an estimate of the reliability of the complete data set, is extended to provide an estimate of the reliability of the inventory table or the environmental profile.
- The allocation rules used will also affect the outcome. Wherever possible it may be useful to assess the influence of alternative allocation rules.
- Soundly-based scientific knowledge about the effects of emissions, etc. is used for the classification. In practice, there is often a problem in that substances are released for which there is no information available about their harmful effects. In such cases a value may be determined by analogy with related substances. Alternatively, the magnitude of the harmful effect may be determined at which the conclusion of the study changes, after which the acceptability of this value can be discussed.
- This method can also be used in the evaluation of the weighting factors. By determining the magnitude of the weighting factors at which the conclusion changes, the sensitivity of the results to these factors can be assessed.
- For some of the process data there are estimates of its uncertainty in the form of margins, e.g. $12 \pm 2$. The range of the data is also known for some classification factors. The backgrounds document discusses a method requiring extensive calculations to determine the effects of these uncertainties on the inventory table, the environmental profile and the environmental index.
- A method of determining the influence of marginal changes in the process data has been developed for the improvement analysis (step 5.2). This method provides information about changes in the inventory table, environmental profile or environmental index as a function of such changes in the process data. However, this method can also be used to investigate which process data must be most accurately defined because a marginal change could have such a major impact.
- In view of the reliability analysis, it is better to estimate an unknown data item than to omit it. The reliability analysis may well show that the item is of minor importance but the insignificance of the actual value of the item can then be demonstrated even more clearly.

**Component 5 - improvement analysis**

STEP 5.1 - DOMINANCE ANALYSIS

- The "true origin" of the environmental interventions or effects is determined in the dominance analysis which makes it possible to take a considered approach to solving a problem.
- During a dominance analysis it is useful to provide an overview in the form of a matrix of all process data based on their occurrence. This matrix approach is developed in the backgrounds document. It is illustrated in the example with this step.

STEP 5.2 - MARGINAL ANALYSIS

- In theory marginal analysis is a powerful tool in determining the options for product improvement. The method has yet to prove itself in practice. It is a new development which has still to be applied and assessed. The approach is described in detail in the backgrounds document.
- An effective method of handling the large quantity of numbers is to make a list in which the calculated numbers are listed in order of decreasing magnitude (in absolute terms).
- There is a close link with the reliability analysis in step 4.2: process data in which small changes may have major consequences are also process data which have to be calculated extremely accurately. Hence marginal analysis should also be used carefully.

# CHAPTER 0

# INTRODUCTION

This chapter describes the contents of this guide, its target group and structure. It provides an introduction to the report itself.

## 0.1 Orientation

First we will describe some terms*. This guide describes the implementation of a *product assessment*. This is limited to the potential effect on the *environment* of the functioning of a given product. The assessment is not restricted to any particular stage in the life of a product: the entire *life cycle* is considered, from production and use to disposal. Hence the term *environmental product life cycle assessment*, which is abbreviated as LCA†. An environmental life cycle assessment, possibly together with the results of other analyses e.g. an economic analysis, may result in an application. LCA applications include product information, product innovation and government regulation. Information provides support when a choice has to be made between alternative products, innovation might include the development of more environmentally-friendly products and regulation might include awarding approvals (*ecolabelling*). When used like this an environmental life cycle assessment can be employed as an instrument to support policy making.

This report describes a method for environmental life cycle assessment. The method is described in general terms in §0.2. Chapters 1 to 5 serve as a practical guide and give *guidelines* for carrying out an LCA. The guidelines in the summary (page 2) list all the guidelines.

When determining the target groups addressed by the method there is a difference with the policy target groups in the Netherlands NEPP‡ (National Environmental Policy Plan) as the policy officials are now one of the target groups. There are four main target groups:

- *those implementing* LCAs, i.e. large companies, consulting engineers and consumer organisations;
- *users* of the results of LCAs, i.e. consumers, the public and private sectors and other organizations;
- *policy officials*, for product policy in the widest sense of the word (including environmental approvals, waste policy and innovation policy);
- *companies and designers*, for design decisions.

The guide described in this section is only intended for *those implementing* LCAs. The aim was to find a compromise between brevity and completeness: everything required to implement an LCA is included in this guide. The reasons behind the choice of methods are included in the backgrounds document.

* A short list of definitions is included in Appendix C.1.

† LCA has slowly developed from an instrument for analysis into one for assessment. This explains the the confusion on the meaning of the abbreviation: is it life cycle analysis or life cycle assessment?

‡ A list of abbreviations is included in Appendix C.2.

None of the practical studies currently available fulfils all the requirements of this method. Thus the method does not reflect current practice, but rather the desired situation. Given the present, limited, level of development of the methods and the lack of complete basic data practical studies are unlikely to meet all the desired requirements in the near future. However, it is possible to indicate the extent to which they meet certain requirements, the methodological status and quality of each step, as well as the quality of the data in these steps. Hence the method is provisional and requires further development, possibly through international cooperation. For this reason the most recent developments should form the basis of each study and the method used as well as its date should be specified.

The wide variety of product assessments created in the past was one of the reasons for the development of this method. Variety is undesirable for all target groups: trade and industry (the private sector), consumers and the public sector. Decisions about investment, procurement, creating the right conditions and the provision of information are not taken on a clear basis. The method presented here aims to provide uniform guidelines for the implementation of an LCA. As progress is made practical studies will continue to be faced with problems and disagreements. A *code of conduct* will have to be created to deal with the remaining problems.

## 0.2 Structure

The following elements are included in the method:

- components;
- steps.

The components are built up into a logical structure which is developed in more detail in each of the steps. The components will be discussed within this structure. The detailed development of the components, as well as their steps, is included in Chapters 1 through 5, i.e. one component per chapter. Each step is discussed in a separate subsection.

### 0.2.1 Structure in components

An environmental life cycle assessment is made up of five *components* which together form a comprehensive structure. These components are:

- goal definition (page 17);
- inventory analysis (page 25);
- classification (page 41);
- evaluation (page 51);
- improvement analysis (page 57).

The concept behind these components will be explained here. The precise nature of the components will be described later. The logical progression of these five components is illustrated in the bold frame in Figure 0.1.

The assessment of a product is concerned with more than just environmental aspects. Financial, social and functional aspects may also be relevant. These other aspects are beyond the scope of this report. The figure shows the position of environmental life cycle assessment compared with other forms of analysis. Applying the results of an environmental life cycle assessment, possibly in combination with other analyses, also lies beyond the scope of providing a description of a method for environmental life cycle assessment.

Each component of an environmental life cycle assessment provides a result which can be used on its own. Hence there is an outward arrow from each component in Figure 0.1. The results of the various components are known as *environmental indicators*. An environmental indicator is a number which provides information about the properties of the product concerned with respect to the environment. The environmental indicators will be included as part of the discussion of the relevance of the components. There are many potential environmental indicators. However not all of them are equally useful or practical. Some of these environmental indicators will be examined in this report. There is some interdependence between the environmental indicators as the outcome of the various components. Environmental indicators should only be used at the same level to obtain useful

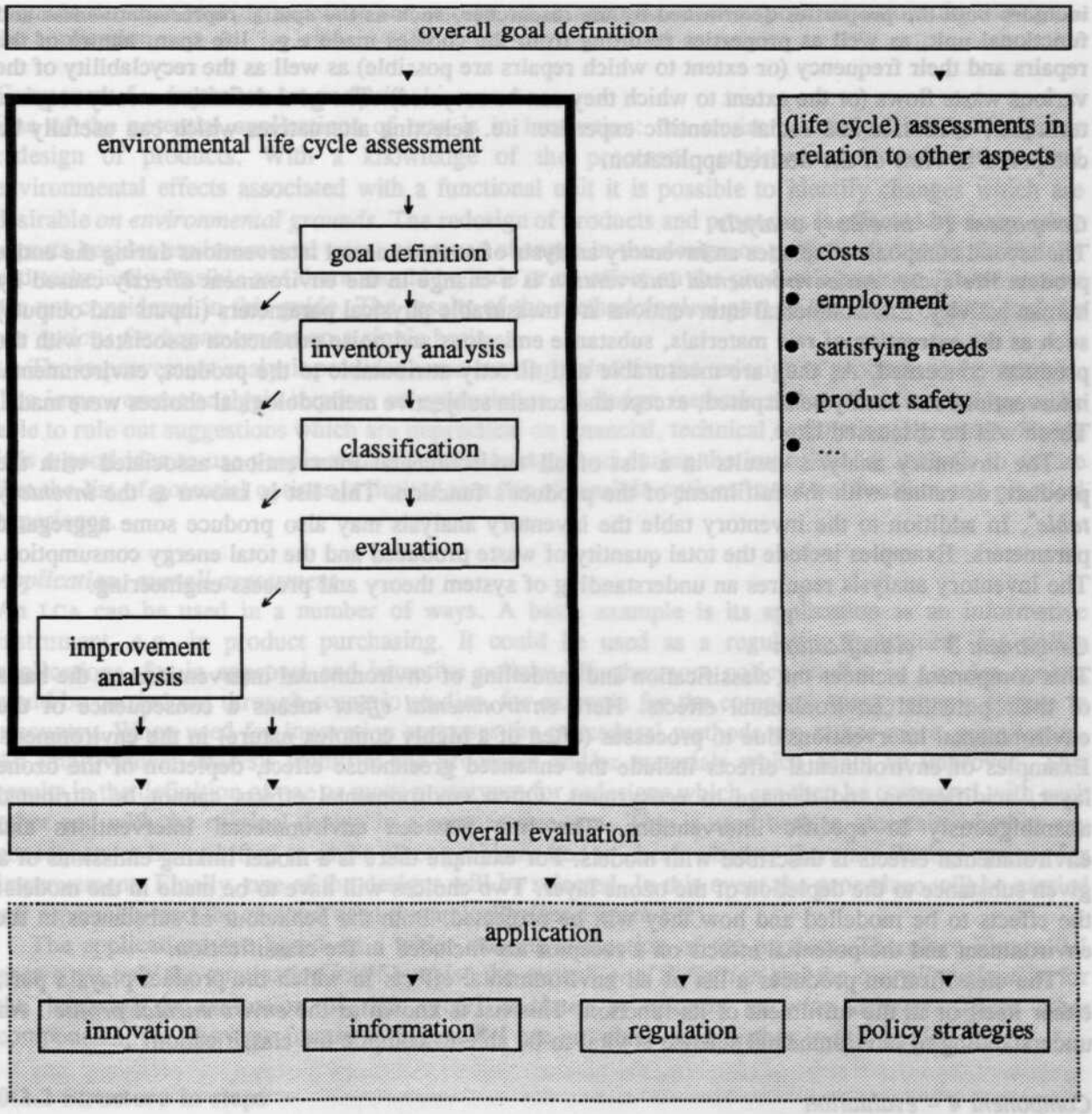


FIGURE 0.1. An LCA comprises the components goal definition, inventory analysis, classification, evaluation and improvement analysis and, with an assessment on other aspects, leads to an application.

information about the properties of a given product.

*Component 1 - goal definition*

The LCA begins with a definition of the goal. The actual goal of the LCA in question is determined. This includes a consideration of the type of decision required for a potential application. The actual application however is beyond the scope of the LCA. The depth of the study will also be determined at this time. Finally, the object of the study is accurately defined. The goal definition produces a fairly accurate specification of the product or products to be investigated. It will also specify the time and place covered by the LCA, and for which the processes should be representative. At this stage the core criterion in the comparison of the relevant product variations or the product is also determined as a *functional unit*. The choice of the numerical value is irrelevant: there is no difference, other than in scale, between 1 kilometre or 1000 kilometres by car.

The goal definition produces an overview of the *product properties* of the products concerned. This

includes both the properties determined by the researcher, such as the spatial representativeness and functional unit, as well as properties resulting from the choices made e.g.: life span, nature of the repairs and their frequency (or extent to which repairs are possible) as well as the recyclability of the various waste flows (or the extent to which they can be recycled). The goal definition mostly requires technical, economic and social scientific expertise: i.e. selecting alternatives which can usefully be compared in view of the desired application.

*Component 2 - inventory analysis*

The second component includes an inventory analysis of environmental interventions during the entire product life cycle. An *environmental intervention* is a change in the environment *directly* caused by human activity. Environmental interventions are measurable physical parameters (inputs and outputs) such as the extraction of raw materials, substance emissions and noise production associated with the products concerned. As they are measurable and directly attributable to the product, environmental interventions can hardly be disputed, except that certain subjective methodological choices were made. These will be discussed later.

The inventory analysis results in a list of all environmental interventions associated with the product, or rather with the fulfilment of the product's function. This list is known as the *inventory table*[*]. In addition to the inventory table the inventory analysis may also produce some aggregated parameters. Examples include the total quantity of waste produced and the total energy consumption. The inventory analysis requires an understanding of system theory and process engineering.

*Component 3 - classification*

This component includes the classification and modelling of environmental interventions on the basis of their potential environmental effects. Here *environmental effect* means a consequence of the environmental interventions due to processes (often of a highly complex nature) in the environment. Examples of environmental effects include the enhanced greenhouse effect, depletion of the ozone layer, acidification and damage to ecosystems. Often environmental effects cannot be attributed unambiguously to specific interventions. The link between environmental interventions and environmental effects is described with models. For example there is a model linking emissions of a given substance to the depletion of the ozone layer. Two choices will have to be made in the models: the effects to be modelled and how they will be projected. Both the behaviour of substances in the environment and the potential effects on a receptor are included in the classification.

The classification produces a list of all environmental effects in which the product plays a part, either itself or in the fulfilment of its function. This list is known as the *environmental profile*[†]. An understanding of environmental science is vital to be able to compile the classification.

*Component 4 - evaluation*

During the evaluation an overall assessment of the product is made based on its potential environmental effects. A single, uniform, parameter is often required when comparing the environmental profiles of two products as in many cases an unweighted comparison will not lead to a clear conclusion. This means that the scores for the various environmental effects of the environmental profiles could be weighted and combined to provide an *environmental index*. Considerations about which environmental effects are most important depends rather more on the situation and personal opinion than considerations made in other components. Hence the value judgements made here are subjective. Apart from a valuation of the environmental effects the assessment is also based on an estimate of the reliability and validity of the analysis.

The result of the evaluation, therefore, will be a set of formally constructed environmental indices or a comparative judgement in which reliability and validity are also considered. The evaluation

[*] The usual term *inventory* comprises both inventory analysis and inventory table. To make a clear distinction between the procedure and the result, the words analysis and table have been included here, although the authors realize that they will often be omitted in practice.

[†] Other terms include eco-profile, environmental balance and eco-balance.

requires decision making expertise and will be of an administrative or political nature depending on the application.

*Component 5 – improvement analysis*

One of the potential applications of LCA is in innovation: the environmentally-friendly design or redesign of products. With a knowledge of the processes, environmental interventions and environmental effects associated with a functional unit it is possible to identify changes which are desirable *on environmental grounds*. The redesign of products and processes is affected by many other aspects besides environmental ones: proposed changes in the design or process should be financially and technically feasible and there should be little or no effect on the product's position. These aspects are not considered in this guide. The results of the methodological part of the improvement analysis are *options for improvement* on a single basis.

The improvement analysis provides some *starting points* for the redesign of products and processes. The improvement analysis requires an appreciation of design methods and process technology to be able to rule out suggestions which are impractical on financial, technical or functional grounds. Hence it is a good idea to use people with a general background during the improvement analysis to ensure that the list of potential options is limited to a list of feasible options based on intuition and practical experience.

*Application; overall assessment*

An LCA can be used in a number of ways. A basic example is its application as an informative instrument, e.g. in product purchasing. It could be used as a regulating instrument for policy applications, for in approval and incentive policies. Furthermore policy studies in a wider context could be carried out through scenario studies, for example for the complete energy supply system in a country. When used for innovation purposes the procedural methods are rather more complicated. An improvement analysis identifies the processes and/or materials which could be improved. This results in the definition of one or more prototypes for redesigns which can then be compared with each other and with the original design in a comparative LCA. This is used both to ascertain whether any consequences have shifted to cause other problems and to check whether there are further options for improvement. Finally, one of the designs will be selected. In this event the procedure will be carried out repeatedly and the method used dynamically (see Figure 5.2).

The applications are based on a wider ranging evaluation of the product. Therefore Figure 0.1 shows not only the application itself but also the *overall goal definition* and the *overall evaluation* for the initiation or evaluation of *(life cycle) analyses in relation to other aspects*. These other components, i.e. the grey frames in Figure 0.1 are not elaborated further in this guide.

### 0.2.2 Structure in steps

During an LCA a number of sequential actions is carried out in each component. A set of associated actions is referred to as a *step*. A step can be seen as a specific implementation in each individual LCA which is supported by a theoretical background (see Figure 0.2).

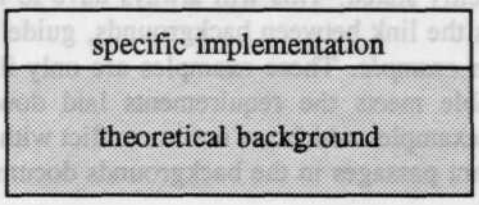


FIGURE 0.2. Structure of a step. The method provides the theoretical basis for the specific development in each situation.

Each step is supported by theoretical considerations which are not essential to the implementation of an LCA. However, these considerations are relevant for other purposes and are discussed in the

other volume of the report, the backgrounds document. The chapter numbering of that document is the same as in this guide but the structure, in sections, differs. Chapters 1 to 5 of this guide cover the components goal definition, inventory analysis, classification, evaluation and improvement analysis. In these chapters each component is also divided into steps. Table 0.2 lists the five components and their constituent steps.

TABLE 0.2. The five components of an environmental LCA: the constituent steps, results and discipline.

| component | step | indicator | expertise |
|---|---|---|---|
| goal definition | determining the application<br>determining the depth of the study<br>defining the subject of the study | product properties: life span, recyclability, etc. | technical, economic, social scientific |
| inventory analysis | drawing up the process tree<br>entering the process data<br>application of the allocation rules<br>creating the inventory table | inventory table with environmental interventions; energy, waste, etc. | system theory, process engineering |
| classification | selection of the problem types<br>definition of classification factors<br>creating the environmental profile<br>normalization of the effect scores | environmental profile with effect scores | environmental science |
| evaluation | evaluation of the environmental profile<br>evaluation of the reliability and validity | environmental index or judgement | decision-making |
| improvement analysis | dominance analysis<br>marginal analysis | starting points for redesign | process engineering |

Each section of text describing a step includes a number of standard items:

- introduction;
- guidelines;
- example;
- backgrounds.

The *introduction* of each section of text describes the function of the step within the method and that component. In certain steps or situations the best solution to certain methodological problems may be impractical. The *guidelines* give in some cases a practical interpretation of the principle itself and in other cases a provisional solution. These guidelines will be effective in most cases in practice but not in all situations, e.g. where data is lacking or the application of the guideline leads to conclusions which are clearly unlikely. Therefore the exceptions are always discussed. Examples of exceptions are included together with the way to handle them. However, it is possible to deviate from the guidelines, even if this option is not explicitly stated. This will always have to be clearly stated and supported with reasons. Figure 0.3 shows the link between backgrounds, guidelines and exceptions.

Each step concludes with an *example*. These examples are only illustrative. Particularly as none of the practical studies available meets the requirements laid down here, it is difficult, if not impossible, to provide realistic examples which are not in conflict with the method itself. The last part of each step refers to the relevant passages in the backgrounds document.

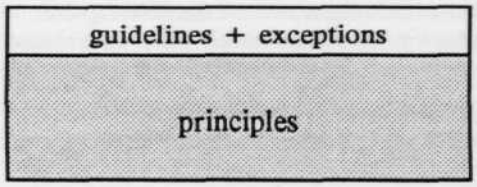


FIGURE 0.3. This report provides guidelines for implementing an LCA, based on the principles in the backgrounds document. If necessary, these guidelines may be departed from if the reasons are stated.

## CHAPTER 1

# GOAL DEFINITION

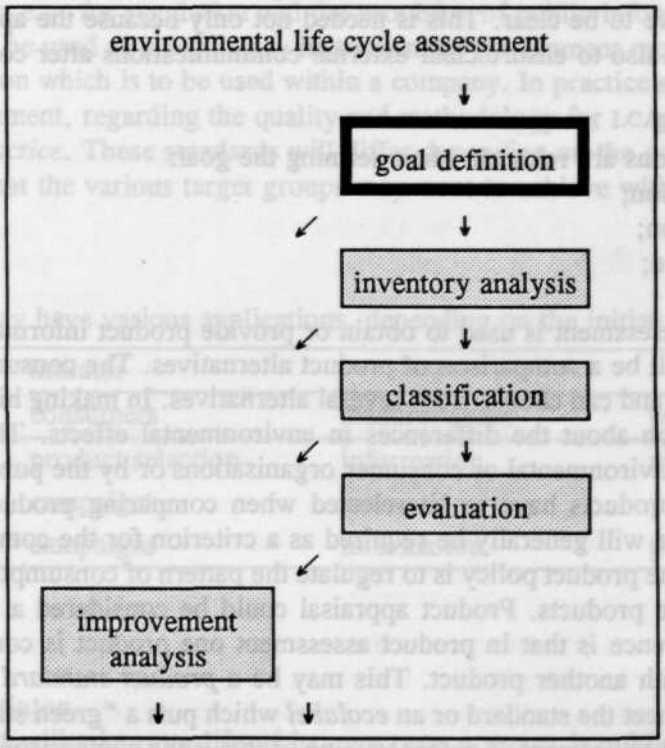


FIGURE 1.1. The goal definition is the component of an LCA in which questions such as "What?", "Why?", "For whom?" and "By whom?" are answered.

The goal definition of the environmental LCA is based on the overall goal definition. The overall goal definition anticipates the application which might be to provide product information (e.g. by comparing product alternatives), government regulation (e.g. product approval based on the results of comparison with a standard), for product or process innovation (e.g. by identifying dominant processes in the environmental profile to obtain information about the potential effects of innovation), or as a tool for strategic studies based on policy scenarios. The depth of the study is also determined at this stage, depending on the time available and intended application. Finally the products to be investigated are defined. Thus, the goal definition comprises three steps:

- determining the application (page 18);
- determining the depth of the study (page 20);
- defining the subject of the study (page 21).

The result of the goal definition includes an accurate description of the products to be investigated. This includes a number of product properties which may be related to effects on the environment. These could include the technical or economic life span, the nature and frequency of repairs, recyclability, the number of times the product is reused, etc. However, the relationship between these product properties and the level of environmental-friendliness is not clear.

## 1.1 Determining the application

INTRODUCTION

During the goal definition component certain decisions are taken which determine the subject of the assessment and its further implementation. As the intended application will determine the course of the LCA the first step is to determine the application. When carrying out an LCA the goal, the target group and the initiator need to be defined. This is to provide the basis for the LCA: the reasons for undertaking a study have to be clear. This is needed not only because the application will affect the course of the study but also to ensure clear external communications after completion of the study.

### 1.1.1 Defining the goal

The following applications are relevant when defining the goal:

- product information;
- product innovation;
- product regulation;
- policy strategies.

When a life cycle assessment is used to obtain or provide product information it is likely that the practical application will be a comparison of product alternatives. The consumer expects a particular function to be provided and can choose from several alternatives. In making his decision the consumer can consider information about the differences in environmental effects. This information may be provided by industry, environmental or consumer organisations or by the public sector. At least two product variations or products have to be selected when comparing products (see §1.3.5), and a common functional base will generally be required as a criterion for the comparison (see §1.3.4).

One of the aims of the product policy is to regulate the pattern of consumption. The results of LCAs can be used to appraise products. Product appraisal could be considered a special case of product comparison. The difference is that in product assessment one product is compared with a standard product, rather than with another product. This may be a *product standard* which aims to exclude products which fail to meet the standard or an *ecolabel* which puts a "green stamp" on products which meet a given minimum requirement. Another version of this is the comparison of a range of variations in order to award such an approval to some of them. Another type of application is the use of LCAs to manage the allocation of financial resources. For example, subsidizing insulation or energy-efficient lighting or the introduction of an *ecotax*.

Product improvement may also include a comparison: between the product before and after redesign, or of a number of prototypes. In most cases however the product improvement will be defined in absolute terms rather than by comparison. Here the aim is to provide recommendations for the redesign based on an awareness of the environmental interventions and effects of all materials and processes associated with the product. An LCA can be used to trace weak links in the life cycle, for example by indicating that the dispersal of toxic substances is largely due to cadmium emissions in a particular process. By selecting a different process or by taking environmental hygiene measures for that process, the environmental profile of the product may be drastically improved. The dynamic and iterative nature of LCAs will be emphasized by this type of application in particular: after inclusion of the recommendations in a new design the new product can be compared with the old in a comparative LCA. In this way environmental effects are not shifted to other stages in the life cycle nor to other environmental effects. All in all, product improvement also includes a comparison albeit that the options for improvement are determined only for one product.

Consideration of scenario studies is also important when defining the government policy, which

can affect the market shares of products through levies or public information campaigns. An LCA may help when carrying out these scenario studies. This method can also be used to set priorities in the policy. This is one of the few examples where it may be useful to compare product groups which are not functionally identical. For example, is encouraging the use of energy-efficient lighting more urgent than encouraging the purchase of high-efficiency central heating boilers, given the limited availability of government funds?

Any secondary objectives which limit the scope of the study should also be considered when defining the goal.

### 1.1.2 Defining the target group

It is important to define who undertakes or commissions an LCA, and for whom. The results of an LCA may be aimed at three separate target groups, i.e.:

- consumers, for information (e.g. for purchasing decisions);
- manufacturers, for innovation and information (e.g. for advertising);
- the public sector, e.g. for regulation and the provision of public information.

A decision which is to be used as a regulatory instrument by government requires a higher degree of reliability than a decision which is to be used within a company. In practice standards will have to be set, possibly by government, regarding the quality and methodology for LCAs. This could be done by means of a *code of practice*. These standards will differ depending on the goal and the target group.

Table 1.1 shows what the various target groups may want to achieve with LCAs.

TABLE 1.1. An LCA may have various applications, depending on the initiator and target group.

| | initiator | | |
|---|---|---|---|
| target group | consumers | manufacturers | public sector |
| consumers | product selection | information | provision of information |
| manufacturers | campaigns | innovation | provision of information |
| public sector | campaigns | information | policy strategies |

### 1.1.3 Defining the initiator

A life cycle assessment will take on a life of its own once a report is published, which may extend beyond the target group. It will therefore have to be clear who the initiator and funding body are. The organizations concerned with the LCA should also be identified, for example by listing the members of any steering committee. Finally, it should be specified whether the data used was provided by an interested party or by an independent organization.

GUIDELINES

- The type of application is determined; examples include:
  - information about existing products;
  - innovation of existing products or prototypes;
  - legislation affecting product policies;
  - assessing policy strategies through the use of scenarios;
  - ...
- The application depends on the choice of target group or groups:
  - consumers;
  - producers;
  - government bodies;
  - ...
- List those concerned:

— those undertaking the study;
— the client and the funding body;
— the steering committee;
— those providing (and possibly verifying) the information required;
— ...

- Such a full explanation will not be required if the LCA is only to be used internally e.g. to optimise a design.

EXAMPLE

This study was carried out to compare different types of window frames. The study was commissioned by Alukoz BV whose product range includes aluminium window frames. The study was estimated to require 250 hours. The client was closely involved in directing the project, particularly in selecting the product alternatives to be compared and provided the process data. Before publication the report was submitted for comment to Ecobouw BV, an independent firm of consulting engineers.

BACKGROUNDS

§0.1 - product assessments
§0.4 - premises
§1.1 - LCA applications

## 1.2 Determining the depth of the study

INTRODUCTION

Normally, a product assessment will require considerable time and funds. A detailed life cycle assessment may be justified for important applications such as government approvals or bans. However, when only a general outline is required a *streamlined method* could be used. Examples of this include applications within a company for product improvement. The streamlining may be achieved by:

- concentrating on the differences between product alternatives;
- excluding some components of the life cycle assessment;
- limiting the number of processes;
- limiting the number of environmental effects;
- ...

The decision to apply some streamlining may imply a reduction in reliability, particularly when it is decided to limit the number of processes or environmental effects considered. This reduction should correspond with the importance of the application. The level of detail will also affect the course of the following steps to some extent. The method described in this guide is based on the assumption that the highest level of detail has been selected. The streamlined methods have not been developed in sufficient detail to be considered as accepted methods.

Besides lack of time, a lack of data may also be one reason to opt for a limited LCA. Information about the use of capital goods, $CO_2$ emissions, distinction between different PAHs, etc. is not always available. This may require the exclusion of certain processes or environmental effects.

Apart from a limitation due to a lack of time or data the relevance to certain applications may lead to a reduction, or even an increase, in the level of detail of an LCA. For example, depending on the occupational hygiene regulations in a particular country, it may be decided to include or exclude occupational hygiene considerations. Alternatively the study could be limited to global environmental problems.

GUIDELINES

- A complete LCA should first be considered: covering all processes and environmental effects and at least the following components: goal definition, inventory analysis, classification and evaluation. At this stage it would not be sensible to omit any elements, this can only be done once an inventory

analysis has provided sufficient information to justify this.
- Identical elements may be excluded when products are being compared. However, this can only be done after defining the process tree in step 2.1.
- When improving a product it may well be feasible to make recommendations for a redesign at the inventory analysis level. However, the new design will have to undergo a complete LCA to assess any shift to other environmental effects.
- In all cases reliability and validity will have to be assessed (step 4.2).

EXAMPLE

An assessment of certain environmental effects has not been specifically excluded from this study of the environmental effects of different types of curtains. However, certain identical elements (i.e. the curtain rail and fixings) in the life cycles have not been considered.

BACKGROUNDS

§0.2 – structure
§1.2 – streamlined LCA methods

## 1.3 Defining the subject of the study

INTRODUCTION

Selecting the subject means:
- defining the product group;
- defining spatial representativeness;
- defining temporal representativeness;
- defining the functional unit;
- defining the product or products.

These elements are closely related. The order in which they are dealt with may differ. For these reasons they are included as a single step made up of sub-steps. However, the five items will be considered separately below where their interrelations will allow this.

### 1.3.1 Defining the product group

The function for which a set of products may be used is selected. This set of products and product variations is known as the *product group*. An example of a product group is "light sources", whose function is "lighting a space". There is no product group if it was decided when determining the type of application, to study policy strategies, in which event it is only necessary to define clearly the functional unit (see §1.3.4).

### 1.3.2 Defining spatial representativeness

The spatial representativeness of the products to be studied must be specified unless it is clear from the specification of the functional unit (§1.3.4). This could be global, continental (e.g. European), regional (e.g. EC), national (e.g. the Netherlands) or at company level (e.g. brand *X*).

### 1.3.3 Defining temporal representativeness

The temporal representativeness has to be determined in a similar manner to spatial representativeness. Generally, a rough indication will suffice, for example, "the '70s", "1991" or (for innovation) "2010".

### 1.3.4 Defining the functional unit

The concept of equal value, as referred to above, is based on the *functional unit*. The functional unit describes the main function performed by a product and indicates how much of this function is considered. Quantitative terms can be included in the process tree once a functional unit has been selected. When comparing products the functional unit forms the basis for the comparison. A

functional unit will also be required for an assessment or any other application. Strictly speaking, the choice of functional unit will consist of a unit and a quantity; the quantity is irrelevant.

Examples of functional units include: "drinking 1 (or 1000) litres of fresh milk", "1 person-transport-kilometre" and "watching TV for one hour". In practice this will be expressed less carefully, for example in functional units such as "1 notepad", which do not express the use-function and the disposal-structure although these are included in the assessment.

Sometimes it is easy to choose the functional unit. However, it is often necessary to choose the main function which is used as the basis for the comparison. Examples include functional units such as "transport kilometres per car" and "person-transport-kilometres by car". In the first example the number of passengers in the car is not relevant, which it is in the second. The definition of the functional unit also defines the alternatives which could be considered. The more strictly the functional unit is described the fewer alternatives there are for it. The functional unit "watching TV for 1 hour" may be specified in greater detail as "watching colour TV for 1 hour", "watching large-screen colour TV for 1 hour", "watching large-screen colour TV with remote control for 1 hour", etc., until there are no product alternatives to compare. The contradiction between an accurate definition of something and allowing for slightly different alternatives means that the accuracy of the definition of the functional unit cannot be cast iron. This is particularly relevant when LCAs are used to plan policy strategies. For example, the functional unit chosen to compare energy-efficient lighting and high efficiency central heating boilers as referred to in §1.1 could be "an energy saving of *x* MJ per capita" or „providing *y* guilders subsidy for energy conservation".

### 1.3.5 Defining the product or products

One or more products are selected from the product group (see §1.3.1) which meet the representativeness criteria in §1.3.2 and §1.3.3. The final outcome of the goal definition will be a list stating the product or products which have to be investigated for a particular purpose, linked by the functional unit. An existing product need not be chosen: it could be a product to be developed. In practice it is advisable to provide an accurate description of the products to be investigated.

GUIDELINES

- Select a functional unit which is clearly defined in detail and covers an activity to the greatest possible extent.
- Provide an accurate specification of the products being assessed. The extent to which the information is representative (in time and space) and the functional properties are particularly important.
- Indicate any product alternatives which meet the specifications fully or almost fully that were not included in the assessment, and the reasons for this.

EXAMPLE

Two light sources will be compared in this investigation:

- incandescent lamp (60 HV ed 51);
- SL-type compact fluorescent lamp (SL-18W prisma).

Table 1.2 gives the functional differences between these lamp types. As both are suitable for providing electric light in living rooms they are considered as product alternatives.

Both types relate to the Netherlands market for light sources. Data from 1986 was used. The functional unit selected was $10^6$ lm·hr light production. The TL-20/x fluorescent tube was not considered as it is soon to be discontinued. The TL-7/c was also excluded as its colour is generally not used for domestic applications.

BACKGROUNDS

§1.3 – the functional unit

TABLE 1.2. Product properties of the two types of light source investigated.

| product property | incandescent lamp (60 HV ed 51) | SL-type fluorescent lamp (SL-18W prisma) | unit |
|---|---|---|---|
| *light-related properties* | | | |
| total power drawn | 60 | 18 | W |
| light flux | 650 | 900 | lm |
| colour temperature | 2600 | 2700 | K |
| colour rendition | 100 | 82 | ra |
| life span | 1000 | 5000 | hr |
| reduction in light flux | 10 | 20 | % |
| average light flux | 617.5 | 810 | lm |
| total light emitted | 617,500 | 4,050,000 | lm·hr |
| *other properties* | | | |
| weight | 30 | 540 | g |
| operating time | 2000 | 2000 | $hr \cdot yr^{-1}$ |
| life of fitting | 20 | 20 | yr |
| depreciate fitting over | 40 | 8 | lamps |

## CHAPTER 2

# INVENTORY ANALYSIS

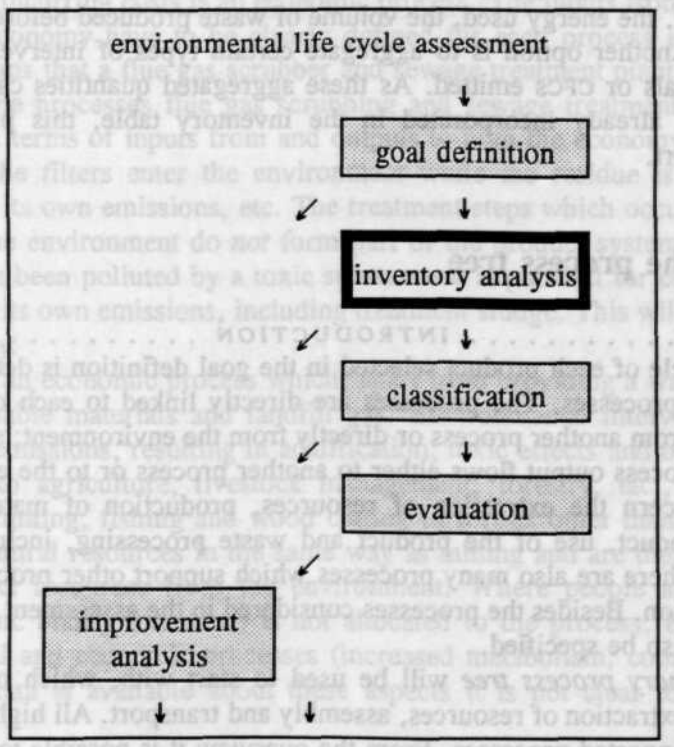


FIGURE 2.1. The product system is central to the inventory analysis of an LCA. The process tree is drawn up and process data entered which can be used to draw up the inventory table.

The inventory analysis is a survey of the interaction between the life cycles of the products under investigation and the environment. The life cycle of a product, which includes all processes required for the functioning of the product "from cradle to grave", is referred to as the *product system*. The product system affects the environment. The interventions have an effect throughout the system made up of all environmental processes (degradation, accumulation, etc.). These processes form the *environmental system*. The sequence from intervention to effect or potential effect is the subject of the classification component (Chapter 3).

The inventory analysis is based on the functional unit of the product defined in the goal definition

and the selected products* which provide this function. The functional unit is realized through a product†, and the product is associated with past and future processes‡. Hence, the first action in an inventory analysis is to draw up an overview of the processes through which the life cycle is implemented in each of the product systems under investigation, which is known as a *process tree*§. Next the process data have to be collected and entered. The aggregation of this data throughout the process tree will ultimately provide a list of all interventions in the environment which are associated with the product system, this is the *inventory table*. There are four separate steps:

- drawing up the process tree (page 26);
- entering the product data (page 29);
- applyication of the allocation rules (page 35);
- creating the inventory table (page 37).

These four steps will be discussed separately.

Instead of using an inventory table the outcome of the inventory analysis could be presented in another form; for example by aggregating quantities (at the process level) which are of particular individual interest, e.g. the energy used, the volume of waste produced before or after processing, or the total space use. Another option is to aggregate certain types of interventions such as the total quantity of heavy metals or CFCs emitted. As these aggregated quantities cannot be assessed in the classification and are already incorporated in the inventory table, this procedure has not been elaborated in this report.

## 2.1 Drawing up the process tree

INTRODUCTION

In step 2.1 the life cycle of each product selected in the goal definition is determined. The life cycle consists of economic processes. The processes are directly linked to each other: each input into a process comes either from another process or directly from the environment; see also figure 2.3 (page 31). Similarly each process output flows either to another process or to the environment.

The processes concern the extraction of resources, production of materials and components, manufacturing the product, use of the product and waste processing, including the processes for recycling and reuse. There are also many processes which support other processes, such as transport and electricity generation. Besides the processes considered in the assessment, the processes that have been omitted should also be specified.

In practice a *summary process tree* will be used to start with, which only includes high-level processes such as the extraction of resources, assembly and transport. All high-level processes consist of a number of interconnected processes. From the overview it is possible to zoom in on each high-level process in the summary process tree which will then reveal the *partial process trees* of the process concerned.

To determine the life cycle of a product more information is required than just the processes to be included in the process tree. The product system also has to be delineated. This step includes the definition of three boundaries:

- delineating the boundary between the product system and the environmental system;

* These could also be product design specifications.

† In many cases there will be one core product performing the function, while the contribution made by other products is less clear. For example, let us consider a functional unit of vacuum cleaning: the vacuum cleaner is the core product while the dust collection bags are essentially a different product based on their function. In this case the different types of vacuum cleaners can be compared, including the relevant type of bag. This is not as clear in other cases. For example, when writing a letter both the paper and the writing implement play equal level roles and various combinations of wood-free paper and recycled paper or ballpoint pen, fountain pen and typewriter may be analysed. Although there is no core product which performs the functional unit the rest of the inventory analysis can be easily discussed using a core product.

‡ In the inventory analysis a process is always taken to mean an economic process. This generally refers to an action under human control. Examples include ore extraction, electricity generation, cleaning a carpet and waste water treatment.

§ When more than one product is studied several process trees will be drawn up.

- delineating the boundary between relevant and irrelevant processes;
- delineating the boundary between the product system and the other product systems.

### 2.1.1 Delineating the boundary between the product system and the environmental system

The complete process tree has to provide the links between the economic inputs and outputs and the environmental inputs and outputs. In this way all economic inputs linking two processes in the product system are traced back to inputs from and outputs to the environment. In this way they are reduced to the system boundary between the economic system and the environmental system. Starting from the process which provides the function defined in the functional units all processes have to be traced back to their origin and followed through to their completion. The chain is only broken if there is recycling to or from other product systems (this is known as *open loop recycling*; see §2.1.3). When going back to the origin each process with multiple inputs from other processes will branch to those processes, which have their own inputs from previous processes which also have their own branches.

Almost any activity incurring costs is an economic process. The inputs from and the outputs to the environment and the economy have to be clearly defined for each process in the process tree*. In practical terms this means that a flue gas scrubber and sewage treatment plant have to be included in the product system. The processes flue gas scrubbing and sewage treatment have to be known as economic processes, in terms of inputs from and outputs to both the economy and the environment. The flue gases from the filters enter the environment while the residue is dealt with in another economic process with its own emissions, etc. The treatment steps which occur after a substance has been introduced into the environment do *not* form part of the product system causing the emission. After surface water has been polluted by a toxic substance it is purified for consumption. This is an economic process with its own emissions, including treatment sludge. This will only be relevant in an LCA of the water supply.

Landfilling waste is an economic process which, apart from providing a waste processing service, may also produce reusable materials and landfill gas. Environmental interventions of this process include space use and emissions, resulting in acidification, toxic effects and odours.

Processes relating to agriculture, livestock management, forestry, etc., are considered to be economic processes. Hunting, fishing and wood cutting in forests other than production forests are processes which use natural resources in the same way as mining and are therefore considered to be processes which extract resources from the environment. Where people are used their presence (including all their basic bodily functions) is not allocated to the process. However, including the additional physiological and economic processes (increased metabolism, commuting, etc.) could be considered. As little data is available about these aspects it is not clear to what extent they are relevant.

After processing waste a material may be reused or find a useful application. This means that the life cycle has not come to an end at the material level. However, after this step the product life cycle is considered complete. A similar approach is taken in relation to the beginning of the life cycle: it starts when the raw material is extracted.

### 2.1.2 Delineating the boundary between relevant and irrelevant processes

When a process tree is drawn up a problem arises which could be described as *infinite regression*: each process refers to a previous or a subsequent process. The hammer used to make a machine was itself made and the waste processing plant used to process the product will itself have to be demolished. A boundary has to be drawn somewhere.

There is a similar problem regarding the delineation within a process: it has to be decided to what extent capital goods and matters such as the canteen for production staff should be included in the assessment.

In practice only the most relevant processes will be considered, particularly in a quick LCA, and

* The actual implementation will only become clear after step 2.2. In essence steps 2.1 and 2.2 are carried out as part of an iterative process; certain parts of the process tree can only be drawn up once the nature of the processes concerned is known.

many processes which could be relevant are excluded. The start of a series of processes to be excluded is always an omitted or dead-end economic input or output of a process already defined. The most important excluded processes will have to be identified, preferably with a qualitative or semi-quantitative estimate of the relative contribution to their expected environmental effects. For example, the production of capital goods required for a particular production process is often excluded. Whether to allocate these and other processes or not to a functional unit of product will be an important decision in a study.

At present it is difficult to say which processes may be excluded and when*. However, an initial indicator is that if the costs of maintenance and depreciation are a substantial part of the product price the environmental intervention of capital goods should not be excluded *a priori*†. In other cases it will usually suffice to include the operation of a capital good and to exclude its production, maintenance and disposal processes. However, such processes cannot be simply left out but should be identified. In this document they are indicated by the term *p.m.*‡ e.g.: "production of capital good *x*: *p.m.*". For energy supply however, Boustead's studies show that the inclusion of these other process does have an effect. Two solutions are possible in this situation. The first is the "proper" method in which all these processes are included and quantified. In the alternative method corrected data is used in which losses due to use anywhere in the chain are considered as a reduction in efficiency.

**2.1.3 Delineating the boundary between the product system and the other product systems**

Many processes produce more than one marketable output. A common example in LCAs is the combined production of chlorine and caustic soda from NaCl. If only one of these outputs is used as the input into another process in a given process tree then only part of the process has to be included in the product system: part of the environmental intervention as well as part of the inputs from earlier processes. This problem is not discussed as part of the compilation of a process tree as it concerns the extent to which a process is included, rather than whether or not to include it. There are three main categories of multiple processes: co-production, combined waste processing and open-loop recycling§. This distribution is known as *allocation* and is carried out in step 2.3 (page 35).

One of the problems associated with allocation can be included in step 2.1. This is the choice whether to include earlier processes in the use of recycled material and later processes in the production of recyclable materials. If a secondary resource such as scrap metal is used in a product system, the complete product system which provided the scrap need not be investigated. This would make the process tree much bigger. In this event the assessment would not be limited to the product systems under consideration but it would be extended to include a number of other product systems, one for each flow of secondary materials. The same problem occurs when material is reused in a following product system. A *cascade* of applications is also common: a primary resource is used in a number of products, one after another. The quality of the material may decline gradually until it is treated as final waste.

When drawing up the process tree it will have to be decided at what point products obtained from another product system become reusable waste. Similarly, when reusable waste is produced the point at these which products are to be included in the product system will have to be defined. To limit the discussion to the central product system the guidelines propose interrupting the materials cascade at a sensible place. As the quality required for the secondary application will determine the collection and reprocessing methods the complete collection and reprocessing process is allocated to the secondary use. The waste stage is eventually allocated to the final product system in the cascade. The

* Practical studies (see e.g. the discussion about streamlined methods in the backgrounds document) will have to demonstrate whether rules of thumb can be given for this.

† This does not imply that the use of capital goods with a low depreciation per functional unit of product need not be included. This is because the price is not proportional to the consequences to the environment.

‡ Abbreviation of the Latin phrase *pro memoria* (as a reminder).

§ Closed loop recycling involves the reuse of materials or products within the same product system. In the definition of the process tree this type of recycling is included through the proper definition of the processes: if a milk bottle is used forty times a functional unit of 1000 litres of milk requires 25 bottles.

primary use has the benefit of waste prevention, however this is offset by the extraction and production which are fully allocated to the primary use.

GUIDELINES

- A process tree is drawn up for each alternative under consideration, i.e. the processes which form part of the product life cycles are determined. The process tree is best laid out as a diagram, often with a summary process tree and separate trees for individual parts of the summary process tree.
- The extraction of raw materials from the environment is considered as the start of the life cycle.
- Although waste processing is considered as the end of the life cycle it is treated as an economic process which affects the environment through the consumption of raw materials, emissions and in other ways. Similarly, waste treatment steps carried out before a substance is introduced into the environment are included as part of the product system.
- The process tree is made up of economic processes.
- Economic processes have at least one economic output – goods (materials, components, products, etc.) or services (transport, energy, waste processing, etc.) – which forms the goal of the process.
- Each economic output of a process is the economic input of another process, with the exception of the service provided by the overall product system which is related to the functional unit.
- There is no need to extend the process tree by following the processes related to associated products and their production or the useful application of residual and waste materials.
- If the life cycle includes open loop recycling extraction and production are fully allocated to the primary application. Collection and upgrading are fully allocated to the secondary application while waste processing is only allocated to the last application in the cascade.
- This allocation system for open loop recycling will result in some of the consequences being shifted elsewhere. In some situations this shift may well be undesirable. In this event the reuse will not be interpreted as recycling in the LCA. The initial proposal for those situations in which there is no open loop recycling but where the rest of the life cycle has to be followed is as follows:
  — reuse of incinerator flue gas scrubbing residue;
  — reuse of incinerator fly ash;
  — application of combustible waste obtained from different, highly varied combustible waste fractions as RDF;
  — reuse of sewage sludge.
- Reuse which is considered to be open loop recycling must be identified.
- All branches of the process tree must be extended to include processes whose inputs are auxiliary environmental sources or whose outputs are emissions, unless they end in processes which are not considered in detail (i.e. indicated as *p.m.* processes).
- When drawing up a process tree the processes which have been excluded should be clearly indicated, where possible with a semi-quantitative estimate of the significance of these processes.

EXAMPLE

Figure 2.2 shows the summary process tree for the use of beverage packaging.

It is apparent that the production of some capital goods is also included and that processes further removed from the product, such as advertising, have not been included. The reason for this is that it is assumed that these will be the same for the product alternatives.

BACKGROUNDS

§1.2 – streamlined methods
§2.1 – the system boundaries

## 2.2 Entering the process data

INTRODUCTION

The process data for all processes in the process tree are collected in step 2.2. As long as there are

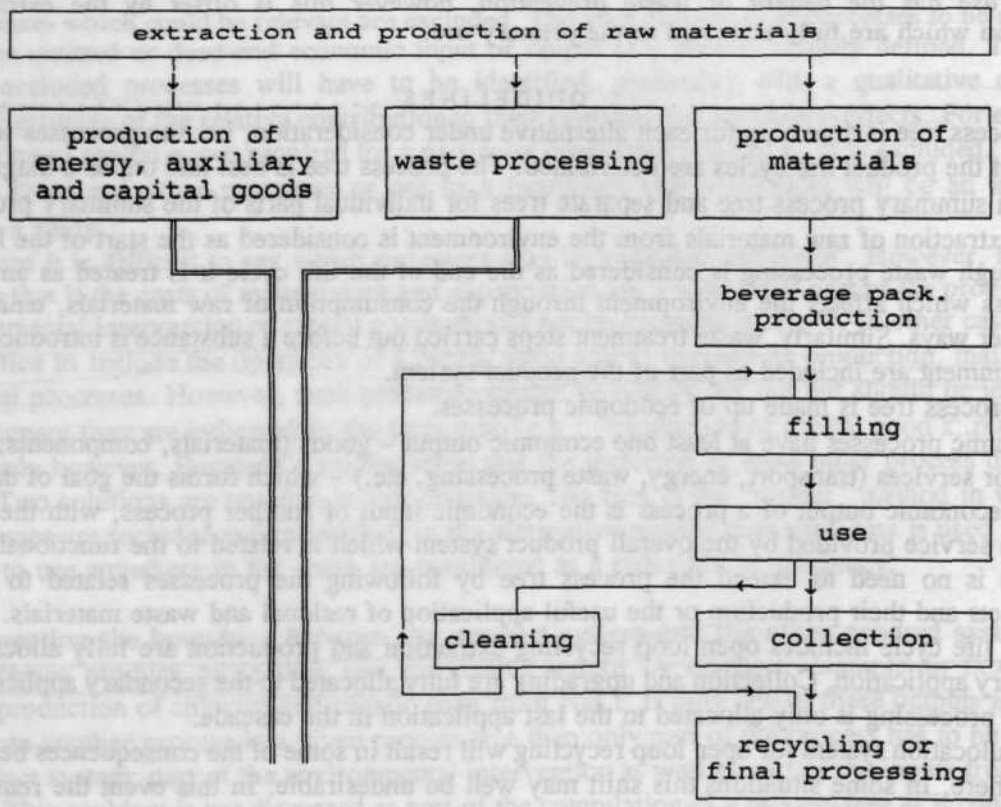


FIGURE 2.2. Summary process tree of the life cycle of beverage packaging. The double line ( ‖ ) represents the flow of energy, auxiliary and capital goods and waste processing services to all processes.

no references to a standard file for common processes the empirical data for the all processes concerned will have to be identified and included in the body of the document or in an appendix. The data should not be aggregated but refer to individual processes (i.e. at plant level) whenever possible.

There are two important aspects per process when presenting the process data:

- quantification of the inputs and outputs;
- the representativeness and quality of the data.

### 2.2.1 Quantification of the inputs and outputs

A special *format* has been developed for the specification and storage of process data. The format consists of a main structure (the *conceptual format*) and rules for entering the process data (the *technical format*). The main structure is based on the main characteristics of a process (see Figure 2.3): input from other economic processes and from the environment and output to other economic processes and to the environment. The conceptual format is illustrated in Table A.1 in Appendix A. The technical format falls beyond the scope of this study. This will also depend on the software used.

All economic processes in the process tree (see step 2.1) are connected by economic flows; when a flow leaves a process it is known as an *output*, when it enters a process it is an *input*. Hence the categories of economic inputs and outputs have to be fully symmetrical. These are: goods, services, materials, energy and waste to be processed. The distinction between these five types cannot always be clearly defined*, but these types of economic flows are largely intended to provide the user with a structure for the format. They also serve as a reminder: "remember to list the waste".

* The terms materials and goods cannot always be clearly delineated, energy can sometimes be considered as a service and it is not always clear whether or not a material is waste. It is not necessary to go to excessive lengths to assign everything to the right category. When a computer is used these categories would therefore have to be considered as a single category.

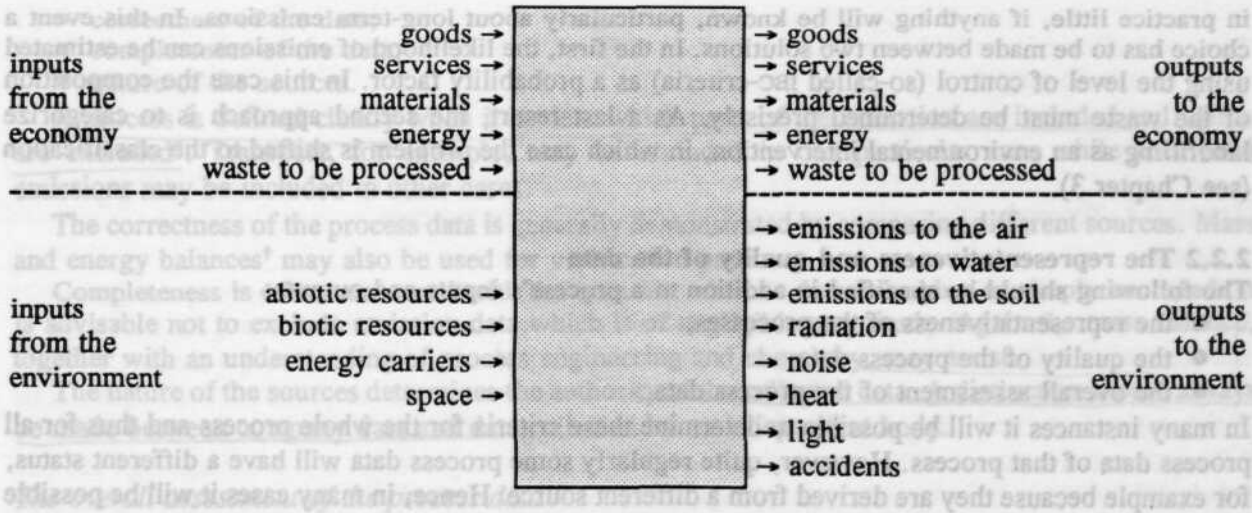


FIGURE 2.3. An economic proces is defined by the magnitude and composition of the flows to and from the economy and the environment.

The input from the environment consists of the extraction of resources (a distinction could be made between abiotic and biotic* resources and energy carriers) and space use. The output to the environment includes emissions of substances, radiation and noise. There are also environmental interventions of a more qualitative nature such as the fragmentation of ecosystems by road building programmes.

„Negative emissions" may occur, particularly in processes on the boundary between the economy and the environment. A production forest takes up $CO_2$ from the atmosphere. When the wood is burned in another process this $CO_2$ is released but it would be wrong to allocate the emissions from that process to a product system which includes forestry as well as the burning of wood. The reason for this is that there is an overall balance: the fixed $CO_2$ is released by the combustion. This can be achieved by including negative $CO_2$ in the forestry process. Processes such as soil clean-up also require special consideration. The removal of benzene from polluted soil is not described as the use of a resource but as a negative emission.

Many processes are non-linear in nature: the ratio between the production volume and the volume of emissions will depend on the production volume. As a life cycle assessment is based on a functional unit with an arbitrary magnitude for a given period the aim is not to consider short-term variations in a process but rather the overall changes in magnitude which may occur during a given period. It is best to use long-term marginal process data. In many cases these can be approximated by using the average process data during normal operations.

The type of presentation does not present any problems for most process data. Whenever possible SI units and notation should be used. For example mass should be expressed in kg, g, mg, μg, etc. Energy can be expressed in J, kJ, MJ, kWh, etc. (note the use of capitals). This document does not include guidelines on the use of decimal points or commas, exponential notation, and so on as this largely depends on the software used.

Some types of data will need conversion to take into account the time scale factor. For example, when noise is generated both the noise level, in dB and the time, in s, during which the noise is produced are relevant. The guidelines indicate how these two aspects can be combined. A similar approach applies to space use.

The inclusion of waste landfilling as an economic process in the process tree means that the process data must be known, i.e. it must be possible to predict emissions even over the long-term. However,

* Occasionally a distinction is made between renewable and non-renewable resources. However as this often leads to semantic confusion so the terms biotic and abiotic are used here. Again the exact categorization is irrelevant for the purposes of the inventory analysis. The categorization is important to the user as a reminder and to provide a structure.

in practice little, if anything will be known, particularly about long-term emissions. In this event a choice has to be made between two solutions. In the first, the likelihood of emissions can be estimated using the level of control (so-called IBC-criteria) as a probability factor. In this case the composition of the waste must be determined precisely. As a last resort, the second approach is to categorize landfilling as an environmental intervention, in which case the problem is shifted to the classification (see Chapter 3).

### 2.2.2 The representativeness and quality of the data

The following should be specified in addition to a process's inputs and outputs:

- the representativeness of the processes;
- the quality of the process data;
- the overall assessment of the process data.

In many instances it will be possible to determine these criteria for the whole process and thus for all process data of that process. However, quite regularly some process data will have a different status, for example because they are derived from a different source. Hence, in many cases it will be possible to make a single assessment which covers all the above criteria for the whole process, and provide specific information where the results of the assessment differ for some of the process data. The nature, quality and overall assessment of the process data can be included in the format together with the quantified process data (table A.1 on page 63).

*The representativeness of the processes*

The representativeness of each of the processes described should be indicated. This should include at least the following aspects:

- scale of the process;
- rough date of the process*;
- duration or capacity of the process;
- status of the process.

The scale indicates whether the selected processes represent a global, continental or national† average or whether the process is typical for the company concerned.

The date should provide an indication of the period for which the processes are representative‡, e.g. "1991" or "the '80s".

The capacity of a process or the time required to produce the volume described may be important as the characteristics of plants of different sizes may be markedly different. This applies not only to industrial processes but also, for example, to transport where there is no linear correlation between the emissions of a truck and its payload. The time required to produce a unit of material or a product is also relevant to some aspects of the inventory analysis (space, noise).

Finally the status indicates whether the process actually exists and has been measured or whether it is a design definition or a process for which an allocation has already been made to several commercial outputs§, or derived data (e.g. obtained through extrapolation). A combination of these terms could also apply.

*The quality of the process data*

The standards imposed on the process descriptions have to be specified. These aspects are:

- clarity of the process definition;

* The specification of the scale as well as the date of individual processes follows a similar approach as for the specification of the products investigated; see §1.3.2 and §1.3.3.

† These words should be interpreted flexibly, they serve only as an indication. For example many processes will be representative for the Western world or for the Northern part of the EC.

‡ Generally the time dimension should be excluded when drawing up a process tree. A hammer used to make a machine which makes a product in 1991 may have been made in 1970 but is also assumed to have been made in 1991.

§ See step 2.3 for the allocation of multiple processes. Generally it is not advisable (on the grounds of completeness and verifiability of the process data) to use allocated process data, but sometimes better data may not be available.

- correctness of the data;
- completeness of the data;
- nature of the sources.

A process is defined clearly when it is clear which parts of the operation are included and which are excluded*. Transport, for example, may be excluded in one particular case while accidental emissions may be included in other cases.

The correctness of the process data is generally demonstrated by comparing different sources. Mass and energy balances† may also be used for verification purposes.

Completeness is often concerned with the question whether data is lacking or simply excluded. It is advisable not to exclude emission data which is of negligible magnitude. Again the mass balance, together with an understanding of process engineering and chemistry, may assist.

The nature of the sources determines the authority of the collected data. A distinction should always be made between company data and data collected by an independent body.

*The overall assessment of the process data*

An overall assessment should be made of a set of process data. This should be based on a description of the representativeness and quality of the data described. When one of the above characteristics is unknown this will contribute most to a negative overall assessment. The assessment of the accuracy and completeness of the data in particular will determine the overall assessment.

GUIDELINES

- The data for all processes is collected and presented as shown in Table A.1. This includes both the input from and the output into other economic processes: the use and production of goods, materials, energy, services and waste to be processed. Other data includes flows to and from the environment in terms of raw materials, space use, and emissions of substances, noise, heat, etc.
- The nature and quality of the process data will be specified for each process. Data whose quality or representativeness does not match the general standard may have to be identified separately.
- Some processes have non-quantifiable aspects. These should also be included; the format makes special provision for them.
- Preferably, the long-term marginal process data should be collected. In many cases this data will be similar to the average process data during normal operations.
- Whenever possible numerical process data should be specified in SI units.
- Space use is a process parameter which requires a special conversion. It is expressed as a relationship between the area of the plant, its annual production and the consumption of a product or material. For a material whose quantity is expressed in kg this could be calculated as follows:

$$space\ use\,(m^2 \cdot yr) = material\ use\,(kg) \times \frac{area\,(m^2)}{annual\ production\,(kg \cdot yr^{-1})} \qquad (2.1)$$

  Thus space use is expressed in $m^2 \cdot s$ or $m^2 \cdot yr$.
- Noise is treated similarly:

$$noise\,(Pa^2 \cdot yr) = material\ use\,(kg) \times \frac{4 \cdot 10^{-10}\,(Pa^2) \times 10^{sound\ pressure\ level\,(dB)/10}}{annual\ production\,(kg \cdot yr^{-1})} \qquad (2.2)$$

  The unit is $Pa^2 \cdot s$ or $Pa^2 \cdot yr$.

* A product system which has been calculated in full can be included in the process file, in which event the economic part will only consist of the functional unit and the environmental part will consist of the inventory table obtained. A considerable amount of detailed information will have been lost by the aggregation of the process tree in a single process. Hence, the major assumptions (where the process tree is cut off, allocation method, etc.) will have to be specified.

† In the event that process data has already been allocated the mass and energy balances of the single process may be incomplete, unless the allocation was made on the basis of mass; see also step 2.3. This provides yet another reason to try to obtain process data in step 2.2 which is obtained empirically and not by allocation. The mass and energy balances should be complete when the allocated single processes are combined to form the original multiple process.

EXAMPLE

The production of PVC is shown as an example in Table 2.1. Note that the volume of waste is included as an economic output.

TABLE 2.1. Example of entering process data: PVC production process.

| | |
|---|---|
| 1 format | |
| 1.1 name or institute | Centre of Environmental Science |
| 1.2 date | 31-OCT-1992 |
| 1.3 comment | this is only an example! |
| 2 process | |
| 2.1 name or code | PVC production |
| 2.2 representativeness | |
| 2.2.1 scale | average situation in the Netherlands |
| 2.2.2 dating | mid 80's |
| 2.2.3 duration or capacity | large plant: approx. 10 Mton/year |
| 2.2.4 status | |
| 2.3 quality | |
| 2.3.1 clarity | no information available |
| 2.3.2 accuracy | very good data; externally checked |
| 2.3.3 completeness | minor gaps, which have been reconstructed |
| 2.4 sources | Registration of emissions (1989) |
| 2.5 overall assessment | good |
| 2.6 comment | emissions of thermal energy production included |
| 3 economic input | 9.28 MJ electrical energy (Netherlands electricity model) |
| 4 environmental input | |
| 4.1 resources | 0.468 kg oil |
| | 1.016 kg brine |
| 4.2 space | 2.3 $m^2 \cdot s$ |
| 5 economic output | 1 kg PVC |
| | 0.01 kg waste chlorine production |
| | 0.015 kg mixed waste (hazardous composition) |
| 6 environmental output | |
| 6.1 emissions to the air | 0.0014 kg vinylchloride |
| | 0.0017 kg 1-2-dichloroethane |
| | 0.0000003 kg Cl |
| | 0.0014 kg hydrocarbons |
| 6.2 emissions to water | 0.0003 kg 2-chloroethanol |
| | 0.0012 kg trichloroethanol |
| | 0.000019 kg phenol |
| 6.3 emissions to the soil | 0.0004 kg scrap |
| 6.4 radiation | none |
| 6.5 sound | unspecified, assumed to be negligible |
| 6.6 heat | approx. 9 MJ to air; none to water |
| 6.7 light | none |
| 6.8 accidents | approx. $10^{-15}$ victim |
| 7 balances | |
| 7.1 mass balancing item | 0.2 kg more input than output; maybe emitted as steam? |
| 7.2 energy balancing item | all missing energy assumed as emission of heat to air |
| 8 comment/other | plant attracts a lot of traffic, including many trucks at night |

BACKGROUNDS

§2.2 – the process data
§2.3 – the format

## 2.3 Application of the allocation rules

INTRODUCTION

Generally the process file will contain processes with more than one output with an economic value. In this event the processes may not have been defined at the most elementary level. If possible the data on the elementary processes should be collected during step 2.2. However, processes will remain for which this cannot be done, such as the combined production of fodder and pharmaceutics from abattoir waste. In such cases a calculation will have to be made, between entering the process data (step 2.2) and the aggregation to the inventory table (step 2.4) to distribute the environmental interventions of such a *multiple process* to the product system in question and the other product systems*. This step – step 2.3 – is known as *allocation*†. Using *allocation rules* the economic inputs and environmental interventions of such a process are divided among the co-products. Essentially allocation is used to split the actual multiple processes into a number of fictitious single processes. The sum of the single processes adds up to the multiple process.

There are three types of multiple processes:

- co-production (concurrent production of several materials, products, services, etc., including waste with a positive value);
- combined waste processing (concurrent processing of several waste flows with a negative value);
- open-loop recycling‡ (processing waste from one product system to material which can be reused in another product system).

These three types could also be considered as a single type, in which case the waste processing process should be considered a service, i.e. an output, and the status of services is similar to that of products§.

Two questions have to be answered for each multiple process to be allocated:

- what is allocated and to what?
- how is the allocation made?

In principle the aim is to make the allocation on a causal basis whenever possible. When this is impossible overall apportioned allocation has to be used, for which some basis will have to be found. For this purpose step 2.3 is divided into two sub-steps.

### 2.3.1 Causal allocation

An analysis of the causal relationships has to be made to answer the above two questions ("what and to what" and "how"). This analysis may be partly chemical-analytical and partly economic in nature as the causality may be either chemical or economic.

The causality is often of a physical nature. Zinc ore contains cadmium, hence zinc and cadmium are produced together and also emitted together. Hence the question arises whether cadmium emissions should be allocated to zinc or vice versa. Mercury emissions by waste incinerators can be allocated

* A process with more than one output with an economic value is sometimes referred to as a *multiple output process* (MO-process); in this case step 2.3 includes a transformation to a *single output process* (SO-process). The terms "outputs with an economic value", "commercial outputs" and "co-products" are equivalent.

† There is some confusion about the term allocation as it is commonly used in a wider context. According to some allocation is actually the issue at the heart of an LCA: which part of the environmental problems on Earth should be allocated to the functional unit under consideration?

‡ In practice a large part of the allocation problem associated with open-loop recycling will be covered in step 2.1 when the process tree is drawn up. In step 2.3 no more will be left than, for example, the distribution of an upgrading process among the two product systems, or the introduction of a degradation factor to quantify the deteriorating quality of the material.

§ In this way all types are reduced to the production of co-products. Hence the terms MO-process and SO-process are also used for the other two types. A more specific term is *multiple input process* (MI-process) or *input-output process* (IO-process), both of which are covered by the term *multiple process*.

to the mercury content of each mercury-containing product to be incinerated. However, $NO_x$ from the same incinerator depends on the calorific value of the products.

In other cases the causality is of an economic nature. Due to market forces processes are "adjusted" in a certain way. The price determines whether something is a material or waste: when there is a demand for the substance its price will be positive as it is a useful output.

The social or physical causality has to be investigated in each case as it is impossible to provide a uniform guideline. In principle, causal allocation may be used for the comprehensive analysis of combined waste processing. At present however, many aspects are unclear and in practice many emissions will require overall apportioned allocation.

### 2.3.2 Overall apportioned allocation

In many cases it may be difficult or even impossible to allocate all interventions properly through an analysis of the causal relationships. Electricity consumption for the co-production of chlorine and caustic soda provides an example of this. There is no obvious reason for allocating this parameter to just one of the co-products. Hence, it can be allocated to the co-production in the same way as a town council divides up certain costs per capita of the local population.

The function should be central to determining the basis for overall apportioned allocation. In many industrial processes it can be claimed that mass provides a good reflection of the function. For other processes this may be area (e.g. for galvanizing), number of items or another physical parameter. In other cases the economic value provides the best indication of the function as it provides a measure of the social causality*. An economic allocation key is also an obvious choice when the SI unit in which the function is expressed is different for some of the co-products.

GUIDELINES

- Allocations are made to outputs with a positive economic value (or, where there is no external market, which have a useful application). The other flows (flows to and from the environment, economic inputs and economic outputs of zero or negative value) are the items which are allocated.
- Whenever possible the causal links should be determined first in an analysis. In this way part of the allocation problem may be neatly solved.
- The remaining allocation problems are solved by overall apportioned allocation.
- If the outputs to which the allocations are made have different units the allocation has to be made on the basis of economic value.
- For co-production allocation is generally made to the relevant physical unit. Normally this will be the unit in which the outputs, to which the allocation is made, are expressed. Generally, this will be mass, although area is not unusual.
- If the economic values of the outputs differ greatly for each physical unit, the allocation is made on the basis of economic value.
- If the allocation key could be open to dispute, it is advisable to use two or more variations of the allocation and consider the difference between the results as a measure of the reliability (see step 4.2).

EXAMPLE

The electricity production process is combined with that of steam for district heating. Table 2.2 lists both the original process as well as the two allocated processes. As some of the steam finds a useful application but is not the main reason for operating the processes, the secondary flows were largely allocated to electricity on the basis of an economic value ratio of $3 \div 1$. The pipes were only allocated to the steam as they are mainly used to transport this. This is one of the reasons why heat emissions were fully allocated to the steam.

* In the co-production of pharmaceutics and animal fodder the pharmaceutics amount to more than 90% of the revenue while their share of the mass is less than 10%.

TABLE 2.2. Example of the allocation of process data: the secondary flows of the coproduction (first column) of electricity and steam are divided between the single processes (second and third columns).

| process parameter | multiple process | single process 1 | single process 2 |
|---|---|---|---|
| *economic inputs* | | | |
| km pipe | 0.2 | 0 | 0.2 |
| *environmental inputs* | | | |
| kg crude oil | 1.0 | 0.9 | 0.1 |
| *economic outputs* | | | |
| MJ electricity | 3 | 3 | 0 |
| MJ steam | 1 | 0 | 1 |
| *environmental outputs* | | | |
| kg $NO_x$ to the atmosphere | 1.0 | 0.9 | 0.1 |
| MJ heat to water | 0.2 | 0 | 0.2 |

BACKGROUNDS

§2.1 – the system boundaries

## 2.4 Creating the inventory table

INTRODUCTION

All environmental interventions of all processes for each functional unit of a product should be as fully quantified as possible. This will provide a large amount of data. For each process concerned there will be a list giving the magnitude of the direct environmental interventions of that process in proportion to that process's contribution to the functional unit. There will also be a list of all economic inputs and outputs required to make that contribution to the functional unit. These inputs and outputs define the relationships with the other processes. The section listing the environmental interventions is known as the *inventory table* of the process.

After step 2.1 the processes to be considered will be apparent. The data for each of these processes collected in step 2.2 is presented in its original state wherever possible. The decisions about allocation are made in step 2.3. All that is left in step 2.4 is to calculate the contribution of each process and present these processes in the correct ratios. By adding the inputs and outputs of all the processes concerned the environmental interventions of the complete product system can be determined. In this way the inventory table for the entire product system is defined. Any references made to *the* inventory table are to this table*.

By definition the product system will not have any inputs from or outputs to the economy after steps 2.1 to 2.4: all demand for and supply of products, materials, energy, services and waste to be processed has been translated to inputs from and outputs to the environment†. The only exception to this rule is the function performed by the product system itself, which is expressed in the functional unit. The product system itself can be described as a process, hence it can be fitted into the format (Table A.1). The natural choice is to use the same format, including the comments on the representativeness and quality of the data as determined in the goal definition.

* Another common term for this is eco-balance or environmental balance. It is advisable not to use these terms as they are sometimes used for the outcome of the classification (here: environmental profile). Furthermore, technically speaking, it is not actually a balance.

† Furthermore there are also the *p.m.* items which represent an interaction with the economy which is not zero but has been adjusted to zero.

It may be useful to divide the inventory table of the product or product system into sub-inventory tables relating to processes or substances. Providing further detail at the level of individual processes or groups of processes is particularly important when making recommendations for product improvement based on a dominance analysis (step 5.1). A distinction between the process groups in the summary process tree (step 2.1) is often required.

The following sub-steps can be distinguished:

- quantification of the environmental interventions;
- representation of the qualitative environmental interventions.

The overall outcome of the empirical inventory is a quantified overview, supplemented with non-quantifiable interventions, of all the environmental interventions which occur during the life cycle of a product.

### 2.4.1 Quantification of the environmental interventions

When the process tree is compiled the environmental interventions for each single process are calculated first by quantifying the process volume. For a good understanding of the backgrounds to the interventions it is recommended that the contribution of all specified processes is included as an appendix for each product alternative. This may produce a very large volume of data. An easy method has been developed in the backgrounds document to this guide by which the volume of the process, including that of networks and recursive processes can be calculated. It would be inappropriate to include this method (based on matrix algebra) in the guide.

### 2.4.2 Representation of the qualitative environmental interventions

All non-quantifiable information could be lost during the quantification step described above. This could include environmental interventions such as the fragmentation of areas by road construction which at present cannot be quantified. To include these aspects an item "qualitative aspects" will have to be included*. Often this item will not permit a clear distinction between the environmental intervention and the environmental impact. Strictly speaking the qualitative *interventions* should be included in step 2.4, while the resulting *impacts* should be included in step 3.3. In practice step 3.3 will involve a considerable repetition of step 2.4 or contain a reference to it.

GUIDELINES

- The quantitative occurrence of all processes in the process tree can be determined by drawing up mass and energy balances for each economic input: the sum of all occurrences in each process must be zero for each economic unit, with the exception of the process producing the functional unit.
- Thereafter the inventory table for the functional unit can be determined by calculating, for each environmental intervention, the sum of all the occurrences of these interventions.
- Additionally, all unquantified interventions for each process are combined and included in the inventory table of the functional unit.
- When a number of products are being compared and a conclusion can clearly be drawn by comparing the inventory tables, the classification and evaluation steps will not have to be carried out. However, the reliability and sensitivity of the result (step 4.2) will need to be determined.

EXAMPLE

This example provides an illustration of the matrix method discussed in the backgrounds document. This example is only relevant to readers interested in using the matrix method.

Table 2.3 includes the data for four processes and the kernel process representing the results of the complete product system.

When applied to the economic part of the process tree the matrix method results in

* Here qualitative is used as the opposite of quantitative, with the meaning "unquantifiable or only partly quantifiable".

TABLE 2.3. Four imaginary processes to illustrate the matrix method. Note that the processes are interconnected: electricity production requires aluminium and vice versa.

| process / entity | electricity production | aluminium production | aluminium foil production | aluminium foil use | kernel process |
|---|---|---|---|---|---|
| MJ electricity | 1 | −50 | −1 | 0 | 0 |
| kg aluminium | −0.01 | 1 | −1 | 0 | 0 |
| kg aluminium foil | 0 | 0 | 1 | −1 | 0 |
| 100 sandwich bags | 0 | 0 | 0 | 1 | 0.1 |
| kg bauxite | 0 | −5 | 0 | 0 | ? |
| kg crude oil | −0.5 | 0 | 0 | 0 | ? |
| kg $CO_2$ | 3 | 0 | 0 | 0 | ? |
| kg solid waste | 2 | 10 | 0 | 1 | ? |

$$A = \begin{bmatrix} 1 & -50 & -1 & 0 \\ -0.01 & 1 & -1 & 0 \\ 0 & 0 & 1 & -1 \\ 0 & 0 & 0 & 1 \end{bmatrix} \tag{2.3}$$

with determinant $\det(A) = 0.5$. Furthermore

$$A^1 = \begin{bmatrix} 0 & -50 & -1 & 0 \\ 0 & 1 & -1 & 0 \\ 0 & 0 & 1 & -1 \\ 0.1 & 0 & 0 & 1 \end{bmatrix} \tag{2.4}$$

hence the determinant $\det(A^1)$ equals 5.1. The occurrence of the first process is now described by

$$p_1 = \frac{\det(A^1)}{\det(A)} \tag{2.5}$$

and is therefore equal to 5.1/0.5 = 10.2. In the same manner the other determinants are found to be 0.01, 0.05 and 0.05 respectively and the other occurrences 0.202, 0.1 and 0.1 respectively.

Aggregation over the complete process tree results in the following environmental interventions

$$\beta = \begin{bmatrix} -1.01 \\ -5.1 \\ 30.6 \\ 22.52 \end{bmatrix} \tag{2.6}$$

This refers to the extraction of 1.01 kg bauxite and 5.1 kg crude oil, the emission of 30.6 kg $CO_2$ and the production of 22.52 kg solid waste.

A fairly simple example was chosen. Hence a more complicated example now follows as an example of an inventory table (the inventory table for milk cartons; Table 2.4).

TABLE 2.4. Example of the inventory table of a functional unit; the life cycle of a milk carton, the functional unit is "packaging 1 litre of milk".

| | |
|---|---|
| 1 format | |
| 1.1 name or institute | Centre of Environmental Science |
| 1.2 date | 31-OCT-1992 |
| 1.3 comment | this is only a hypothetical example! |
| 2 process | |
| 2.1 name or code | milk packaging in carton |
| 2.2 representativeness | |
| 2.2.1 scale | situation in the Netherlands, covering 30% of the market |
| 2.2.2 dating | around 1988 |
| 2.2.3 duration or capacity | average consumption rate: 1.5 day/consumer |
| 2.2.4 status | combination of estimated and empirical data |
| 2.3 quality | |
| 2.3.1 clarity | accidental emissions not included |
| 2.3.2 accuracy | overall clarity: sufficient |
| 2.3.3 completeness | most items present, emissions of CO2 have been deducted |
| 2.4 sources | calculated with data from SimaPro 1.0 |
| 2.5 overall assessment | a little out of date, but still reliable |
| 2.6 comment | this design does not refer to any actual product |
| 3 economic input | none (this is a life cycle) |
| 4 environmental inputs | |
| 4.1 resources | $9.9302 \cdot 10^{-4}$ kg apatite |
| | $7.4564 \cdot 10^{-4}$ kg coal |
| | $4.5919 \cdot 10^{-3}$ kg coating materials (considered as p.m.) |
| | $5.0600 \cdot 10^{-2}$ kg wood (notice that wood is considered here as a resource, whereas it is actually grown in a production forest) |
| 4.2 space | 5 $m^2 \cdot s$ (no information concerning type of space consumption) |
| 5 economic output | life cycle of 1 carton milk package |
| 6 environmental output | |
| 6.1 emissions to the air | $2.9080 \cdot 10^{-3}$ kg $CO_2$ |
| | $7.4392 \cdot 10^{-5}$ kg $NO_x$ |
| | $6.5580 \cdot 10^{-5}$ kg dust |
| | $1.4927 \cdot 10^{-5}$ kg hydrocarbons (unspecified) |
| 6.2 emissions to water | $2.1733 \cdot 10^{-7}$ kg $H_2S$ |
| | $2.0240 \cdot 10^{-6}$ kg aluminum |
| | $1.1056 \cdot 10^{-5}$ kg other pollutants (unspecified!) |
| | $8.8163 \cdot 10^{-6}$ kg total nitrogen |
| 6.3 emissions to the soil | $3.0245 \cdot 10^{-5}$ kg aluminium |
| | $4.2098 \cdot 10^{-4}$ kg ash |
| 6.4 radiation | no information available |
| 6.5 sound | 12 $Pa^2 \cdot s$ |
| 6.6 heat | 15.2 MJ to air |
| 6.7 light | no information available |
| 6.8 accidents | no information available |
| 7 balances | |
| 7.1 mass balancing item | none |
| 7.2 energy balancing item | none |
| 8 comments/other | some drying occurs during wood growth |

# CHAPTER 3

# CLASSIFICATION

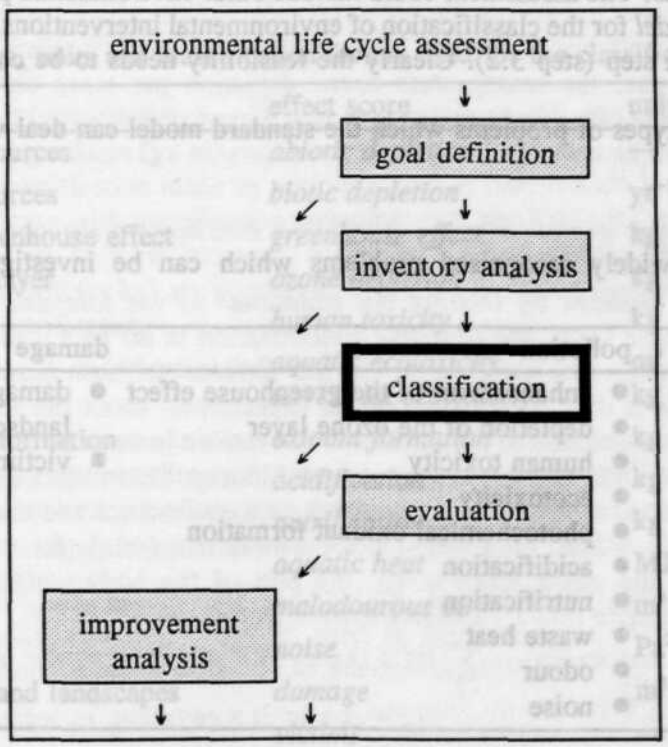


FIGURE 3.1. During the classification component of an LCA the potential environmental impact of interventions in the environment is determined.

Models are used to interpret the environmental interventions of a product (or rather a functional product unit). These models indicate how environmental interventions eventually lead to potential environmental effects. The environmental effects describe the contribution a functional unit of product makes to environmental problems. This includes environmental problems such as acidification, depletion of the ozone layer, etc. Eventually this results in the *environmental profile** of the product under consideration. During the classification the physical and other environmental interventions are projected onto the potential environmental effects in four steps:

- selection of the problem types (page 42);

* You are referred to footnote * on page 37 for other terms such as eco-balance.

- definition of the classification factors (page 43);
- creating the environmental profile (page 46);
- normalization of the effect scores (page 48).

Comprehensive guidelines have been drawn up for the first two steps. These provide a *standard model* for the classification. These steps provide the opportunity to deviate from the model provided the reasons for this are substantiated. The actual calculations are carried out during the third and fourth steps.

## 3.1 Selection of the problem types

INTRODUCTION

The problems which the assessment will address are selected in step 3.1. These will be exclusively *environmental* problems. The assessment could include other environmental problems than those used here. The *standard model* for the classification of environmental interventions as environmental effects is provided in the next step (step 3.2). Clearly the feasibility needs to be considered when selecting the type of problems.

Table 3.1 lists the types of problems which the standard model can deal with*.

TABLE 3.1. List of widely recognised problems which can be investigated with the standard classification model.

| depletion | pollution | damage |
|---|---|---|
| • depletion of abiotic resources<br>• depletion of biotic resources | • enhancement of the greenhouse effect<br>• depletion of the ozone layer<br>• human toxicity<br>• ecotoxicity<br>• photochemical oxidant formation<br>• acidification<br>• nutrification<br>• waste heat<br>• odour<br>• noise | • damage to ecosystems and landscapes<br>• victims |

GUIDELINES

- The provisional classification system is shown in Table 3.1. It indicates the environmental effects under consideration and which are to be used in step 3.2.
- If necessary, a different set may be chosen provided the reasons for this are given.

EXAMPLE

The standard classification model was largely followed in this study. However, due to lack of data the damage to ecosystems and landscapes has not been considered.

BACKGROUNDS

§3.1 – general principles

* As explained above this table lists environmental effects, not environmental interventions, such as energy consumption and waste production.

## 3.2 Definition of the classification factors

### INTRODUCTION

This section describes how the effect scores of the environmental effects listed in Table 3.1 can be calculated. The backgrounds document explains the range of models available to describe environmental processes. This section provides the standard model for the classification of environmental interventions as environmental effects. Classification models other than this standard model may be selected in step 3.2 of the life cycle assessment procedure. When another model is selected an explanation should be given in this step. The standard model specifies the environmental effects which should be considered in the assessment. The model is described in Table 3.2 and explained in the guidelines*. The calculations should be carried out as described in the guidelines unless good reasons have been given for departing from the standard model.

TABLE 3.2. Effect scores, units and classification factors used for the classification.

| environmental effect | effect score | unit | classification factor |
|---|---|---|---|
| depletion of abiotic resources | *abiotic depletion* | — | 1/reserves |
| depletion of biotic resources | *biotic depletion* | $yr^{-1}$ | BDF |
| enhancement of the greenhouse effect | *greenhouse effect* | kg | GWP |
| depletion of the ozone layer | *ozone depletion* | kg | ODP |
| human toxicity | *human toxicity* | kg | HCA, HCW, HCS |
| ecotoxicity | *aquatic ecotoxicity* | $m^3$ | ECA |
| | *terrestrial ecotoxicity* | kg | ECT |
| photochemical oxidant formation | *oxidant formation* | kg | POCP |
| acidification | *acidification* | kg | AP |
| nutrification | *nutrification* | kg | NP |
| waste heat | *aquatic heat* | MJ | 1 |
| odour | *malodourous air* | $m^3$ | 1/OTV |
| noise | *noise* | $Pa^2 \cdot s$ | 1 |
| damage to ecosystems and landscapes | *damage* | $m^2 \cdot s$ | 1 |
| victims | *victims* | — | 1 |

### GUIDELINES

- The depletion of abiotic raw materials is assessed by comparing the nett quantity used of each raw material with the reserves (Table B.1 on page 65) of that raw material. This produces a dimensionless expression:

$$abiotic\ depletion = \sum_i \frac{material\ use_i(\text{kg})}{reserves_i(\text{kg})} \qquad (3.1)$$

- The depletion of biotic raw materials is assessed by comparing the nett quantity used of each raw material with its reserves and its reserves/production-ratio. These two together provide a *biotic depletion factor* (BDF; Table B.2 on page 65). The result is an expression in $yr^{-1}$:

* The calculation method for some aspects has not yet been fully developed, or essential data to make the calculations is lacking. A temporary solution to some of these aspects is provided. Other aspects will have to be disregarded for the time being. The backgrounds document discusses how all these aspects may be implemented eventually.

$$\textit{biotic depletion}(\mathrm{yr}^{-1}) = \sum_i \textit{BDF}_i(\mathrm{kg}^{-1}\cdot\mathrm{yr}^{-1}) \times \textit{material use}_i(\mathrm{kg}) \qquad (3.2)$$

- For some substances which contribute to the enhancement of the greenhouse effect parameters have been developed in the form of a *global warming potential* (GWP; see Table B.3 on page 66). These parameters can be used to express the potential direct* contribution to the greenhouse effect in a single effect score. The GWP is a relative parameter which uses $CO_2$ as a reference†: the extent to which a mass unit of a given substance can absorb infrared radiation compared with a mass unit of $CO_2$. In this way atmospheric emissions (in kg) can be converted to $CO_2$ emissions (in kg) with an equivalent greenhouse effect:

$$\textit{greenhouse effect}(\mathrm{kg}) = \sum_i \textit{GWP}_i \times \textit{emission}_i \textit{ to the air}(\mathrm{kg}) \qquad (3.3)$$

- For some substances which contribute to the depletion of the ozone layer parameters have been developed in the form of an *ozone depletion potential* (ODP; see Table B.4 on page 67). These parameters can be used to express the potential contribution which these substances make to the depletion of the ozone layer in a single effect score. The ODP is a relative parameter which uses CFC-11 as a reference: the *steady state* ozone depletion per mass unit of gas emitted to the atmosphere per year is calculated relative to that of a mass unit of CFC-11. In this way atmospheric emissions (in kg) can be converted to CFC-11 emissions (in kg) resulting in an equivalent depletion of the ozone layer:

$$\textit{ozone depletion}(\mathrm{kg}) = \sum_i \textit{ODP}_i \times \textit{emission}_i \textit{ to the air}(\mathrm{kg}) \qquad (3.4)$$

- Human toxicity is assessed by relating the emissions‡ to the *tolerable daily intake* (TDI), the *acceptable daily intake* (ADI), the *tolerable concentration in air* (TCL), the *air quality guidelines*, the *maximum tolerable risk level* (MTR) or the *C-value for soil based on human toxicology considerations*. This is data from toxicological experiments about the maximum daily intake or concentration which is considered acceptable. A conversion is made so that emissions to water, the atmosphere and soil can be combined in an acceptable way. This results in the definition of *human toxicological classification factors* which depend on the substance and the environmental medium concerned (see Table B.5 on page 68): for the atmosphere (HCA), for water (HCW) and for soil (HCS). The unit of the effect score is kg: the part of the body weight in kg exposed to the toxicologically acceptable limit. This is calculated as follows:

$$\begin{aligned}\textit{human toxicity}(\mathrm{kg}) = \sum_i & \textit{HCA}_i(\mathrm{kg}\cdot\mathrm{kg}^{-1}) \times \textit{emission}_i \textit{ to the air}(\mathrm{kg}) + \\ & \textit{HCW}_i(\mathrm{kg}\cdot\mathrm{kg}^{-1}) \times \textit{emission}_i \textit{ to water}(\mathrm{kg}) + \\ & \textit{HCS}_i(\mathrm{kg}\cdot\mathrm{kg}^{-1}) \times \textit{emission}_i \textit{ to the soil}(\mathrm{kg})\end{aligned} \qquad (3.5)$$

- The assessment of substances with an ecotoxic effect on species in the ecosystem is based on *maximum tolerable concentrations* (MTCs) determined according to the EPA-method. This results in the definition of two groups of *ecotoxicological classification factors*: one for aquatic ecosystems (ECA) and one for terrestrial ecosystems (ECT); see Table B.6 on page 77. The unit of aquatic ecotoxicity is $m^3$ polluted water:

$$\textit{aquatic ecotoxicity}(\mathrm{m3}) = \sum_i \textit{ECA}_i(\mathrm{m}^3\cdot\mathrm{mg}^{-1}) \times \textit{emission}_i \textit{ to water}(\mathrm{mg}) \qquad (3.6)$$

and for terrestrial ecosystems, it is kg polluted soil:

* The indirect contribution is included as a qualitative aspect, see §3.3.1.

† In addition to $CO_2$ another reference gas which is commonly used is CFC-12. As CFC-11 is also used occasionally the term GWP should be used with some caution.

‡ In the context of this study it was proposed that the properties of toxic substances in the environment be included in the assessment. This has already been done with some other effect scores; for GWP for example, the degradation of the substance in the environment has also been considered. For human toxicity this results in the definition of a *human toxicity potential* (HTP) and a reference substance. However, HTP has not yet been implemented.

$$terrestrial\ ecotoxicity(\text{kg}) = \sum_i ECT_i(\text{kg·mg}^{-1}) \times emission_i\ to\ the\ soil(\text{mg}) \quad (3.7)$$

- *Photochemical ozone creation potential* parameters (POCP; see Table B.7 on page 83) have been developed* for some substances† which contribute to the formation of photochemical oxidants. These values can be used to express the potential contribution made by these substances to this problem as a single effect score. The POCP is a relative measure which uses ethylene ($C_2H_4$) as a reference: the extent to which a mass unit of a substance forms oxidants compared with a mass unit of ethylene. In this way atmospheric emissions (in kg) can be converted to ethylene emissions (in kg) with equivalent oxidant formation:

$$oxidant\ formation(\text{kg}) = \sum_i POCP_i \times emission_i\ to\ the\ air(\text{kg}) \quad (3.8)$$

- The contribution to acidification made by various forms of intervention in the environment can be determined by weighting with *acidification potentials* (AP; see Table B.8 on page 86) which are a measure of the propensity to release $H^+$ compared with sulfur dioxide ($SO_2$). Atmospheric emissions (in kg) are converted, using the AP, to sulfur dioxide emissions (in kg) resulting in equivalent acidification:

$$acidification(\text{kg}) = \sum_i AP_i \times emission_i\ to\ the\ air(\text{kg}) \quad (3.9)$$

- The contribution to nutrification made by various forms of intervention in the environment can be determined by weighting with *nutrification potentials* (NP; see Table B.9 on page 87) which are a measure of the capacity to form biomass, compared with phosphate ($PO_4^{3-}$). Emissions to the atmosphere, water or soil (in kg) are converted, using the NP, to an equivalent phosphate emission (in kg) in terms of nutrification:

$$nutrification(\text{kg}) = \sum_i NP_i \times emission_i(\text{kg}) \quad (3.10)$$

- Until the consequences of waste heat have been sufficiently determined, the release of heat, as a form of environmental intervention, can only be taken directly from the inventory analysis and aggregated. Only waste heat emissions into water are included:

$$aquatic\ heat(\text{MJ}) = energy\text{-}emissions_{water}(\text{MJ}) \quad (3.11)$$

- The odour threshold values in air (OTV; see Table B.10 on page 87) which have been determined for the most important substances can be used to assess odours. Atmospheric emissions are converted to the volume of air polluted up to the odour threshold:

$$malodourous\ air(\text{m}^3) = \sum_i \frac{emission_i\ to\ the\ air(\text{kg})}{OTV_i(\text{kg·m}^{-3})} \quad (3.12)$$

- To assess noise, sound production data from the inventory analysis are aggregated:

$$noise(\text{Pa}^2\text{·s}) = sound(\text{Pa}^2\text{·s}) \quad (3.13)$$

- As the exhaustive effects of space use are inextricably bound up with displacement effects, they are combined in a single effect score. A maximum of ten forms of intervention of this nature are collected during the inventory. At present categories I, II and III are considered "natural" and categories IV and V as "unnatural". Thus the ten forms of intervention are combined in a single effect score with the unit $m^2$·s:

* As the use of the POCP for this purpose is disputed, a further indication could be obtained by adding the quantities of VOC and $NO_x$ without further weighting; see step 4.2.

† No POCP has yet been defined for nitrogen oxides hence the quantity of $NO_x$ emitted is included separately as a "flag", see §3.3.1.

$$\begin{aligned} damage\,(m^2 \cdot s) = {} & space\ use_{I \to IV}(m^2 \cdot s) + \\ & space\ use_{I \to V}(m^2 \cdot s) + \\ & space\ use_{II \to IV}(m^2 \cdot s) + \\ & space\ use_{II \to V}(m^2 \cdot s) + \\ & space\ use_{III \to IV}(m^2 \cdot s) + \\ & space\ use_{III \to V}(m^2 \cdot s) \end{aligned} \qquad (3.14)$$

- In the inventory analysis processes hazards were determined as the number of fatalities directly attributable to an accident. This parameter is included in the classification without further weighting:

$$victims = number\ of\ victims \qquad (3.15)$$

EXAMPLE

The standard method was used for all problems listed in step 3.1. An effect score for radiation was also introduced by relating the data in the inventory analysis on radiation released to the *annual limit of intake* (ALI).

BACKGROUNDS

§3.1 – general principles
§3.2 – operationalisation
§3.3 – development of the classification factors

## 3.3 Creating the environmental profile

INTRODUCTION

An inventory table listing the environmental interventions associated with a functional unit of a product was drawn up during the inventory analysis. A table containing the potential environmental effects in the form of *effect scores* can now be drawn up by sorting, weighting and adding up all the interventions. The models in step 3.2 are used to sort and add up all the weighted data. The table of effect scores is known as the *environmental profile*. Besides the method described in the guide there are several other procedures for calculating effects on the basis of interventions, each based on different models and premises. The choice made in this guide may be debatable, therefore it has not been included in the inventory analysis, which should be as objective as possible*.

The environmental profile is created in two sub-steps:

- quantification of the environmental effects;
- representation of the qualitative environmental effects.

Often it is not only desirable to create an environmental profile for the product system but also to calculate it at the level of processes or groups of processes, or substances or groups of substances. Thus creating the environmental profile is very similar to drawing up the inventory table (step 2.4).

### 3.3.1 Quantification of the environmental effects

Once the modelling choices have been made (see step 3.2) calculating the effect scores and creating the environmental profile are relatively easy. The formulas described in step 3.2 or defined by the user are applied to all the environmental interventions in the inventory table, to calculate the potential contribution of each environmental effect in the environmental profile.

Often the quantified effect scores will be presented as a graph as well as in a table. The contribution of the various process groups to each effect score is easily visualized in a bar graph by

* However, the reason for separating the inventory analysis and classification is the fact that the subjects of the study, and therefore the disciplines concerned, are different. The inventory analysis is about economic processes while the classification is about environmental processes.

building each bar up with different colours or shading. The most widely used product or the highest effect score can be used as the 100% level in a bar graph. However, there are also some disadvantages. A graphical representation may assist in the comprehension of information but this will only be from a certain perspective. It is easy to create the wrong impression. For example the worst product alternative could be set at 100% as a result of which all other alternatives will appear to be about equally good. This can be improved by using a logarithmic scale but this often leads to problems of interpretation. It will have to be decided in each individual case whether some form of normalization or the use of a logarithmic scale provides an acceptable form of presentation.

A graph could also result in an implicit evaluation: "five longer bars and three shorter bars means that there is an increase", without a discussion of the relative significance of the different problems.

### 3.3.2 Representation of the qualitative environmental effects

Besides the quantified effects there are also unquantifiable effects. This is initially due to the unquantified environmental interventions (see step 2.4) in the inventory table. The second cause is that it is not possible to model all quantified interventions in step 3.2. For example, some substances are known to be toxic but there is no further information available about their toxicity. Thus, they cannot be quantified with the standard model. The GWP of some greenhouse gases is under discussion because their direct contribution has been excluded (see Table B.3). The use of the POCP is also being discussed. We recommend that the total (unweighted) quantities of VOC and $NO_x$ are listed as additional information.

Such cases can be included in the qualitative part of the environmental profile. This information may put the bar graphs referred to above in a completely different light. However, this should be considered in the evaluation rather than in the classification.

#### GUIDELINES

- The standard classification model (possibly amended or extended) is applied to the quantitative part of the inventory table.
- Forms of intervention which may contribute to more than one effect (CFC emissions for example contribute to the greenhouse effect as well as to ozone depletion) are included more than once.
- The qualitative aspects of the inventory table appear as a qualitative part of the environmental profile, wherever possible in the form of effects.
- It is preferable not to use graphs at this stage as they may give the wrong impression or depend solely on the choice of scale used in the graphs.
- Caution is advised when discussing the environmental profile, otherwise the classification could include an implicit evaluation.
- When products are being compared it may happen that all effect scores and all qualitative aspects point in the same direction. In such an event there will be no need to take steps 3.4 and 4.1. However, the reliability and validity will have to be considered; see step 4.2.

#### EXAMPLE

Table 3.3 lists the fictitious environmental profiles for two types of desk chair.

Notes:

- the process data on wood production was very incomplete;
- VOC emissions are estimates, hence the effect score for oxidant formation is rather unreliable;
- the inventory analysis provided no data on noise, space use and victims.

#### BACKGROUNDS

§3.1 – general principles

TABLE 3.3. Example of an environmental profile: comparison of two desk chairs.

| effect score | desk chair 1 | desk chair 2 |
|---|---|---|
| *abiotic depletion* | 0.10 | 0.11 |
| *biotic depletion* ($yr^{-1}$) | 0 | 0 |
| *greenhouse effect* (kg) | 12 | 17 |
| *ozone layer depletion* (kg) | 0 | 0.002 |
| *human toxicity* (kg) | 13.2 | 9.2 |
| *aquatic ecotoxicity* ($m^3$) | 0.03* | 0.01 |
| *terrestrial ecotoxicity* (kg) | 0.02 | 0.03 |
| *oxidant formation* (kg) | $1 \cdot 10^{-7}$ | $3 \cdot 10^{-8}$ |
| *acidification* (kg) | 1.1 | 2.7 |
| *nutrification* (kg) | 2.3 | 3 |
| *malodourous air* ($m^3$) | $3 \cdot 10^{-5}$ | $1 \cdot 10^{-5}$ |
| *noise* ($Pa^2 \cdot s$) | ? | ? |
| *damage* ($m^2 \cdot s$) | ? | ? |
| *victims* | ? | ? |

* Uncertain due to the lack of some classification factors.

## 3.4 Normalization of the effect scores

INTRODUCTION

It is difficult to interpret the effect scores which constitute the environmental profile. The reason for this is that the order of magnitude and units of the various effect scores differ. Strictly speaking, it is not necessary to interpret the effect scores in the classification, rather this task should be undertaken during the evaluation. Nevertheless, a step has still been included in which the effect scores, and thus the environmental profile, become more meaningful by adding purely empirical information.

The effect scores are normalized in this step. The contribution made by a given product to an environmental effect is linked to the contribution made by a given community to the same problem over a given period of time. The scale of the community considered here should match the model on which the classification is based. For the global standard model this means that the global contribution over a certain period is calculated using the same classification model. The period of time used to calculate the contribution is irrelevant as this is expressed in the resulting unit. Generally the contribution over a year can be obtained from annual statistical reports or other sources.

The ratio between each effect score and the global contribution to that effect score over a year provides the *normalized environmental profile* consisting of *normalized effect scores*, all of which are expressed in years.

The normalization of the effect scores has not been included in this guide as it was not possible to calculate all global contributions in accordance with the standard model. In principle this should not be too difficult: data is available for a range of effect scores (depletion of abiotic resources, enhanced greenhouse effect, depletion of the ozone layer). However, this is much more difficult for effects lower down on the scale (toxicity, noise). As a temporary solution the normalization could be based on the quantities for e.g. the Netherlands.

GUIDELINES

- To make the effect scores of the environmental profile more meaningful they can be normalized by relating them to the magnitude of the problem in a given period. For this purpose the same classification model should be used as that used to draw up the environmental profile; the difference being that the magnitude of the environmental intervention in one year, for example, is

used as the input data rather than the magnitude of the environmental intervention of a single functional unit. This results in a normalized environmental profile, comprising a number of normalized effect scores all with the unit yr. For an effect score expressed in kg this results in:

$$\textit{normalized effect score}\,(\mathrm{yr}) = \frac{\textit{effect score}\,(\mathrm{kg})}{\textit{annual volume}\,(\mathrm{kg \cdot yr^{-1}})} \qquad (3.16)$$

- Although these normalized effect scores have the same unit they should never be added to each other in the classification.
- While information about the global magnitude of the effect scores is not available, the magnitude in e.g. the Netherlands alone will have to be used.
- As it will continue for some time to be difficult to obtain all the required information for the normalization this step will often have to be dispensed with.

EXAMPLE

The environmental profile used in the preceding step was normalized. Table 3.4 lists the scale of the (purely fictitious) global contributions and the normalized effect scores.

TABLE 3.4. Example of a normalized environmental profile: the example used in the preceding step was normalized using fictitious data about global volumes in one year.

| normalized effect score | desk chair 1 | desk chair 2 |
|---|---|---|
| *abiotic depletion* (yr) | $8.0 \cdot 10^{-7}$ | $8.8 \cdot 10^{-7}$ |
| *biotic depletion* (yr) | 0 | 0 |
| *greenhouse effect* (yr) | $3.6 \cdot 10^{-11}$ | $5.1 \cdot 10^{-11}$ |
| *depletion of the ozone layer* (yr) | 0 | $3.0 \cdot 10^{-15}$ |
| *human toxicity* (yr) | $6.1 \cdot 10^{-9}$ | $4.6 \cdot 10^{-9}$ |
| *aquatic ecotoxicity* (yr) | $3.0 \cdot 10^{-7}$* | $2.0 \cdot 10^{-7}$ |
| *terrestrial ecotoxicity* (yr) | $2.0 \cdot 10^{-12}$ | $3.0 \cdot 10^{-12}$ |
| *oxidant formation* (yr) | $1.0 \cdot 10^{-17}$ | $3.0 \cdot 10^{-18}$ |
| *acidification* (yr) | $5.5 \cdot 10^{-4}$ | $1.35 \cdot 10^{-3}$ |
| *nutrification* (yr) | $4.6 \cdot 10^{-8}$ | $6.0 \cdot 10^{-8}$ |
| *malodourous air* (yr) | $6.0 \cdot 10^{-14}$ | $2.0 \cdot 10^{-14}$ |
| *noise* (yr) | ? | ? |
| *damage* (yr) | ? | ? |
| *victims* (yr) | ? | ? |

* Unclear due to the lack of some classification factors.

BACKGROUNDS

§3.1 – general principles

# CHAPTER 4

# EVALUATION

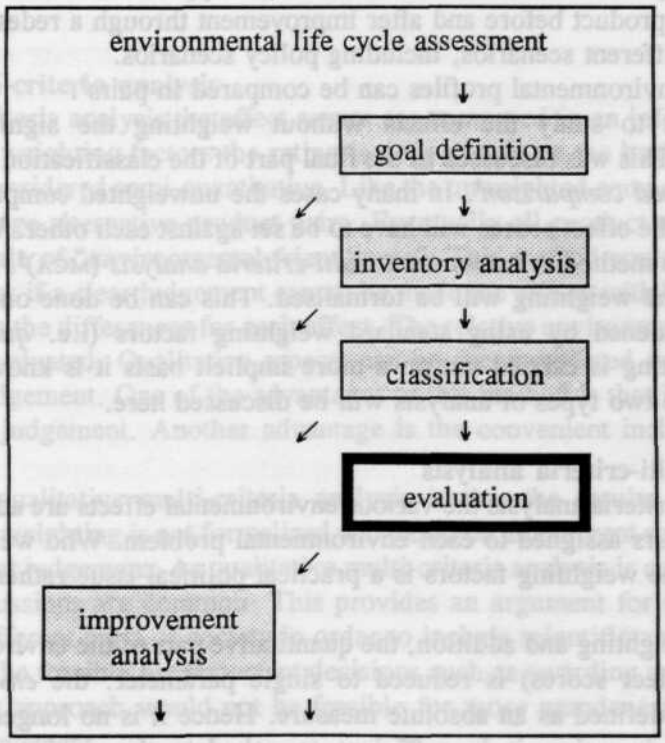


FIGURE 4.1. During the evaluation the results of the classification are evaluated in two respects: the effect scores are weighted or weighed, and the reliability is examined.

The potential environmental effects of the products can be evaluated on the basis of the environmental profiles drawn up during the classification. The relative magnitudes of the effect scores are an important element in this. The validity of the environmental profiles is also relevant to the evaluation. The environmental profile should always be evaluated, unless a product alternative has a higher or lower score for all effects (see step 3.3). However, even in this case the validity will still need to be considered.

Thus the evaluation consists of two steps:

- evaluation of the environmental profile (page 52);
- evaluation of the reliability and validity (page 54).

During the first step the effect scores in the environmental profiles of each product alternative are assessed. Two methods for this assessment will be discussed: quantitative multi-criteria analysis and

qualitative multi-criteria analysis. Each of these methods has its own advantages and disadvantages. In step 4.2 the outcome of the evaluation will be examined in the context of the reliability and validity of all steps carried out during the life cycle assessment. This may result in a refinement of the conclusion. Therefore this step should not be omitted in the evaluation of an environmental profile, even when it is not necessary to weight or weigh the effect scores.

## 4.1 Evaluation of the environmental profile

INTRODUCTION

Evaluation of the different environmental profiles drawn up during the classification will generally involve a comparison*:

- comparison of a number of products;
- comparison of a product with a standard for official approval or an ecolabel;
- comparison of a product before and after improvement through a redesign;
- comparison of different scenarios, including policy scenarios.

In all these cases the environmental profiles can be compared in pairs†.

The first option is to study the effects without weighting the significance of the various environmental effects. This was discussed as the final part of the classification (step 3.3), where it was referred to as *unweighted comparison*‡. In many cases the unweighted comparison will not result in a clear conclusion and the effect scores will have to be set against each other. When the environmental effects are weighted the method is known as a *multi-criteria analysis* (MCA)§. If the weighting factors are explicitly defined the weighting will be formalised. This can be done on an *ad hoc* basis or the validity could be broadened by using standard weighting factors (i.e. *quantitative multi-criteria analysis*). If the weighting is carried out on a more implicit basis it is known as *qualitative multi-criteria analysis*. These two types of analysis will be discussed here.

### 4.1.1 Quantitative multi-criteria analysis

In a quantitative multi-criteria analysis the various environmental effects are added after multiplication with the weighting factors assigned to each environmental problem. Who weights the environmental effects or determines the weighting factors is a practical political issue rather than a methodological matter.

As a result of the weighting and addition, the quantitative part of the environmental profile (which consists of a set of effect scores) is reduced to single parameter: the *environmental index*. The environmental index is defined as an absolute measure. Hence it is no longer necessary to compare environmental profiles in pairs, it is sufficient to calculate the environmental index for each environmental profile and to arrange them on an interval scale¶.

One of the advantages of this method is that the result is reproducible and does not depend on experts' estimates. However this requires a consensus about the weighting factors used. Given a standard set of weighting factors the method is also quick and cheap.

A major disadvantage of quantitative multi-criteria analysis is that it is difficult to deal with the

* The most important application of LCA which is not included here is in innovation. During the improvement analysis (Chapter 5) recommendations for a redesign are made on the basis of an understanding of the process tree and the environmental effects. Improvements due to these recommendations can then be assessed in a comparative LCA (see Figure 5.2).

† The comparison of $N$ products will require at most $\frac{1}{2}N(N-1)$ paired comparative assessments. This number will often be smaller due to the transitive properties of an ordinal scale: when it is known that product A is worse than product B and that product B has a poorer score than product C it is clear that product A will also be inferior to product C.

‡ This is often referred to as *dominance analysis*. However in this report this term is reserved for the analysis in step 5.1.

§ Alternative terms include multi-criteria method and multi-criteria evaluation.

¶ There is no ratio scale since there is no proper origin; this is because many choices have been made, about the inclusion of capital goods and the selection of relevant environmental effects, for example.

qualitative aspects. These qualitative aspects may be regarded as unquantified increases or decreases in the effect scores. As they are unquantified they can only be included as qualitative aspects in the environmental index as a comment on the number. One way of dealing with qualitative aspects is to provide a rough quantitative indication and evaluate the sensitivity of the result.

Another disadvantage, this time of a more psychological nature, is that the creation of an environmental index might suggest scientific accuracy. However, due to the methodological choices made in the goal definition, inventory analysis, classification and evaluation the outcome has gradually become less objective.

However, the main problem associated with quantitative multi-criteria analysis is the definition of the weighting factors. The backgrounds document gives the technical requirements which the weighting factors must meet and the solutions available. This report does not provide any weighting factors. However, it will be an interesting challenge to attempt to develop the basis provided in the background document and eventually to provide a set of weighting factors like the classification factors which reflect current scientific and social values. This set could be included as an appendix to the next version of this guide.

### 4.1.2 Qualitative multi-criteria analysis

In a qualitative multi-criteria analysis the effect scores are compared in an informal way. This means that instead of defining weighting factors the rating is done purely on the basis of expert judgement. This method could be considered semi-quantitative. Like the unweighted comparison, this method will generally be used to judge alternative product pairs. Eventually all product alternatives can then be plotted on an ordinal scale of "environmental-friendliness". This method could be used subsequent to unweighted comparisons: if a clear judgement cannot be made the effects with higher and lower scores are considered as well as the differences for each effect. The relative environmental-friendliness of two products can then be evaluated. Qualitative aspects can be accommodated without difficulty in this individual subjective judgement. One of the advantages of this method is that it will almost always be possible to arrive at a judgement. Another advantage is the convenient inclusion of all qualitative aspects.

A disadvantage of qualitative multi-criteria analysis is that the results will often be open to discussion. Because the weighting is not formalized and based on an inherent subjectivity someone else could arrive at a different judgement. As qualitative multi-criteria analysis is currently the most widely used method such discussions are common. This provides an argument for setting up a panel with representatives from different parts of society in order to include scientific and social opinions in the judgement. This would be feasible for important decisions such as awarding an official environmental approval. However this approach would not be feasible for more mundane applications such as in-company product improvement.

There are many different ways to judge effect scores. The simplest method is by crossing them off ("three higher effects and five lower effects works out as less"). A more thorough approach would be to use a semi-quantitative scale, for example by ranging the differences from $---$ to $+++$, and calculating the net result. The disadvantage of these methods is that there is no link with the seriousness of the problems. Extremely abstract parameters such as kg CFC-11 equivalent and moles $H^+$ are used in the calculations and an approach in which more of one is offset by less of another leads to very odd conclusions. An example of this is provided by a comparison of landfilling and incinerating waste. Incineration produces dioxins but landfilling results in less energy recovery. Besides using normalization* making a comparison on the basis of a scientifically or socially accepted level could be considered. This would demonstrate that waste incineration is responsible for a large part of the dioxin production while the recovered energy amounts to only a small proportion of the overall energy consumption. This does not result in a weighting of the problems but at least the abstract parameters in the environmental profile have been replaced by aspects of a problem whose consequences are known to some extent. In this way the evaluation can be made on a more responsible

* To be able to make a better estimate of the significance of these differences it was suggested that the effect scores be compared with the global magnitude of the problem in step 3.4.

basis.

The advantages and disadvantages of quantitative and qualitative MCA are listed in Table 4.1 and compared with the advantages and disadvantages of unweighted comparisons.

TABLE 4.1. Each method for the evaluation of environmental profiles has advantages and disadvantages in terms of its application and validity.

| | unweighted comparison | qualitative MCA | quantitative MCA |
|---|---|---|---|
| convincing | − | + | + |
| includes qualitative aspects | + | + | − |
| reproducible | + | − | + |
| less open to discussion | + | − | □ |

Legend: +: yes; □: moderately; −: no.

GUIDELINES

- There are two methods for the evaluation of environmental profiles: quantitative and qualitative multi-criteria analyses. Quantitative multi-criteria analysis is preferable as it provides greater transparency but at present it is only used to a limited extent, if at all.
- As the evaluation will, for the time being, mostly be undertaken through qualitative multi-criteria analysis, the highest possible level of transparency should be aimed for. Hence, the reasons for preferring one product alternative over another will have to be specified in discussion.

EXAMPLE

As an unweighted comparison of the effect scores in the previous example (step 3.4) did not result in a conclusion and as weighting factors are not yet available, an informal weighting was provided by a panel including representatives of the client and those undertaking the assessment (see step 1.2 for a list of those involved). The panel's view was that alternative 1 is better for more effect scores but that the scores in which 2 does better are more important (toxicity!). However, the major contribution to acidification made by both alternatives means that the lesser of the two (1) is preferred.

BACKGROUNDS

§4.1 – quantitative multi-criteria analysis

## 4.2 Evaluation of the reliability and validity

INTRODUCTION

The reliability and validity of the results of the life cycle assessment will be assessed during this step. Reliability depends on the influence of uncertainty in the data. Validity is about the effects of choices and assumptions. These two subjects will be discussed separately in the sensitivity analysis:

- reliability analysis;
- validity analysis.

This step examines the value of the calculations and conclusions made in previous steps. This may affect all components (goal definition, inventory analysis, classification and evaluation). For example, it may be that the functional unit was not defined accurately enough in the goal definition, the quality of process data affects the inventory analysis, the classification depends on the choice of standards and the evaluation depends on the weighting factors. In many cases a sensitivity analysis can be used to

convert uncertainties to variations and sub-variations of the product system. If this does not affect the results of the life cycle assessment this indicates that the reliability is high.

Uncertain assumptions are made in all components of a life cycle assessment. These uncertainties affect the end results and in some cases they may result in drastic changes in the conclusion. Hence it is advisable to make an early estimate of certain uncertainties and to determine the stability of the results through a sensitivity analysis. The guidelines below show how, and during which steps of an LCA, this can be done.

### 4.2.1 Reliability analysis

A reliability analysis is used to determine the effects of uncertainties in the data. It is worthwhile to attempt to obtain estimates of the uncertainty margins of some process data. Such information about some classification factors is listed in the tables in Appendix B. A mathematical method to calculate the effects of these uncertainties has been developed in the backgrounds document. If the basic information required (such as the uncertainty of the process data) is known this method can be used systematically to determine the reliability of the outcome.

Marginal analysis (see also backgrounds document and step 5.2) can identify the process data whose magnitude has a major effect on the results. It is advisable to employ marginal analysis to determine the crucial process data and then to ensure that this data is as accurate as possible.

### 4.2.2 Validity analysis

Validity analysis is used to estimate the validity of the result in view of the assumptions and choices made during the course of the project. This includes choices and assumptions associated with the method (e.g. the decision to allocate open-loop recycling to two product systems in a particular way) as well as choices and assumptions associated with the study itself (e.g. the number of times return packaging is actually returned). There are many assumptions and choices. It would be impossible to include a complete list of important topics here. The guidelines and backgrounds document contain some examples.

Another option is an analysis of the reversal points. During such an analysis a choice is changed until the conclusion is reversed. A reversal may be defined as the point where the other alternative suddenly becomes more environmentally friendly, for example by varying the life span of a product. The likelihood of this life span can then be discussed. Missing classification factors can also be determined artificially in this way in order to discuss the effects of the absence of these classification factors.

GUIDELINES

- The functional unit may be formulated differently in the goal definition. For example, in a comparison of plastic coffee cups and porcelain cups, the calculations could be performed for cups with and without saucers.
- During the inventory analysis the exact definition of the system boundary in step 2.1 should not be relevant, so the inclusion of capital goods, for example, should not change the conclusion.
- In step 2.2 – when the process data are collected – there are generally some uncertainties included in the data. The aim is to provide a clear presentation by using the format and by estimating the quality of the data. However, the data will often be obtained from indefinite sources. In this step the estimate of the quality of individual process data, which in step 2.2 was converted to an estimate of the reliability of the complete data set, is extended to provide an estimate of the reliability of the inventory table or the environmental profile.
- The allocation rules used will also affect the outcome. Wherever possible it may be useful to assess the influence of alternative allocation rules.
- Soundly-based scientific knowledge about the effects of emissions, etc. is used for the classification. In practice, there is often a problem in that substances are released for which there is no information available about their harmful effects. In such cases a value may be determined by analogy with related substances. Alternatively, the magnitude of the harmful effect may be determined at which the conclusion of the study changes, after which the acceptability of this value can be discussed.

- This method can also be used in the evaluation of the weighting factors. By determining the magnitude of the weighting factors at which the conclusion changes, the sensitivity of the results to these factors can be assessed.
- For some of the process data there are estimates of its uncertainty in the form of margins, e.g. $12 \pm 2$. The range of the data is also known for some classification factors. The backgrounds document discusses a method requiring extensive calculations to determine the effects of these uncertainties on the inventory table, the environmental profile and the environmental index.
- A method of determining the influence of marginal changes in the process data has been developed for the improvement analysis (step 5.2). This method provides information about changes in the inventory table, environmental profile or environmental index as a function of such changes in the process data. However, this method can also be used to investigate which process data must be most accurately defined because a marginal change could have such a major impact.
- In view of the reliability analysis, it is better to estimate an unknown data item than to omit it. The reliability analysis may well show that the item is of minor importance but the insignificance of the actual value of the item can then be demonstrated even more clearly.

### EXAMPLE

The uncertainty of the process data is not known. A marginal analysis shows that there is only one process parameter where a minor inaccuracy has an amplified effect: a 1% uncertainty in the energy consumption of the production process of PE results in a 3.2% uncertainty of the effect score for acidification. Verification through other sources confirms the magnitude of the process parameter.

When an alternative which can be used repeatedly is returned 40 times instead of 30 times the conclusions do not alter significantly. Between 40 times and 121 times (unrealistic), only the effect score for the depletion of the ozone layer reverses. It is likely that the lack of a classification factor for some of the emitted substances has little effect on the toxicity effect scores.

You are referred to the appendix for a discussion of the numerical method. In general the evaluation of the environmental profile will be relatively insensitive to variations in the most obvious parameters.

### BACKGROUNDS

§4.2 – sensitivity analysis
§5.2 – marginal analysis

# CHAPTER 5

# IMPROVEMENT ANALYSIS

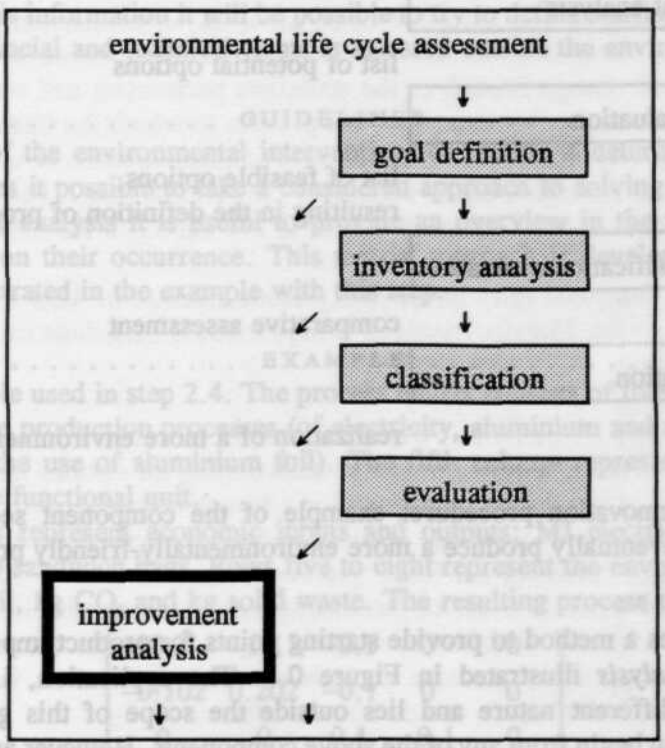


FIGURE 5.1. In the improvement analysis the information gathered during the inventory analysis, classification and evaluation is used to provide starting points for product improvement.

As discussed in the introduction a life cycle assessment may be used for a range of applications: product information, regulation, product innovation and the development of policy strategies. All these applications involve a *decision* which is not exclusively based on environmental considerations. This extends beyond the field of environmental life cycle assessment and requires the application of other disciplines such as consumer research, process engineering, cost-benefit analysis, etc. As shown in Figure 0.1 the guide does not include the analysis of other aspects and applications.

Product improvement is more complicated. An understanding of the process tree, of the processes concerned from the extraction of raw materials to all their emissions and the potential environmental effects to which the environmental interventions contribute provides *starting points* for product improvement. Once it is established which processes and substances make a significant contribution to the environmental profile an effective search can be made to find a more environmentally-friendly

redesign or for process modifications. Other skills will then be needed to assess the feasibility of these recommendations. This will then lead to a decision which is taken partly on the basis of the environmental LCA. Process engineers, economists and market specialists will have to judge whether the suggestions are feasible in technical, financial and marketing terms. Product improvement is a cyclic process: any improvements suggested will have to be assessed in the light of their effectiveness. It is always possible to look for other options for product improvement. Figure 5.2 provides an example for a life cycle assessment procedure for product innovation.

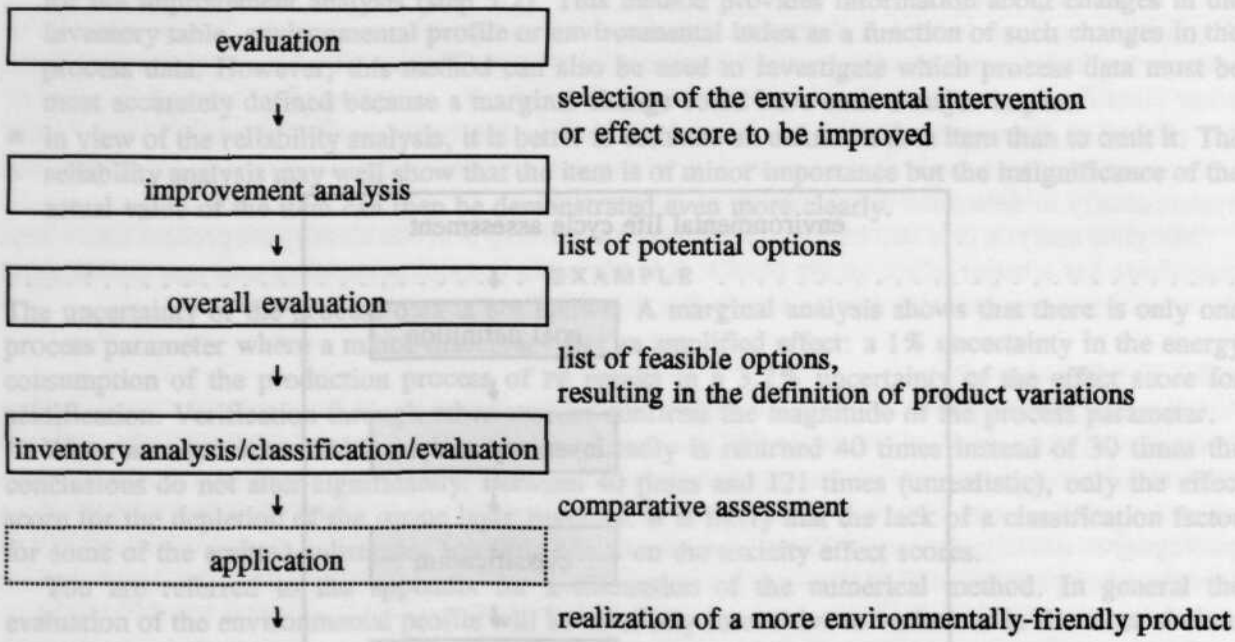


FIGURE 5.2. Product innovation procedure: example of the component sequence in a life cycle assessment which will eventually produce a more environmentally-friendly product.

This chapter describes a method to provide starting points for product improvement. This method is the *improvement analysis* illustrated in Figure 0.1. The application, i.e. the actual *product improvement*, is of a different nature and lies outside the scope of this guide. In principle, an improvement analysis can begin from any of the above components. However an improvement analysis is unlikely to start at the goal definition. The reason for this is that the product properties in the goal definition do not provide enough information about the interaction between the product system and the environmental system. The inventory table and the environmental profile however, provide excellent bases for an improvement analysis. The improvement analysis can be divided into two supplementary analysis techniques:

- dominance analysis (page 58);
- marginal analysis (page 60).

These methods will be discussed below.

## 5.1 Dominance analysis

### INTRODUCTION

A dominance analysis is used to identify those substances and processes responsible for a substantial part of the environmental interventions, environmental effects or the environmental index. Knowledge of these dominant aspects provides a starting point for the redesign of more environmentally-friendly products. Examples include:

- the use of less material;
- the use of alternative materials;
- changing process engineering aspects;
- logistical changes;
- etc.

During the inventory analysis a process tree was drawn up in step 2.1. Normally this will be a summary process tree which includes sub-process trees. Comprehension may be aided by subdividing the inventory table, environmental profile or environmental index at the process level. This can be done using a *process matrix* which provides an overview of all the processes and all data and its occurrences. Dominant aspects of the inventory table may be revealed by studying the environmental part of this matrix. The volume of data could be reduced to a manageable level through aggregation by process groups as used in the summary process tree, i.e. by creating an inventory table or environmental profile for the production stage, the usage stage, maintenance, etc.

The parts of the life cycle where the major problems occur can be identified quickly with this method. Armed with this information it will be possible to try to define starting points. The feasibility of the indicators in financial and technical terms is assessed outside the environmental LCA.

### GUIDELINES

- The "true origin" of the environmental interventions or effects is determined in the dominance analysis which makes it possible to take a considered approach to solving a problem.
- During a dominance analysis it is useful to provide an overview in the form of a matrix of all process data based on their occurrence. This matrix approach is developed in the backgrounds document. It is illustrated in the example with this step.

### EXAMPLE

We return to the example used in step 2.4. The process matrix consists of five columns. The first four columns represent three production processes (of electricity, aluminium and aluminium foil) and one consumptive process (the use of aluminium foil). The fifth column represents the fully aggregated process resulting in the functional unit.

The first four rows represent economic inputs and outputs: MJ electricity, kg aluminium, kg aluminium foil and 100 sandwich bags. Rows five to eight represent the environmental interventions: kg bauxite, kg crude oil, kg $CO_2$ and kg solid waste. The resulting process matrix looks like this:

$$\begin{bmatrix} 10.2 & -10.1 & -0.1 & 0 & 0 \\ -0.102 & 0.202 & -0.1 & 0 & 0 \\ 0 & 0 & 0.1 & -0.1 & 0 \\ 0 & 0 & 0 & 0.1 & 0.1 \\ 0 & -1.01 & 0 & 0 & -1.01 \\ -5.1 & 0 & 0 & 0 & -5.1 \\ 30.6 & 0 & 0 & 0 & 30.6 \\ 20.4 & 2.02 & 0 & 0.1 & 22.52 \end{bmatrix} \quad (5.1)$$

Most of the waste (22.52 kg) is due to electricity production (20.4 kg, i.e. about 90%). The economic section also shows that the production of aluminium accounts for the largest share (10.1 MJ, i.e. 99%) of the electricity consumption (10.2 MJ).

Improvements in the subsequent design process may be found in a different choice of material for the functional unit, improving the efficiency of the aluminium production process, the use of a different energy source for aluminium production and waste reduction during electricity production.

### BACKGROUNDS

§5.1 – dominance analysis

## 5.2 Marginal analysis

### INTRODUCTION

A dominance analysis clearly shows the processes or emissions which are largely responsible for high effect scores. One of the problems associated with dominance analysis is that changes in the economic inputs and outputs of a process are not easily traced. When an economic process parameter is changed it implies that a number of processes in the process tree are used to a greater or lesser extent. As a result a minor change in an economic process parameter can have a major effect on the inventory table; a greater effect than would be expected from the dominance analysis. Obviously some economic process parameters could be changed and the complete inventory table recalculated. This would be time consuming and would be incompatible with the method of systematic process improvement described. However, the information provided by the quantified process tree can be used to undertake a *marginal analysis*, which provides information about the effects of marginal process changes on the inventory table.

The crux of the method is that marginal changes in an environmental intervention (inventory analysis), environmental effect (classification) or the environmental index (evaluation) are studied as a function of the marginal change in each of the economic parameters and environmental parameters of the processes. This illustrates the changes in the process to which the intervention, effect or index is most sensitive. In this way the inventory table, environmental profile or environmental index may be improved considerably through a small change in the process data*. The method shows where a small modification will have a major effect. Whether or not this small modification can be carried out easily is a different matter.

Marginal analysis is described fully in the backgrounds document. This form of analysis requires a large number of calculations. Marginal analysis is impractical unless these calculations can be carried out by a computer program.

### GUIDELINES

- In theory marginal analysis is a powerful tool in determining the options for product improvement. The method has yet to prove itself in practice. It is a new development which has still to be applied and assessed. The approach is described in detail in the backgrounds document.
- An effective method of handling the large quantity of numbers is to make a list in which the calculated numbers are listed in order of decreasing magnitude (in absolute terms).
- There is a close link with the reliability analysis in step 4.2: process data in which small changes may have major consequences are also process data which have to be calculated extremely accurately. Hence marginal analysis should also be used carefully.

### EXAMPLE

Marginal analysis was applied to the example in step 2.4 and step 5.1. Solid waste ($k = 4$) was selected as the environmental intervention. The elements calculated were included in a matrix:

$$\begin{bmatrix} -1.902 & 1.883 & 0.019 & 0 & 0 \\ 0.996 & -1.973 & 0.977 & 0 & 0 \\ 0 & 0 & -0.996 & 0.996 & 0 \\ 0 & 0 & 0 & -1.000 & 1 \\ 0 & 0 & 0 & 0 & 0 \\ 0 & 0 & 0 & 0 & 0 \\ 0 & 0 & 0 & 0 & 0 \\ 0.906 & 0.090 & 0 & 0.004 & 1 \end{bmatrix} \quad (5.2)$$

The largest number, in absolute terms, is $-1.973$ which refers to the quantity of aluminium created

* The numbers obtained are approximations which are only valid if the marginal change is small.

by the aluminium production process. This means that if the efficiency of the process is increased by 1% the total volume of waste will be reduced by approximately 1.9%.

BACKGROUNDS

§5.2 – marginal analysis

## APPENDIX A

# FORMAT FOR STORING PROCESS DATA

This appendix describes the conceptual format for the storage of process data. Technical specifications concerning decimal points, record length, etc. are not included.

TABLE A.1. Main structure of the format. The shaded level gives an optional further subdivision of the preceding level. The decimal classification may be used for simple references.

| level 1 | level 2 | level 3 | code |
|---|---|---|---|
| format | name or institute | | 1.1 |
| | date | | 1.2 |
| | comment | | 1.3 |
| process | name or code | | 2.1 |
| | representativeness | scale | 2.2.1 |
| | | date | 2.2.2 |
| | | duration | 2.2.3 |
| | | status | 2.2.4 |
| | quality | clarity | 2.3.1 |
| | | accuracy | 2.3.2 |
| | | completeness | 2.3.3 |
| | sources | | 2.4 |
| | overall assessment | | 2.5 |
| | comment | | 2.6 |
| economic input | | | 3 |
| | goods | | 3.1 |
| | services | | 3.2 |
| | materials | | 3.3 |
| | energy | | 3.4 |
| | waste to be processed | | 3.5 |
| environmental input | resources | | 4.1 |
| | | abiotic resources | 4.1.1 |
| | | biotic resources | 4.1.2 |
| | | energy carriers | 4.1.3 |

| level 1 | level 2 | level 3 | code |
|---|---|---|---|
| | space | | 4.2 |
| economic output | | | 5 |
| | goods | | 5.1 |
| | services | | 5.2 |
| | materials | | 5.3 |
| | energy | | 5.4 |
| | waste to be processed | | 5.5 |
| environmental output | emissions to air | | 6.1 |
| | emissions to water | | 6.2 |
| | emissions to soil | | 6.3 |
| | radiation | | 6.4 |
| | sound | | 6.5 |
| | heat | | 6.6 |
| | light | | 6.7 |
| | accidents | | 6.8 |
| balances | mass balancing item | | 7.1 |
| | energy balancing item | | 7.2 |
| comments/other | | | 8 |

# APPENDIX B

# CLASSIFICATION FACTORS

This appendix contains tables with classification factors to indicate how the classification is carried out according to the standard model. The formulas to be used are also repeated. You are referred to the guidelines in step 3.2 for an explanation of how to use the tables.

## B.1 Depletion

### B.1.1 Depletion of abiotic resources

TABLE B.1. Classification factors for the effect score abiotic depletion.

| formula | substance | reserves | unit |
|---|---|---|---|
| *energy carriers* | | | |
| — | crude oil | 123,559 | Mton |
| — | natural gas | 109,326 | $10^9$ m$^3$ |
| U | uranium | 1,676,820 | ton |
| *metals* | | | |
| Cd | cadmium | 0.535 | Mton |
| Cu | copper | 350 | Mton |
| Pb | lead | 75 | Mton |
| Hg | mercury | 0.005,7 | Mton |
| Ni | nickel | 54 | Mton |
| Sn | tin | 4.260 | long Mton |
| Zn | zinc | 147 | Mton |

Recoverable reserves of abiotic resources whose reserves may become insufficient within 100 years. Source: *World Resources Institute* (1990-1991). The effect score for the depletion of abiotic resources is calculated as follows:

$$abiotic\ depletion = \frac{material\ use\,(\mathrm{kg})}{reserves\,(\mathrm{kg})} \qquad (B.1)$$

### B.1.2 Depletion of biotic resources

TABLE B.2. Classification factors for the depletion of biotic resources.

| species | BDF |
|---|---|
| black rhino | $4 \cdot 10^{-5}$ |
| great indian elephant | ? |
| northern white rhino | ? |
| sumatran rhino | ? |
| african elephant | $4 \cdot 10^{-8}$ |
| Kemp's Ridley sea turtle | ? |
| chinese alligator | ? |
| cuban crocodile | ? |
| estuarine crocodile | ? |
| morelet's crocodile | ? |
| siamese crocodile | ? |
| sperm whale | $2 \cdot 10^{-6}$ |
| humpback whale | $1 \cdot 10^{-7}$ |
| fin whale | $2 \cdot 10^{-5}$ |
| blue whale | ? |

*Biotic depletion factor* (BDF) in $yr^{-1}$ for a number of animal species threatened with extinction. Sources: World Resources Institute, 1990: *World Resources 1990-1991. A report by the World Resources Institute in collaboration with the United Nations Environment Programme and the United Nations Development Programme.* Oxford University Press, New York/Oxford; World Wildlife Fund, 1990: *Atlas of the environment. The most up-to-date report on the state of the world.* Arrow Books Ltd., London. The effect score for biotic depletion is calculated with:

$$\textit{biotic depletion}(yr^{-1}) = \textit{BDF}(yr^{-1}) \times \textit{species use} \qquad \text{(B.2)}$$

## B.2 Pollution

### B.2.1 Enhancement of the greenhouse effect

TABLE B.3. Classification factors for the effect score greenhouse effect.

| formula | substance | $GWP_{20}$ | $GWP_{100}$ | $GWP_{500}$ | indirect |
|---|---|---|---|---|---|
| $CO_2$ | carbon dioxide | 1 | 1 | 1 | 0 |
| $CH_4$ | methane | 35 | 11 | 4 | + |
| $N_2O$ | dinitrogen oxide | 260 | 270 | 170 | 0 |
| $CFCl_3$ | trichlorofluoromethane (CFC-11) | 4,500 | 3,400 | 1,400 | – |
| $CF_2Cl_2$ | dichlorodifluoromethane (CFC-12) | 7,100 | 7,100 | 4,100 | – |
| $CF_3Cl$ | chlorotrifluoromethane (CFC-13) | 11,000 | 13,000 | 15,000 | – |
| $CF_4$ | tetrafluoromethane (CFC-14) | >3,500 | >4,500 | >5,300 | 0 |
| $CHF_2Cl$ | chlorodifluoromethane (HCFC-22) | 4,200 | 1,600 | 540 | – |
| $C_2F_3Cl_3$ | 1,1,2-trichloro-1,2,2-trifluoroethane (CFC-113) | 4,600 | 4,500 | 2,500 | – |
| $C_2F_4Cl_2$ | 1,2-dichlorotetrafluoroethane (CFC-114) | 6,100 | 7,000 | 5,800 | – |
| $C_2F_5Cl$ | chloropentafluoroethane (CFC-115) | 5,500 | 7,000 | 8,500 | – |
| $C_2F_6$ | hexafluoroethane (CFC-116) | >4,800 | >6,200 | >7,200 | 0 |
| $CHCl_2CF_3$ | 1,1-dichloro-2,2,2-trifluoroethane (HCFC-123) | 330 | 90 | 30 | – |

| formula | substance | $GWP_{20}$ | $GWP_{100}$ | $GWP_{500}$ | indirect |
|---|---|---|---|---|---|
| $CHFClCF_3$ | 1-chloro-1,2,2,2-tetrafluoroethane (HCFC-124) | 1,500 | 440 | 150 | – |
| $CHF_2CF_3$ | pentafluoroethane (HFC-125) | 5,200 | 3,400 | 1,200 | 0 |
| $CH_2FCF_3$ | 1,1,1,2-tetrafluoroethane (HFC-134a) | 3,100 | 1,200 | 400 | 0 |
| $CH_3CFCl_2$ | 1,1-dichloro-1-fluoroethane (HCFC-141b) | 1,800 | 580 | 200 | – |
| $CH_3CF_2Cl$ | 1-chloro-1,1-difluoroethane (HCFC-142b) | 4,000 | 1,800 | 620 | – |
| $CH_3CF_3$ | 1,1,1-trifluoroethane (HFC-143a) | 4,700 | 3,800 | 1,600 | 0 |
| $CH_3CHF_2$ | 1,1-difluoroethane (HFC-152a) | 530 | 150 | 49 | 0 |
| $CCl_4$ | tetrachloromethane (HC-10) | 1,800 | 1,300 | 480 | – |
| $CH_3CCl_3$ | 1,1,1-trichloroethane (HC-140a) | 360 | 100 | 34 | – |
| $CF_3Br$ | bromotrifluoromethane (HALON-1301) | 5,600 | 4,900 | 2,300 | – |
| $CHCl_3$ | trichloromethane (chloroform) | 92 | 25 | 9 | – |
| $CH_2Cl_2$ | dichloromethane | 54 | 15 | 5 | – |
| CO | carbon monoxide | – | – | – | + |
| – | non-methane hydrocarbons (NMHC) | – | – | – | + |
| $NO_x$ | nitrogen oxides | – | – | – | 0 |

*Global warming potential* (GWP) relative to $CO_2$, with time horizons of 20, 100 and 500 years. The last column provides a qualitative indication of the indirect contribution to the greehouse effect: +: positive indirect contribution; −: negative indirect contribution; 0: no indirect contribution. Source: Houghton, J.T., B.A. Callander & S.K. Varney, 1992: *Climate change 1992. The supplementary report to the IPCC scientific assessment.* Cambridge University Press, Cambridge. The effect score of the greenhouse effect is calculated with:

$$\textit{greenhouse effect}(\text{kg}) = \textit{GWP} \times \textit{emission to the air}(\text{kg}) \tag{B.3}$$

### B.2.2 Depletion of the ozone layer

TABLE B.4. Classification factors for the effect score ozone depletion.

| formula | substance | ODP | range |
|---|---|---|---|
| $CFCl_3$ | trichlorofluoromethane (CFC-11) | 1.0 | 1.0-1.0 |
| $CF_2Cl_2$ | dichlorodifluoromethane (CFC-12) | 1.0 | 0.88-1.06 |
| $C_2F_3Cl_3$ | 1,1,2-trichloro-1,2,2-trifluoroethane (CFC-113) | 1.07 | 0.92-1.07 |
| $C_2F_4Cl_2$ | 1,2-dichlorotetrafluoroethane (CFC-114) | 0.8 | 0.57-0.82 |
| $C_2F_5Cl$ | chloropentafluoroethane (CFC-115) | 0.5 | 0.29-0.5 |
| $CHF_2Cl$ | chlorodifluoromethane (HCFC-22) | 0.055 | 0.032-0.08 |
| $CHCl_2CF_3$ | 1,1-dichloro-2,2,2-trifluoroethane (HCFC-123) | 0.02 | 0.013-0.020 |
| $CHFClCF_3$ | 1-chloro-1,2,2,2-tetrafluoroethane (HCFC-124) | 0.022 | 0.016-0.034 |
| $CH_3CFCl_2$ | 1,1-dichloro-1-fluoroethane (HCFC-141b) | 0.11 | 0.10-0.12 |
| $CH_3CF_2Cl$ | 1-chloro-1,1-difluoroethane (HCFC-142b) | 0.065 | 0.035-0.07 |
| | HCFC-225ca | 0.025 | 0.016-0.025 |
| | HCFC-225cb | 0.033 | 0.023-0.033 |
| $CCl_4$ | tetrachloromethane (HC-10) | 1.08 | 1.03-1.15 |
| $CH_3CCl_3$ | 1,1,1-trichloroethane (HC-140a) | 0.12 | 0.11-0.13 |
| $CF_3Br$ | bromotrifluoromethane (HALON-1301) | 16 | 10.0-17.2 |
| $CF_2BrCl$ | bromochlorodifluoromethane (HALON-1211) | 4 | 1.8-5.0 |

| formula | substance | ODP | range |
|---|---|---|---|
| | HALON-1202 | 1.25 | 1.25-1.7 |
| $C_2F_4Br_2$ | dibromotetrafluoroethane (HALON-2402) | 7 | 5.9-10.2 |
| | HALON-1201 | 1.4 | 1.4-1.4 |
| | HALON-2401 | 0.25 | 0.25-0.4 |
| | HALON-2311 | 0.14 | 0.14-0.3 |
| $CH_3Br$ | | 0.6 | 0.44-0.7 |

*Ozone depletion potential* (ODP) relative to CFC-11, with an indication of the range. Source: World Meteorological Organization, 1991: *Scientific assessment of ozone depletion: 1991.* Global Ozone Research and Monitoring Project – Report no. 25. The ozone depletion effect score is calculated with:

$$\textit{ozone depletion}\,(\text{kg}) = \textit{ODP} \times \textit{emission to the air}\,(\text{kg}) \qquad \text{(B.4)}$$

### B.2.3 Human toxicity

TABLE B.5. Classification factors for the effect score human toxicity.

| formula | substance | HCA | HCW | HCS |
|---|---|---|---|---|
| *metals* | | | | |
| As | arsenic | 4,700 | 1.4 | 0.043 |
| Ba | barium | 1.7 | 0.14 | 0.019 |
| Cd | cadmium* | 580 | 2.9 | 7.0 |
| $Cr^{3+}$ | chromium(III) | 6.7 | 0.57 | 0.018 |
| $Cr^{6+}$ | chromium(VI) | 47,000 | 4,100 | 130 |
| Co | cobalt | 24 | 2.0 | 0.065 |
| Cu | copper | 0.24 | 0.020 | 0.005,2 |
| Fe | iron | 0.042 | 0.003,6 | |
| | (excluding iron oxides) | | | |
| | iron oxides | 0.067 | 0.005,7 | |
| Pb | lead | 160 | 0.79 | 0.025 |
| Mn | manganese | 120 | | |
| Hg | mercury | 120 | 4.7 | 0.15 |
| | methylmercury (as Hg) | 120 | 7.1 | 0.15 |
| Mo | molybdenum | 3.3 | 0.29 | 0.70 |
| Ni | nickel | 470 | 0.057 | 0.014 |
| Sn | tin | 0.017 | 0.001,4 | 0.000,045 |
| V | vanadium | 120 | | |
| Zn | zinc | 0.033 | 0.002,9 | 0.007,0 |
| *inorganic compounds* | | | | |
| $NH_4^+$ | ammonium | 0.020 | 0.001,7 | |
| | asbestos | † | | |
| $Br^-$ | bromide | 0.033 | 0.002,9 | |
| | calcium disodium-EDTA | 0.013 | 0.001,1 | |
| CO | carbon monoxide | 0.012 | | |

| formula | substance | HCA | HCW | HCS |
|---|---|---|---|---|
| $CN^-$ | cyanide (free) | 0.67 | 0.057 | 1.4 |
| | cyanide (bound in complex; as CN) | 2.6 | 0.22 | 5.4 |
| | EDTA | → calcium disodium-EDTA | | |
| $F^-$ | fluoride | 0.48 | 0.041 | |
| $H_2S$ | hydrogen sulfide | 0.78 | | |
| $NO_3^-$ | nitrate | 0.009,1 | 0.000,78 | |
| $NO_2^-$ | nitrite | 0.26 | 0.022 | |
| $NO_x$ | nitrogen oxides‡ | 0.78 | | |
| | phosphates (excluding sodium aluminium-phosphate; as P) | 0.000,48 | 0.000,041 | |
| | sodium aluminium phosphate | 0.005,6 | 0.000,48 | |
| $SO_3^{2-}$ | sulfite | 0.038 | 0.003,3 | |
| | sulfur dioxide (combined with black (coal) smoke) | 2.3 | | |
| $SO_2$ | sulfur dioxide§ | 1.2 | | |
| $SCN^-$ | thiocyanate | 3.0 | 0.26 | 6.4 |
| *unhalogenated aromatic hydrocarbons* | | | | |
| $C_6H_6$ | benzene | 3.9 | 0.66 | |
| | catechol | → 1,2-dihydroxybenzene | | |
| | cresols | 0.67 | 0.057 | 0.46 |
| $C_6H_4(OH)_2$ | dihydroxybenzenes (general) | 1.3 | 0.11 | |
| | 1,2-dihydroxybenzene (catechol) | 0.83 | 0.071 | 1.4 |
| | 1,3-dihydroxybenzene (resorcinol) | 1.7 | 0.14 | 2.8 |
| | 1,4-dihydroxybenzene (hydroquinone) | 1.3 | 0.11 | 2.4 |
| $C_6H_5C_2H_5$ | ethylbenzene | 1.5 | 0.021 | 0.15 |
| | hydroquinone | → 1,4-dihydroxybenzenes | | |
| | 2-hydroxybiphenyl | → 2-phenylphenol | | |
| $C_6H_5OH$ | phenol | 0.56 | 0.048 | 0.62 |
| $C_6H_4C_5H_5OH$ | 2-phenylphenol (2-hydroxybiphenyl) | 1.7 | 0.14 | |
| | phthalates (general) | 1.3 | 0.11 | |
| | di(2-ethyl)hexylphthalate | 1.3 | 0.11 | 0.002,9 |
| | butylbenzylphthalate | 1.3 | 0.11 | 0.092 |
| $C_5H_5N$ | pyridine | 33 | 2.9 | 31 |
| | resorcinol | → 1,3-dihydroxybenzenes | | |
| $C_6H_5CHCH_2$ | styrene (vinylbenzene) | 0.15 | 0.037 | 0.17 |
| $C_6H_5CH_3$ | toluene | 0.039 | 0.006,6 | 0.098 |
| | vinylbenzene | → styrene | | |

| formula | substance | HCA | HCW | HCS |
|---|---|---|---|---|
| | xylenes | 2.2 | 0.29 | 1,5 |
| *halogenated aromatic hydrocarbons* | | | | |
| | chlorobenzenes (general) | 0.19 | 5.7 | |
| $C_6H_5Cl$ | monochlorobenzene | 0.11 | 0.009,5 | 0.073[1] |
| $C_6H_4Cl_2$ | 1,2-dichlorobenzene | 0.19 | 0.004,8 | |
| $C_6H_4Cl_2$ | 1,4-dichlorobenzene | 0.097 | 0.015 | 0.042[1] |
| $C_6H_3Cl_3$ | 1,2,4-trichlorobenzene | 0.19 | 5.7 | 6.8 |
| $C_6H_2Cl_4$ | 1,2,3,4-tetrachlorobenzene | 0.19 | 5.7 | 3.9 |
| $C_6HCl_5$ | pentachlorobenzene | 0.19 | 5.7 | 2.9 |
| $C_6Cl_6$ | hexachlorobenzene | 0.19 | 5.7 | 2.6 |
| | chlorophenols (general; excluding pentachlorophenol) | 11 | 0.95 | 0 |
| $C_6H_4ClOH$ | 2-monochlorophenol | 11 | 0.95 | 4.5 |
| $C_6H_3Cl_2OH$ | 2,4-dichlorophenol | 11 | 0.95 | 2.1 |
| $C_6H_2Cl_3OH$ | 2,3,4-trichlorophenol | 11 | 0.95 | 1.3[1] |
| $C_6HCl_4OH$ | 2,3,4,5-tetrachlorophenol | 11 | 0.95 | 2.9[1] |
| $C_6Cl_5OH$ | pentachlorophenol (PCP) | 1.1 | 0.095 | 0.98[1] |
| | dioxin | → 2,3,7,8-TCDD | | |
| | PCP | → pentachlorophenol | | |
| | polychlorobiphenyls (general) | 370 | 32 | |
| $C_6H_3Cl_2C_6H_4Cl$ | 2,5,2-trichlorobiphenyl | 370 | 32 | 13 |
| $C_{12}H_4Cl_6$ | hexachlorobiphenyl | 370 | 32 | 7.6 |
| $(C_6H_2Cl_2)_2O_2$ | 2,3,7,8-TCDD (2,3,7,8-tetrachlorodibenzo-p-dioxin; „dioxin") | 3,300,000 | 290,000 | |
| | TEQ (2,3,7,8-TCDD-toxicity equivalents) | 3,300,000 | 290,000 | |
| *polycyclic aromatic hydrocarbons (PAHs)* | | | | |
| | anthracene | 0.67 | 0.057 | 0.000,45 |
| | benzo(a)anthracene | 1.7 | 0.14 | 0.001,3 |
| | benzo(k)fluoroanthene | 1.7 | 0.14 | 0.001,2 |
| | benzo(ghi)perylene | 1.7 | 0.14 | 0.001,1 |
| | benzo(a)pyrene | 17 | 1.4 | 0.013 |
| | chloro-PAH (general) | 67 | 5.7 | |
| | chloronaphthalene | 67 | 5.7 | 7.2[1] |
| | chrysene | 17 | 1.4 | 0.33 |
| | fluoroanthene | 1.7 | 0.14 | 0.066 |
| | indeno(1,2,3,c,d)pyrene | 1.7 | 0.14 | 0.001,1 |
| | naphthalene | 0.7 | 0.057 | 0.11[1] |
| | phenanthrene | 1.7 | 0.14 | 0.11 |
| | pyrene | 1.7 | 0.14 | 0.012 |

| formula | substance | HCA | HCW | HCS |
|---|---|---|---|---|
| *unhalogenated aliphatic hydrocarbons* | | | | |
| $CH_2CHCN$ | acrylonitrile | 23 | | |
| $C_4H_{10}(OH)_2$ | 1,3-butanediol (1,3-butyleneglycol) | 0.0083 | 0.000,71 | |
| | 1,3-butyleneglycol | → 1,3-butanediol | | |
| $CS_2$ | carbon disulfide | 1.2 | | |
| $C_6H_{10}O$ | cyclohexanone | 0.86 | 0.000,62 | 0.005,7[1] |
| $CH_3CO_2C_2H_5$ | ethylacetate | 0.001,3 | 0.000,11 | |
| $C_7H_{16}$ | heptane | 1.6 | 0.000,92 | 0.055 |
| | isopropanol | → 2-propanol | | |
| $C_8H_{18}$ | octane | 1.6 | 0.000,92 | 0.000,013 |
| | petrol | 1.7 | 0.000,92 | |
| $CH_3CHOHCH_2OH$ | 1,2-propanediol (propyleneglycol) | 0.0013 | 0.000,11 | |
| $CH_3CHOHCH_3$ | 2-propanol (isopropanol) | 0.022 | 0.001,9 | |
| | propyleneglycol | → 1,2-propanediol | | |
| $C_4H_8O$ | tetrahydrofuran | 3.3 | 0.29 | 68 |
| $C_4H_8S$ | tetrahydrothiophene | 3.3 | 0.29 | 5.8[1] |
| $C_{12}H_{20}O_6$ | triethylcitrate | 0.003,3 | 0.000,29 | |
| *halogenated aliphatic hydrocarbons* | | | | |
| | chloroalkanes | | | |
| $CH_2Cl_2$ | dichloromethane (methylenechloride) | 0.069 | 0.048 | 1.6 |
| $CHCl_3$ | trichloromethane (chloroform) | 1.2 | 0.095 | 3.3 |
| $CCl_4$ | tetrachloromethane | 1.9 | 0.71 | 32 |
| $CH_2ClCH_2Cl$ | 1,2-dichloroethane | 2.4 | 0.20 | 7.1 |
| | chloroalkenes | | | |
| $CH_2CHCl$ | monochloroethene (vinylchloride) | 1.2 | 0.82 | 320 |
| $CHClCCl_2$ | trichloroethene | 0.061 | 0.005,3 | 0.10 |
| $C_2Cl_4$ | tetrachloroethene (perchloroethene) | 0.047 | 0.18 | 7.6 |
| | chloroform | → trichloromethane | | |
| $CCl_2F_2$ | dichlorodifluoromethane | 0.022 | 0.001,9 | |
| | perchloroethene | → tetrachloroethene | | |
| | vinylchloride | → monochloroethene | | |
| *pesticides* | | | | |
| | acephate | 1.1 | 0.095 | |
| | acrilonitrile | 23 | | |
| | aldicarb | 6.7 | 0.57 | |

| formula | substance | HCA | HCW | HCS |
|---|---|---|---|---|
| | aldrin | 330 | 29 | 4.5 |
| | aminocarb | 8.3 | 0.71 | |
| | amitraz | 11 | 0.95 | |
| | amitrol | 1,100 | 95 | |
| | anilazin | 0.33 | 0.029 | |
| | atrazine | 6.7 | 0.57 | 3.2[1] |
| | azinphos-methyl | 13 | 1.1 | |
| | azocyclotin | 11 | 0.95 | |
| | benalaxyl | 0.67 | 0.057 | |
| | bendiocarb | 8.3 | 0.71 | |
| | benomyl | 1.7 | 0.14 | |
| | benzenehexachloride (BHC) | → hexachlorocyclohexane | | |
| | BHC | → hexachlorocyclohexane | | |
| | bitertanol | 3.3 | 0.29 | |
| | bromide | 0.033 | 0.002,9 | |
| | bromophos | 0.83 | 0.071 | |
| | bromophos-ethyl | 11 | 0.95 | |
| | bromomethane | → methylbromide | | |
| | bromopropylate | 4.2 | 0.36 | |
| | captan | 0.33 | 0.029 | |
| | carbamates (general) | 33 | 2.9 | |
| | carbaryl | 3.3 | 0.29 | 0.10 |
| | carbendazim | 3.3 | 0.29 | |
| | carbophenothion | 67 | 5.7 | |
| | carbofuran | 3.3 | 0.29 | 0.10 |
| | carbosulfan | 3.3 | 0.29 | |
| | cartap | 0.3 | 0.029 | |
| | chlorobenzide | 3.3 | 0.29 | |
| | chlorobenzilate | 1.7 | 0.14 | |
| | chlorocholinechloride | → chloromequat | | |
| | chlordane | 67 | 5.7 | |
| | chlorfenson | 3.3 | 0.29 | |
| | chlorfenvinphos | 17 | 1.4 | |
| | chlormequat | 0.67 | 0.057 | |
| | chlorthalonil | 11 | 0.95 | |
| | chlorpyrifos | 3.3 | 0.29 | |
| | chlorpyrifos-methyl | 3.3 | 0.29 | |
| | clofentezine | 1.7 | 0.14 | |
| | crufomate | 0.33 | 0.029 | |
| | cyanazine | 17 | 1.4 | |
| | cyfluthrin | 1.7 | 0.14 | |
| | cyhalothrin | 1.7 | 0.14 | |
| | cyhexatin | 4.2 | 0.36 | |

| formula | substance | HCA | HCW | HCS |
|---|---|---|---|---|
| | cypermethrin | 0.67 | 0.058 | |
| | 2,4 D (2,4-dichlorophenoxy acetic acid) | 0.11 | 0.009,5 | |
| | daminozide | 0.067 | 0.005,7 | |
| | DDD | 1.7 | 0.14 | |
| | DDE | 1.7 | 0.14 | |
| | DDT | 1.7 | 0.14 | |
| | decamethrin | → deltamethrin | | |
| | deltamethrin | 3.3 | 0.29 | |
| | demeton-S-methyl | 110 | 9.5 | |
| | demeton-S-methylsulfon | → demeton-S-methyl | | |
| | demeton-S-methyl-sulfoxide | → oxydemetonmethyl | | |
| | diazinon | 17 | 1.4 | |
| | 1,2-dibromoethane as $Br^-$) | 0.033 | 0.002,9 | |
| | dichlofluanide | 0.11 | 0.009,5 | |
| | 2,4-dichlorophenoxy acetic acid | → 2,4-D | | |
| | dichlorovos | 8.3 | 0.71 | |
| | dichloran | 1.1 | 0.095 | |
| | dicofol | 1.3 | 0.11 | |
| | dieldrin | 330 | 29 | 13 |
| | diphenyl | 0.27 | 0.023 | |
| | diphenylamine | 1.7 | 0.14 | |
| | diflubenzuron | 1.7 | 0.14 | |
| | dimethipin | 1.7 | 0.14 | |
| | dimethoate | 3.3 | 0.29 | |
| | dimethyl-dithiocarbamates (DMDC; general) | 6.7 | 0.57 | |
| | dinocap | 33 | 2.9 | |
| | dioxathion | 22 | 1.9 | |
| | diquat | 4.2 | 0.36 | |
| | disulfoton | 17 | 1.4 | |
| | DMDC | → dimethyl-dithiocarbamates | | |
| | dodine | 3.3 | 0.29 | |
| | drins (general) | 330 | 29 | |
| | EBDC | → ethylenebis-dithiocarbamates | | |
| | edifenphos | 11 | 0.95 | |
| | endosulfan | 5.6 | 0.48 | |
| | endrin | 330 | 29 | 16 |
| | ethiofencarb | 0.33 | 0.029 | |
| | ethion | 5.6 | 0.48 | |
| | ethoprophos | 110 | 9.5 | |
| | ethoxyquin | 0.56 | 0.048 | |
| | ethylene-dibromide | → 1,2-dibromomethane | | |

| formula | substance | HCA | HCW | HCS |
|---|---|---|---|---|
| | ethylenebis-dithiocarbamates (EBDC; general) | 0.67 | 0.057 | |
| | ethylenethio-urea (ETU) | 17 | 1.4 | |
| | etrimfos | 11 | 0.95 | |
| | ETU | → ethylenethio-urea | | |
| | fenamiphos | 67 | 5.7 | |
| | fenbutatin oxide | 1.1 | 0.095 | |
| | fenchlorphos | 3.3 | 0.29 | |
| | fenitrothion | 6.7 | 0.57 | |
| | fensulfothion | 110 | 9.5 | |
| | fenthion | 33 | 2.9 | |
| | fenthoate | 11 | 0.95 | |
| | fentin acetate | 67 | 5.7 | |
| | fentin chloride | 67 | 5.7 | |
| | fentin hydroxide | 67 | 5.7 | |
| | fentin compounds (general) | 67 | 5.7 | |
| | fenvalerate | 1.7 | 0.14 | |
| | ferbam | 1.7 | 0.14 | |
| | flucythrinate | 1.7 | 0.14 | |
| | flusilazole | 33 | 2.9 | |
| | folpet | 3.3 | 0.29 | |
| | formothion | 1.7 | 0.14 | |
| | glyphosphate | 0.11 | 0.009,5 | |
| | guazatine | 1.1 | 0.095 | |
| | HCH | → hexachlorocyclohexane | | |
| | heptachloro/ heptachloro-epoxide | 67 | 5.7 | |
| | α-hexachlorocyclohexane (α-HCH) | 470 | 2.9 | 3.4[1] |
| | β-hexachlorocyclohexane (β-HCH) | 1,700 | 140 | 113[1] |
| | γ-hexachlorocyclohexane (γ-HCH; lindane) | 470 | 2.9 | 3.4[1] |
| | δ-hexachlorocyclohexane (δ-HCH) | 470 | 2.9 | 2.9[1] |
| | 2-hydroxybiphenyl | → 2-phenylphenol | | |
| | imazalil | 3.3 | 0.29 | |
| | iprodione | 0.11 | 0.009,5 | |
| | isofenphos | 33 | 2.9 | |
| | lindane | → γ-hexachlorocyclohexane | | |
| | malathion | 1.7 | 0.14 | |
| | maleic hydrazide | 0.0067 | 0.000,58 | |
| | mancozeb | 0.67 | 0.057 | |
| | maneb | 0.67 | 0.057 | 0.000,44 |

| formula | substance | HCA | HCW | HCS |
|---|---|---|---|---|
| | mecarbam | 17 | 1.4 | |
| | metalaxyl | 1.1 | 0.095 | |
| | methacrifos | 11 | 0.95 | |
| | methamidophos | 56 | 4.8 | |
| | methidathion | 6.7 | 0.57 | |
| | methiocarb | 33 | 2.9 | |
| | methomyl | 1.1 | 0.095 | |
| | methoprene | 0.33 | 0.029 | |
| | methoxychloro | 0.33 | 0.029 | |
| | methyl bromide (bromomethane; as $Br^-$) | 0.033 | 0.002,9 | |
| | methyl parathion | → parathion-methyl | | |
| | mevinphos | 22 | 1.9 | |
| | monocrotophos | 56 | 4.8 | |
| | omethoate | 110 | 9.5 | |
| | OPP | → 2-phenylphenol | | |
| | oxamyl | 1.1 | 0.095 | |
| | oxydemeton-methyl | 110 | 9.5 | |
| | oxythioquinox | → chinomethionaat | | |
| | paclobutrazol | 0.33 | 0.029 | |
| | paraquat | 8.3 | 0.71 | |
| | parathion | 6.7 | 0.57 | |
| | parathion-methyl | 1.7 | 0.14 | |
| | permethrin | 0.67 | 0.057 | |
| | phenothrin | 0.48 | 0.041 | |
| | 2-phenylphenol (2-hydroxybiphenyl; OPP. SOPP) | 1.7 | 0.14 | |
| | phorate | 170 | 14 | |
| | phosalone | 5.6 | 0.48 | |
| | phosamidon | 67 | 5.7 | |
| | phosmet | 1.7 | 0.14 | |
| | phoxim | 33 | 2.9 | |
| | piperonylbutoxide | 1.1 | 0.095 | |
| | pirimicarb | 1.7 | 0.14 | |
| | pirimiphos-methyl | 3.3 | 0.29 | |
| | prochloraz | 3.3 | 0.29 | |
| | procymidone | 0.33 | 0.029 | |
| | prometryn | 8.3 | 0.71 | |
| | propamocarb | 0.33 | 0.029 | |
| | propargite | 0.22 | 0.019 | |
| | propazine | 13 | 1.1 | |
| | propiconazole | 0.83 | 0.071 | |
| | propoxur | 1.7 | 0.14 | 0.11 |

| formula | substance | HCA | HCW | HCS |
|---|---|---|---|---|
| | pyrethrins | 0.83 | 0.071 | |
| | quinomethionate (oxythioquinox) | 5.6 | 0.48 | |
| | quintozene | 4.8 | 0.41 | |
| | simazine | 17 | 1.4 | |
| | SOPP | → 2-phenylphenol | | |
| | 2,4,5-T | 1.1 | 0.095 | |
| | tecnazene | 3.3 | 0.29 | |
| | terbufos | 170 | 14 | |
| | terbutryn | 33 | 2.9 | |
| | terbutyl-azin | 11 | 0.95 | |
| | tetrachlorovinphos | 1,700 | 140 | |
| | thiabendazole | 0.11 | 0.009,5 | |
| | thiodicarb | 1.1 | 0.095 | |
| | thiophanate-methyl | 0.42 | 0.038 | |
| | thiometon | 11 | 0.95 | |
| | tin and organo-tin compounds | → fentin compounds | | |
| | tolylfluanide | 0.33 | 0.029 | |
| | triadimefon | 1.1 | 0.095 | |
| | triadimenol | 0.67 | 0.057 | |
| | triazines (general) | 17 | 1.4 | |
| | triazofos | 170 | 14 | |
| | trichlorfon | 3.3 | 0.29 | |
| | triforine | 1.7 | 0.14 | |
| | triphenyl tin compounds | → fentin compounds | | |
| | vamidothion | 4.2 | 0.36 | |
| | vinclozolin | 0.48 | 0.041 | |
| | hydrogen cyanide | 0.67 | 0.057 | |
| | zineb | 0.67 | 0.057 | |
| | ziram | 1.7 | 0.14 | |

* Based on the basic data for the air quality guideline for cadmium which represents the *direct* toxicty.

† Value: $0.12 \cdot 10^{-9} \times F_s/m^3$ or $0.23 \cdot 10^{-9} \times F_o/m^3$, where $F_s$ = number of critical fibres emitted as determined by scanning electron microscopy and $F_o$ = number of critical fibres emitted determined by optical microscopy. Critical fibres are fibres that are $\geq 5\mu m$ long, $\leq 3\mu m$ in diamter and with aspect ratio $\geq 3 \div 1$.

‡ The value for $NO_2$ was adopted for $NO_x$.

§ This value is based on the air quality guideline for the combined toxicity of $SO_2$ and black (coal) smoke in equal mass ratios. It was assumed that $SO_2$ and smoke particles are each responsible for half of the combined effect.

¶ Value deviates from Dutch original report.

Human toxicological classification factor for the air (HCA), human toxicological classification factor for water (HCW) and human toxicological classfication factor for the soil (HCS). Sources: see backgrounds document §3.3. The effect score for human toxicity is calculated as follows:

$$\begin{aligned} \textit{human toxicity}\,(\text{kg}) = {} & \textit{HCA}\,(\text{kg}\cdot\text{kg}^{-1}) \times \textit{emission to the air}\,(\text{kg}) + \\ & \textit{HCW}\,(\text{kg}\cdot\text{kg}^{-1}) \times \textit{emission to water}\,(\text{kg}) + \\ & \textit{HCS}\,(\text{kg}\cdot\text{kg}^{-1}) \times \textit{emission to the soil}\,(\text{kg}) \end{aligned} \qquad \text{(B.5)}$$

**B.2.4 Ecotoxicity**

TABLE B.6. Classification factors for the effect scores terrestrial and aquatic ecotoxicity.

| formula | substance | ECA | ECT* |
|---|---|---|---|
| *metals* | | | |
| As | arsenic | 0.20 | 3.6 |
| Cd | cadmium | 200 | 13 |
| Cr | chromium | 1.0 | 0.42 |
| Co | cobalt | | 0.42 |
| Cu | copper | 2.0 | 0.77 |
| Pb | lead | 2.0 | 0.43 |
| Hg | mercury | 500 | 29 |
| Ni | nickel | 0.33 | 1.7 |
| Zn | zinc | 0.38 | 2.6 |
| *unhalogenated aromatic hydrocarbons* | | | |
| $C_6H_5NOCCH_3$ | acetanilide (N-phenylacetamide) | | 5.9 |
| $C_6H_5NH_2$ | aniline (phenylamine) | 5.0 | 5.9 |
| $C_6H_5CHO$ | benzaldehyde | | 0.32 |
| $C_6H_6$ | benzene | 0.029 | |
| | 1,2-benzenedicarboxylic acids | → phthalates | |
| $(C_6H_5)_2$ | biphenyl (phenylbenzene) | | 2.9 |
| $C_6H_4OHCH_3$ | *o*-cresol (2-hydroxytoluene) | | 2.0 |
| $C_6H_4OHCH_3$ | *m*-cresol (3-hydroxytoluene) | | 2.1 |
| $C_6H_4(NH_2)_2$ | 1,2-diaminobenzene (*o*-phenylenediamine) | | 10 |
| | 2,5-diaminotoluenesulfate | | 0.20 |
| $C_6H_3OH(NO_2)_2$ | 2,4-dinitrophenol | | 2.0 |
| $C_6H_5C_2H_5$ | ethylbenzene | 0.023 | |
| | hydroxynaphthalene | → naphthol | |
| | hydroxytoluene | → cresol | |
| | mercaptobenzene | → thiophenol | |
| $C_{10}H_7OH$ | α-naphthol (1-hydroxynaphthalene) | | 4.0 |
| $C_{10}H_7OH$ | β-naphthol (2-hydroxynaphthalene) | | 2.3 |
| $C_6H_5NO_2$ | nitrobenzene | | 4.3 |
| $C_6H_4OHNO_2$ | *m*-nitrophenol | | 2.0 |
| $C_6H_4OHNO_2$ | *p*-nitrophenol | | 26 |
| $C_6H_4OHC_9H_{19}$ | 4-nonylphenol | | 0.32 |
| $C_6H_5OH$ | phenol | 5.9 | 5.3 |
| | N-phenylacetamide | → acetanilide | |
| | phenylamine | → aniline | |
| | phenylbenzene | → biphenyl | |
| | *o*-phenylenediamine | → 1,2-diaminobenzene | |
| | phthalates (1,2-benzenedicarboxylic acids) | | |

| formula | substance | ECA | ECT* |
|---|---|---|---|
| $C_6H_4(CO_2CH_3)_2$ | dimethylphthalate | | 200 |
| $C_6H_4(CO_2C_2H_5)_2$ | diethylphthalate | | 1.5 |
| $C_6H_4(CO_2C_4H_9)_2$ | dibutylphthalate | | 0.20 |
| | di(2-ethyl)hexylphthalate | | 0.20 |
| $C_5H_5N$ | pyridine | | 1.0 |
| $C_6H_5SH$ | thiophenol (mercaptobenzene) | | 1.0 |
| $C_6H_5CH_3$ | toluene | | 0.63 |
| *halogenated aromatic hydrocarbons* | | | |
| | chloroanilines (chlorophenylamines) | | |
| $C_6H_4NH_2Cl$ | monochloroanilines (general) | 0.010 | |
| | 2-monochloroaniline | | 6.3 |
| | 3-monochloroaniline | | 13 |
| | 4-monochloroaniline | | 7.7 |
| $C_6H_3NH_2Cl_2$ | dichloroanilines | | |
| | 2,4-dichloroaniline | | 6.7 |
| | 3,4-dichloroaniline | | 20 |
| | 3,5-dichloroaniline | | 15 |
| $C_6H_2NH_2Cl_3$ | trichloroanilines | | |
| | 2,4,5-trichloroaniline | | 11.8 |
| | 2,4,6-trichloroaniline | | 8.3 |
| $C_6HNH_2Cl_4$ | tetrachloroanilines | | |
| | 2,3,4,5-tetrachloroaniline | | 8.3 |
| | 2,3,4,6-tetrachloroaniline | | 13 |
| $C_6NH_2Cl_5$ | pentachloroaniline | | 0.42 |
| | chlorobenzenes | | |
| $C_6H_5Cl$ | monochlorobenzenes (general) | | 1.0 |
| $C_6H_4Cl_2$ | dichlorobenzenes (general) | 0.16 | |
| | 1,4-dichlorobenzene | | 0.83 |
| $C_6H_3Cl_3$ | trichlorobenzenes (general) | 0.83 | |
| | 1,2,3-trichlorobenzene | | 53 |
| | 1,2,4-trichlorobenzene | | 7.7 |
| | 1,3,5-trichlorobenzene | | 1.6 |
| $C_6H_2Cl_4$ | tetrachlorobenzenes (general) | 2.3 | |
| | 1,2,3,4-tetrachlorobenzene | | 6.3 |
| | 1,2,3,5-tetrachlorobenzene | | 150 |
| $C_6HCl_5$ | pentachlorobenzene | 18 | 3.6 |
| $C_6Cl_6$ | hexachlorobenzene | 53 | 0.20 |
| | chlorophenols | | |
| $C_6H_4ClOH$ | monochlorophenols | | |
| | 2-chlorophenol | | 4.5 |
| | 3-chlorophenol | | 29 |
| $C_6H_3Cl_2OH$ | dichlorophenols | | |

| formula | substance | ECA | ECT* |
|---|---|---|---|
| | 2,4-dichlorophenol | | 3.7 |
| | 3,4-dichlorophenol | | 3.2 |
| | 3,5-dichlorophenol | | 6.3 |
| $C_6H_2Cl_3OH$ | trichlorophenols | | |
| | 2,3,5-trichlorophenol | | 22 |
| | 2,4,5-trichlorophenol | | 9.1 |
| | 2,4,6-trichlorophenol | | 17 |
| $C_6HCl_4OH$ | tetrachlorophenols | | |
| | 2,3,4,5-tetrachlorophenol | | 3.4 |
| $C_6Cl_5OH$ | pentachlorophenol (PCP) | 5.6 | 5.9 |
| | chlorophenylamines | → chloroanilines | |
| $C_6H_3ClCH_3OH$ | chloromethylphenols | | |
| | 4-chloro-3-methylphenol | | 3.0 |
| | 4-chloro-2-methylphenol | | 3.0 |
| $C_6H_4ClNO_2$ | chloronitrobenzenes | | |
| | 1-chloro-2-nitrobenzene | | 37 |
| | 1-chloro-3-nitrobenzene | | 17 |
| | polychlorobiphenyls (PCBs) | | |
| | PCB-28 | 16 | |
| | PCB-52 | 430 | |
| | PCB-101 | 40 | |
| | PCB-118 | 360 | |
| | PCB-138 | 71 | |
| | PCB-153 | 100 | |
| | PCB-180 | 130 | |
| | Aroclor 1254 | | 40 |
| | 2,3,7,8-TCDD (dioxin) | | 1,400 |
| *polycyclic aromatic hydrocarbons (PAHs)* | | | |
| | anthracene | 2.0 | |
| | benz(a)anthracene | 18 | |
| | benzo(b)fluoroanthene | 160 | |
| | benzo(k)fluoroanthene | 40 | |
| | benzo(ghi)perylene | 140 | |
| | benzo(a)pyrene | 40 | |
| | chrysene | 18 | |
| | dibenzo(a,h)anthracene | 33 | |
| | fluoroanthene | 6.2 | |
| | fluoroene | | 5.9 |
| | indeno(1,2,3,c,d)pyrene | 91 | |
| | naphthalene | | 0.31 |
| | phenanthrene | 2.1 | |
| | pyrene | 7.5 | |

| formula | substance | ECA | ECT* |
|---|---|---|---|
| *unhalogenated aliphatic hydrocarbons* | | | |
| $NH_2COCHCH2$ | acrylamide | | 1.3 |
| $CH_3CO_2C_4H_9$ | n-butylacetate | | 0.14 |
| | crude oil | 0.050 | |
| $NH_2CO(C_4H_9)_2$ | dibutylamide | | 0.56 |
| $NH_2CO(C_3H_7)_2$ | dipropylamide | | 0.53 |
| $(NH_2CO)_2C_2H_2$ | ethenediamide | | 0.29 |
| $C_4H_4O$ | furan | | 0.32 |
| | isobutylalcohol | → methylpropanol | |
| $(CH_3)_2CH_2CH_2OH$ | methylpropanol | | 0.56 |
| $C_3H_3NOS_2$ | rhodamine (4-thioxo-4-thiazolidone) | | 6.3 |
| | trypan blue (dye) | | 0.67 |
| *halogenated aliphatic hydrocarbons* | | | |
| $NH_2COCH_2Cl$ | chloroacetamide | | 250 |
| | chloroalkanes | | |
| $CHCl_3$ | trichloromethane (chloroform) | 0.17 | |
| $CCl_4$ | tetrachloromethane | 0.007,4 | |
| $(CH_2Cl)_2$ | 1,2-dichloroethane | 0.000,94 | |
| $CH_3CCl_3$ | 1,1,1-trichloroethane | 0.002,8 | |
| $C_2Cl_6$ | hexachloroethane | 0.14 | |
| $CH_3CHClCH_2Cl$ | 1,2-dichloropropane | | 0.24 |
| | chloroalkenes | | |
| $C_2HCl_3$ | trichloroethene | 0.046 | |
| $C_2Cl_4$ | tetrachloroethene (perchloroethene) | 0.020 | 11 |
| $CH_2ClCHCHCl$ | 1,3-dichloropropene | 0.083 | |
| $C_2H_5ClOCClCH_2$ | 2-chloroethylvinylether | | 1.4 |
| | perchloroethene | → tetrachloroethene | |
| *pesticides* | | | |
| | aldicarb | 3.1 | 290 |
| | aldrin | 83 | 1,400 |
| | arasan | | 3.7 |
| | atrazin | 5.0 | 150 |
| | azinphos-ethyl | 100 | |
| | azinphos-methyl | 100 | 200 |
| | benomyl | | 1400 |
| | bentazon | | 33 |
| | benzenehexachloride (BHC) | → hexachlorocyclohexane | |
| | BHC | → hexachlorocyclohexane | |

| formula | substance | ECA | ECT* |
|---|---|---|---|
| | bifenthrin | 910 | |
| | bupirimate | | 11 |
| | calcium cyanamide | | 9.1 |
| | captafol | 33 | 2.0 |
| | captan | 19 | 4.8 |
| | carbendazim | 5.0 | 5.0 |
| | carbofuran | | 250 |
| | chlorocholinechloride | → chloromequat | |
| | chlorodane | 100 | 230 |
| | chlorodimeform | | 20 |
| | chlorofenvinphos | | 0.77 |
| | chloromequat | | 2.5 |
| | chlorpyrifos | | 910 |
| | copper-oxychloride | | 12 |
| | cumafos | 2,000 | |
| | cypermethrin | 250 | |
| | 2,4 D (2,4-dichlorophenoxy acetic acid) | 0.25 | 370 |
| | dasanit | | 400 |
| | DDD | 1.3 | |
| | DDE | 1.3 | |
| | DDT | 1.3 | 112 |
| | decamethrin | → deltamethrin | |
| | deltamethrin | 1000 | |
| | demeton | 14 | |
| | demeton-S-methyl-sulfoxyde | → oxydemetonmethyl | |
| | dialifos | | 7.7 |
| | diazinon | 50 | 1,400 |
| | 3,3-dichlorobenzidine | 10 | |
| | 1,4-dichlorophenoxy acetic acid | → 2,4-D | |
| | dichlorovos | 2,000 | 13 |
| | dieldrin | 83 | 900 |
| | dimetilan | | 0.80 |
| | dinoseb | 200 | |
| | disulfoton | 3.8 | 910 |
| | DNOC | 15 | 48 |
| | dymid | | 4.0 |
| | endosulfan | 100 | 150 |
| | endrin | 53 | 2,000 |
| | ethiofencarb | | 3.8 |
| | ethyl-parathion | → parathion-ethyl | |
| | fenitrothion | 100 | 200 |
| | fenmidfan | | 5.9 |

| formula | substance | ECA | ECT* |
|---|---|---|---|
| | fensulfothion | | 200 |
| | fenthion | 250 | |
| | fentin compounds (general) | 20 | |
| | fentin-acetate | 20 | 37 |
| | folpet | | 2.9 |
| | heptachloro | 12 | 2,000 |
| | heptachloro-epoxide | 12 | |
| | hexachlorobutadiene | 11 | |
| | γ-hexachlorocyclohexane (γ-HCH; lindane) | 2.5 | 1,300 |
| | isobenzan | | 5,000 |
| | isodrin | 170 | |
| | leptophos | | 20 |
| | lindane | → γ-hexachlorocyclohexane | |
| | linuron | 20 | |
| | malathion | 67 | 25 |
| | mancozeb | | 2.9 |
| | maneb | 1.1 | 2.9 |
| | MCPA (monochlorophenoxy acetic acid) | 17 | |
| | MCPP | → mecoprop | |
| | mecoprop (MCPP) | 25 | |
| | mercaptodimethur | | 7.7 |
| | methamidophos | | 59 |
| | metham sodium | 290 | |
| | methaphenamifos | | 3.1 |
| | methidathion | | 280 |
| | methomyl | | 400 |
| | methyl-parathion | → parathion-methyl | |
| | mevinphos | 1,000 | 7.7 |
| | mexacarbate | | 34 |
| | monochlorophenoxy acetic acid | → MCPA | |
| | monochloronitrobenzene | 0.10 | |
| | monocrotophos | | 13 |
| | NaDDC | | 0.080 |
| | oxamyl | 2.4 | 11 |
| | oxydemeton-methyl | 53 | |
| | paraquat | | 5.9 |
| | parathion-ethyl | 250 | 1,400 |
| | parathion-methyl | 8.3 | 200 |
| | pentachloronitrobenzene | 3.2 | |
| | permethrin | 710 | |
| | phorate | | 2,000 |

| formula | substance | ECA | ECT* |
|---|---|---|---|
| | phoxim | 50 | |
| | potassium bromate | | 2.6 |
| | potassium dichromate | | 2.4 |
| | propachloro | 59 | |
| | propoxur | | 220 |
| | pyrazophos | 2,100 | |
| | simazin | 1.0 | |
| | sodium chlorate | | 1.5 |
| | 2,4,5-T | | 20 |
| | TBTO | 63 | |
| | terbufos | | 250 |
| | tetrachlorovinphos | | 50 |
| | thiophene | | 0.63 |
| | thiram | 63 | 2.9 |
| | trematan | | 0.40 |
| | triadimefon | | 3.7 |
| | triazofos | 200 | 8.3 |
| | tributyl tin oxide and salts | 250 | |
| | trichloroacetate (TCA) | | 9.1 |
| | trichlorfon | 1,000 | 14 |
| | triphenyl tin compounds | → fentin compounds | |
| | trifluarin | 5.0 | |
| | zineb | 0.63 | 1.5 |
| | zinophos | | 2,900 |

* Values calculated for standard soil containing 10% organic matter and 25% argillaceous material (Parliamentary Documents II, 1987).

Ecotoxicolocial classification factor for terrestrial ecosystems (ECT) in kg soil·kg$^{-1}$ substance and the ecotoxicological classification factor for aquatic ecosystems (ECA) in m$^3$ water·kg$^{-1}$ substance. Sources: see backgrounds document §3.3. The effect score for aquatic toxicity is calculated with:

$$\textit{aquatic ecotoxicty}\,(\mathrm{m^3}) = \textit{ECA}\,(\mathrm{m^3 \cdot mg^{-1}}) \times \textit{emission to water}\,(\mathrm{mg}) \qquad \text{(B.6)}$$

The effect score for terrestrial ecotoxicity is calculated with:

$$\textit{terrestrial ecotoxicty}\,(\mathrm{kg}) = \textit{ECT}\,(\mathrm{kg \cdot mg^{-1}}) \times \textit{emission to the soil}\,(\mathrm{mg}) \qquad \text{(B.7)}$$

### B.2.5 Photochemical oxidant formation

TABLE B.7. Classification factors for the effect score oxidant formation.

| formula | substance | POCP | range |
|---|---|---|---|
| *alkanes* | | | |
| | methane | 0.007 | 0.000-0.030 |
| | ethane | 0.082 | 0.020-0.300 |
| | propane | 0.42 | 0.160-1.240 |
| | n-butane | 0.41 | 0.150-1.150 |

| formula | substance | POCP | range |
|---|---|---|---|
| | i-butane | 0.315 | 0.190-0.590 |
| | n-pentane | 0.408 | 0.090-1.050 |
| | i-pentane | 0.296 | 0.120-0.680 |
| | n-hexane | 0.421 | 0.100-1.510 |
| | 2-methylpentane | 0.524 | 0.190-1.400 |
| | 3-methylpentane | 0.431 | 0.110-1.250 |
| | 2,2-dimethylbutane | 0.251 | 0.120-0.490 |
| | 2,3-dimethylbutane | 0.384 | 0.250-0.650 |
| | n-heptane | 0.529 | 0.130-1.650 |
| | 2-methylhexane | 0.492 | 0.110-1.590 |
| | 3-methylhexane | 0.492 | 0.110-1.570 |
| | n-octane | 0.493 | 0.120-1.510 |
| | 2-methylheptane | 0.469 | 0.120-1.460 |
| | n-nonane | 0.469 | 0.100-1.480 |
| | 2-methyloctane | 0.505 | 0.120-1.470 |
| | n-decane | 0.464 | 0.080-1.560 |
| | 2-methylnonane | 0.448 | 0.080-1.530 |
| | n-undecane | 0.436 | 0.080-1.440 |
| | n-duodecane | 0.412 | 0.070-1.380 |
| — | alkanes (average) | 0.398 | 0.114-1.173 |
| *halogenated hydrocarbons* | | | |
| | methylcyclohexane | — | — |
| | methylenechloride | 0.010 | 0.000-0.030 |
| | chloroform | — | — |
| | methylchloroform | 0.001 | 0.000-0.010 |
| | trichloroethylene | 0.066 | 0.010-0.130 |
| | tetrachloroethylene | 0.005 | 0.000-0.020 |
| | allylchloride | — | — |
| — | halogenated hydrocarbons (average) | 0.021 | 0.003-0.048 |
| *alcohols* | | | |
| | methanol | 0.123 | 0.090-0.210 |
| | ethanol | 0.268 | 0.040-0.890 |
| | i-propanol | — | — |
| | butanol | — | — |
| | i-butanol | — | — |
| | ethyleneglycol | — | — |
| | propyleneglycol | — | — |
| | but-2-diol | — | — |
| | dimethylether | — | — |
| | methyl-t-butylether | — | — |
| | ethyl-t-butylether | — | — |

| formula | substance | POCP | range |
|---|---|---|---|
| — | alcohols (average) | 0.196 | 0.065-0.550 |
| *ketones* | | | |
| | acetone | 0.178 | 0.100-0.270 |
| | methyl-ethylketone | 0.473 | 0.170-0.800 |
| | methyl-i-butylketone | — | — |
| — | ketones (average) | 0.326 | 0.135-0.535 |
| *esters* | | | |
| | methylacetate | 0.025 | 0.000-0.070 |
| | ethylacetate | 0.218 | 0.110-0.560 |
| | i-propylacetate | 0.215 | 0.140-0.360 |
| | n-butylacetate | 0.323 | 0.140-0.910 |
| | i-butylacetate | 0.332 | 0.210-0.590 |
| — | esters (average) | 0.223 | 0.120-0.498 |
| *ethers* | | | |
| | propyleneglycolmethyleneether | — | — |
| | propyleneglycolmethyletheracetate | — | — |
| — | ethers (average) | — | — |
| *olefins* | | | |
| | ethylene | 1.000 | 1.000-1.000 |
| | propylene | 1.030 | 0.750-1.630 |
| | 1-butene | 0.959 | 0.570-1.850 |
| | 2-butene | 0.992 | 0.820-1.570 |
| | 1-pentene | 1.059 | 0.400-2.880 |
| | 2-pentene | 0.930 | 0.650-1.600 |
| | 2-methyl-1-butene | 0.777 | 0.520-1.130 |
| | 2-methyl-2-butene | 0.779 | 0.610-1.020 |
| | 3-methyl-1-butene | 0.895 | 0.600-1.540 |
| | isobutene | 0.643 | 0.580-0.760 |
| | isoprene | — | — |
| — | olefins (average) | 0.906 | 0.650-1.498 |
| *acetylenes* | | | |
| | acetylene | 0.168 | 0.100-0.420 |
| *aromatics* | | | |
| | benzene | 0.189 | 0.110-0.450 |
| | toluene | 0.563 | 0.410-0.830 |
| | o-xylene | 0.666 | 0.410-0.970 |
| | m-xylene | 0.993 | 0.780-1.350 |

| formula | substance | POCP | range |
|---|---|---|---|
| | p-xylene | 0.888 | 0.630-1.800 |
| | ethylbenzene | 0.593 | 0.350-1.140 |
| | 1,2,3-trimethylbenzene | 1.170 | 0.760-1.750 |
| | 1,2,4-trimethylbenzene | 1.200 | 0.860-1.760 |
| | 1,3,5-trimethylbenzene | 1.150 | 0.740-1.740 |
| | o-ethyltoluene | 0.668 | 0.310-1.300 |
| | m-ethyltoluene | 0.794 | 0.410-1.400 |
| | p-ethyltoluene | 0.725 | 0.360-1.350 |
| | n-propylbenzene | 0.492 | 0.250-1.100 |
| | i-propylbenzene | 0.565 | 0.350-1.050 |
| — | aromatics (average) | 0.761 | 0.481-1.285 |
| *aldehydes* | | | |
| | formaldehyde | 0.421 | 0.220-0.580 |
| | acetaldehyde | 0.527 | 0.330-1.220 |
| | proprionaldehyde | 0.603 | 0.280-1.600 |
| | butyraldehyde | 0.568 | 0.160-1.600 |
| | i-butyraldehyde | 0.631 | 0.380-1.280 |
| | valeraldehyde | 0.686 | 0.000-2.680 |
| | acrolein | — | — |
| | benzaldehyde | −0.334 | (−0.820)-(−0.120) |
| — | aldehydes (average) | 0.443 | 0.079-1.263 |
| — | hydrocarbons (average) | 0.377 | 0.194-0.808 |
| — | non-methane hydrocarbons (average) | 0.416 | 0.195-0.799 |

*Photochemical ozone creation potential* (POCP) relative to ethylene, based on three scenarios and nine days: Germany-Ireland, France-Sweden and the UK. The range is based on three scenarios and 11 days. Source: United Nations - Economic Commission for Europe, 1991: *Protocol to the convention on longe-range transboundary air pollution concerning the control of emissions of volatile organic compounds or their transboundary fluxes*. Geneva. The effect score for the formation of photochemical oxidants is calculated with:

$$\textit{oxidant formation}(\text{kg}) = \textit{POCP} \times \textit{emission to the air}(\text{kg}) \qquad \text{(B.8)}$$

### B.2.6 Acidification

TABLE B.8. Classification factors for the effect score acidification.

| formula | substance | AP |
|---|---|---|
| $SO_2$ | sulfur dioxide | 1.00 |
| NO | nitrogen monoxide | 1.07 |
| $NO_2$ | nitrogen dioxide | 0.70 |
| $NO_x$ | nitrogen oxides | 0.70 |
| $NH_3$ | ammonia | 1.88 |
| HCl | hydrochloric acid | 0.88 |

| formula | substance | AP |
|---|---|---|
| HF | hydrogen fluoride | 1.60 |

*Acidification potential* (AP) relative to $SO_2$, based on the potential amount of $H^+$ per mass unit relative to the same parameter for $SO_2$. The effect score for acidification is calculated with:

$$acidification(\text{kg}) = AP \times emission\ to\ the\ air(\text{kg}) \quad \text{(B.9)}$$

### B.2.7 Nutrification

TABEL B.9. Classification factors for the effect score nutrification.

| formula | substance | NP |
|---|---|---|
| NO | nitrogen monoxide | 0.20 |
| $NO_2$ | nitrogen dioxide | 0.13 |
| $NO_x$ | nitrogen oxides | 0.13 |
| $NH_4^+$ | ammonium | 0.33 |
| N | nitrogen | 0.42 |
| $PO_4^{3-}$ | phosphate | 1.00 |
| P | phosphorus | 3.06 |
| COD | chemical oxygen demand (as $O_2$) | 0.022 |

*Nutrification potential* (NP) relative to $PO_4^{3-}$, based on the average composition of biomass $C_{106}H_{263}O_{110}N_{16}P$, relative to phosphate. The nutrification effect score is calculated with:

$$nutrification(\text{kg}) = NP \times emission(\text{kg}) \quad \text{(B.10)}$$

### B.2.8 Odour

TABEL B.10. Classification factors for the effect score malodourous air.

| formula | substance | OTV |
|---|---|---|
| | acetic acid | 0.061 |
| | ammonia | 1.0 |
| | butanal (butyraldehyde) | 0.000,84 |
| | butanoic acid (butyric acid) | 0.000,35 |
| | 1-butanol | 0.077 |
| | 2-butanone | 0.68 |
| | n-butylacetate | 0.031 |
| | butylacrylate | 0.001,5 |
| | n-butylpropionate | 0.086 |
| $CS_2$ | carbon disulfide | 0.18 |
| | chlorobenzene | 1.0 |
| | decaline | 2.8 |
| | dichloromethane | 640 |
| | diethylamine | 0.09 |
| | dimethylamine | 0.001,4 |
| | 1,2-dimethylbenzene (o-xylene) | 0.78 |
| | 1,3-dimethylbenzene (m-xylene) | 0.54 |

| formula | substance | OTV |
|---|---|---|
| | 1,4-dimethylbenzene (p-xylene) | 0.52 |
| | ethanal (acetaldehyde) | 0.000,27 |
| | ethanethiol (ethylmercaptan) | 0.000,044 |
| | ethanol | 0.64 |
| | ethylacetate | 2.1 |
| | ethylacrylate | 0.000,82 |
| | 2-ethyl-5,5-dimethyl-1,3-dioxane | 0.000,005,6 |
| | ethylbutyrate | 0.000,03 |
| | ethylthioethane (diethylsulfide) | 0.001,4 |
| $H_2S$ | hydrogen sulfide | 0.000,43 |
| | isopentylacetate (iso-amylacetate) | 0.075 |
| | isopropylbenzene (cumene) | 0.073 |
| | isopropylpropionate | 0.32 |
| | methanal (formaldehyde) | 0.49 |
| | methanethiol (methylmercaptan) | 0.000,24 |
| | methanol | 73 |
| | methylacetate | 22 |
| | methylamine | 0.001,2 |
| | 3-methylbutanoic acid (isovaleric acid) | 0.000,22 |
| | methyldithiomethane | 0.001,5 |
| | methylmethacrylate | 0.63 |
| | 4-methylpentanon-2 (methylisobutylketone, MIKB) | 0.69 |
| | *o*-cresol (2-methylphenol) | 0.001,8 |
| | *m*-cresol (3-methylphenol) | 0.000,57 |
| | *p*-cresol (4-methylphenol) | 0.000,18 |
| | 2-methylpropanoic acid (isobutyric acid) | 0.005 |
| | 2-methylpropanol-1 (isobutanol) | 0.035 |
| | 2-methylpropene (isobutene) | 15 |
| | methylacrylate | 0.01 |
| | methylpropionate | 3.5 |
| | methylthiomethane (dimethylsulfide) | 0.000,3 |
| | pentanal (valeraldehyde) | 0.002,4 |
| | phenol | 0.039 |
| | propanal (propionaldehyde) | 0.003,5 |
| | propanoic acid (propionic acid) | 0.005,2 |
| | 2-propanon (acetone) | 72 |
| | 2-propenal (acrolein) | 0.069 |
| | pyridine | 0.12 |
| | styrene (vinylbenzene) | 0.068 |
| | tetrachloroethene (per) | 8.3 |
| | terephthaloyldichloride | 0.003,2 |
| | toluene | 3.8 |
| | trichloroethene (tri) | 3.9 |

| formula | substance | OTV |
|---|---|---|
| | 1,1,1-trichloroethane | 5.3 |
| | trimethylamine | 0.000,26 |
| | 1,2,4-trimethylbenzene | 0.14 |
| | 1,3,5-trimethylbenzene (mesitylene) | 0.18 |

Odour threshold value in air (OTV) in $mg \cdot m^{-3}$. Source: Roos, C., 1989: *Vooronderzoek financiële consequenties van een geurbelevingsnorm.* MT-TNO, report no. 88-230. The effect score for malodourous air is calculated with:

$$malodourous\ air(m^3) = \frac{emission\ to\ the\ air(mg)}{OTV(mg \cdot m^{-3})} \qquad (B.11)$$

# APPENDIX C

# GLOSSARY AND LIST OF ABBREVIATIONS

This appendix provides definitions of the most important terms. It also includes a list of the abbreviations used.

## C.1 Glossary

This glossary provides a list of the most common terms used in the method for environmental life cycle assessment of products. The glossary is limited to terms defined in this report or whose meaning is slightly different or narrower in this context than normal.

**abiotic resource** (non-renewable resource)
Resources which are considered abiotic and therefore not renewable. Zinc ore and crude oil are examples of abiotic resources.

**allocation**
Step (2.3) in an LCA in which it is determined how environmental interventions of a multiple process will be distributed to the various process functions. A distinction can be made between causal allocation and overall apportioned allocation.

**biotic resource** (renewable resource)
Resources which are considered biotic and therefore renewable. The rain forest and elephants are examples of biotic resources.

**causal allocation**
Form of allocation in which it is attempted to allocate subflows (such as emissions) to main flows on a causal basis, using the rules of chemistry.

**classification**
The third component of a life cycle assessment in which the contribution made by the environmental interventions to the potential environmental effects is determined through model-based calculations.

**classification factor**
Result of the modelling of environmental effects which represents the effect as a result of one unit of the environmental intervention.

**closed loop recycling**
Form of recycling in which the product system which produced the waste can reuse the waste, possibly after upgrading.

**combined waste processing** (MI process)
Method of waste processing in which more than one product or material is simultaneously processed.

**component**
One of the five main elements of an environmental life cycle assessment. Each component (goal definition, inventory analysis, classification, evaluation and improvement analysis) produces a result which can be used independently (→ environmental indicator) and requires specific expertise.

**co-production** (MO process)
Production process resulting in more than one marketable output.

**damage**
A deterioration in the quality of the environment not directly attributable to depletion or pollution.

**depletion**
Result of the extraction of non-renewable resources from the environment or the extraction of renewable resources faster than they can be renewed.

**difference analysis**
A life cycle assessment which concentrates on the differences between given product alternatives.

**dominance analysis**
One of the two techniques for improvement analysis. The aim of dominance analysis is to uncover the basic causes of a poor environmental profile.

**economic flow**
The flow from one economic process to another, consisting of goods, materials, services, energy, waste, etc. used in the other process, i.e. in the economy.

**economic process**
Deliberate transformation of or to goods with a financial value.

**effect score**
Number representing the potential contribution of a process, group of processes or product system to a given environmental effect.

**emission**
Discharge of chemical or physical entities (substances, heat, noise, etc.) from the product system to the environmental system.

**environmental effect**
The consequence of an environmental intervention in the environmental system.

**environmental flow**
Flow from the environment to a process or vice versa: resources, emissions, etc.

**environmental index**
Parameter representing the harmfulness of a product to the environment, obtained by quantitative weighting.

**environmental indicator**
One of the results of an environmental life cycle assessment. Environmental indicators are produced in all five components: the goal definition provides the product properties (e.g. life span), the inventory analysis results in the inventory table and a set of aggregated parameters (e.g. energy consumption), the classification results in the environmental profile comprising a number of the effect scores (e.g. acidification), the evaluation results in an environmental index or assessment and the improvement analysis provides starting points for the design or redesign. When product information is transferred all that information should be restricted to the level of a single component.

**environmental intervention**
Physical interaction between a product system and the environmental system, defined in terms of the extraction of resources, substance emissions to the environmental media, space occupied by waste and plant, etc.

**environmental life cycle assessment** (LCA)
Part of an overall life cycle assessment in which only the environmental consequences are considered.

**environmental medium**
One of the three environmental domains, i.e. air, water and soil.

**environmental process**
The set of events in the environmental system which determine what happens to a pollutant (accumulation, leaching, etc.) and what effect it will have.

**environmental profile** (environmental balance, eco-profile, eco-balance)
List of effect scores for all environmental effects associated with the life cycle of the product under consideration.

**environmental system**
The environment and all the processes which occur in it.

**evaluation**
The fourth component of a life cycle assessment in which different product systems are assessed in comparison with each other or in which potential environmental effects of different kinds are compared.

**extraction**
Use of materials obtained directly from the environment (→ resource) by a product system.

**final waste**
Landfilled solid waste which will not undergo further processing.

**format**
System for the representation and possibly processing of quantitative process data.

**functional unit**
Specification of the material or immaterial function of a product or product system used as a basis for the selection of one or more products which could provide that function.

**goal definition**
The first component of a life cycle assessment in which the functional unit is specified and the product group is delineated.

**improvement analysis**
Component of a life cycle assessment carried out only when the assessment is undertaken for product improvement. Improvement analysis provides starting points for the redesign of the product and processes concerned and the use of different materials.

**inventory table** (eco-balance, environmental balance)
List of entities added to and taken from the environment through economic actions which are directly related to a product system and which have a potential effect on the environment.

**inventory analysis**
The second component of a life cycle assessment in which an analysis is made of the environmental interventions associated with the processes required for that functional product unit. Such an analysis should be as much as possible objective and adequately substantiated.

**life cycle**
The combination of processes needed by a product to fulfil the function specified by the functional unit. Life cycle stages include production, use and processing after disposal, including the processing of the waste generated in these stages.

**life cycle assessment** (LCA)
See overall life cycle assessment and environmental life cycle assessment.

**main flows**
All flows to and from an economic process which are the goal of the process and to which allocations are made. These flows are economic flows with a positive value.

**marginal analysis**
One of the two techniques for improvement analysis. Marginal analysis is used to detect process data where a minor change will have a major effect on the environmental profile. This may provide an efficient way to improve the product.

**multi-criteria analysis** (MCA; multi-criteria evaluation)
Method by which a formal or informal structure can be applied to the weighting of the effect scores in a life cycle assessment.

**multiple process**
A process which produces more than one economically valuable good (product, material, service, energy, waste with a positive value). Co-production, combined waste processing and recycling are all multiple processes.

**normalized effect score**
Effect score related to the scale of the overall effect in a given area over a given period as predicted by the classification model

**normalized environmental profile**
Environmental profile consisting of the normalized effect scores.

**normalizing**
Relating all the effect scores of a functional unit in the environmental profile to the overall magnitude of the same effect scores in a given area over a certain period. This results in the normalized environmental profile which consists of normalized effect scores.

**open loop recycling** (IO process)
Form of recycling in which the primary and secondary applications occur in different product systems.

**overall apportioned allocation**
Form of allocation in which all subflows which cannot be allocated to main flows on a causal basis are distributed among the main flows. The allocation could be based on physical or economic grounds.

**overall life cycle assessment**
Study of one or more aspects of a product, process, etc. in which the complete life cycle of the study object is considered and which covers a range of aspects such as the environment, costs and safety.

**pollution**
Consequence of emissions to the environment of undegradable substances or emissions.

**process**
Event occurring in a product system (→ economic process) or in the environmental system (→ environmental process).

**process tree**
Graphical representation of the interconnected economic processes which make up the life cycle of a product.

**product**
A tradeable good or service produced by an economic process which is or may be used in a different economic process.

**product system**
Set of processes and flows of goods and services which contribute to the life cycle of a functional unit. The product system covers the complete life cycle.

**recycling**
Processor set of processes to collect and/or process waste from a product system to result in a useful application in the same (→ closed loop recycling) or in another product system (→ open loop recycling).

**reliability analysis**
One of the two analyses made during step 4.2. The uncertainty of the data on the processes, environmental models, etc. is used to judge the reliability of the results.

**resource**
Material found in the environment which can be extracted from the environment in an economic process. There are biotic and abiotic resources.

**reversal point**
In a validity analysis (step 4.2): value of the parameter under consideration at which a result, such as the difference in environmental indices of product A and product B is reversed. The parameter under consideration could be a missing classification factor.

**sensitivity analysis**
Analysis to determine the sensitivity of the outcome of a calculation to small changes in the assumptions or to variations in the range within which the assumptions are assumed to be valid. This includes changes in the process data.

**standard model**
Method used in this guide to model environmental effects.

**step**
Part of a component of an environmental life cycle assessment. Each step covers a complete action.

**system boundary**
Border between one system and another (product system, environmental system, etc.)

**subflows**
All flows to and from an economic process which do not form part of the process goal and which have to be allocated. This includes environmental flows and economic flows with a negative value.

**subprocess tree**
Process tree focussed on a given main process group. For example this could reveal the details of the electricity supply.

**summary process tree**
Process tree limited to the main groups of relevant processes, such as the extraction of resources, energy supply, assembly, transport, use, maintenance and disposal.

**validity analysis**
One of the two analyses included in step 4.2. The influence of choices and assumptions on the outcome is assessed by means of a validity analysis.

**waste**
Materials without any positive economic value created by an economic process. (Sometimes a byproduct with a low value or which makes only a small contribution to the total revenues is also considered as waste.) A distinction can be made between waste to be processed (which is processed in the economic system) and final waste (which is introduced into the environment).

## C.2 List of abbreviations

| | |
|---|---|
| ADI | acceptable daily intake |
| ALI | annual limit of intake |
| AP | acidification potential |
| AVI | waste incinerator |
| BDF | biotic depletion factor |
| B&G | Fuel and Raw Materials Bureau |
| CFC | chlorofluorocarbon |
| CML | Centre of Environmental Science (part of Leiden University) |
| DGM | Directorate-General of Environmental Management (part of VROM) |
| ECA | ecotoxicological classification factor for aquatic ecosystems |
| ECT | ecotoxicological classification factor for terrestrial ecosystems |
| EIA | environmental impact assessment |
| ETP | ecotoxicity potential |
| GWP | global warming potential |
| GFT | putrescible waste |
| HCA | human toxicological classification factor for the air |
| HCS | human toxicological classification factor for the soil |
| HCW | human toxicological classification factor for water |
| HTP | human toxicity potential |
| IBC | isolation, control, monitoring |
| IBPC | Industry, Construction Sector, Products, Consumers (part of DGM) |
| IMET | Institute of Environmental and Energy Technology (part of TNO) |

| | |
|---|---|
| LCA | life cycle assessment |
| MCA | multi-criteria analysis |
| NEPP | National Environmental Policy Plan (1990-1994) |
| NOEC | no observed effect concentration |
| NOH | National Reuse of Waste Research Programme |
| NOVEM | Netherlands Agency for Energy and the Environment |
| NP | nutrification potential |
| ODP | ozone depletion potential |
| OTV | odour threshold value |
| p.m. | *pro memoria* (as a reminder) |
| POCP | photochemical ozone creation potential |
| RDF | refuse derived fuel |
| RIVM | National Institute of Public Health and Environmental Protection |
| RMNO | Advisory Council for Research on Nature and the Environment |
| RUL | Leiden University |
| SI | *Système International des Unités* |
| SR | Substances and Risk Management (now IBPC) |
| TCL | tolerable concentration in air |
| TDI | tolerable daily intake |
| TMTC | terrestrial maximum tolerable concentration |
| TNO | Netherlands Organisation for Applied Scientific Research |
| VOC | volatile organic compound |
| VROM | Ministry of Housing, Planning and Environment |

Eurachem

*A focus for analytical chemistry in Europe*

# The Fitness for Purpose of Analytical Methods

## A Laboratory Guide to Method Validation and Related Topics

**Second Edition 2014**

Eurachem

*A focus for analytical chemistry in Europe*

# Eurachem Guide

# The Fitness for Purpose of Analytical Methods

## A Laboratory Guide to Method Validation and Related Topics

## Second edition


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### Project group


| | |
|---|---|
| Vicki Barwick | LGC (UK) |
| Pedro P. Morillas Bravo | Canal de Isabel II Gestión (ES) |
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| Ulla Oxenbøll Lund | Eurofins Miljø A/S (DK) |
| Bertil Magnusson (editor) | SP Technical Research Institute of Sweden (SE) |
| Hans-Thomas Müller | Mersin (TR) |
| Marina Patriarca | Istituto Superiore di Sanità (IT) |
| Barbara Pohl | Merck KGaA (DE) |
| Piotr Robouch | European Commission (EU) |
| Lorens P. Sibbesen (chairman) | Labquality International (DK) |
| Elvar Theodorsson | University Hospital in Linköping (SE) |
| Florent Vanstapel | University Hospital Leuven, Leuven (BE) |
| Isabelle Vercruysse | BELAB (BE) |
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| Perihan Yolci Ömeroglu | Okan University (TR) |
| Ulf Örnemark (editor) | Emendo Dokumentgranskning (SE) |





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**Subject to journal requirements*

# Contents

# Foreword to the second edition

Since the first edition of this Guide in 1998, a number of important developments in analytical quality have taken place. Firstly, the ISO 9000 series of standards, which is widely used to provide a basis for a quality management system, has been revised. Its philosophy forms an integral part of international conformity assessment standards and guides, which underpins competence requirements for laboratories, proficiency testing (PT) providers and reference material (RM) producers. These documents all stress the importance of using validated methods.

Secondly, several general or sector-specific guides on method validation have been revised or developed. EU legislation contains mandatory requirements for analytical measurements in many sectors.

Thirdly, much effort has been invested by the analytical community in implementing the uncertainty concept. For example, in its Harmonized guidelines for single-laboratory validation of methods of analysis (2002) IUPAC predicted that, "...with an increasing reliance on measurement uncertainty as a key indicator of both fitness for purpose and reliability of results, analytical chemists will increasingly undertake measurement validation to support uncertainty estimation...". In the following years, accreditation bodies issued policies and guidance documents clearly recognising the use of method validation data in the measurement uncertainty estimation process.

Furthermore, the International vocabulary of metrology – Basic and general concepts and associated terms (VIM) has been substantially revised, taking into account chemical and biological measurements. Although terminology related to method validation is far from harmonised, the situation has improved. VIM is also a normative document for laboratories accredited to, e.g. ISO/IEC 17025 and ISO 15189.

The second edition of this Guide aims to reflect changes in international standards and guidance documents and puts less emphasis on terms and definitions. Instead the Guide refers to the VIM and other readily available sources. As a consequence, the list of terms and definitions has been omitted from the Annex. Literature cited in this edition of this Guide are listed in the Bibliography at the end. Additional sources and literature related to method development and validation is available as a 'Reading list' under the menu item 'Publications' on the Eurachem website at www.eurachem.org. Annex A is revised as a consequence of changes to ISO 78-2. This edition has also been extended to include information on the statistical basis of limit of detection calculations (Annex B), analysis of variance (Annex C) and qualitative analysis (Annex D).

It is becoming increasingly common among routine laboratories, especially in the clinical sector, to use commercially available measuring systems. This means that the responsibility for validation mainly lies with the manufacturer. The laboratory's work will focus on verifying the manufacturer's published performance data and demonstrate that the method works on the end-user's premises.

However, looking back to the foreword to the first edition, we conclude that the six principles stated there are still relevant, and are consistent with the requirements of international standards such as ISO/IEC 17025.

# Foreword to the first edition*

An initiative in the UK to promote good practice in analytical measurement has identified six principles of analytical practice which, taken together, are considered to constitute best practice. The six principles which are described in more detail in a separate guide† are:

1. "Analytical measurements should be made to satisfy an agreed requirement." (i.e. to a defined objective).
2. "Analytical measurements should be made using methods and equipment which have been tested to ensure they are fit for purpose."
3. "Staff making analytical measurements should be both qualified and competent to undertake the task." (and demonstrate that they can perform the analysis properly).
4. "There should be a regular independent assessment of the technical performance of a laboratory."
5. "Analytical measurements made in one location should be consistent with those made elsewhere."
6. "Organisations making analytical measurements should have well defined quality control and quality assurance procedures."

These principles are equally relevant to laboratories whether they are working in isolation or producing results which need to be compared with those from other laboratories.

This document is principally intended to assist laboratories in implementing Principle 2, by giving guidance on the evaluation of testing methods to show that they are fit for purpose.

* The first edition (1998) of this Guide was developed by a Eurachem Working Group from a draft originally produced by LGC. The following persons were members of the Eurachem group at that time:
D. Holcombe, P. De Bièvre, D. Böttger, C. Eastwood, J. Hlavay, M. Holmgren, W. Horwitz, M. Lauwaars, B. Lundgren, L. Massart, J. Miller, J. Morkowski, B. te Nijenhuis, B. Nyeland, R. Philipp, P. Radvila, J. Smeyers-Verbeke, R. Stephany, M. Suchanek, C. Vandervoorst, H. Verplaetse, H. Wallien, M. Walsh, W. Wegscheider, D. Westwood, H. J. van de Wiel.

† The manager's guide to VAM, UK Department of Trade and Industry, Valid Analytical Measurement Programme. Published as VAM Principles M. Sargent. Anal. Proc., 1995, 32, 201-202.

# Abbreviations and symbols

The following abbreviations, acronyms and symbols occur in this Guide.

| | |
|---|---|
| AMC | Analytical Methods Committee |
| ANOVA | Analysis of variance |
| AOAC International | a globally recognized standards developing organization |
| ASTM International | a globally recognized standards developing organization |
| BIPM | International Bureau of Weights and Measures |
| CCQM | Consultative Committee for Amount of Substance – Metrology in Chemistry |
| CEN | European Committee for Standardization |
| CITAC | Cooperation on International Traceability in Analytical Chemistry |
| CLSI | Clinical and Laboratory Standards Institute |
| CRM | certified reference material |
| EA | European co-operation for Accreditation |
| EC | European Commission |
| EPA | Environmental Protection Agency |
| EQA | external quality assessment |
| EU | European Union |
| GUM | Evaluation of measurement data – Guide to the expression of uncertainty in measurement |
| ICH | International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use |
| IEC | International Electrotechnical Commission |
| ISO | International Organization for Standardization |
| IUPAC | International Union of Pure and Applied Chemistry |
| JCGM | Joint Committee for Guides in Metrology |
| LOD | limit of detection |
| LOQ | limit of quantification |
| NATA | National Association of Testing Authorities |
| QA | quality assurance |
| QC | quality control |
| RSC | Royal Society of Chemistry |
| SANCO | European Commission's Directorate-General for Health and Consumers |
| SOP | standard operating procedure |
| PT | proficiency testing |
| RM | reference material |
| RSD | relative standard deviation |
| UV/VIS | ultraviolet/visible |
| VIM | International vocabulary of metrology – Basic and general concepts and associated terms |

| | |
|---|---|
| $b$ | absolute bias |
| $b(\%)$ | relative bias in % |
| $k_Q$ | multiplier used in calculating limit of quantification |
| $m$ | number of measurements |
| $n$ | number of replicate observations averaged when reporting results |
| $n_b$ | number of blank observations averaged when calculating the blank correction |
| $r$ | repeatability limit |
| $R$ | reproducibility limit |
| $R(\%)$ | relative recovery (apparent recovery) in per cent |
| $R'(\%)$ | relative spike recovery in per cent |
| $s$ | standard deviation |
| $s_0$ | estimated standard deviation of single results at or near zero concentration |
| $s_0'$ | standard deviation used for calculating an LOD or LOQ |
| $s_I$ | intermediate precision standard deviation |
| $s_r$ | repeatability standard deviation |
| $s_R$ | reproducibility standard deviation |
| $u$ | standard uncertainty |
| $\overline{x}$ | mean value (arithmetic average) |
| $x_{\text{ref}}$ | reference value |
| $\bar{x}_{\text{ref}}$ | mean value of measurements with an alternative method, e.g. a reference method |
| $\bar{x}'$ | mean value of spiked sample in a recovery experiment |
| $x_{\text{spike}}$ | added concentration in a recovery experiment |

# 1 Introduction

## 1.1 Rationale and scope for this Guide

Method validation is an important requirement in the practice of chemical analysis. Most analytical chemists are aware of its importance, but why it should be done and when, and exactly what needs to be done, is not always clear to them. Some analysts used to see method validation as something that can only be done in collaboration with other laboratories and therefore refrained from it. Requirements in standards such as ISO/IEC 17025 [1], ISO 15189 [2] and ISO 15195 [3] have helped in clarifying this. For example, the need to demonstrate that methods are fit for purpose is stressed in Clause 5.4.2 of ISO/IEC 17025:

"*The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests and/or calibrations it undertakes...*" and further: "*When the customer does not specify the method to be used, the laboratory shall select appropriate methods...*".

The purpose of this Guide is to discuss the issues related to method validation and increase readers' understanding of what is involved, why it is important, and give some idea of how it can be accomplished.

The Guide is expected to be of most use to a) laboratory managers responsible for ensuring that the methods under their supervision are adequately validated and b) analysts responsible for planning and carrying out studies on methods for validation purposes. Other staff may find the guidance of use as a source of background information – senior staff from a management point of view and junior staff from a technical or educational point of view.

The Guide focuses on single-laboratory validation. It aims to direct the reader towards established protocols where these exist and where they do not, give a simple introduction to the processes involved in validation and provide some basic ideas to enable the reader to design their own validation strategies. It includes references to further material on particular technical aspects of validation.

This Guide is aimed at the validation of quantitative methods. However, some of the principles described here are also relevant for qualitative methods for determining the presence of one or more analytes, e.g. the concepts of selectivity and limit of detection (LOD).

The Guide avoids emphasis on the use of statistics although undoubtedly those with a working knowledge of elementary statistics will find the method validation process easier to understand and implement. Several references are made to publications on basic statistics for chemists [4, 5, 6].

The analyst's understanding of method validation is inhibited by the fact that many of the metrological and technical terms used to describe processes for evaluating methods vary in different sectors of analytical measurement, both in their meaning and the way they are determined. This Guide cannot say where a term is used correctly or incorrectly although it is intended to provide some clarification. The best advice when using a term that may be misunderstood, is to state the source and which convention has been used.

It is implicit in the method validation process that the studies to determine method performance characteristics[*] are carried out using equipment that is within specification, working correctly, and adequately calibrated. Therefore, this Guide does not cover specifically the concepts of 'equipment qualification' or 'instrument qualification'. Likewise the analyst carrying out the studies must be competent in the field of work under study, and have sufficient knowledge related to the work to be able to make appropriate decisions from the observations made as the study progresses.

## 1.2 Notes on the use of this Guide

### *1.2.1 Terminology*

In the revision of this Guide the main focus has been on updating the terminology and literature references to reflect developments since the Guide was first published fifteen years ago. With regards to terminology we have, where possible, followed the 3rd edition of the VIM first published in 2007 [7, 8]. This has been supplemented, where necessary, with

[*] Commonly used synonyms for method performance characteristics are 'method performance parameters', 'metrological characteristics' and 'performance properties'.

terminology used in ISO/IEC 17025:2005 [1], other ISO documents [9, 10, 11] and the IUPAC Harmonized Guidelines for Single-Laboratory Validation from 2002 [12] to reflect terms commonly used in analytical laboratories.

In some cases it may be difficult to decide which term to use when several similar terms are in use. For clarity it has been considered important to use a term consistently throughout the Guide. One example is the term used to describe the document that gives a detailed description of the method to be validated using personnel and equipment in a particular laboratory. For quantitative analysis VIM refers to the *measurement procedure*, in ISO/IEC 17025 this is the *method*, in ISO 15189 [2] it is the *examination procedure* and many laboratories refer to their *standard operating procedure* (*SOP*). The working group has decided to adhere to ISO/IEC 17025 and use the generic term *method*. Consequently, this Guide uses the commonly recognised term 'method validation' although 'procedure validation' would be more correct.

The terms 'ruggedness' and 'selectivity' are preferred to 'robustness' and 'specificity' [13] since the former are used by IUPAC [12].

Various terms, e.g. 'calibration', 'measurement', 'testing', 'analysis' and 'examination' are used to describe laboratory work. This Guide uses 'analysis' in a general sense and specifies, where necessary, the circumstances. Similarly, this Guide often refers to a measured concentration although several other quantities are regularly investigated in the chemistry laboratory [14].

In the processes of sampling, sample preparation and analysis terms such as 'sampling target', 'primary sample', 'increment', 'composite sample', 'subsample', 'laboratory sample', 'test sample', 'test portion' and 'test solution' may be used [15, 16]. In this Guide we normally use the general term 'sample' or 'test sample' [17].[*] The most important terms used in the Guide are defined in the text. Definitions in VIM, ISO 9000 [9] and IUPAC [17, 18] have been provided wherever possible. The terms in VIM related to analytical chemistry are further explained in the Eurachem Guide "Terminology in analytical measurement" [8]. Users should note that there is still no universal agreement on the definition of some of the terms used in method validation.

### *1.2.2 Quick References*

In Section 6, the shaded boxes provide '*Quick Reference*' advice related to the specific performance characteristic of a method. However, it is recognised that in many cases laboratories will not have the time and resources to carry out experiments in the detail described here. Carrying out the operations described in the boxes, using less replication than suggested, will still yield useful information and is certainly better than no work at all. However, the information provided will be less reliable than if full replication had been utilised.

[*] Test sample: Sample, prepared from the laboratory sample, from which test portions are removed for testing or for analysis [17].

# 2 What is method validation?

## 2.1 Definitions

Definitions of ***validation*** from three international documents are given in Table 1. ***Method validation*** is basically the process of defining an analytical requirement, and confirming that the method under consideration has capabilities consistent with what the application requires. Inherent in this is the need to evaluate the method's performance. The judgement of method suitability is important; in the past method validation tended to concentrate only on evaluating the performance characteristics.

Method validation is usually considered to be very closely tied to method development. Many of the method performance characteristics (Table 2) that are associated with method validation are usually evaluated, at least approximately, as part of method development. However, it is important to remember that formal validation of the final version of the method (the documented procedure) should be carried out.

Some sectors use the concepts of 'primary validation' and 'secondary validation', the latter in the sense of verification [19]. The concepts 'qualification' and 'metrological confirmation' [20] also seem to cover verification (Table 1).

## 2.2 What is the difference between validation and verification?

ISO 9000 [9] defines verification as "confirmation, through provision of objective evidence, that specified requirements have been fulfilled". This is very similar to the definition of validation in Table 1. The VIM [7] states that verification is "provision of objective evidence that a given item fulfils specified requirements" and that validation is a "verification, where the specified requirements are adequate for an intended use".

A laboratory may adopt a validated procedure which, e.g. has been published as a standard, or buy a complete measuring system to be used for a specific application from a commercial manufacturer. In both these cases, basic validation work has already been carried out but the laboratory will still need to confirm its ability to apply the method. This is **verification**. It means that some experimental work must be done to demonstrate that the method works in the end-user's laboratory. However, the workload is likely to be considerably less compared to validation of a method that has been developed in-house.

The terms validation and verification are further discussed in the Eurachem Guide on terminology in analytical measurement [8].

**Table 1 – Definitions of the concept 'validation' in ISO 9000, ISO/IEC 17025 and VIM**

| Definition | Reference |
|---|---|
| confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled | ISO 9000 [9][a] |
| confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled | ISO/IEC 17025 [1] |
| verification, where the specified requirements are adequate for an intended use | VIM [7][b] |

[a] ISO 9000 defines 'qualification process' as "process to demonstrate the ability to fulfil specified requirements".

[b] VIM defines 'verification' as "provision of objective evidence that a given item fulfils specified requirements"

**Table 2 – Overview of performance characteristics commonly evaluated during method validation**

| **Performance characteristic** |
|---|
| Selectivity |
| Limit of detection (LOD) and limit of quantification (LOQ) |
| Working range |
| Analytical sensitivity |
| Trueness<br>• bias, recovery |
| Precision<br>• repeatability, intermediate precision and reproducibility |
| Measurement uncertainty[a] |
| Ruggedness (robustness) |
| [a] Strictly, measurement uncertainty is not a performance characteristic of a particular measurement procedure but a property of the results obtained using that measurement procedure. |

# 3 Why is method validation necessary?

## 3.1 Importance of analytical measurement

Millions of tests, measurements and examinations are made every day in thousands of laboratories around the world. There are innumerable reasons underpinning them, for example: as a way of valuing goods for trade purposes; supporting healthcare; checking the quality of drinking water, food and feed; analysing the elemental composition of an alloy to confirm its suitability for use in aircraft construction; forensic analysis of body fluids in criminal investigations. Virtually every aspect of society is supported in some way by analytical work.

The cost of carrying out these measurements is high and additional costs may arise from decisions made on the basis of the results. For example, tests showing food to be unfit for consumption may result in compensation claims; tests confirming the presence of banned drugs could result in fines, imprisonment or even, in some countries, execution. Clearly it is important to make a correct measurement and be able to show that the result is correct.

## 3.2 The professional duty of the analytical chemist

If the result of an analysis cannot be trusted then it has little value and the analysis might as well have not been carried out. When customers commission analytical work from a laboratory, it is assumed that the laboratory has a degree of expert knowledge that the customers do not have themselves. The customer expects to be able to trust results reported and usually only challenges them when a dispute arises. Thus the laboratory and its staff have an obvious responsibility to justify the customer's trust by providing the right answer to the analytical part of the problem, in other words results that have demonstrable 'fitness for purpose'. Implicit in this is that the tests carried out are appropriate for the analytical part of the problem that the customer wishes solved, and that the final report presents the analytical data in such a way that the customer can readily understand it and draw appropriate conclusions. Method validation enables chemists to demonstrate that a method is 'fit for purpose'.

For an analytical result to be fit for its intended use it must be sufficiently reliable that any decision based on it can be taken with confidence. Thus the method performance must be validated and the uncertainty on the result, at a given level of confidence, estimated. Uncertainty should be evaluated and quoted in a way that is widely recognised, internally consistent and easy to interpret [21]. Most of the information required to evaluate uncertainty can be obtained during validation of the method. This topic is dealt with briefly in Section 6.7 and in more detail in the Eurachem/CITAC Guide Quantifying Uncertainty in Analytical Measurement [22].

Regardless of how good a method is and how skilfully it is used, an analytical problem can be solved by the analysis of samples only if those samples are appropriate to the problem. Taking appropriate samples is a skilled job, requiring an understanding of the problem and its related chemistry. A laboratory should, wherever possible, offer advice to the customer on the taking of samples as part of its customer care. Clearly there will be occasions when the laboratory cannot themselves take or influence the taking of the samples. On these occasions results of analysis will need to be reported on the basis of the samples as received, and the report should make this distinction clear.

We have mostly (and rightly) focused on the overall objective of performing method validation, i.e. demonstrating that methods are 'fit for purpose'. However, it should be recognised that a method validation study gives additional benefits to the laboratory undertaking the validation. It provides a solid knowledge and experience of the practical details of performing the method, including awareness of any critical steps in the process. Validation gives the laboratory and its employees a greater confidence in their own results.

## 3.3 Method development

The validation work is preceded by a development phase which may involve different staff and which can take a number of forms.

At one extreme, it may involve adapting an existing method by making minor changes so that it is suitable for a new application. For example, a method required to determine toluene in water might be adapted from an established method for benzene in water. The matrix is the same, and the two analytes have broadly similar

properties. It is likely that the same principles of isolation, identification, and quantification that are applied to benzene can also be applied to toluene. If, on the other hand, a method is required to determine benzene in soil, adaptation of the benzene in water method may not be the best option. Adaptation of some other method for determining organics in soil may be a better starting point.

At the other extreme, the analytical chemist may start out with a few sketchy ideas and apply expertise and experience to devise a suitable method. This clearly involves a great deal more work and a degree of doubt as to whether the final method will be successful. It is not unusual for method development to involve work on a number of different ideas simultaneously before eventually choosing one winner.

Regardless of how much effort has been invested during method development, there is no guarantee the method will perform adequately during validation (or under routine conditions in a particular laboratory). When different staff are involved in the development and validation phase this offers the possibility of checking that the instructions (the measurement procedure) can be understood and implemented.

# 4 When should methods be validated or verified?

## 4.1 Method validation

A method should be validated when it is necessary to demonstrate that its performance characteristics are adequate for use for a particular purpose. For example, it is stated in Clause 5.4.5.2 of ISO/IEC 17025 [1] that the laboratory shall validate:

- non-standard methods;
- laboratory-designed/developed methods;
- standard methods used outside their intended scope;
- amplifications and modifications of standard methods.

Validation must be as extensive as necessary to meet the requirements in connection with the given use or the given application [23]. The extent ('scale', 'scope') of validation will depend on the application, the nature of the changes made, and the circumstances in which the method is going to be used.

Validation is also required when it is necessary to demonstrate the equivalence of results obtained by two methods, e.g. a newly developed method and an existing standard/regulatory method.

## 4.2 Method verification

For standard(ised) methods, such as those published by, e.g. ISO or ASTM, validation by the laboratory using the method is not necessary. However, the laboratory needs to verify the performance of the method as detailed in ISO/IEC 17025 Clause 5.4.2:

*…The laboratory shall confirm that it can properly operate standard methods before introducing the tests or calibrations*.

Verification is also required when there is an important change such as a new but similar instrument, relocation of equipment etc.

In laboratory medicine a majority of measurements and tests are performed with commercial procedures which have already been validated by the manufacturer, but which need to be verified by the end-user [24]. ISO 15189 [2] stresses that *examination procedures used without modification shall be subject to independent verification by the laboratory before being introduced into routine use.* This could also include when an instrument is updated with new software, or when quality control indicates that the performance of an established method is changing with time.

# 5 How should methods be validated?

## 5.1 Who carries out method validation?

### 5.1.1 Approaches to method validation

Once the initial method development is finished, the laboratory should document the measurement procedure in detail (see Annex A). It is this documented procedure that is taken forward for the formal validation.

There are two main approaches to method validation; the interlaboratory comparison approach and the single-laboratory approach. Regardless of the approach, it is the laboratory using a method which is responsible for ensuring that it is fit for the intended use and, if necessary, for carrying out further work to supplement existing validation data.

### 5.1.2 Interlaboratory approach

Much has been published in the literature concerning method validation by dedicated interlaboratory comparisons often referred to as 'collaborative studies' or 'cooperative studies'. There are a number of protocols relating to this type of validation [25, 26, 27, 28], as well as the ISO 5725 standards [29] which can be regarded as the most generally applicable. If a method is being developed which will have wide-ranging use, perhaps as a published standardised procedure, then a collaborative study involving a group of laboratories is probably the preferred way of carrying out the validation. A published method validated in this way is demonstrated to be robust. Published information normally contains precision (repeatability, reproducibility and/or corresponding precision limits) and, sometimes, bias estimates. Where a method has been validated by a standards approving organisation, such as ISO, CEN or AOAC International, the user will normally need only to verify published performance data and/or establish performance data for their own use of the method. This approach, therefore, reduces the workload for the laboratory using the method.

### 5.1.3 Single-laboratory approach

Laboratories will from time to time find that a method is needed but not available as a published standard. If the method is developed for use in one laboratory, for example because there is no general interest in the method or because other laboratories are competitors, the single-laboratory approach is appropriate [12].

Whether or not methods validated in a single laboratory will be acceptable for regulatory purposes depends on any guidelines covering the area of measurement concerned. It should normally be possible to get a clear policy statement from the appropriate regulatory body.

## 5.2 Extent of validation studies

The laboratory has to decide which performance characteristics (see Table 2 and Section 6) need to be investigated in order to validate the method and, in some cases, how detailed the investigation of a single performance characteristic should be. The IUPAC protocol [12] lists a number of situations, which takes into account, among other things, the status of the method and the competence of the laboratory.

Where the scope of the analytical work is well defined and applications are similar over time, it may be possible for an organisation or sector to issue general guidelines for the extent of validation studies. An example from the pharmaceutical sector is shown in Table 3.

Starting with a carefully considered analytical specification given in the scope of the documented procedure (see A.5 in Annex A) provides a good base on which to plan the validation process, but it is recognised that in practice this is not always possible. The assessment of method performance may be constrained. This is acknowledged in ISO/IEC 17025, clause 5.4.5.3 as *Validation is always a balance between costs, risks and technical possibilities*. The laboratory should do its best within the constraints imposed, taking into account customer and regulatory requirements, existing experience of the method, available tools (Section 5.4), and the need for metrological compatibility [7] with other similar methods already in use within the laboratory or used by other laboratories. Some performance characteristics may have been determined approximately during the method development or method implementation stage. Often a particular set of experiments will yield information on several performance characteristics, so with careful planning the effort required to get the necessary information can be minimised.

**Table 3 – Extent of validation work for four types of analytical applications. Example from the pharmaceutical sector [13]. 'x' signifies a performance characteristic which is normally validated.**

| Performance characteristic | Type of analytical application | | | |
|---|---|---|---|---|
| | Identification test | Quantitative test for impurity | Limit test for impurity | Quantification of main component |
| Selectivity | x | x | x | x |
| Limit of detection | | | x | |
| Limit of quantification | | x | | |
| Working range including linearity | | x | | x |
| Trueness (bias) | | x | | x |
| Precision (repeatability and intermediate precision) | | x | | x |
| NOTE The table is simplified and has been adapted to the structure and terminology used in this Guide. | | | | |

The implications of the constraints discussed above are particularly critical where the method is not going to be used on a routine basis. The process of validating methods which are going to be used on a routine basis is comparatively well-defined. Clearly the same principles apply for ad hoc analysis as for routine testing. It is necessary to have an adequate level of confidence in the results produced. Establishing the balance between time and cost constraints and the need to validate the method is difficult. In some circumstances it may be more appropriate to subcontract the analyses to another laboratory where they can be performed on a routine basis.

## 5.3 Validation plan and report

The validation work shall be performed, and the results reported, according to a documented procedure.

The outline of a validation plan ('validation protocol') and validation report may be stated in sectoral guidelines (see Section 5.5). National accreditation bodies may point to minimum requirements for this documentation [23]. However, a simple template for a combined validation plan and validation report could, e.g. consist of the following sections.

- Title: This section should identify the method and when and who is performing the work. Brief information about the method scope and a short description of the method should be given, as well as details of the status of the method (e.g. an international standard, a method developed in-house etc.), the analyte, measurand, measurement unit, types of sample and the intended use. Sampling and subsampling can be part of the measurement procedure and must, in those cases, be validated. Even if these steps are performed elsewhere, it is useful to include information about them in the validation plan/report.
- Planning: This section should outline the purpose, e.g. full validation of a new method, verification of performance of a standardised method, extension to method scope, etc. The extent of the validation work should be indicated, i.e. the performance characteristics which will be investigated and any associated requirements.
- Performance characteristics: This section should give a brief explanation of the performance characteristic, repeat any specific requirements, outline the experiments which will be done and how the results are to be evaluated. Results and conclusions from the experiments should be stated. Separate sections are used for each performance characteristic.
- Summary: The last section should summarise the validation work and the results. Implications concerning routine use, and internal and external quality control, can be given. Most importantly, a concluding statement as to whether the method is fit for purpose shall be given. Note that this is a requirement in ISO/IEC 17025 [1].

## 5.4 Validation tools

### 5.4.1 Blanks

Use of various types of blanks enables assessment of how much of the measured signal is attributable to the analyte and how much to other causes. Various types of blank are available to the analyst:

- **Reagent blanks**[*]: Reagents used during the analytical process (including solvents used for extraction or dissolution) are analysed in order to determine whether they contribute to the measurement signal.
- **Sample blanks**. These are essentially sample matrices with no analyte present, e.g. a human urine sample without a specific drug of abuse, or a sample of meat without hormone residues. Sample blanks may be difficult to obtain but such materials are necessary to give a realistic estimate of interferences that would be encountered in the analysis of test samples.

### 5.4.2 Routine test samples

Routine test samples are useful because of the information they provide on precision, interferences etc. which could be realistically encountered in day-to-day work. If the analyte content of a test material is accurately known, it can be used to assess measurement bias. An accurate assessment of analyte content can be obtained using a reference method, although such methods are not always available.

### 5.4.3 Spiked materials/solutions

These are materials or solutions to which the analyte(s) of interest have been deliberately added. These materials or solutions may already contain the analyte of interest so care is needed to ensure the spiking does not lead to analyte levels outside of the working range of the method. Spiking with a known amount of analyte enables the increase in response to the analyte to be measured and calculated in terms of the amount added, even though the absolute amounts of analyte present before and after addition of the spike are not known. Note that most methods of spiking add the analyte in such a way that it will not be as closely bound to the sample matrix as it would be if it was present naturally. Therefore, bias estimates obtained by spiking can be expected to be over-optimistic.

Spiking does not necessarily have to be restricted to the analyte of interest. It could include anything added to the sample in order to gauge the effect of the addition. For example, the sample could be spiked with varying amounts of a particular interference in order to judge the concentration of the interferent at which determination of the analyte is adversely affected. The nature of the spike obviously needs to be identified.

### 5.4.4 Incurred materials

These are materials in which the analyte of interest may be essentially alien, but has been introduced to the bulk at some point prior to the material being sampled. The analyte is thus more closely bound in the matrix than it would be had it been added by spiking. The analyte value will depend on the amounts of analyte in contact with the material, the rate of take-up and loss by the matrix and any other losses through metabolism, spontaneous disintegration or other chemical or physical processes. The usefulness of incurred samples for validation purposes depends on how well the analyte value can be characterised. The following are examples of incurred materials:

1. Herbicides in flour from cereal sprayed with herbicides during its growth;
2. Active ingredients in pharmaceutical formulations added at the formulation stage.
3. Egg-white powder (known protein content) added to a cookie dough before baking when investigating allergens.

### 5.4.5 Measurement standards

Care must be taken when referring to ‘standards’ as the term also applies to written documents, such as ISO standards. Where the term refers to substances used for calibration or identification purposes it is convenient to refer to them as measurement standards or calibrants/calibrators [7]. These are traditionally thought of as solutions of single substances but in practice can be anything in which a particular parameter or property has been characterised to the extent it can serve as a metrological reference.

It is important to distinguish between reference materials (RMs) and certified reference materials (CRMs) [7, 30] because of the significant difference in how they can be used in the method validation process (6.5.2). RMs can be virtually any material used as a basis for reference, and could include laboratory reagents of known purity, industrial chemicals, or other artefacts. The property or analyte of interest needs to be

[*]A reagent blank taken through the entire analytical procedure is sometimes called a ‘procedural blank’.

stable and homogenous but the material does not need to have the high degree of characterisation, metrological traceability, uncertainty and documentation associated with CRMs.

The characterisation of the parameter of interest in a CRM is generally more strictly controlled than for an RM, and in addition the characterised value is certified with a documented metrological traceability and uncertainty. Characterisation is normally done using several different methods, or a single primary measurement procedure, so that as far as possible, any bias in the characterisation is reduced or even eliminated.

Assessment of bias requires a reliable reference point, preferably, a CRM with the same matrix and analyte concentrations as the test samples.

### *5.4.6 Statistics*

Statistical methods are essential for summarising data and for making objective judgements on differences between sets of data (significance testing). Analysts should familiarise themselves with at least the more basic elements of statistical theory particularly as an aid to evaluation of precision, bias, linear range, LOD, LOQ and measurement uncertainty. A number of useful books introducing statistics for analytical chemistry are referenced [5, 6, 31, 32, 33, 34].

## 5.5 Validation requirements

Requirements for how to carry out method validation may be specified in guidelines within a particular sector relevant to the method [13, 25, 35 for example]. Where such requirements exist, it is recommended they are followed. This will ensure that particular validation terminology, together with the statistics used, is interpreted in a manner consistent within the relevant sector. Official recognition of a method may require characterisation using a collaborative study.

## 5.6 Method validation process

Faced with a particular customer problem, the laboratory must first set the analytical requirement which defines the performance characteristics that a method must have to solve that problem (Figure 1).

In response to these requirements, the laboratory needs to identify a suitable existing method, or if necessary develop/modify a method. Note that certain regulations may require a particular method to be followed. Table 4 shows the type of questions which might be posed in formalising an analytical requirement (column 1) and the corresponding performance characteristics of the method which may need to be evaluated (column 2). The laboratory will then identify and evaluate relevant performance characteristics and check them against the analytical requirement. The validation process ends with a conclusion and statement of whether or not the analytical requirement is met. If the analytical requirement is not met, further method development is necessary. This process of development and evaluation continues until the method is deemed capable of meeting the requirement.

In reality an analytical requirement is rarely agreed with the customer beforehand in such a formal way. Customers usually define their requirements in terms of cost and/or time and rarely know how well methods need to perform, although performance requirements for methods may be specified where the methods support a regulatory requirement or compliance with a specification. For example, the European Union (EU) have published requirements, e.g. for the analysis of drinking water [36], for analyses performed within the water framework directive [37], for the determination of the levels of veterinary drug residues in food of animal origin [38] and of pesticide residues in food and feed [39].

However, it will usually be left to the analyst's discretion to decide what performance is required. Very often this will mean setting an analytical requirement in line with the method's known capability (e.g. as published in standardised methods, as observed in proficiency testing (PT) schemes or estimated from mathematical models, such as the Horwitz function [40]).

Financial constraints may dictate that development of a method that satisfies a particular analytical requirement is not economically feasible, in which case the decision must be taken whether to relax the requirement to a more achievable level or rethink the justification for the analysis.

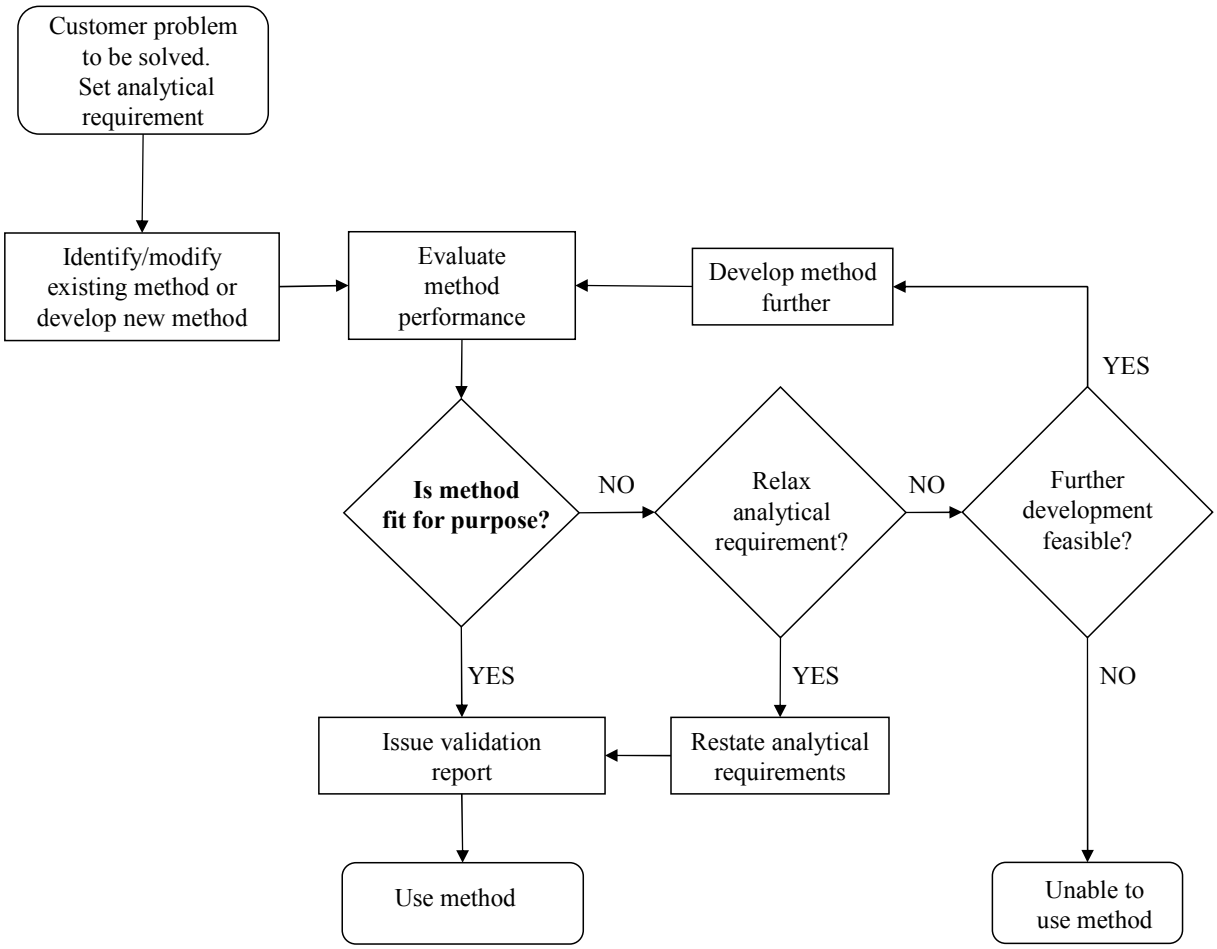



**Figure 1 – The method validation process: from the customer problem to the laboratory decision on whether or not the customer request can be carried out with an identified method. Note: method validation consists of a stage where performance characteristics are evaluated and then compared with analytical requirements. Regardless of what existing performance data may be available for the method, fitness for purpose will be determined by how the method performs when used by the designated analyst with the available equipment/facilities.**

**Table 4 – Questions which might be posed in formalising an analytical requirement, and related performance characteristics with references to the appropriate sections in this Guide**

| Question | Performance characteristic | Section | Note |
|---|---|---|---|
| Do resource constraints apply and how – people, time, money, equipment and reagents, laboratory facilities? | - | - | a) |
| Is sampling and subsampling required (and will this be done within the laboratory)? | | | |
| Are there any restrictions on sample size/availability? | | | |
| What is the chemical, biological and physical nature of the matrix? | | | |
| Is the analyte dispersed or localised? | | | |
| | | | |
| Is a qualitative or quantitative answer required? | Selectivity<br>LOD and LOQ | 6.1<br>6.2 | |
| What are the analytes of interest and the likely levels present (%, µg/g, ng/g, etc.....)? Are the analytes present in more than one chemical form (e.g. oxidation states, stereoisomers), and is it necessary to be able to distinguish between different forms? | Selectivity<br>LOD and LOQ<br>Working and linear ranges | 6.1<br>6.2<br>6.3 | |
| What quantity is intended to be measured ('the measurand')? Is it the 'total' concentration of the analyte present that is of interest, or the 'amount extracted' under specified conditions? | Recovery | 6.5 | |
| What trueness and precision are required? What is the target uncertainty and how is it to be expressed? | Trueness and recovery<br>Repeatability, intermediate precision, reproducibility<br>Uncertainty | 6.5<br>6.6<br>6.7 | b) |
| What are the likely interferences to the analyte(s)? | Selectivity | 6.1 | |
| Have tolerance limits been established for all parameters, critical for performing the analysis (e.g. time of extraction, incubation temperature)? | Ruggedness | 6.8 | c) |
| Do results need to be compared with results from other laboratories? | Uncertainty | 6.7 | b) |
| Do results need to be compared with external specifications? | Uncertainty | 6.7 | b) |

a) Not all of the elements of the analytical requirement link directly to method validation requirements but dictate more generally as to whether particular techniques are applicable. For example, different techniques will be applicable according to whether the analyte is dispersed through the sample or isolated on the surface.

b) One essential element of the analytical requirement is that it should be possible to judge whether or not a method is suitable for its intended purpose and thus must include the required uncertainty expressed either as a standard uncertainty or an expanded uncertainty.

c) Published standardised procedures have normally been shown to be rugged within the scope of the procedure, i.e. matrix types and working range. Therefore single-laboratory verification for implementation of a published standardised procedure need not normally include ruggedness.

# 6 Method performance characteristics

## 6.1 Selectivity

### 6.1.1 Terms and definitions

Analytical selectivity relates to "*the extent to which the method can be used to determine particular analytes in mixtures or matrices without interferences from other components of similar behaviour"* [41].

Definitions in various documents [7, 18, 42] more or less agree with this interpretation. While IUPAC recommends the term 'selectivity', some areas, e.g. the pharmaceutical sector [13], use 'specificity' or 'analytical specificity'. The latter is recommended to avoid confusion with 'diagnostic specificity' as used in laboratory medicine [43].

### 6.1.2 Effects of interferences

In general, analytical methods can be said to consist of a measurement stage which may or may not be preceded by an isolation stage. In the measurement stage, the concentration of an analyte is normally not measured directly. Instead a specific property (e.g. intensity of light) is quantified. It is, therefore, crucial to establish that the measured property is only due to the analyte and not to something chemically or physically similar, or arising as a coincidence thus causing a bias in the measurement result. The measurement stage may need to be preceded by an isolation stage in order to improve the selectivity of the measuring system.

Interferences may cause a bias by increasing or decreasing the signal attributed to the measurand. The size of the effect for a given matrix is usually proportional to the signal and is therefore sometimes called a 'proportional' effect. It changes the slope of the calibration function, but not its intercept. This effect is also called 'rotational' [44].

A 'translational' or 'fixed effect' arises from a signal produced by interferences present in the test solution. It is therefore independent of the concentration of the analyte. It is often referred to as a 'background' or 'baseline' interference. It affects the intercept of a calibration function, but not its slope.

It is not unusual for both proportional and translational effects to be present simultaneously. The method of standard additions can only correct for proportional effects.

### 6.1.3 Assessment of selectivity

The selectivity of a procedure must be established for in-house developed methods, methods adapted from the scientific literature and methods published by standardisation bodies used outside the scope specified in the standard method. When methods published by standardisation bodies are used within their scope, selectivity will usually have been studied as part of the standardisation process.

The selectivity of a method is usually investigated by studying its ability to measure the analyte of interest in samples to which specific interferences have been deliberately introduced (those thought likely to be present in samples). Where it is unclear whether or not interferences are already present, the selectivity of the method can be investigated by studying its ability to measure the analyte compared to other independent methods. Example 1 and Example 2 below and Quick Reference 1 illustrate the practical considerations regarding selectivity.

Confirmatory techniques can be useful as a means of verifying identities. The more evidence one can gather, the better. Inevitably there is a trade-off between costs and time taken for analyte identification, and the confidence with which one can decide if the identification has been made correctly.

Whereas evaluation of repeatability requires the measurement to be repeated several times by one technique, confirmation of analyte identity requires the measurement to be performed by several, preferably independent, techniques. Confirmation increases confidence in the technique under examination and is especially useful when the confirmatory techniques operate on significantly different principles. In some applications, for example, the analysis of unknown organics by gas chromatography, the use of confirmatory techniques is essential. When the measurement method being evaluated is highly selective, the use of other confirmatory techniques may not be necessary.

An important aspect of selectivity which must be considered is where an analyte may exist in the sample in more than one form such as: bound or unbound; inorganic or organometallic; or different oxidation states. The definition of the measurand is hence critical to avoid confusion.

**Example 1 – Chromatography.** A peak in a chromatographic trace may be identified as being due to the analyte of interest on the basis that an RM containing the analyte generates a signal at the same point on the chromatogram. But, is the signal due to the analyte or to something else which coincidentally co-elutes, i.e. a fixed effect? It could be either or both. Identification of the analyte, by this means only, is unreliable and some form of supporting evidence is necessary. For example, the chromatography could be repeated using a column of different polarity, employing a different separation principle to establish whether the signal and the signal generated by the RM still appear at the same time. Where a peak is due to more than one compound, a different polarity column may be a good way of separating the compounds. In many cases modern mass spectrometric instruments can offer a high selectivity, e.g. gas or liquid chromatography with mass spectrometric detection.

**Example 2 – Spectroscopy.** In infrared spectroscopy, identification of unknown compounds may be made by matching absorbance signals (i.e. 'peaks') in the analyte spectrum with those of reference spectra stored in a spectral library. Once it is believed the correct identification has been made, a spectrum of an RM of the analyte should be recorded under exactly the same conditions as for the test portion. The larger the number of peaks which match between analyte and RM, the better the confidence that can be placed on the identification being correct. It would also be worthwhile examining how dependant the shape of the spectrum was with respect to how the analyte was isolated and prepared for infrared analysis. For example, if the spectrum was recorded as a salt disc, the particle size distribution of the test portion in the disc might influence the shape of the spectrum.

**Quick Reference 1 – Selectivity**

| What to do | How many times | What to calculate/determine from the data | Comments |
|---|---|---|---|
| Analyse test samples, and RMs by candidate and other independent methods. | 1 | Use the results from the confirmatory techniques to assess the ability of the method to confirm analyte identity and its ability to measure the analyte in isolation from other interferences. | Decide how much supporting evidence is reasonably required to give sufficient reliability. |
| Analyse test samples containing various suspected interferences in the presence of the analytes of interest. | 1 | Examine effect of interferences. Does the presence of the interferent inhibit detection or quantification of the analytes? | If detection or quantification is inhibited by the interferences, further method development will be required. |

## 6.2 Limit of detection and limit of quantification

### *6.2.1 Terms and definitions*

Where measurements are made at low concentrations, there are three general concepts to consider. First, it may be necessary to establish a value of the result which is considered to indicate an analyte level that is significantly different from zero. Often some action is required at this level, such as declaring a material contaminated. This level is known as the 'critical value', 'decision limit' or, in EU directives, CCα [38].

Second, it is important to know the lowest concentration of the analyte that can be detected by the method at a specified level of confidence. That is, at what true concentration will we confidently exceed the critical value described above? Terms such as 'limit of detection' (LOD), 'minimum detectable value', 'detection limit', or, in EU directives, CCβ [38] are used for this concept.

Third, it is also important to establish the lowest level at which the performance is acceptable for a typical application. This third concept is usually referred to as the limit of quantification (LOQ)*.

* Synonyms used include 'quantification limit', 'quantitation limit', 'limit of quantitation', 'limit of

Terminology relating to all these concepts is very diverse and varies between sectors. For example, the terms 'limit of detection' (LOD) or 'detection limit' (DL) were previously not generally accepted, although used in some sectoral documents [13, 38]. However, they are now incorporated into the VIM [7] and IUPAC Gold Book [17]. ISO uses as a general term 'minimum detectable value of the net state variable' which for chemistry translates as 'minimum detectable net concentration' [45, 46, 47, 48]. In this Guide the terms 'critical value', 'limit of detection (LOD)' and 'limit of quantification' (LOQ) are used for the three concepts above. In method validation, it is the LOD and LOQ that are most commonly determined.

It is also necessary to distinguish between the instrument detection limit and the method detection limit. The instrument detection limit can be based on the analysis of a sample, often a reagent blank, presented directly to the instrument (i.e. omitting any sample preparation steps), or on the signal-to-noise ratio in, e.g. a chromatogram. To obtain a method detection limit, the LOD must be based on the analysis of samples that have been taken through the whole measurement procedure using results calculated with the same equation as for the test samples. It is the method detection limit that is most useful for method validation and is therefore the focus of this Guide.

The following paragraphs describe the experimental estimation of LOD and LOQ. The statistical basis for the calculation of the LOD is given in Annex B. Because the LOD and LOQ both depend on the precision at or near zero, Section 6.2.2 first describes the experimental estimation of the standard deviation of results near zero.

### *6.2.2 Determination of the standard deviation at low levels*

Both LOD and LOQ are normally calculated by multiplying a standard deviation ($s_0'$) by a suitable factor. It is important that this standard deviation is representative of the precision obtained for typical test samples, and that sufficient replicate measurements are made to give a reliable estimate. In this section, the standard deviation $s_0'$ is based on a standard deviation $s_0$ for single results near zero, adjusted for any averaging or blank correction used in practice (see below). Alternative approaches are discussed in Section 6.2.5

The following issues should be considered in determining LOD and LOQ from an experiment using simple replication.

**Suitable samples for estimating LOD and LOQ:** The samples used should preferably be either a) blank samples, i.e. matrices containing no detectable analyte, or b) test samples with concentrations of analyte close to or below the expected LOD. Blank samples work well for methods where a measurable signal is obtained for a blank, such as spectrophotometry and atomic spectroscopy. However for techniques such as chromatography, which rely on detecting a peak above the noise, samples with concentration levels close to or above the LOD are required. These can be prepared by, for example, spiking a blank sample (see Section 5.4).

When blank samples or test samples at low concentrations are not available, reagent blanks* can often be used. When these reagent blanks do not go through the whole measurement procedure, and are presented directly to the instrument, the calculation based on these measurements will give the instrument LOQ/LOD.

**Covering the scope of the method:** For methods with a scope covering very different matrices it may be necessary to determine the standard deviation for each matrix separately.

**Ensuring representative replication:** The standard deviation should be representative of the performance of the method as used in the laboratory, i.e. the standard deviation is to be calculated based on test results where analyses are performed exactly according to the whole documented measurement procedure, including any sample preparation steps. The values used for calculating the standard deviation $s_0$ should be in the measurement units specified in the procedure.

**Conditions of measurement:** The standard deviation is normally obtained under repeatability conditions and this is the procedure described in this section. However, a more reliable estimate can be obtained from the use of

determination', 'reporting limit', 'limit of reporting' and 'application limit'.

* There is confusion regarding the terminology relating to blanks – for further discussion see Section 5.4.1.

intermediate precision conditions. This approach is discussed further in Section 6.2.5.

**Number of observations:** The number of replicates ($m$) should be sufficient to obtain an adequate estimate of the standard deviation. Typically between 6 and 15 replicates are considered necessary; 10 replicates are often recommended in validation procedures/protocols (see Section 6.2.5.1).

**Allowing for averaging:** In many measurement procedures the mean of replicates is reported in routine use of the method, where each replicate is obtained by following the entire measurement procedure. In this case the standard deviation of single results $s_0$ should be corrected by dividing with the square root of $n$, where $n$ is the number of replicates averaged in routine use.

**Allowing for the effect of blank corrections:** If blank corrections are specified in the measurement procedure, care needs to be taken when determining the standard deviation used to calculate the LOD or LOQ. If the results obtained during the validation study were all corrected by the same blank value – the approach recommended here for simplicity – the standard deviation of the results will be smaller than that seen in practice when results are corrected by different blank values obtained in different runs.

In this case $s_0$ should be corrected by multiplying by $\sqrt{\frac{1}{n}+\frac{1}{n_b}}$ where $n$ is the number of replicate observations averaged when reporting results where each replicate is obtained following the entire measurement procedure, and $n_b$ is the number of blank observations used to calculate the blank correction.

Note that under intermediate precision conditions results will be corrected by different blank values so no correction of the standard deviation is necessary (see Section 6.2.5).

Example 3 illustrates these calculations and the flow chart in Figure 2 summarises the corrections required for averaging and blank correction.

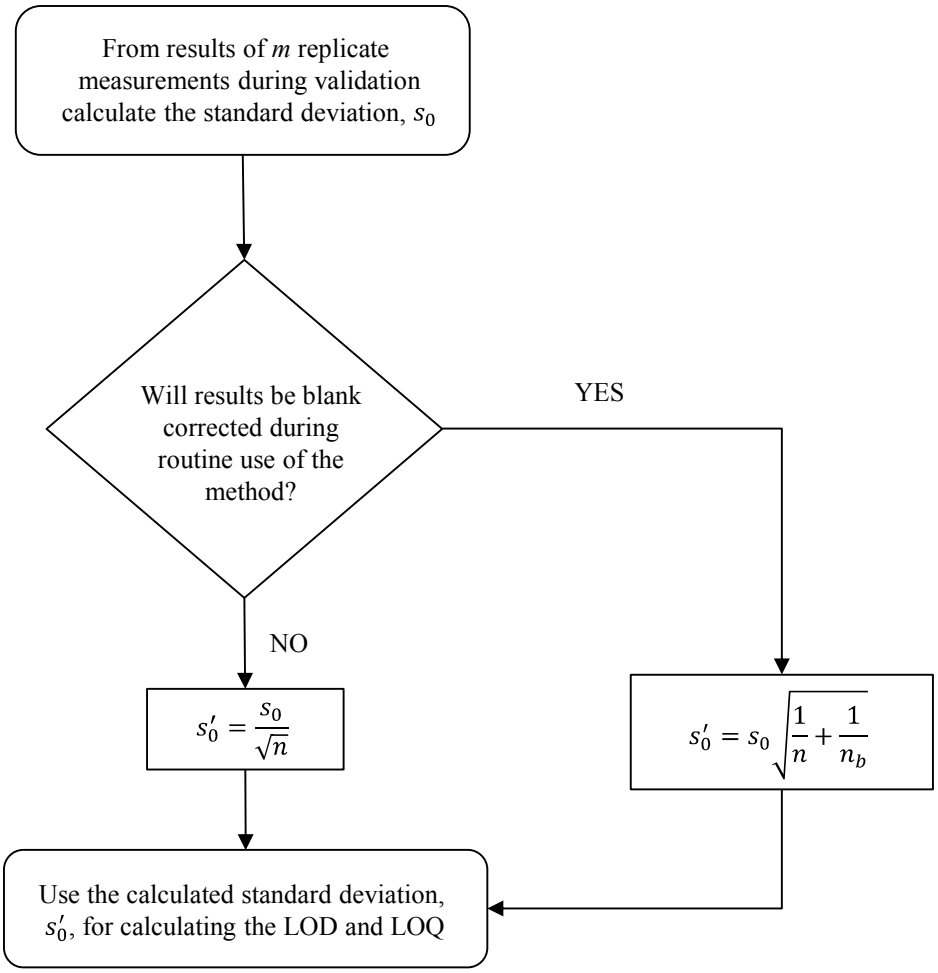
**Example 3 –** A validation exercise is based on the analysis of a sample blank. Ten ($m$) independent measurements of the sample blank are made under repeatability conditions. The results have a mean value of 2 mg/kg and a standard deviation $s_0$ of 1 mg/kg.

Case 1 – The measurement procedure states that test samples should be measured once ($n$=1) and the results corrected by the result for a single sample blank sample ($n_b$=1). In a series of measurements each run consists of single replicates of routine samples and one ($n_b$) blank sample. The standard deviation for calculating LOD/LOQ is then, according to Figure 2 equal to:

$$s_0' = s_0\sqrt{\frac{1}{n}+\frac{1}{n_b}} = 1\sqrt{\frac{1}{1}+\frac{1}{1}} = 1\sqrt{2} = 1.4 \text{ mg/kg}$$

Case 2 – The measurement procedure states that test samples should be analysed in duplicate ($n$=2) and also that the blank sample should be analysed in duplicate. In a series of measurements each run consists of duplicates ($n$=2) of routine samples and two ($n_b$) blank samples. The concentration obtained for routine samples is corrected by subtracting the mean value of the two blank samples. The standard deviation for calculating LOD/LOQ is then, according to Figure 2 equal to:

$$s_0' = s_0\sqrt{\frac{1}{n}+\frac{1}{n_b}} = 1\sqrt{\frac{1}{2}+\frac{1}{2}} = 1 \text{ mg/kg}$$




$s_0$ is the estimated standard deviation of *m* single results at or near zero concentration.

$s_0'$ is the standard deviation used for calculating LOD and LOQ.

$n$ is the number of replicate observations averaged when reporting results where each replicate is obtained following the entire measurement procedure.

$n_b$ is the number of blank observations averaged when calculating the blank correction according to the measurement procedure.

**Figure 2 – Calculation of the standard deviation, $s_0'$ to be used for estimation of LOD and LOQ. The flow chart starts with an experimental standard deviation, $s_0$ calculated from the results of replicate measurements under repeatability conditions on a sample near zero concentration, either without blank correction or with a blank correction applied to all results as specified by the method. This blank correction may be based on a single blank observation or on a mean of several blank observations.**

### 6.2.3 Estimating LOD

For validation purposes it is normally sufficient to provide an approximate value for the LOD, i.e. the level at which detection of the analyte becomes problematic. For this purpose the '3*s*' approach shown in Quick Reference 2 will usually suffice.

Where the work is in support of regulatory or specification compliance, a more exact approach is required, in particular taking into account the degrees of freedom associated with $s_0$. This is described in detail by IUPAC [49] and others [50, 51]. Where the critical value and/or LOD are used for making decisions, the precision should be monitored and the limits may need to be recalculated from time to time. Different sectors and/or regulations may use different approaches to LOD estimation. It is recommended that the convention used is stated when quoting a detection limit. In the absence of any sectoral guidance on LOD estimation, the approaches given in the Quick Reference 2 can be used as a general guidance.

### 6.2.4 Estimating LOQ

The LOQ is the lowest level of analyte that can be determined with acceptable performance. ('Acceptable performance' is variously considered by different guidelines to include precision, precision and trueness, or measurement uncertainty [52]. In practice, however, LOQ is calculated by most conventions to be the analyte concentration corresponding to the obtained standard deviation ($s_0'$) at low levels multiplied by a factor, $k_Q$. The IUPAC default value for $k_Q$ is 10 [49] and if the standard deviation is approximately constant at low concentrations this multiplier corresponds to a relative standard deviation (RSD) of 10 %. Multipliers of 5 and 6 have also sometimes been used which corresponds to RSD values of 20 % and 17 % respectively [53, 54]. See further Reference [8] and Quick Reference 3.

**Quick Reference 2 – Limit of detection (LOD)**

| What to do | How many times | What to calculate from the data | Comments |
|---|---|---|---|
| a) Replicate measurements of blank samples, i.e. matrices containing no detectable analyte.<br>or<br>Replicate measurements of test samples with low concentrations of analyte. | 10 | Calculate the standard deviation, $s_0$ of the results.<br>Calculate $s_0'$ from $s_0$ following the flow chart in Figure 2.<br>Calculate LOD as LOD = $3 \times s_0'$. | |
| b) Replicate measurements of reagent blanks.<br>or<br>Replicate measurements of reagent blanks spiked with low concentrations of analyte. | 10 | Calculate the standard deviation, $s_0$ of the results.<br>Calculate $s_0'$ from $s_0$ following the flow chart in Figure 2.<br>Calculate LOD as LOD = $3 \times s_0'$. | Approach b) is acceptable, when it is not possible to obtain blank samples or test samples at low concentrations.<br>When these reagent blanks are not taken through the whole measurement procedure, and are presented directly to the instrument, the calculation will give the instrument LOD. |

NOTES

1) For some analytical techniques, e.g. chromatography, a test sample containing too low a concentration or a reagent blank might need to be spiked in order to get a non-zero standard deviation.
2) The entire measurement procedure should be repeated for each determination.
3) The standard deviation is expressed in concentration units. When the standard deviation is expressed in signal domain the LOD is the concentration corresponding to the blank signal $y_B + 3 \times s_0'$. A short example of LOD calculations in the signal domain is given also in Reference [5].

**Quick Reference 3 – Limit of quantification (LOQ)**

| What to do | How many times | What to calculate from the data | Comments |
|---|---|---|---|
| a) Replicate measurements of blank samples, i.e. matrices containing no detectable analyte.<br>or<br>Replicate measurements of test samples with low concentrations of analyte. | 10 | Calculate the standard deviation, $s_0$ of the results.<br>Calculate $s_0'$ from $s_0$ following the flow chart in Figure 2.<br>Calculate LOQ as LOQ = $k_Q \times s_0'$. | The value for the multiplier $k_Q$ is usually 10, but other values such as 5 or 6 are commonly used (based on 'fitness for purpose' criteria). |
| b) Replicate measurements of reagent blanks.<br>or<br>Replicate measurements of reagent blanks spiked with low concentrations of analyte. | 10 | Calculate the standard deviation, $s_0$ of the results.<br>Calculate $s_0'$ from $s_0$ following the flow chart in Figure 2.<br>Calculate LOQ as LOQ = $k_Q \times s_0'$. | Approach b) is acceptable, when it is not possible to obtain blank samples or test samples at low concentrations.<br>When these reagent blanks are not taken through the whole measurement procedure and are presented directly to the instrument the calculation will give the instrument LOQ. |
| NOTES<br>1) For some analytical techniques, e.g. chromatography, a test sample containing too low a concentration or a reagent blank might need to be spiked in order to get a non-zero standard deviation.<br>2) The entire measurement procedure should be repeated for each determination.<br>3) The standard deviation is expressed in concentration units. | | | |

### *6.2.5 Alternative procedures*

The previous sections have described a general approach to estimating LOD and LOQ, based on the standard deviation of results at concentrations near zero, obtained under repeatability conditions. This approach is widely applied but alternative procedures are given in other standards and protocols.

In some cases, e.g. where blank values differ significantly from day-to-day, intermediate precision conditions are preferred to repeatability conditions. For example, if quality control results for test samples at low concentration levels are available, the standard deviation of these results can be used in the estimation of LOD and LOQ. Where the standard deviation used to calculate LOD and LOQ is obtained under intermediate precision conditions, the adjustment to take account of blank correction shown in Figure 2 is not required. Therefore the experimental standard deviation obtained from the internal quality control is equal to the standard deviation $s_0'$ to be used for calculating LOD and LOQ. ISO 11843-2 [46] describes how the instrument LOD can be obtained directly from a calibration curve.

#### 6.2.5.1 Reliability of estimates of LOD and LOQ

It should be noted that even with the 10 replicates indicated in Quick Reference 2 and Quick Reference 3, estimates of a standard deviation are inherently variable. Therefore, the estimate of LOD/LOQ obtained during validation should be taken as an indicative value. This will be sufficient if an estimate of LOD/LOQ is required simply to demonstrate that the concentrations of samples will be well above the LOD/LOQ. Where laboratory samples are expected to contain low concentrations of the analyte, the LOD/LOQ should be monitored on a regular basis.

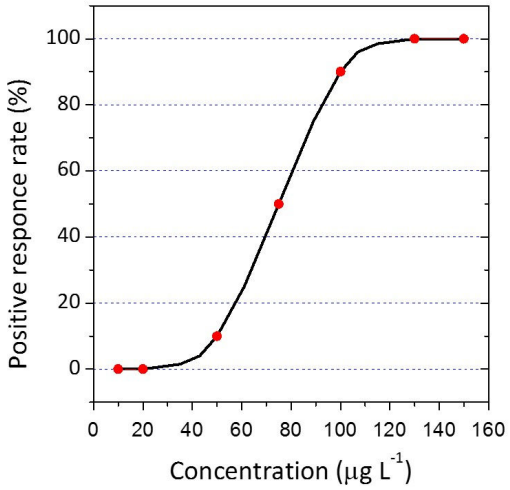
### *6.2.6 Capability of detection for qualitative analysis*

A qualitative analysis (Annex D) involves identification or classification of substances and is effectively a 'yes'/'no' answer at a given cut-off concentration of an analyte [55]. For qualitative methods, precision cannot be expressed as a standard deviation or relative standard deviation, but may be expressed as true and false positive and negative rates.

In a validation study the cut-off concentration can be determined by establishing the false positive and negative rates at a number of levels below and above the expected cut-off concentration. The cut-off limit is where false negative rates for concentrations above the limit are low – with a stated probability, e.g. 5 %. During validation the proposed cut-off limit given in the documented procedure is assessed. (See Example 4 and Quick Reference 4).

**Example 4** – Determination of cut-off concentration for a qualitative method with a stated cut-off equal to 100 µg $L^{-1}$. Ten observations were recorded at each level. A response curve with fraction (in %) of positive results versus concentration was constructed, from which it was possible to determine, by inspection, the threshold concentration at which the test becomes unreliable. With a criterion of < 5 % false negative results, the cut-off concentration is between 100 and 130 µg $L^{-1}$.

| *C* (µg $L^{-1}$) | No. of positive/negative results |
|---|---|
| 150 | 10/0 |
| 130 | 10/0 |
| 100 | 9/1 |
| 75 | 5/5 |
| 50 | 1/9 |
| 20 | 0/10 |
| 10 | 0/10 |




**Quick Reference 4 – Limit of detection (LOD) for qualitative analysis**

| What to do | How many times | What to calculate/determine from the data |
|---|---|---|
| Measure, in random order, sample blanks spiked with the analyte at a range of concentration levels. | 10 | A response curve of % positive or negative results versus concentration should be constructed, from which it will be possible to determine, by inspection, the threshold concentration at which the test becomes unreliable. |

## 6.3 Working range

### 6.3.1 Definition

The 'working range'* is the interval over which the method provides results with an acceptable uncertainty. The lower end of the working range is bounded by the limit of quantification LOQ. The upper end of the working range is defined by concentrations at which significant anomalies in the analytical sensitivity are observed. An example of this is the plateauing effect at high absorbance values in UV/VIS spectroscopy.

### 6.3.2 Considerations for the validation study

The working range of the method to be validated should be stated in the scope of the documented procedure (see A.5 in Annex A). During validation it is necessary to confirm that the method can be used over this interval. In order to assess the working range, the laboratory needs to consider both the method linearity and the proposed calibration procedure given in the method.

### 6.3.3 Method and instrument working range

Many methods rely on the test sample received in the laboratory (the laboratory sample) being processed (digested, extracted, diluted) before it can be presented to the measuring instrument and a signal recorded. In these cases there are two working ranges. The method working range, given in the scope of the method (e.g. Section A.5 in Annex A), relates to the concentration in the laboratory sample. It is expressed, for example, in mg $kg^{-1}$ for a solid test sample. The instrument working range is defined in terms of the concentration in a processed test sample presented to the instrument for measurement (e.g. mg $L^{-1}$ in a solution after extracting the sample). An example of an instrument working range is given in Figure 3A where the concentrations in the calibration standards are plotted versus instrument signal. An example of a method working range is given in Figure 3B where the known test sample concentrations are plotted versus measured concentration. The measured concentration is the result obtained by applying the measurement procedure (including any sample preparation) using the instrument calibrated according to the written method.

In the course of the validation both the instrument working range and the method working range should be assessed. Data on the working range is often generated during method development. In such cases it will be sufficient to include this data in the validation report.

### 6.3.4 Assessing instrument working range

Between the LOQ and the upper end of the instrument working range, the response of the instrument obeys a known relationship, e.g. linear, curvilinear etc. During validation it is necessary to *i*) confirm this relationship, *ii*) demonstrate that the instrument working range is compatible with the interval stated in the method scope, and *iii*) verify that the proposed instrument calibration procedure (single point, bracketing, or multiple points) is adequate.

In order to assess the instrument working range and confirm its fitness for purpose, calibration standards with a concentration span that exceeds the expected concentration range by ± 10 % or even ± 20 % should be studied and the signals plotted (see Quick Reference 5 step 1). For a range 1 to 100 mg $L^{-1}$, ± 20 % indicates from 0.8 to 120 mg $L^{-1}$. The chosen concentrations should be evenly spaced across the range. The initial assessment of the working range is by a visual inspection of the response curve. The next step is to confirm the relationship between concentration and instrument response by examining the regression statistics and residual plot for the chosen model (e.g. linear, quadratic) (see Quick Reference 5 step 2). The assessment may also include special statistical measures, such as 'goodness of fit' tests [56, 57]. From the response curve and the supporting statistics obtained over the instrument working range, the analyst can assess if the suggested calibration procedure given in the method is appropriate. This is further assessed by evaluating the method working range.

* The VIM term [7] is 'measuring interval' or 'working interval'

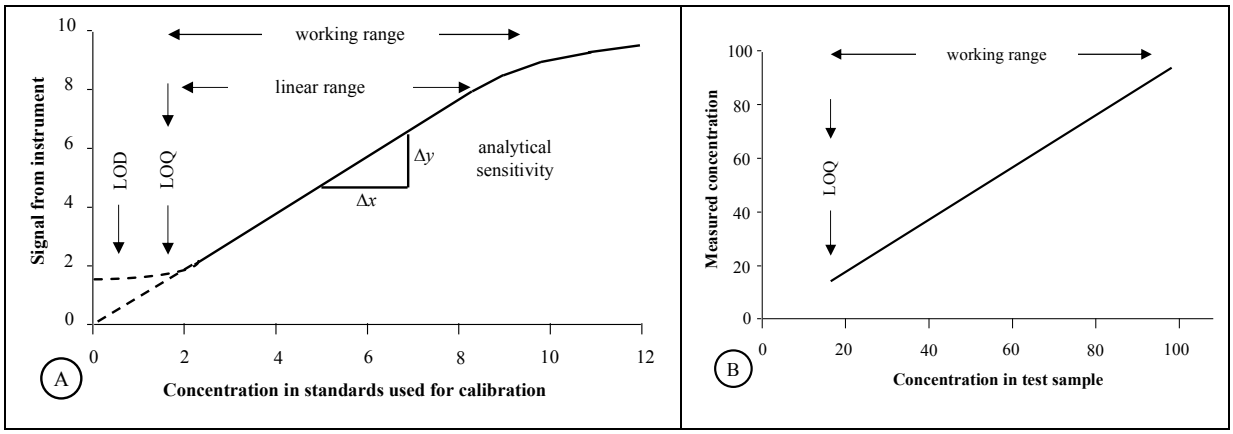



**Figure 3 – A) Typical example of response curve obtained with an instrumental method. The performance characteristics 'working range', 'linear range', 'analytical sensitivity', 'LOD' and 'LOQ' are identified. B) Typical example of a curve obtained with a measurement procedure where the test sample concentration is plotted versus measured concentration.**

### *6.3.5 Assessing method working range*

In order to assess the method working range 1) samples with known concentrations and sample blanks should be available; 2) the samples used should be taken through the entire measurement procedure; 3) the concentrations of the different samples should preferably cover the whole range of interest and 4) the instrument should have been calibrated according to the suggested calibration procedure. The measurement result for each test sample is calculated according to the written procedure (see step 3 in Quick Reference 5). These values are plotted on the *y*-axis against the known concentrations of the samples (*x*-axis) as in Figure 3B. The method working range and linearity are assessed by visual inspection of the plot, supported by statistics and a residuals plot from a linear regression.

The assessment of the working range will be supported by data from precision and bias studies (see Sections 6.5.2 and 6.6.2.1), providing that these studies cover concentrations across the whole method working range.

The method working range needs to be established for each matrix covered in the method scope. This is because interferences can cause non-linear responses, and the ability of the method to extract/recover the analyte may vary with the sample matrix.

**Quick Reference 5 – Working and linear range**

| What to do | How many times | What to calculate from the data | Comments |
|---|---|---|---|
| 1) Measure blank plus calibration standards, at 6-10 concentrations evenly spaced across the *range of interest.* | 1 | Plot response (y axis) against concentration (x axis).<br><br>Visually examine to identify approximate linear range and upper and lower boundaries of the working range for the instrument.<br><br>then go to 2). | This will give visual confirmation of whether or not the instrument working range is linear.<br><br>Note: When the signal is not directly proportional to concentration, e.g. when working with pH or other ion selective electrodes or immunometric methods, a transformation of the measured values is needed before linearity can be assessed. |
| 2) Measure blank plus calibration standards, 2-3 times at 6-10 concentrations evenly spaced across the *linear range.* | 1 | Plot response (y axis) against concentration (x axis). Visually examine for outliers which may not be reflected in the regression.<br><br>Calculate appropriate regression statistics. Calculate and plot residuals (difference between observed y value and calculated y value predicted by the straight line, for each x value). Random distribution of residuals about zero confirms linearity. Systematic trends indicate non-linearity or a change in variance with level. | This stage is necessary to test a working range, thought to be linear and especially where the method uses a two point calibration.<br>If the standard deviation is proportional to concentration then consider using a weighted regression calculation rather than a simple non-weighted linear regression.<br>It is unsafe to remove an outlier without first checking it using further measurements at nearby concentrations.<br>In certain circumstances for instrument calibration it may be better to try to fit a non-linear curve to the data. The number of samples then needs to be increased. Functions higher than quadratic are generally not advised. |
| 3) Calibrate the instrument according to the proposed calibration procedure. Measure, according to the written method, blank plus reference materials or spiked sample blanks 2-3 times at 6-10 concentrations evenly spaced across the range of interest. | 1 | Plot the measured concentration (*y*-axis) against the concentration of the test samples (*x*-axis).<br>Visually examine to identify approximate linear range and upper and lower boundaries of the working range.<br>Calculate appropriate regression statistics. Calculate and plot residuals (difference between observed y value and calculated y value predicted by the straight line, for each x value). Random distribution of residuals about zero confirms linearity. Systematic trends indicate non-linearity. | This step is required to assess whether the proposed instrument range and calibration procedure are fit for purpose.<br><br>If data are available from bias and precision studies that cover the range of interest, a separate method working range study may not be required. |

## 6.4 Analytical sensitivity

### 6.4.1 Definition

Analytical sensitivity is the change in instrument response which corresponds to a change in the measured quantity (for example an analyte concentration), i.e. the gradient of the response curve [7, 18]. The prefix 'analytical' is recommended to avoid confusion with 'diagnostic sensitivity' used in laboratory medicine [43]. The term 'sensitivity' is sometimes used to refer to limit of detection but this use is discouraged in the VIM.

### 6.4.2 Applications

Analytical sensitivity is not a particularly important performance characteristic. There are, however, at least two useful applications:

1. The theoretical analytical sensitivity is sometimes known. Many ion selective electrodes show a Nernstian behaviour, e.g. the signal from a well-functioning glass electrode is expected to change by 59 mV/pH.
2. In spectrophotometric measuring systems the absorbance can be predicted from the Beer-Lambert law. This can be used as a check of instrument performance and standards sometimes require such checks to be made [58].

## 6.5 Trueness

### 6.5.1 Terminology to describe measurement quality

In this Guide we use the three related performance characteristics *trueness*, *precision* and *uncertainty* to describe the quality of results obtained with a method. However, scientists frequently use different concepts, such as types of error (random, systematic and gross errors), accuracy (trueness and precision) and uncertainty. Some of these concepts have a qualitative meaning and some are quantitative. Over the years, terms as well as definitions have changed and new terms have been introduced. In addition, different sectors still favour different terms, all of which leads to a great deal of confusion. Figure 4 illustrates the links between the terms and further details are given in VIM [7] and the Eurachem Guide on terminology [8].

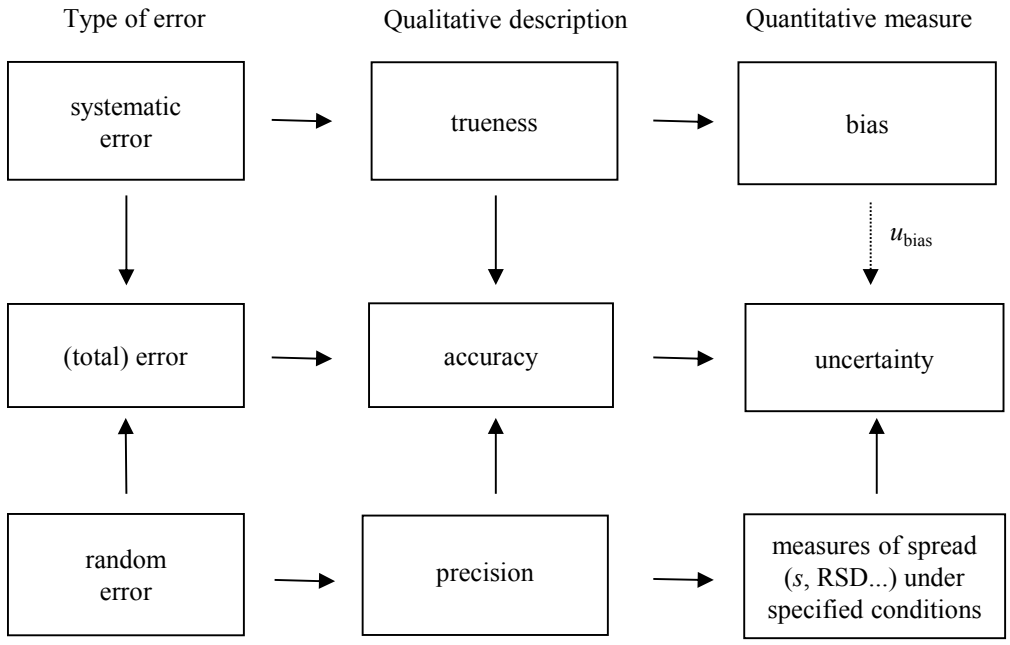



**Figure 4 – Illustration of the links between some fundamental concepts used to describe quality of measurement results (based on the work of Menditto et al. [59]). An uncertainty evaluation according to GUM [21] assumes correction for known bias and that the uncertainty of the bias correction $u_{bias}$ is included in the final uncertainty statement. This is implied by the dotted arrow below the box 'bias'. Both the accuracy concept and the uncertainty concept assume that measurements are performed according to the documented procedure and that effects of 'gross errors' (mistakes) are not included.**

Measurement 'accuracy' expresses the closeness of a single result to a reference value* [29, 48]. (for the exact definition see VIM 2.13). Method validation seeks to investigate the accuracy of results by assessing both systematic and random effects on single results. Accuracy is, therefore, normally studied as two components: 'trueness' and 'precision'. In addition, an increasingly common expression of accuracy is 'measurement uncertainty', which provides a single figure. The evaluation of trueness is described below while precision is discussed in Section 6.6 and uncertainty in Section 6.7.

Measurement 'trueness' is an expression of how close the mean of an infinite number of results (produced by the method) is to a reference value. Since it is not possible to take an infinite number of measurements, trueness cannot be measured. We can, however, make a practical assessment of the trueness. This assessment is normally expressed quantitatively in terms of 'bias'.

### 6.5.2 Determination of bias

A practical determination of bias relies on comparison of the mean of the results ($\bar{x}$) from the candidate method with a suitable reference value ($x_{\text{ref}}$).* Three general approaches are available: a) analysis of reference materials, b) recovery experiments using spiked samples, and c) comparison with results obtained with another method – see Quick Reference 6. Bias studies should cover the method scope and may therefore require the analysis of different sample types and/or different analyte levels. To achieve this, a combination of these different approaches may be required.

The bias can be expressed in absolute terms

$$b = \bar{x} - x_{\text{ref}} \qquad \text{(Eq. 1)}$$

or relative in per cent

$$b(\%) = \frac{\bar{x} - x_{\text{ref}}}{x_{\text{ref}}} \times 100 \qquad \text{(Eq. 2)}$$

or as a relative spike recovery

$$R'(\%) = \frac{\bar{x}' - \bar{x}}{x_{\text{spike}}} \times 100 \qquad \text{(Eq. 3)}$$

where $\bar{x}'$ is the mean value of the spiked sample and $x_{\text{spike}}$ is the added concentration.

However in some sectors of analytical measurement, the relative recovery ('apparent recovery') in per cent is also used [60].

$$R(\%) = \frac{\bar{x}}{x_{\text{ref}}} \times 100 \text{ (Eq. 4)}$$

To determine the bias using an RM, the mean and standard deviation of a series of replicate measurements are determined and the results compared with the assigned property value of the RM. The ideal RM is a certified matrix reference material with property values close to those of the test samples of interest. CRMs are generally accepted as providing traceable values [61, 62]. It is also important to remember that a particular RM should only be used for one purpose during a validation study. For example, an RM used for calibration shall not also be used to evaluate bias.

Compared to the wide range of sample types and analytes encountered by laboratories the availability of RMs is limited, but it is important that the chosen material is *appropriate to the use.* It may be necessary to consider how the RM was characterised, for example if the sample preparation procedure used during characterisation of the material is not intended to give the total analyte concentration but the amount extracted under certain conditions. For regulatory work, a relevant certified material, ideally matrix-matched if available, should be used. For methods used for long-term in-house work, a stable in-house material can be used to monitor bias but a CRM should be used in the initial assessment.

In the absence of suitable RMs, recovery studies (spiking experiments) may be used to give an indication of the likely level of bias. Analytes may be present in a variety of forms in the sample and sometimes only certain forms are of interest to the analyst. The method may thus be deliberately designed to determine only a particular form of the analyte. A failure to determine part of or all of the analyte present may reflect an inherent problem with the method. Hence, it is necessary to assess the efficiency of the method for detecting all of the analyte present [60, 63].

Because it is not usually known how much of a particular analyte is present in a test portion, it is difficult to be certain how successful the method has been at extracting it from the sample matrix. One way to determine the efficiency of extraction is to spike test portions with the analyte at various concentrations, then extract the spiked test portions and measure the analyte concentration. The inherent problem with this is that analyte introduced in such a way will probably not be bound as strongly as that which

* The reference value is sometimes referred to as a 'true value' or a 'conventional true value'.

is naturally present in the test portion matrix and so the technique will give an unrealistically high impression of the extraction efficiency.

It may be possible to assess bias by comparing results from the candidate method with those obtained from an alternative method. There are two general types of alternative method which may be encountered – a reference method or a method currently in routine use in the laboratory. A reference method is intended to provide an 'accepted reference value' for the property being measured and will generally give results with a smaller uncertainty than the candidate method. A particular type of reference method is a primary method.[*] The second case arises when the purpose of the validation is to demonstrate that the candidate method gives results that are equivalent to an existing method. Here the aim is to establish that there is no significant bias in relation to the results produced by the existing method (although this method may itself be biased).

In both cases the results from the candidate and alternative methods, for the same sample or samples, are compared. The sample(s) may be in-house RMs, or simply typical test samples. The advantage of this approach is that the materials do not need to be CRMs as the alternative method provides the reference value. The method can therefore be tested on 'real' samples that are representative of those that will be encountered routinely by the laboratory.

[*] 'Primary method': a method having the highest metrological qualities, whose operation is completely described and understood in terms of SI units and whose results are accepted without reference to a standard of the same quantity (CCQM). The corresponding VIM term (see 2.8 in [7]) is 'primary reference measurement procedure'.

**Quick Reference 6 – Trueness**

| What to do | How many times | What to calculate/determine from the data | Comments |
|---|---|---|---|
| a) Measure RM using candidate method. | 10 | Compare mean value, $\bar{x}$ with reference value $x_{\text{ref}}$ for the RM. Calculate bias, $b$, per cent relative bias, $b(\%)$ or the relative per cent recovery (apparent recovery).<br>$b = \bar{x} - x_{\text{ref}}$<br>$b(\%) = \frac{\bar{x} - \text{x}_{\text{ref}}}{x_{\text{ref}}} \times 100$<br>$R(\%) = \frac{\bar{x}}{x_{\text{ref}}} \times 100$ | Gives a measure of bias taking into account the effect of both method and laboratory bias. |
| b) Measure matrix blanks or test samples unspiked and spiked with the analyte of interest over a range of concentrations. | 10 | Compare the difference between mean spiked value $\bar{x}'$ and mean value $\bar{x}$ with the added concentration $x_{\text{spike}}$. Calculate the relative spike recovery $R'(\%)$ at the various concentrations:<br>$R'(\%) = \frac{\bar{x}' - \bar{x}}{x_{\text{spike}}} \times 100$ | Spiked samples should be compared with the same sample unspiked to assess the net recovery of the added spike.<br>Recoveries from spiked samples or matrix blanks will usually be better than for routine samples in which the analyte is more tightly bound. |
| c) Measure RM/test sample using candidate method and alternative method. | 10 | Compare mean value $\bar{x}$ with mean value $\bar{x}_{\text{ref}}$ of measurements made using alternative method. Calculate bias $b$ or per cent relative bias $b(\%)$ or the relative per cent recovery (apparent recovery).<br>$b = \bar{x} - \bar{x}_{\text{ref}}$<br>$b(\%) = \frac{\bar{x} - \bar{\text{x}}_{\text{ref}}}{\bar{x}_{\text{ref}}} \times 100$<br>$R(\%) = \frac{\bar{x}}{x_{\text{ref}}} \times 100$ | Gives a measure of the bias relative to the alternative method. The alternative method may be a reference method or, if the intention is to replace one method with another and there is a need to demonstrate equivalent performance, a method currently in use in the laboratory.<br>The alternative method may itself be biased, in which case the experiment will not provide an absolute measure of trueness. |
| NOTE Bias may vary with matrix and concentration level which means that the number of matrices and concentration levels to be examined must be stated in the validation plan. | | | |

### *6.5.3 Interpreting bias measurements*

Figure 5 shows two components of bias, here referred to as 'method bias' and 'laboratory bias'.

The method bias arises from systematic errors inherent to the method, irrespective of which laboratory uses it. Laboratory bias arises from additional systematic errors specific to the laboratory and its interpretation of the method. In isolation, a laboratory can only estimate the combined (total) bias from these two sources. However, in checking bias, it is important to be aware of the conventions in force for the particular purpose. For example, for some food applications, regulatory limits are set in terms of the results obtained from the specified empirical ('operationally defined') standard method. Method bias for 'empirical' measurement procedures is by definition zero. Bias arising solely from the particular method (see Figure 5) is then ignored, and metrological comparability with other laboratories using the same method is the main concern. In this situation, the laboratory should ideally determine bias using a reference material certified by the particular regulatory or empirical method under investigation, in which case the usual guidance for checking and interpreting bias applies. Where no such material is available, or to add further information, the laboratory may use alternative materials, but should then take care to consider any known differences between the method under investigation and the method(s) used to obtain the reference value when they interpret the results.

To fulfil a particular analytical requirement, the same analyte may be measured using several different measuring instruments at many sites within the same organisation. In this case, numerous and complex sources of bias arise within the organisation. In this common and complex situation, the organisation may establish procedures for estimating a representative uncertainty covering all sites/instruments for each application. This should preferably use material having the same properties, including sample matrix, as the samples intended to be measured. Variance component analysis can be used to identify the main causes of variation contributing to the overall measurement uncertainty, allowing follow-up action to reduce differences across the organisation.

For most purposes, however, acceptability of bias should be decided on the basis of overall bias measured against appropriate RMs, spiked materials or reference methods, taking into account the precision of the method and any uncertainties in reference values, and the accuracy required by the end use. Statistical significance tests are recommended [64, 65].

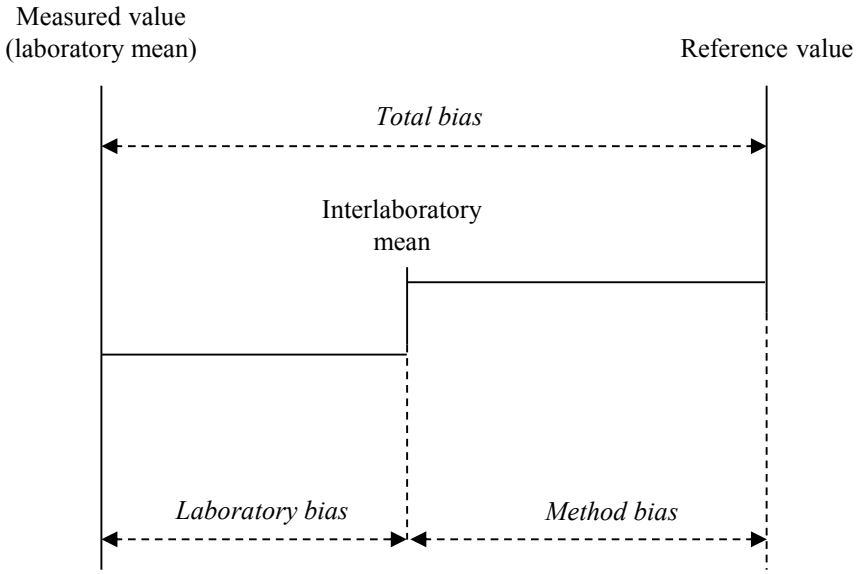



**Figure 5 – The total measured bias consists of method bias and laboratory bias. Note: Laboratory and method biases are shown here acting in the same direction. In reality this is not always the case.**

## 6.6 Precision

### *6.6.1 Replication*

Replication is essential for obtaining reliable estimates of method performance characteristics such as precision and bias. Experiments involving replicate analysis should be designed to take into account all of the variations in operational conditions which can be expected during routine use of the method. The aim should be to determine typical variability and not minimum variability.

### *6.6.2 Precision conditions*

Precision (measurement precision) is a measure of how close results are to one another [7, 29]. It is usually expressed by statistical parameters which describe the spread of results, typically the standard deviation (or relative standard deviation), calculated from results obtained by carrying out replicate measurements on a suitable material under specified conditions. Deciding on the 'specified conditions' is an important aspect of evaluating measurement precision – the conditions determine the type of precision estimate obtained.

'Measurement repeatability' and 'measurement reproducibility' represent the two extreme measures of precision which can be obtained. Documentation of standardised methods (e.g. from ISO) will normally include both repeatability and reproducibility data where applicable.

Repeatability, expected to give the smallest variation in results, is a measure of the variability in results when a measurement is performed by a single analyst using the same equipment over a short timescale.[*]

Reproducibility, expected to give the largest variation in results, is a measure of the variability in results between laboratories.[†]

Between these two extremes, 'intermediate (measurement) precision' gives an estimate of the variation in results when measurements are made in a single laboratory but under conditions that are more variable than repeatability conditions. The exact conditions used should be stated in each case. The aim is to obtain a precision estimate that reflects all sources of variation that will occur in a single laboratory under routine conditions (different analysts, extended timescale, different pieces of equipment etc.).[‡]

#### 6.6.2.1 Estimates of precision – general aspects

Precision is generally dependent on analyte concentration, and so should be determined at a number of concentrations across the range of interest. This could include a particular concentration of interest (such as a regulatory limit) plus concentrations at the limits of the measuring interval. If relevant, the relationship between precision and analyte concentration should be established. In cases where the measured concentration is well above the detection limit, the precision is often found to be proportional to analyte concentration. In such cases it may be more appropriate to express precision as a relative standard deviation since this is approximately constant over the range of interest.

For qualitative methods, precision cannot be expressed as a standard deviation or relative standard deviation, but may be expressed as true and false positive (and negative) rates [55] (see Section 6.2.6).

Evaluation of precision requires sufficient replicate measurements to be made on suitable materials. The materials should be representative of test samples in terms of matrix and analyte concentration, homogeneity and stability, but do not need to be CRMs. The replicates should also be independent, i.e. the entire measurement process, including any sample preparation steps, should be repeated. The minimum number of replicates specified varies with different protocols, but is typically between 6 and 15 for each material used in the study.

It should be kept in mind that it is difficult to estimate a reliable standard deviation from data sets with few replicates. If admissible, the values calculated from several small sets of replicate measurements can be combined (pooled) to obtain estimates with sufficient degrees of freedom.

[*] Repeatability is sometimes referred to as 'within-run', 'within-batch' or 'intra-assay' precision.

[†] In validation reproducibility refers to the variation between laboratories using the same method. Reproducibility may also refer to the variation observed between laboratories using different methods but intending to measure the same quantity [7].

[‡] Intermediate precision is sometimes referred to as 'within-laboratory reproducibility', 'between-run variation', 'between batches variation' or 'inter-assay variation'.

Certain experimental designs, analysed using analysis of variance (ANOVA), are an efficient way of obtaining estimates of repeatability and intermediate precision with a suitable number of degrees of freedom (see Section 6.6.4 and Annex C for further explanation of this approach). See Quick Reference 7 for information on experiments to assess precision.

### 6.6.3 Precision limits

From the standard deviation $s$ it is useful to calculate a 'precision limit' [29, 48]. This enables the analyst to decide whether there is a significant difference, at a specified level of confidence, between results from duplicate analyses of a sample obtained under specified conditions. The repeatability limit ($r$) is calculated as follows:

$$r = \sqrt{2} \times t \times s_r \quad \text{(Eq. 5)}$$

where the factor $\sqrt{2}$ reflects the difference between two measurements, $t$ is the two-tailed Student $t$-value for a specified number of degrees of freedom (which relates to the estimate of $s_r$) and at the required level of confidence. For relatively large numbers of degrees of freedom, $t \approx 2$ at the 95 % confidence level, so the repeatability limit is often approximated as:

$$r = 2.8 \times s_r \quad \text{(Eq. 6)}$$

The intermediate precision limit and the reproducibility limit ($R$) are calculated in a similar way, replacing $s_r$ with $s_I$ and $s_R$, respectively.

Documentation of standardised methods (e.g. from ISO) will normally include data for both the repeatability limit and reproducibility limit where applicable.

### 6.6.4 Simultaneous determination of repeatability and intermediate precision

Approaches to simultaneous determination of repeatability and intermediate precision are described in ISO 5725-3 [29]. In addition, a design based on the Harmonized guidelines for single-laboratory validation of methods of analysis [12] offers the possibility to determine repeatability and intermediate precision from a single study. Subsamples of the selected test material are analysed in replicate under repeatability conditions across a number of different runs, with maximum variation in conditions between the runs (different days, different analysts, different equipment, etc.). Via one-way ANOVA [5, 6], repeatability can be calculated as the within-group precision, while the intermediate precision is obtained as the square root of the sum of squares of the within-group and between-group precision. This type of design can provide an efficient way of obtaining sufficient degrees of freedom for estimates of repeatability and between-group precision. For example, 8 groups of 2 replicates leads to 8 and 7 degrees of freedom for the estimates of repeatability and between run precision, respectively. See further Annex C.

**Quick Reference 7 – Repeatability, intermediate precision and reproducibility**

| What to do | How many times | What to calculate/determine from the data | Comments |
|---|---|---|---|
| Measure RMs, surplus test samples or spiked sample blanks at various concentrations across working range. Repeatability and intermediate precision can be determined from separate studies (see a) and b) below) or simultaneously in a single study (see c) below. | | | |
| a) Same analyst and equipment, same laboratory, short timescale. | 6-15 replicates for each material. | Determine standard deviation *(s)* of results for each material. | Estimates repeatability standard deviation $s_r$ for each material.[a] |
| b) Different analysts and equipment, same laboratory, extended timescale. | 6-15 replicates for each material. | Determine standard deviation *(s)* of results for each material. | Estimates intermediate precision standard deviation $s_I$ for each material. |
| c) Different analysts and equipment, same laboratory, extended timescale. | 6-15 groups of duplicate measurements[b] obtained under repeatability conditions on different days/equipment for each material. | Calculate repeatability standard deviation from ANOVA results for each material.<br><br>Calculate between-group standard deviation from ANOVA and combine with repeatability standard deviation for each material. | Estimates repeatability standard deviation $s_r$ for each material.<br><br>Estimates intermediate precision standard deviation $s_I$ for each material. |
| d) Different analysts and equipment, different laboratories, extended timescale. | 6-15 groups of duplicate measurements[b] obtained under repeatability conditions in different laboratories for each material. | Calculate repeatability standard deviation from ANOVA results for each material.<br><br>Calculate between-laboratory standard deviation from ANOVA results and combine with repeatability standard deviation for each material. | Estimates repeatability standard deviation $s_r$ for each material.<br><br>Estimates reproducibility standard deviation $s_R$ for each material. This requires a special inter-laboratory comparison ('collaborative trial'). |

[a] A repeatability standard deviation can also be estimated by pooling of several small data sets, e.g. $n$ =2, from different days.

[b] Duplicate measurements within each group will provide a balanced number of degrees of freedom for the estimates of the within- and between-group standard deviations. Increasing the number of replicates per group will increase the number of degrees of freedom associated with the estimate of the repeatability.

## 6.7 Measurement uncertainty

A full discussion of (measurement) uncertainty is beyond the scope of this Guide but detailed information can be found elsewhere [21, 22]. Uncertainty is an interval associated with a measurement result which expresses the range of values that can reasonably be attributed to the quantity being measured. An uncertainty estimate should take account of *all recognised effects* operating on the result. The uncertainties associated with each effect are combined according to well-established procedures.

Several approaches to obtaining an uncertainty estimate for the results from chemical measurements are described [22, 66, 67, 68]. These take into account:

- the overall, long-term precision of the method (i.e. the intermediate precision or reproducibility);
- bias and its uncertainty, including the statistical uncertainty involved in the bias measurements, and the uncertainty in the reference value [69, 70, 71, 72, 73];
- equipment calibration. Uncertainties associated with calibration of equipment such as balances, thermometers, pipettes and flasks are often negligibly small in comparison to the overall precision and the uncertainty in the bias. If this can be verified then calibration uncertainties do not need to be included in the uncertainty estimate;
- any significant effects operating in addition to the above. For example, temperature or time ranges permitted by the method may not be fully exercised in validation studies, and their effect may need to be added. Such effects can be usefully quantified by ruggedness studies (see Section 6.8), or related studies which establish the size of a given effect on the result.

Where the contribution of individual effects is important, for example in calibration laboratories, it will be necessary to consider the individual contributions from all individual effects separately.

Note that, subject to additional consideration of effects outside the scope of a collaborative study, the reproducibility standard deviation forms a working estimate of combined standard uncertainty provided that the laboratory's bias, measured on relevant materials, is small with respect to the reproducibility standard deviation, the in-house repeatability is comparable to the standard method repeatability, and the laboratory's intermediate precision is not larger than the published reproducibility standard deviation [67].

## 6.8 Ruggedness

### *6.8.1 Definition*

The 'ruggedness' ('robustness') of an analytical procedure is "a measure of its capacity to remain unaffected by small, but deliberate variations in method parameters. Ruggedness provides an indication of the method's reliability during normal usage" [13].

### *6.8.2 Ruggedness test*

In any method there will be certain stages which, if not carried out sufficiently carefully, will have a significant effect on method performance and may even result in the method not working at all. These stages should be identified, usually as part of method development, and if possible, their influence on method performance evaluated using a 'ruggedness test' ('robustness test'). The AOAC has defined this term and describes an established technique for how to carry out such a test using a Plackett-Burman experimental design [74].

A 'ruggedness test' involves making deliberate changes to the method, and investigating the subsequent effect on performance.[*] It is then possible to identify the variables in the method which have the most significant effect and ensure that, when using the method, they are closely controlled. Where there is a need to refine the method further, improvements can probably be made by concentrating on those parts of the method known to be critical.

The ruggedness of a procedure must be established for in-house developed methods, methods adapted from the scientific literature and methods published by standardisation bodies used outside the scope specified in the standard method. When methods published by standardisation bodies are used within the scope of the method, ruggedness will usually have been studied as part of the standardisation process. Therefore a ruggedness study is in most cases not necessary at the single-laboratory level. Information about ruggedness should be indicated in the laboratory procedure in the form

[*] The effect on the measurand is normally studied but an alternative is to investigate the effect on an experimental parameter, e.g. the peak resolution in a chromatogram.

of stated tolerance limits for the critical experimental parameters (See Example 5 and Quick Reference 8).

**Example 5 –** Extracts from ISO 11732 [58]. The instructions indicate the criticality of some experimental parameters.

- $NH_4Cl$ dried to constant mass at 105 ± 2 °C.
- The given quantities can be reduced (e.g. by one tenth).
- Being stored in a plastic bottle (polyethylene) at room temperature, the solution is stable for about 1 month.
- The absorbance of the solution should be should be 0.3 – 0.5.
- Degas and purify the solution..., fill it into the reagent reservoir and let it stand for at least 2 hours.
- This solution may be stored in a refrigerator for at most one week.
- Containers of glass, polyalkenes or polytetrafluoroethylene (PTFE) are suitable for sample collection.
- In exceptional cases, the sample may be stored up to two weeks, provided the sample has been membrane-filtered after acidification.

**Quick Reference 8 – Ruggedness**

| What to do | How many times | What to calculate/determine from the data | Comments |
|---|---|---|---|
| Identify variables which could have a significant effect on method performance.<br><br>Set up experiments (analysing RMs or test samples) to monitor the effect on measurement results of systematically changing the variables. | Most effectively evaluated using experimental designs. E.g. 7 parameters can be studied in 8 experiments using a Plackett-Burman experimental design [74]. | Determine the effect of each change of condition on the measurement results.<br><br>Rank the variables in order of the greatest effect on method performance.<br><br>Carry out significance tests to determine whether observed effects are statistically significant. | Design quality control or modify the method in order to control the critical variables, e.g. by stating suitable tolerance limits in the standard operating procedure. |

# 7 Using validated methods

When using someone else's method, whether it is a method developed elsewhere within the laboratory, a published method, or even a standard or regulatory method, there are two issues which need to be considered.

Firstly is the existing validation data adequate for the required purpose or is further validation necessary? It should be noted that, in addition to the amount of information provided on the method performance, the reliability of the validation data sources is also an issue. Data obtained in collaborative studies or by recognised standardisation organisations are generally considered reliable, less so data published only in the scientific literature or provided by manufacturers of equipment and/or reagents. Secondly, if the existing validation data is adequate, is the laboratory able to verify the performance claimed possible in the method? (see Section 2.2). Are the available equipment and facilities adequate? If the method has been validated by extensive testing under all extremes of operating conditions, then a new competent analyst will probably operate satisfactorily within the existing performance data. However, this should always at least be checked. It is usually sufficient to test the analyst's ability to achieve the stated repeatability and to check for any bias, provided that the standard method is used within its scope. This is covered more fully below.

Standardised methods are generally produced by some form of collaborative study and the standardisation bodies which produce them frequently have statistical experts to help ensure that validation studies are correctly designed, performed and evaluated. The standard ISO 5725 [29] describes a model on which interlaboratory comparisons of methods should be based in order to provide reliable information on the method's performance. This model is increasingly applied, but not all standard methods have been subjected to it. It would be dangerous to assume that all standard methods have been properly validated and it is the analyst's responsibility to check whether or not the information provided on the method's performance is adequate.

Similarly, it is often assumed that standard methods can be used straight off the shelf and the published performance data achieved straight away by whoever uses the method. This is not a safe assumption. Even those who are familiar or expert in the particular field of chemistry covered by the method will need to practice before becoming fully proficient.

When using validated methods (or for that matter any method) the following rules are recommended to ensure that acceptable performance is achieved.

1. Firstly, the analyst should be completely familiar with a new method before using it for the first time. Ideally the method will first be demonstrated to the analyst by someone already expert in its use. The analyst should then use it under initially close supervision. The level of supervision will be stepped down until the analyst is deemed sufficiently competent to 'go solo'. For example competence might be established in terms of the analyst's ability to achieve the levels of performance stated in the method, such as repeatability, limit of detection, etc. This is typical of the way someone might be trained to use a new method and laboratory training procedures will frequently be designed in this way with objective measures in place to test competence at intervals during the training. In any case, the analyst should have read through the method and familiarised themselves with the theory behind the measurement, mentally rehearsing the various stages, identifying points where breaks can be taken, and parts of the process where the analyst is committed to continuous work. Where reagents need to be prepared, how stable are they once prepared? Do they need to be prepared in advance? A classic pitfall is to spend several hours preparing a number of samples and then finding the preparation of the reagent needed for the next stage of the work involves a complicated synthesis, in the meantime the samples themselves may be degrading.
2. Secondly, an assessment needs to be made of how many samples can be conveniently handled at a time. It is better to analyse a few samples well than to try to analyse a large number and have to repeat most of them.
3. Finally, make sure everything needed for the method is available before work is started. This involves gathering together the right equipment, reagents and standards (with any

attendant preparation), perhaps reserving space in fume hoods, etc.

If it is necessary to adapt or change someone else's validated method then appropriate revalidation will be necessary. Depending on their nature, the changes may well render the original validation data irrelevant.

# 8 Using validation data to design quality control

## 8.1 Introduction

'Quality assurance' (QA) and 'quality control' (QC) are terms whose meanings are often varied according to the context. According to ISO, quality assurance addresses the activities the laboratory undertakes to provide confidence that quality requirements will be fulfilled, whereas quality control describes the individual measures which are used to actually fulfil the requirements [9].

Method validation gives an idea of a method's capabilities and limitations which may be experienced in routine use while the method is in control. Specific controls need to be applied to the method to verify that it remains in control, i.e. is performing in the way expected. During the validation stage the method was largely applied to samples of known content. Once the method is in routine use it is used for samples of unknown content. Suitable internal QC can be applied by continuing to measure stable test samples, thus allowing the analyst to decide whether the variety of answers obtained truly reflects the diversity of samples analysed or whether unexpected and unwanted changes are occurring in the method performance. In practice these known samples should be measured with every batch of samples as part of the quality control process. The checks made will depend on the nature, criticality and frequency of the analysis, batch size, degree of automation and test difficulty, and also on the lessons learnt during development and validation processes. Quality control can take a variety of forms, both inside the laboratory (internal) and between the laboratory and other laboratories (external).

## 8.2 Internal quality control

Internal QC refers to procedures undertaken by laboratory staff for the continuous monitoring of operations and measurement results in order to decide whether results are reliable enough to be released [18, 75]. This includes replicate analysis of stable test samples, blanks, standard solutions or materials similar to those used for the calibration, spiked samples, blind samples and QC samples [76]. The use of control charts is recommended for monitoring of QC results [76, 77]. The QC adopted must be demonstrably sufficient to ensure the validity of the results. Different kinds of quality control may be used to monitor different types of variation within the process. QC samples, analysed at intervals in the analytical batch will indicate drift in the system; use of various types of blank will indicate what the contributions to the instrument signal besides those from the analyte are; duplicate analyses give a check of repeatability.

QC samples are typical samples which over a given period of time are sufficiently stable and homogeneous to give the same result (subject to random variation in the performance of the method), and available in sufficient quantities to allow repeat analysis over time. Over this period the intermediate precision of the method can be checked by monitoring values obtained from analysis of the QC sample, usually by plotting them on a control chart. Limits are set for the values on the chart (conventionally 'warning limits' are set at $\pm 2s$ about the mean value, and 'action limits' are set at $\pm 3s$ about the mean value). Provided the plotted QC values conform to certain rules pertaining to the set limits, the QC is deemed to be satisfactory. As long as the QC sample value is acceptable it is likely that results from samples in the same batch as the QC sample can be taken as reliable. The acceptability of the value obtained with the QC sample should be verified as early as practicable in the analytical process so that in the event of a problem, as little effort as possible has been wasted on unreliable analysis of the samples themselves.

During method validation initial estimates of different precision measures are obtained. In order to set realistic limits on the control chart, the measurements must reflect the way the method is actually intended to be used on a day-to-day basis. Thus measurements during validation should mimic all possible variations in operating conditions: different analysts; variations in laboratory temperature etc. If this is not done, then the standard deviation will be unrealistically small, resulting in limits being set on the chart which cannot possibly be complied with in normal use. For this reason, it is generally advised to reassess the stated limits after one year or when a sufficient number of results have been collected [76].

The use of various types of blanks enables the analyst to ensure that calculations made for the analyte can be suitably corrected to remove any contributions to the response which are not

attributable to the analyte. Replicate analysis of routine test samples provides a means of checking for changes in precision in an analytical process, which could adversely affect the result [78]. Replicates can be adjacent in a batch to check repeatability.

Analysis of blind samples is effectively a form of repeat analysis and provides a means of checking precision. It consists of replicated test portions placed in the analytical batch, possibly by the laboratory supervisor, and is so-called because the analyst is not normally aware of the identity of the test portions or that they are replicates. Thus the analyst has no preconceived ideas that the particular results should be related.

Standards or materials similar to those used for calibration, placed at intervals in an analytical batch, enable checks to be made that the response of the analytical process to the analyte is stable.

It is the responsibility of the laboratory management to set and justify an appropriate level of quality control, based on risk assessment, taking into account the reliability of the method, the criticality of the work, and the feasibility of repeating the analysis if it doesn't work correctly first time. It is widely accepted that for routine analysis, a level of internal QC of 5 % is reasonable, i.e. 1 in every 20 samples analysed should be a QC sample. However, for robust, routine methods with high sample throughput, a lower level of QC may be reasonable. For more complex procedures, a level of 20 % is not unusual and on occasions even 50 % may be required. For analyses performed infrequently, a full system validation should be performed on each occasion. This may typically involve the use of an RM containing a certified or known concentration of analyte, followed by replicate analyses of the sample and a spiked sample (a sample to which a known amount of the analyte has been deliberately added). Those analyses undertaken more frequently should be subject to systematic QC procedures incorporating the use of control charts and check samples.

## 8.3 External quality control

Regular participation in proficiency testing (PT), also known as external quality assessment (EQA) is a recognised way for a laboratory to monitor its performance against both its own requirements and the norm of peer laboratories. PT helps to highlight variation between laboratories (reproducibility), and systematic errors (bias).

PT schemes and other types of interlaboratory comparison are accepted as being an important means of monitoring the degree of equivalence of analytical results at national and international level. Accreditation bodies recognise the benefit of these schemes and strongly encourage laboratories to participate in PT/EQA as an integral part of their quality management [79]. It is important to monitor PT results as part of the QC procedures and take action as necessary.

In certain instances, accreditation bodies may specify participation in a particular PT scheme as a requirement for accreditation. The value of PT is of course only as good as the schemes themselves. Requirements for the competence of PT providers are described in the standard ISO/IEC 17043 [80]. Practical information on how to select, use and interpret PT schemes is presented in a Eurachem Guide [81]. Information about a large number of schemes can be found in the EPTIS database (www.eptis.bam.de). However, for emerging fields of analysis or rare applications in particular, there may be no scheme that is fully appropriate. These and other limitations are now considered in a recent guidance document [82] that requires accredited laboratories to derive a strategy for their participation in PT.

# 9 Documentation of validated methods

## 9.1 From draft to final version

The method subject to validation, is performed using a documented procedure which should be considered a draft until the validation report is approved. Once the validation process is complete it is important to document the analytical procedure so that the method can be clearly and unambiguously implemented. There are a number of reasons for this.

- The various assessments of the method made during the validation process assume that, in use, the method will be used in the same way each time. If it is not, then the actual performance of the method will not correspond to the performance predicted by the validation data. Thus the documentation must limit the scope for introducing accidental variation to the method.
- Proper documentation is also necessary for auditing and evaluation purposes and may also be required for contractual or regulatory reasons.
- Appropriate documentation of the method will help to ensure that application of the method from one occasion to the next is consistent. Since the quality of documentation has a direct effect on how consistently the method can be applied, it is likely to have an influence on the precision and measurement uncertainty. In fact, the uncertainty contribution associated with inadequately documented methods could be so large that it effectively makes the method useless. Any anomalies in the documentation must be resolved before a sensible estimate of the uncertainty can be obtained.

## 9.2 Recommendations

### *9.2.1 Checking the instructions*

It is not easy to document a method properly. Information should appear in roughly the order that the user will be expected to need it. A common trap is to assume that everyone will understand the mechanics of the method to the same extent as the person who has developed and documented it. This assumed knowledge can be dangerous. A useful way to test the documentation is for a competent colleague to work through the documentation exactly in the way described. If this corresponds to what was intended then the documented method should stand up well to use by a variety of analysts and deliver consistent results. If not then redrafting is necessary to describe the procedures in more detail and reduce ambiguity.

### *9.2.2 Recommendations in standards*

A number of standards provide guidance on what type of information should be included when documenting a method. From the chemists' point of view probably the most useful are the ISO 78 series, which describe the documentation of a number of different types of chemical analysis methods (standardisation bodies produce, validate and of course document a large number of methods each year, and need as consistent an approach as possible and produce these standards principally for the benefit of their own technical committees). ISO 78-2 [83] advises on method documentation for general chemical methods. A layout based around this standard is included in Annex A. The standards indicate a logical order for material with recommended headings and advice on the information which should appear under each heading. When using these standards the reader should note the need to balance flexibility of approach against consistency. Whilst it is desirable that all methods should have the same document format, it should also be recognised that not all methods warrant the same degree of detail and frequently it will be appropriate to omit some of the recommended sections from the documentation.

### *9.2.3 Document control*

A laboratory documenting its own methods may well benefit from developing a 'house style'. As well as presenting relevant information in a logical easy-to-use way, it also enables the burden of the documentation work to be spread across a number of authors. Drafts generated by a number of authors can be checked for consistency using a single checking authority.

Documented methods form an important part of a laboratory's quality management system and should be subject to an appropriate degree of document control. The purpose of this is to ensure that only methods and procedures which have been authorised as fit for use are actually used. Therefore, as part of the documentation process, methods should carry information which enables the user to judge whether the method has been authorised for use and whether it is complete. Other information should be available

regarding the version number and date of the method; the author; how many copies of the method exist; and any copying restrictions.

From time to time methods may require updating. The technology underpinning the procedure may have been improved, for example. Document control enables the smooth withdrawal of obsolete methods and issue of revised methods. These days the process of document control is greatly simplified using specific software. Changes should be made only by those so authorised. This may be controlled in the software where the relevant files may have widespread 'read-only' access and very limited 'write' access.

# 10 Implications of validation data for calculating and reporting results

It is important that the analyst is able to translate the data, generated during analysis of samples using the validated method, into results which directly contribute to solving the customer's problem. The performance characteristics established during the validation process help to do this. Data for repeatability, intermediate precision and reproducibility can be used to establish whether differences found when analysing samples are significant. Quality controls based on the validation data can be used to confirm that the method is in control and producing meaningful results. Estimation of the measurement uncertainty enables expression of the result as a range of values with an accepted level of confidence.

It is important that the analyst has access to validation data which can be used to support the validity of the results. Whether or not such information is passed to the customer is another matter. Very often the customer will not have the technical skills to appreciate the significance of the data. In such circumstances it is perhaps safer to make the data available on request.

Issues such as method validation, variability and measurement uncertainty need to be treated carefully in certain circumstances, for example in legal or forensic contexts. It may be better to be open about the existence of uncertainty attached to measurements and be prepared to justify decisions made in the light of knowing that uncertainty.

Care needs to be taken when trying to use an analytical result with its accompanying uncertainty to try to decide whether or not the original consignment from which the sample has been taken complies with a specification or limit [84]. Such a decision may not be the responsibility of the analyst, although the analyst may be required to provide technical advice to assist in the decision making process.

When reporting results, the analyst must decide whether to correct for any biases which may have been detected or to report results uncorrected but acknowledge the existence of the bias.

Care should be taken when reporting results as 'not detected'. On its own this statement is uninformative and should be accompanied by an explanation of what the limit of detection is in that instance. Sometimes it is appropriate to report a numerical value even though this may be below the apparent limit of detection. Authorities may sometimes request that the limit of quantification be stated.

Where a statement of uncertainty is required with the result, it may be appropriate to quote an expanded uncertainty by applying a suitable coverage factor. For example, a coverage factor of 2 corresponds to an interval with a level of confidence of approximately 95 %. For further guidance on how to report measurement uncertainty, see Section 9 in the Eurachem/CITAC Guide [22].

# Annex A – Method documentation protocol

The adequate documentation of methods is discussed in Section 9 of the Guide. The following format is included for reference as a suitable layout. It is based on ISO 78-2 [83], but contains some additional advice on calibration, quality control, and document control. Annex A is for guidance only and should be adapted to suit any special requirements.

## A.1 Foreword

### A.1.1 Update and review summary

This section has a twofold purpose. Firstly, it is intended to enable minor changes to be made to the text of the method without the need for a full revision and reprint of the method. Secondly, it is recommended that every method should be reviewed for fitness-for-purpose periodically and the summary serves as a record that this has been done. The summary typically would be located at the front of the method, just inside the front cover.

### A.1.2 Updates

Any hand written changes to the text of the method would be accepted provided the changes were also recorded in the table below (hand-written entries acceptable) and appropriately authorised. It would be implicit that the authorisation endorsed the fact that the effects of the changes on the method validation had been investigated and caused no problems, and that the changes had been made to all copies of the method.

| # | Section | Nature of amendment | Date | Authorisation |
|---|---|---|---|---|
| 1 (e.g.) | 3.4 | Change flow rate to 1.2 ml $min^{-1}$ | 8/2/96 | DGH |
| | | | | |

### A.1.3 Review

At any given time it would be expected that the date at which a method was seen to be in use would be between the *review* and *next review* dates, as shown in the table.

| Review date | Outcome of review | Next review date | Authorisation |
|---|---|---|---|
| | | | |

## A.2 Introduction

The introduction is used, if necessary, to present information, such as comments concerning the technical content of the procedure or the reasons for its preparation. If background information on the method is required, it should preferably be included in this clause.

## A.3 Title

The title shall express the sample types to which the test method applies, the analyte or the characteristic to be determined and the principle of the determination. It should be limited, wherever possible, to the following information. Preferred format:

Determination of A{*analyte or measurand*} (in the presence of B{*interference*}) in C {*matrix*} using D {*principle*}.

## A.4 Warnings

Draw attention to any hazards and describe the precautions necessary to avoid them. Detailed precautions may be given in the relevant sections, but notice must be drawn to the existence of hazards and need for precautions here. Provide suitable warnings of any hazards involved with:

- handling the samples;
- handling or preparing solvents, reagents, standards, or other materials;
- operation of equipment;

- requirements for special handling environments, e.g. fume cupboards;
- consequences of scaling up experiment (explosion limits).

### A.5 Scope

This section enables a potential user to see quickly whether the method is likely to be appropriate for the desired application, or whether limitations exist. The following details should be covered:

- a description of the underlying problem (why the method is needed);
- the analyte(s) or measurand(s) which can be determined by the method;
- the form in which analyte(s) is determined – speciation, total/available etc.;
- the sample matrix(es) within which those analyte(s) may be determined;
- a working range (measuring interval) over which the method may be used. This should refer to properties, e.g. concentrations, in the laboratory sample;
- known interferences which prevent or limit the use of the method;
- the instrumental technique used in the method;
- the minimum sample size.

The food sector [35] uses the concept 'applicability' as a synonym for scope and defines it as "the analytes, matrices, and concentrations for which a method of analysis may be used satisfactorily".

### A.6 (Normative) references

This clause shall give a list of those documents which are necessary for the application of the method. Documents which have merely served as references in the preparation of the method shall be indicated in a bibliography at the end of the document.

### A.7 Definitions

Give any definitions of terms used in the text that may be necessary for its complete understanding. Use ISO definitions wherever possible. Quote sources. Analytical structures can be included here if relevant.

### A.8 Principle

Outline the essential steps of the method, the principle by which the analytical technique operates. A flow chart or cause-and-effect diagram may help. This section should be written so as to allow an at-a-glance summary of how the method works. Include an explanation on the principle of the calculation. Where appropriate to clarify the working of the method or calculations, include details of any relevant chemical reactions (for example, this may be relevant where derivatisation is involved, or in titrimetry).

E.g. "The concentration is derived from a 6 point calibration curve by reading off the concentration, corresponding to the sample absorbance, corrected for the blank value, and multiplying it by the concentration factor."

### A.9 Reactions

This clause shall indicate the essential reactions, if they are considered necessary for the comprehension of the text or the calculations. They justify the calculations made from the data obtained in the determinations and may lead to a better understanding of the method, especially if several successive changes occur in the state of oxidation of the element being determined. When titrations are involved, they are particularly useful in indicating the number of equivalents in each mole of reactant.

### A.10 Reagents and materials

List all reagents and materials required for the analytical process, together with their essential characteristics (concentration, density, etc.) and numbered for later reference. List:

- Chemical Abstract Service (CAS) Registry numbers (if available);
- details of any associated hazards including instructions for disposal;
- analytical grade or purity;
- need for calibration and QC materials to come from independent batches;

- details of preparation, including need to prepare in advance;
- containment and storage requirements;
- shelf life of raw material and prepared reagent;
- required composition with notes of type of concentration or other quantity;
- labelling requirements.

### A.11 Apparatus

Describe individual equipment and how they are connected in sufficient detail to enable unambiguous set-up. Number the items for later reference. Diagrams and flowcharts may assist clarity. Any checking of the functioning of the assembled apparatus shall be described in the "Procedure" clause in a subclause headed "Preliminary test" or "Check test" (see A.13).

List minimum performance requirements and verification requirements, cross-referenced to the calibration section (A.13) and any relevant instrument manuals. If appropriate, refer to International Standards or other internationally acceptable documents concerning laboratory glassware and related apparatus. Include environmental requirements (fume cupboards etc.).

### A.12 Sampling

The sampling in this protocol includes both the sampling to obtain the laboratory sample and the subsampling in the laboratory to obtain the test sample from which the test portion will be drawn.

If sampling for the preparation of the laboratory sample is independent of the chemical analysis as such, it is generally sufficient to refer informatively to the relevant procedure dealing specifically with this question. If no such relevant procedure exists, the sampling clause may include a sampling plan and sampling procedure, giving guidance on how to avoid alteration of the product and taking into account requirements concerning the application of statistical methods.

The sampling clause should give all the information necessary for the preparation of the test sample from the laboratory sample. Include storage, conditioning/pretreatment and disposal details. If this stage is particularly complicated, a separate document describing individual steps may be justified.

### A.13 Procedure

Describe each sequence of operations. If the method to be described is already given in another standard, the phrase "use the method specified in ISO 12345" or "use one of the methods specified in ISO 12345" shall be used, with an indication of any modification, if necessary. Mention operations for which special safety precautions are necessary. The 'Procedure' clause shall normally include subclauses on the following.

- test portion (its preparation from the test sample or laboratory sample and the required mass or volume);
- blank tests (conditions and limitations);
- preliminary test or check test (e.g. to verify the performance of a measuring instrument);
- determination(s) or test(s). This includes mentioning the number of measurements or tests (e.g. duplicate) and detailed description of all steps;
- calibration. Identify the critical parts of the analytical process. These will have to be controlled by careful operation and calibration. Cross-reference to the relevant sections above. Include calibration of equipment – what needs to be calibrated, how, with what, and how often? Consider appropriate metrological traceability of calibrants.

### A.14 Calculation

Describe how the result(s) are calculated. Include information about the units in which the result and other quantities are to be expressed; the equation used for the calculation; the meanings of the algebraic symbols used in the equation; the number of decimal places or significant figures to which the result is to be given. The symbols of quantities shall be in accordance with ISO 80000 [14].

### A.15 Precision

For methods that have been subjected to an interlaboratory comparison, the precision data (i.e. the repeatability and reproducibility) shall be indicated. The precision data shall be calculated, and should preferably also be published, in accordance with the relevant part of ISO 5725 or in accordance with

another suitable International Standard (which shall be referenced). Clearly state whether the precision values are expressed in absolute or relative terms, or as precision limits.

### A.16 Quality assurance and quality control

One outcome from the validation exercise should be a description of the internal and external (proficiency testing) quality control procedures to follow. Explain what form the quality control takes, frequency of quality control checks during batch analysis, pass/fail criteria, action to take in the event of a failure. Cross-reference to the relevant sections above.

### A.17 Special cases

Include any modifications to the procedure necessitated by the presence or absence of specific components in the product to be analysed. The modifications shall already have been referred to in the "Scope" clause. Each special case shall be given a different title.

### A.18 Test report

This clause should specify the information to be given in the test report. The following aspects of the test should normally be included.

- a reference to the method used;
- the result(s) and an indication of the associated quality (precision, specified uncertainty; confidence interval) if applicable, including a reference to the "Calculation" clause;
- any deviations from the procedure;
- any unusual features observed;
- the date of the test.

### A.19 Annexes

To improve readability, some information is more conveniently presented in an annex. It shall be clearly stated whether the annex is normative or informative. Examples of information which can be annexed are data from the method validation work, risk analysis and uncertainty calculations. For the latter, the major sources of uncertainty relating to the method should be identified and the assigned values listed. Insignificant contributions not used in the final calculation should be mentioned. The combined standard uncertainty and/or the expanded uncertainty should be listed together with an explanation of how it was derived. A more detailed treatment may be in a cross-referenced file.

### A.20 Bibliography

If informative references are considered necessary, these may be given at the point in the text at which they are referred to or, if there are several, in a bibliography at the end of the document.

# Annex B – Statistical basis of limit of detection calculations*

Quick Reference 2 in Section 6.2.3 indicated that the limit of detection (LOD) can be calculated by multiplying a suitable standard deviation by a factor of 3. This Annex describes the statistical basis for this factor.

The aim when determining the LOD is typically to establish the lowest concentration of the analyte present in a sample that can be detected, using a given measurement procedure, with a specified level of confidence. Defining the LOD is a two-step process. First a 'critical value' is established. This value is set so that the probability of obtaining a measurement result that exceeds the critical value is no greater than $\alpha$, if a sample actually contains *none* of the analyte. The critical value sets a criterion for declaring a sample to be 'positive'. A false positive probability of $\alpha = 0.05$ is generally used; this leads to a critical value of approximately $1.65s$ (where $s$ is the standard deviation of a large number of results for a blank sample or a sample containing a low concentration of the analyte, and 1.65 is the one-tailed Student $t$-value for infinite degrees of freedom at a significance level, $\alpha = 0.05$). The critical value is most conveniently expressed in terms of concentration, though in principle it may be any observation, such as peak area. Any result exceeding the critical value should be declared positive.

However, if the true value for the concentration in a sample were exactly equal to the critical value (expressed in terms of concentration), approximately half of the measurement results would be expected to fall below the critical value, giving a false negative rate of 50 %. A false negative rate of 50 % is obviously too high to be of practical use; the method does not reliably give results above the critical value if the concentration is equal to the critical value. The LOD is intended to represent the true concentration for which the false negative rate is acceptable given the critical value. The false negative error, $\beta$, is usually set equal to the false positive error, this is largely for historical reasons (IUPAC recommends default values of $\alpha = \beta = 0.05$ [49]). Using $\alpha = \beta = 0.05$, the LOD needs to be $1.65s$ above the value specified for the critical value. The factor for calculating the LOD with $\alpha = \beta = 0.05$ is thus $1.65+1.65 = 3.30$. This is frequently rounded to give the '$3s$' calculation shown in Quick Reference 2. This approach is based on several approximations which are described in the literature [49].

The multiplier of 3, as calculated in the previous paragraph, arises from the one-tailed Student $t$-value for infinite degrees of freedom, rounded down to one significant figure. For a statistically rigorous estimate of the LOD, the multiplying factor used should take into account the number of degrees of freedom associated with the estimate of $s$. For example, if $s$ is obtained from 10 replicate measurements, the Student $t$-value at $\alpha = 0.05$ is 1.83 (9 degrees of freedom). This leads to an LOD calculated as $3.7s$.

* The text is based on the Eurachem Guide on Terminology in Analytical Measurement [8].

# Annex C – Analysis of variance (ANOVA)

The central idea behind 'analysis of variance' (ANOVA) is that where a set of replicate data can be grouped in some way, e.g. by analyst, instrument, day, laboratory, method etc., the total variation in the whole set can be represented as the combination of the variances ($s^2$) between and within the groups. ANOVA can be used to evaluate results from the type of experimental study shown in Figure C 1. In this 'nested design', replicate measurements (typically obtained under repeatability conditions) are repeated in different measurement runs to provide $p$ groups of data. To estimate intermediate precision from such a study there should be maximum variation in conditions between the runs (different days, analysts, etc.).

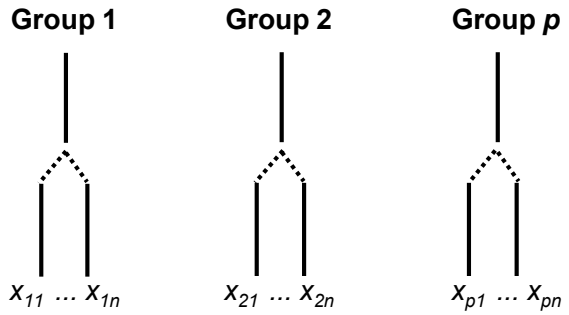



**Figure C 1 – Example of a 'nested design' for an experiment from which different precision measures can be evaluated using ANOVA**

The general form of a table for one-way ANOVA, for a total of $N$ results in $p$ groups of $n$ observations, and with ν degrees of freedom, is shown in Figure C2. Each line of the table relates to a different source of variation. The first row relates to variation between the means of the groups; the second describes the variation within the groups and the third describes the variation of the data set as a whole. Spreadsheet programmes and statistical software also provide the $F$ and $F$ critical value, and corresponding $P$ (probability) value.

| **Source of variation** | **Sum of squares (SS)** | **ν** | **Mean square (MS)** | ***F*** | ***P*** | $F_{crit}$ |
|---|---|---|---|---|---|---|
| Between groups | $SS_b$ | $p$-1 | $MS_b = SS_b/(p\text{-}1)$ | $MS_b/MS_w$ | | |
| Within group (residuals) | $SS_w$ | $N$-$p$ | $MS_w = SS_w/(N\text{-}p)$ | | | |
| Total | $SS_{tot} = SS_b+SS_w$ | $N$-1 | | | | |

**Figure C2 – Anatomy of a table for a one-way ANOVA**

The values related to the between-group variation are almost always either referred to as 'between-group' terms or are identified by the grouping factor (e.g. analyst, day or laboratory). Several different terms are used in software, textbooks etc. to describe the within-group variation – 'within-group', 'residual', 'error' or 'measurement' being the most common.

Assuming that the nested design shown in Figure C 1 is executed by a single laboratory, that the replicates within each group were obtained under repeatability conditions, and that the analytical conditions were varied between the groups, the repeatability and intermediate precision can be calculated as follows.

1. The repeatability standard deviation $s_r$, is obtained by taking the square root of the within-group mean square term which represents the within-group variance:

$$s_r = \sqrt{MS_w} \qquad \text{(Eq. C1)}$$

2. The contribution to the total variation from the grouping factor ($s_{\text{between}}$) is also obtained from the ANOVA table:

$$s_{\text{between}} = \sqrt{\frac{MS_{\text{b}} - MS_{\text{w}}}{\text{n}}} \qquad \text{(Eq. C2)}$$

3. The intermediate precision $s_I$ can now be calculated by combining the within- and between-group variance components above:

$$s_I = \sqrt{s_r^2 + s_{\text{between}}^2} \qquad \text{(Eq. C3)}$$

The experiment referred to in Section 6.6.4 can be illustrated as follows. As part of a method validation exercise in a single laboratory, duplicate measurements were carried out during each of eight days (Table C1). The measurements on each day were performed under repeatability conditions but with different analysts, different equipment etc. on the different days, in order to mimic the conditions under which the method will be used routinely.

**Table C1 – Example of experimental set-up that enables repeatability and intermediate precision to be evaluated using one-way ANOVA with acceptable degrees of freedom**

| **Day:** | 1 | | 2 | | 3 | | 4 | | 5 | | 6 | | 7 | | 8 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Result:** | $x_{1,1}$ | $x_{1,2}$ | $x_{2,1}$ | $x_{2,2}$ | $x_{3,1}$ | $x_{3,2}$ | $x_{4,1}$ | $x_{4,2}$ | $x_{5,1}$ | $x_{5,2}$ | $x_{6,1}$ | $x_{6,2}$ | $x_{7,1}$ | $x_{7,2}$ | $x_{8,1}$ | $x_{8,2}$ |

A one-way ANOVA can be used to separate the variation inherent within the method (repeatability) and the variation due to differences in the measurement conditions, i.e. different analysts, equipment, extended timescale (intermediate precision). Note that with this approach, it is not possible to draw conclusions about which of the parameters – analyst, equipment, time – contributes most to the intermediate precision but this is normally not needed at the validation stage.

Applying a one-way ANOVA to the results in Table C1 will provide a results table similar to that in Figure C2. The *F,* critical *F* and *P* values allow direct conclusions to be drawn on whether the variation between results obtained on different days is significantly greater than the variation in results obtained on the same day. The values for the two precision measures ($s_r$ and $s_I$) are then readily calculated from Eq. C1 – Eq. C3 above. The associated number of degrees of freedom (ν) will be $N$-$p$ = 16-8 = 8 for $s_r$. The value of ν for the intermediated precision is more complex but will not be smaller than $p$-1, i.e. 7 in this example (see Figure C2). This results in a reasonable compromise between workload and the uncertainty of the precision estimates.

# Annex D – Notes on qualitative analysis

Qualitative analysis follows the basic principles of quantitative analysis but unique concepts need to be applied when describing the properties of the method and in the interpretation of the results. This appendix introduces qualitative analysis briefly and points to relevant guidance.

Qualitative analysis is defined by IUPAC as: *analysis in which substances are identified or classified on the basis of their chemical or physical properties, such as chemical reactivity, solubility, molecular weight, melting point, radiative properties (emission, absorption), mass spectra, nuclear half-life, etc.* [17]. This means that results are expressed on a nominal scale, which is inferior to expressing results on a ratio scale. Qualitative analysis, instead of quantitative analysis, is therefore recommended primarily for screening purposes using low-cost methods or at analyte concentrations near to the limit of detection (LOD).

A 'qualitative method' gives effectively a 'Yes'/'No' answer at a given cut-off concentration of an analyte [55]. Validation involves identification of the cut-off concentration in order to **classify/diagnose a condition**, e.g. the presence or absence of a polluting agent in water where there is a directive, law etc. defining which cut-off concentration applies.

In order to characterise the properties of a qualitative method, a quantitative method with superior metrological properties (confirmatory method), e.g. lower LOD, is optimal in order to determine the true state of with- or without a condition. Properties of the qualitative method should be determined at a number of concentrations, below, at and above the cut-off concentration. The use of a confirmatory quantitative method is preferable to the use of spiked and non-spiked blank samples.

For qualitative methods, precision cannot be expressed as a standard deviation or relative standard deviation, but may be expressed as true and false positive rates, and true and false negative rates [55, 85, 86, 87]. This is illustrated in Figure D1.

| | **Samples above cut-off** | **Samples below cut-off** | |
|---|---|---|---|
| **Positive test** | **True positive tests** | **False positive tests (type I error)** | **Total number of positive tests** |
| **Negative test** | **False negative tests (type II error)** | **True negative tests** | **Total number of negative tests** |
| | **Total number of samples above cut-off** | **Total number of samples below cut-off** | |

**Figure D1 – A 2 × 2 table serving as the basis for calculating false positive and false negative rates**

The 'diagnostic sensitivity' is the proportion of samples with a condition, e.g. concentration above cut-off, which have positive qualitative test results. The diagnostic sensitivity is a fundamental feature of a qualitative method, which expresses its ability to detect small amounts of the analyte in a sample to produce the binary Yes/No response at a predefined level of probability.

$$Diagnostic\ sensitivity = \frac{number\ of\ true\ positive\ samples}{total\ number\ of\ samples\ with\ condition} \qquad \text{(Eq. D1)}$$

The 'diagnostic specificity' is the proportion of samples without a condition, e.g. concentration below cut-off, which have negative qualitative test results

$$Diagnostic\ specificity = \frac{number\ of\ true\ negative\ samples}{total\ number\ of\ samples\ without\ condition} \qquad \text{(Eq. D2)}$$

Data from a confirmatory method comparison should be used if available. Otherwise, spiked and non-spiked blank samples can be measured.

The important parameters for the measurement quality in qualitative analysis are the LOD and the cut-off limit (Figure D2). The LOD is similarly defined as in quantitative analysis; the concentration of an analyte which provides a signal that can be statistically distinguished from the mean signal of relevant blank samples. The cut-off limit, if correctly determined, is where false negative rates for concentrations above the limit are low – with a stated probability. In the validation the proposed cut-off limit given in the documented procedure is assessed.

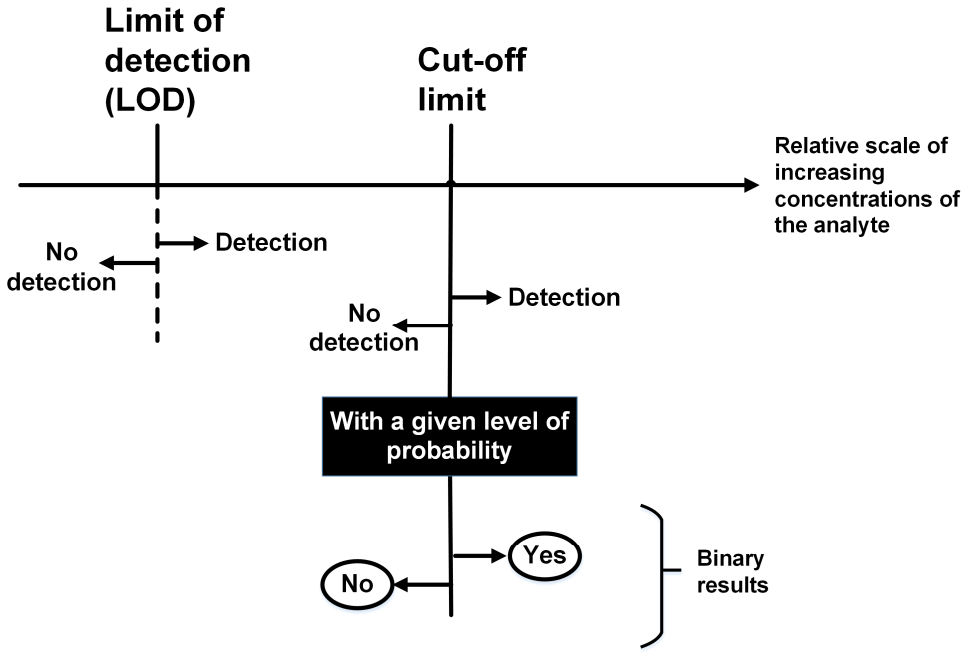



**Figure D2 – There are two quantitative references that produce a binary response in the sample qualification/classification type of qualitative analysis: 1. The limit of detection (LOD) which is inherent to the method, 2. The cut-off limit given in the documented procedure. They are placed in an imaginary increasing concentration scale. In the detection zone, above the detection limit, the cut-off limit allows one to distinguish concentration zones of the component in which the correct binary response is produced: i.e. No below the limits and Yes above them.**

Several additional concepts are used in qualitative analysis (Table D1). The **predictive values** of the results can be increased by increasing the prevalence of concentration above cut-off in the samples tested by the qualitative method, e.g. by other sources of information than the qualitative chemical method. This will substantially improve the practical value of the qualitative measurement method.

The **selectivity** of a qualitative method is an ordinal concept: the extent to which analytes other than the one included in the specification interferes with the analysis. This fundamental feature of the method can also be defined as its ability to produce results which are not influenced by matrix effects. The better the selectivity, the better the certainty of identity and sample classification.

**Table D1 – Definition and calculation of concepts describing the diagnostic properties of measurement methods, including qualitative measurement methods**

| Concept (symbol) | Description | Formula |
|---|---|---|
| Positive likelihood ratio (*LR*+) | The ratio of the true positive rate to the false positive rate. | $LR+= \frac{dignostic\ sensitivity}{1 - diagnostic\ specificity}$ |
| Negative likelihood ratio (*LR*-) | The ratio of the false negative rate to the true negative rate. | $LR-= \frac{1 - diagnostic\ sensitivity}{diagnostic\ specificity}$ |
| Diagnostic odd ratio (*DOR*) | This combines the concepts of diagnostic sensitivity, diagnostic specificity and likelihood ratios into a single number. | $DOR = \frac{LR+}{LR-}$ |
| Positive predictive value (*PPV*) | The proportion of the samples with a positive qualitative test result which have the condition. This takes into account the prevalence of the condition in the target population of samples. | $PPV = \frac{Number\ of\ true\ positives}{Total\ number\ of\ positives}$ |
| Negative predictive value (*NPV*) | The proportion of the samples with negative qualitative test results which do not have the condition. This takes into account the prevalence of the condition in the target population of samples. | $PPV = \frac{Number\ of\ true\ negatives}{Total\ number\ of\ negatives}$ |

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