SCORELCA

**STUDY N° 2015-03**

# EVALUATION OF HUMAN TOXICITY IN LCA

## SUMMARY

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The SCORE LCA association is an assessment and research organization dedicated to projects involving Life Cycle Analysis (LCA) and environmental quantification. Its aim is to encourage and organize the collaboration between companies, institutes and scientists in order to achieve a shared and recognized evolution, both at a European and an international level, of the Life Cycle analysis method and its use in practice.

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- ✓ The views and recommendations expressed in this publication are those of the authors and do not necessarily reflect, unless otherwise stated, the views of all members of SCORE**LCA**.

- ✓ The information and conclusions presented in this document are based upon scientific data, practices, regulations and norms valid at the date of publication.

The identification and quantification of the impacts on human health due to the emission of toxic substances is an essential point to consider in the development of sustainable products and technologies, as well as the prevention of any risks that these may incur. In practice, numerous evaluation methods (such as the quantitative health risk assessment (QHRA) or Life Cycle Analysis (LCA)) and varied indicators are used throughout the life cycle of the product to assess its impact on human health and any potential risks. The details of these approaches are not well known and their potential interactions are little understood, at least by the majority of practitioners. For this reason, the members of SCORE LCA decided to conduct a study in order to clarify the different approaches, the factors to consider and their respective limits.

More specifically, the aims of this study are:

- to provide a better understanding of the « human toxicity » issue (within LCA and beyond) for a product by:
  - Describing the methodological principles for quantitative health risk assessment (QHRA), and identifying its different applications.
  - Presenting the different methods for the evaluation of human toxicity in LCA.
  - Describing the underlying LCA models (scientific basis, perimeter, limits etc.).
- to study the differences between LCA and QHRA in terms of field of application, methods and data used and their respective objectives.
- to identify the points of convergence and divergence between the LCA and QHRA approaches, and in particular to propose some techniques to use the two methods in a complementary manner.
- to encourage the cooperation between the practitioners of LCA and QHRA.

It has been decided **to concentrate the analysis on the comparison of the "human toxicity" impact assessment from LCA and the QHRA method**, as both approaches are quantitative and both include numerous stages considering successively the substance toxicity and the exposure of populations.

This study initially presents a summary of each method. As the members of SCORE LCA are from varied scientific backgrounds, a synthesis of the objectives of each method and on the vocabulary used is essential. Specifically, the terms "impact", "exposure", "environmental fate model" and "long-term emissions" are defined.
After a brief presentation of the concepts, the second chapter compares the two approaches step by step. The third chapter is aimed at practitioners, and discusses the complementary and divergent points of the two approaches. This last chapter concludes with recommendations for the communication of results and an update on current works on this topic in the field of LCA.

# Comparison of the two methods

Overall, the two methods comprise steps that can be considered in parallel:

| | LCA | QHRA |
|---|---|---|
| Step 1 | • definition of the system<br>• inventory | • identification of the dangers<br>• definition of exposure scenarios |
| Step 2 | • impact analysis | • determination of the dose-response relationship<br>• exposure quantification |
| Step 3 | • results interpretation | • risk characterization |

## Step 1

It is possible to draw a parallel between the first step of LCA (Definition of the system and inventory) and the first step of QHRA (Identification of the dangers and definition of the exposure scenarios).
An **LCA** study, due to its global perimeter (complete life-cycle), covers a **generic population** (averaged) whereas a **QHRA** study covers **specific individuals** (real or fictitious). This difference in the scope has direct consequences on the modelling choices for the two methods.
In LCA, in order to create an appropriate model for the large number of substances taken into account, simplifying assumptions are used, and a large amount of data is required. Contrary to QHRA, the LCA indicator does not take into account the manner in which a substance is emitted nor which specific populations are exposed. Not accounting for the spatial and temporal factors in LCA results makes the physico-chemical and toxicological properties of the substance predominating the geographical and temporal parameters of the emission. **In LCA, the diversity of spatial parameters is therefore not a factor in the effect on the population.**
QHRA requires the description of exposure scenarios **specific to the site or product under evaluation**, the **conditions of emission** and the **target populations**.

## Step 2

The chapter dedicated to the second step of the two approaches presents the **methodology framework** for the evaluation of human toxicity in LCA and compares the 5 main LCA methods available (ReCiPe 2008, IMPACT 2002+, IMPACT WORLD, TRACI2-ILCD PEF/OEF,EDIP 2003). These methods are explained in further detail in the individual methodology sheets in the appendix.

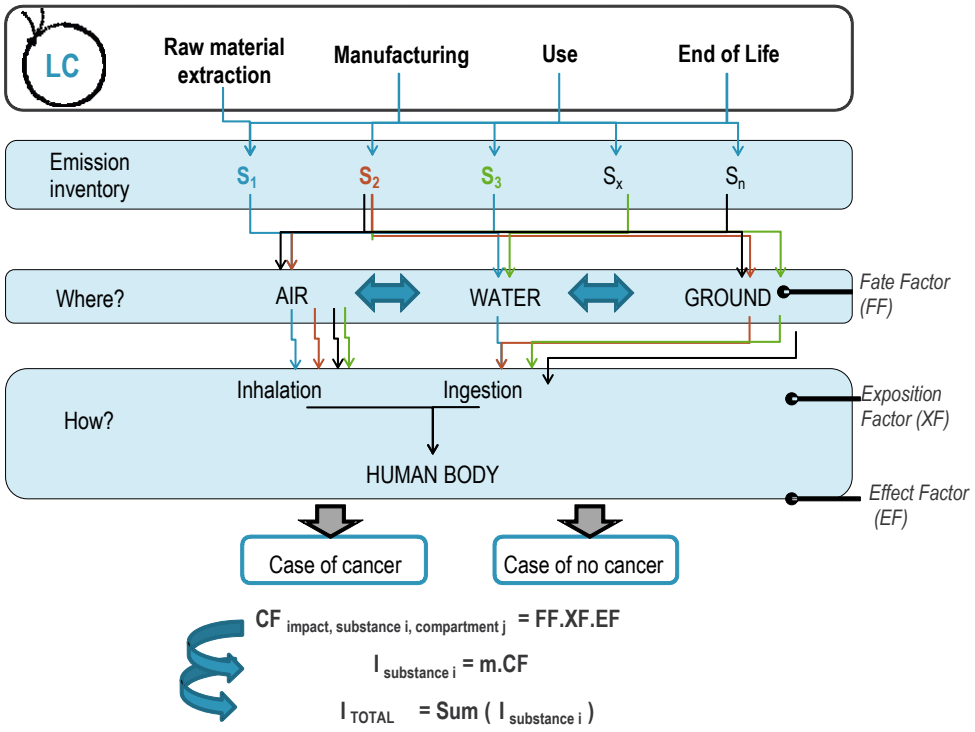


*Figure 1 Calculation principle for the toxicity impact in LCA*

The method used in QHRA for determining the exposure and the dose-response relationship is also presented in detail.
It is important to keep in mind that although LCA and QHRA are based upon the same sources of toxicology data, the treatment of this data is completely different, especially in the use of differing extrapolation factors.
It should be reminded that the model used in LCA for the dose-response relationship is linear, whether it is for carcinogenic effects or not.
In QHRA, the threshold and non-threshold effects are distinguished. For the non-threshold effects (those most often carcinogenic), the relationship between the dose and the probability of the effect is linear.

For the threshold effects (those most often non-carcinogenic), the relationship is binary with no relation to the proportionality between parts of the threshold.

Contrary to the approach used in QHRA where a target population is exposed to accurate and specific conditions, in LCA the exposure is estimated on the global population. In consequence, the LCA **applies a unique model representing an average artificial world to all of the emissions**. Whether the emissions are aggregated at each step or for the entire life cycle, the same result is achieved. However, the QHRA requires the adaptation of the exposure model for specific sources and populations, and the evaluation of each risk independently for each step.

## Step 3

In LCA, the indicator "human toxicity potential" is presented alongside a dozen impact indicators (climate change potential, ozone layer destruction potential, acidification potential etc.). It therefore provides a **global view of the issues of hundreds of substances emitted** to the environment for the studied system; **the aim is not to precisely characterize the risk of an individual substance for a particular context**. It does, however, allow the **identification of main environmental "hotspots"**, presented in terms of life cycle steps or substances of concern.
In QHRA, 2 types of indicator are calculated according to the type of effect, for each route of exposure: the Hazard Quotients (HQ, ratio between the level of exposure and the reference toxicology value) for the threshold effects and the Excess Lifetime Risk (ELR), expressed for an individual as the additional probability of developing a critical effect (cancer) linked to the exposure. The interpretation of these results is carried out by **comparing these values with the levels of risk deemed socially acceptable**. Of course there is no absolute threshold of acceptability; the acceptability thresholds are usually allowed by national or international organizations (in France particularly "l'Institut de Veille Sanitaire" - the French national health monitoring institute) and by regulations (e.g. REACH) are 1 for the HQ and $10^{-5}$ for the ELR.

The essential difference in interpreting the results is therefore:

- LCA **compares the impacts of multiple products** (across all life-cycle steps, process options and substances) to advise a choice between 2 products or technologies, for example
- QHRA **compares risk indicators to levels of acceptability** to guide decisions, often regulatory (whether or not to authorize a product, an installation etc.), in the interest of risk prevention.

## Methodological perspectives

In order to align with current opinions from the scientific community and the members of SCORE LCA, a chapter of the report is dedicated to the methodological perspectives of the two methods, as well as the questions and reflections brought up by the members of SCORE LCA during the meetings. These are points that the LCA practitioner or toxicologist should keep in mind when considering the subject of human toxicity evaluation during LCA or QHRA.

### Complementarity and divergence of the approaches

This chapter summarizes the complementarity and divergence of the methods both in terms of perimeter and technical points (number of substances covered, dose-response model considered etc.);
Figure 2 shows the differences in scope between the two approaches: LCA covers all of the life-cycle steps whilst QHRA focuses on a particular site and a targeted population.

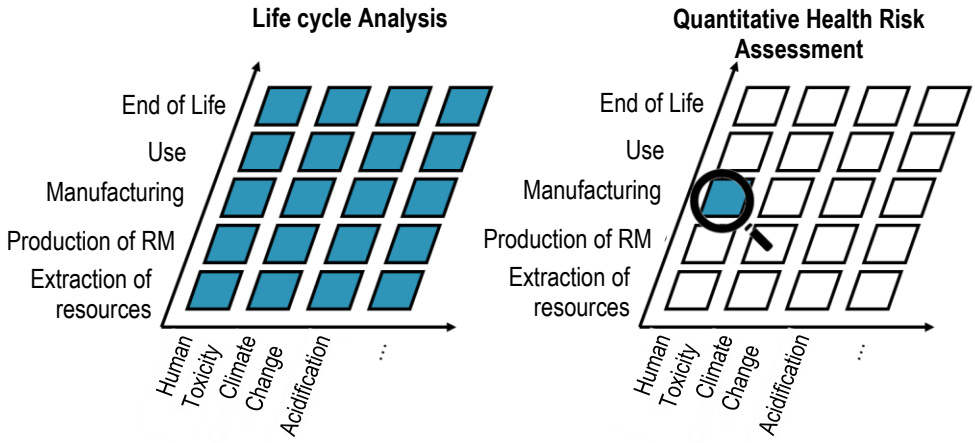


*Figure 2 LCA and QHRA study perimeter*

Figure 3 highlights that LCA applies to a product across multiple sites (life-cycle), as opposed to QHRA which is essentially a site-specific analysis that may concern multiple several products manufactured on the same site.

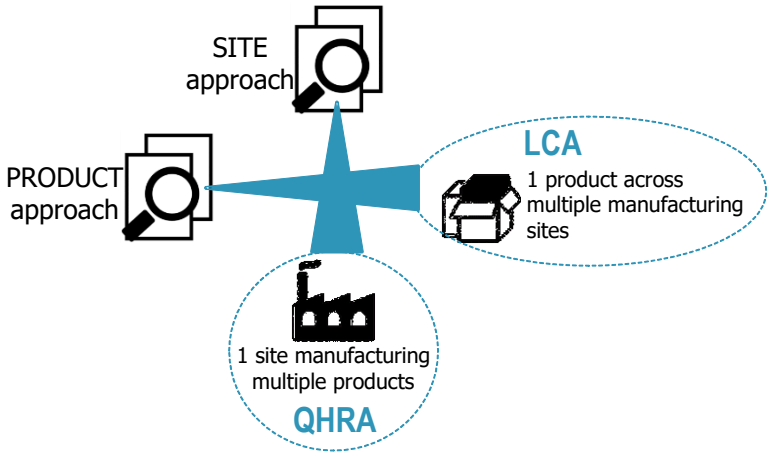


Figure 3 Two different approaches: product approach for LCA and site approach for QHRA

The previous chapter shows that the two approaches are **not complementary in their methodologies, scopes or their respective objectives** (no interaction in the methodology) but they do complement one another in the questions to which they respond.

| | Human Toxicity in LCA | Quantitative Health Risk Assessment |
|---|---|---|
| **Population** | Global (average) | Local and specific (workers, consumers, children etc.) |
| **Number of substances covered** | 100 - 1000 depending on the model selected | Generally a few substances, less than 10 |
| **Representativity** | Average | "Worst case" |
| **Exposure Time** | One lifespan of an individual to multiple generations depending on the case | One year to the lifespan of an individual |
| **Spatial Scale** | Generic: global approach via a model representing an average world | Specific: scope defined specifically via exposure scenarios dependent on the context |
| **Reference** | Unit of product | Production of a site |
| **Dose-response** | Linear, no threshold | Non-linear for threshold effects |

| | | |
|---|---|---|
| | | Linear for non-threshold effects |
| **Sources** | All emissions during the life-cycle of the product | All emissions of a site or product |
| **Conclusion** | **Global and exhaustive method (life-cycle, thousands of substances) but not very precise or specific** | **Precise method adapted for a specific context** |

*Table 1 Summary of the divergences between the methods* *Source: Cornelus et al. SETAC Nantes 2016*

As shown in Figures 4 & 5, the two approaches can be used in parallel on the life-cycle of a product or for a company, these are their complementary instructions.

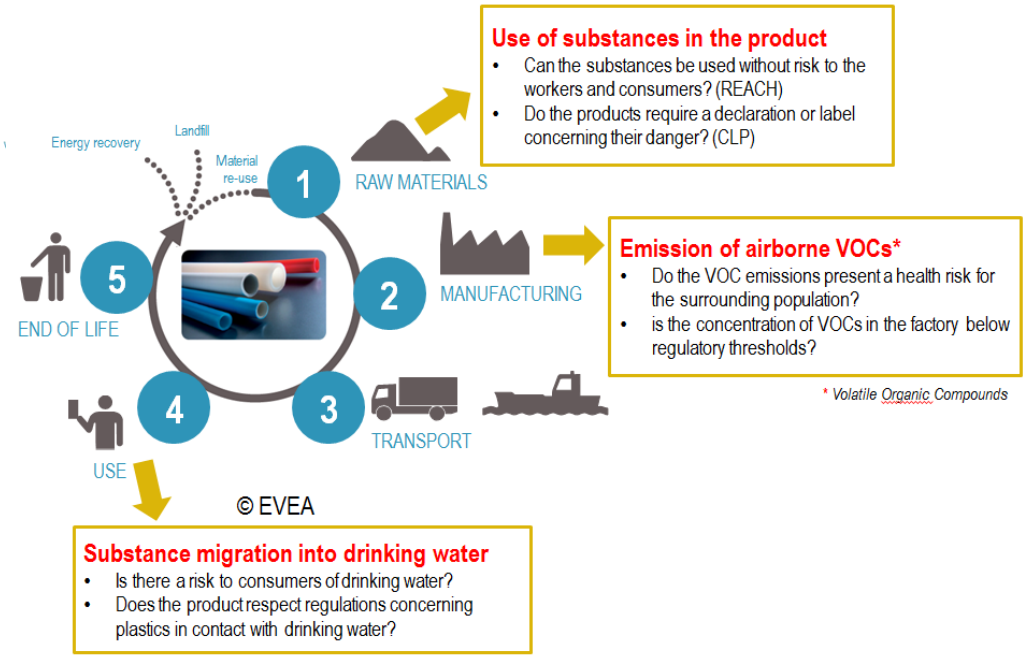


*Figure 4 Example using a QHRA approach on the life-cycle of a product (figure adapted from G. Castellan)*

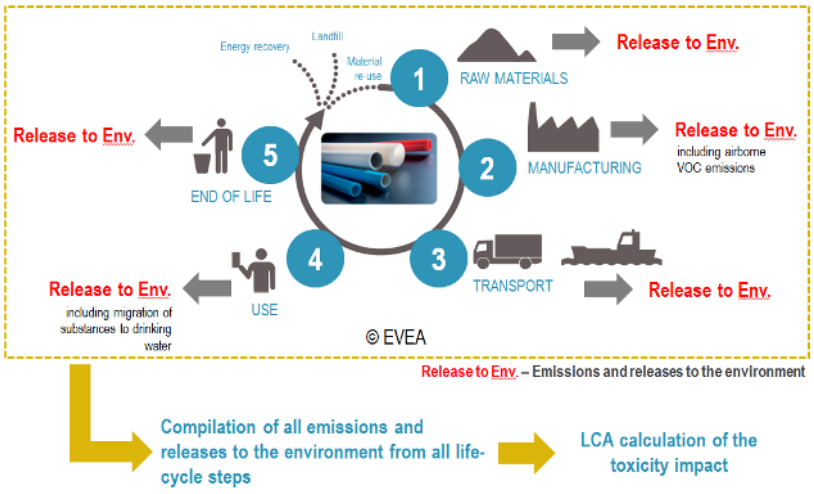


*Figure 5 LCA approach for the life-cycle of a product (figure adapted from G. Castellan)*

Furthermore, Figure 6 shows what elements LCA can add to an evaluation of health risks. Using LCA to evaluate the environmental impacts of the substitution of a molecule presenting a health risk by another molecule, can help to ensure there is no transfer of impacts.

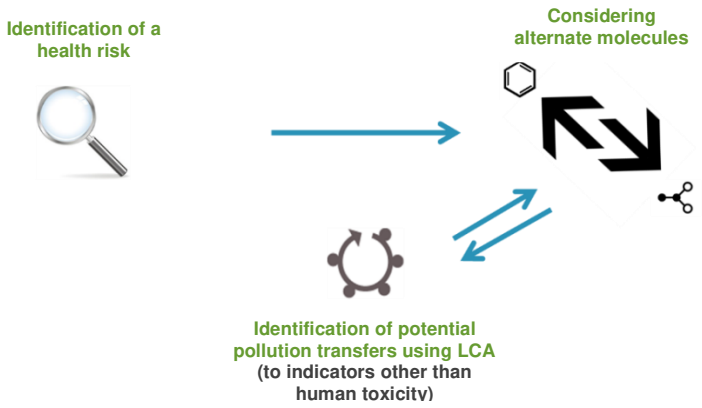


*Figure 6 Using LCA to identify impact transfers whilst considering alternate options for molecules, which present health risks*

By their very nature, the two approaches are different. **LCA is intended as a global environmental evaluation tool**, which requires simplifying assumptions: spatial-temporal considerations are limited or even excluded, depending on the impact analysis method selected. However, this method can therefore compile many thousands of substances emitted at different links of the supply chain, different locations and at different times. It is a method which allows the very complex integration of a large amount of data comprising many hypotheses. In LCA the practitioner aims to remain generic so that the results (potential impacts) will be comparable. The objective of LCA is not to characterize the population health risks but to allow a general comparison - of multiple environmental indicators – between two products across their entire life-cycles, so as to evaluate the transfer of pollution and identify which product has the least impact.
**QHRA is based upon the characterization of risks to a target population within a defined and limited spatial-temporal scope**. In QHRA, the practitioner aims to be specific. The risk is not characterized for a generic population, but for a particular group of individuals (real or fictitious), such as users of the product in the workplace or people who live near to a source of pollution, for example. The results are not meant to be compared to each other, but should be estimated and then compared to an "acceptable" risk value. **QHRA is a health risk prevention tool** designed to evaluate if a given exposure scenario in a given context is likely to lead to a concerning health risk. As such, it allows the determination of whether the implemented risk management strategies are sufficient to protect the health of the people exposed.

| | Question | QHRA | LCA indicator human toxicity |
|---|---|---|---|
| General issue | Is the product without risk? | ✓ | - |
| Issues concerning private companies | Where might the use of my product create a problem in terms of human toxicity? | ✓ | ✓ |
| | Which ingredients/processes should I replace in priority? | - | ✓ |
| | How much better is the alternative to my product/process?* | - | ✓* |
| | Does my product respect the regulations? | ✓ | - |
| | Is my product without risk for workers, the local population and the consumers? | ✓ | - |
| Issues concerning public organizations | Which substances should be regulated in priority? | ✓ | ✓ |
| | What are the compromises between local and global issues? | ✓ | ✓ |

*Table 7 Examples of issues dealt with by the two approaches*

**The difference in impact for the indicator human toxicity must be at least 3 orders of magnitude to be deemed significant.*

Figure 8 shows an example of a joint use of the two approaches by a single company.

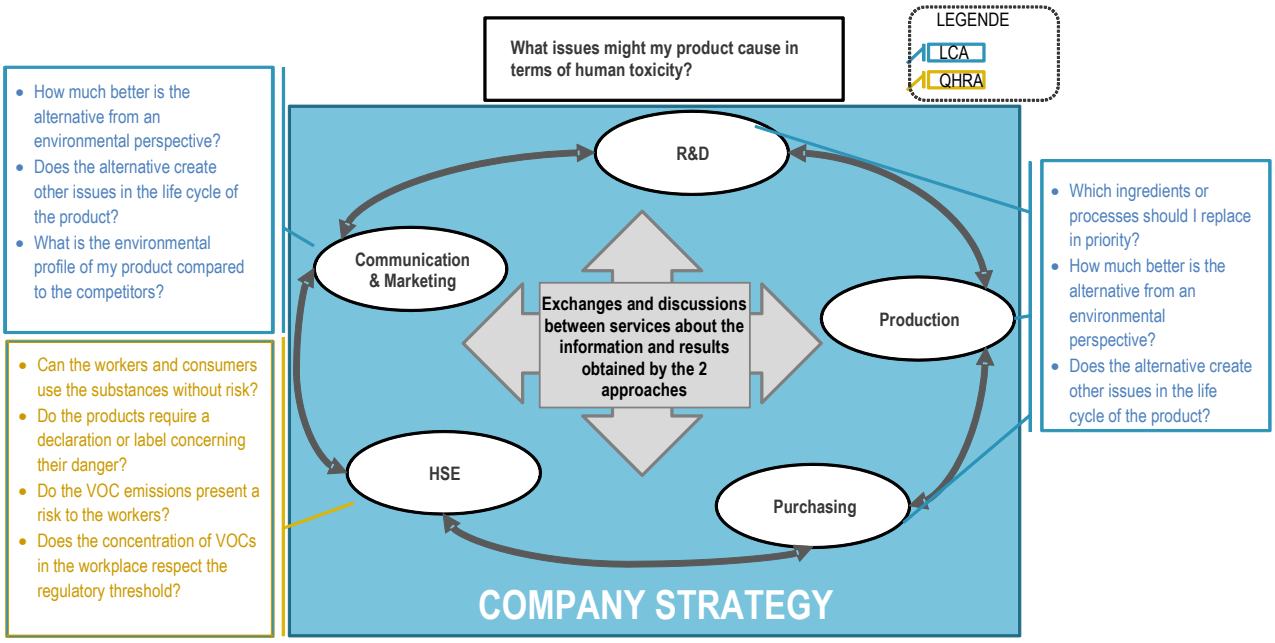


*Figure 8 Use of the two methods by the services of a company*

**Upon considering the divergent and complementary points of the two methods, the following conclusions have been made:**

- **LCA and QHRA are different methods responding to different objectives. They share some source data, particularly about the toxicity of substances, however this data is treated very differently.**
- **LCA aims to aggregate a large amount of data in an averaged and approximated manner, whereas QHRA involves a specific evaluation of health risks for a particular context (source and target population).**
- **QHRA cannot be applied to the entire life cycle of a product nor for the entirety of substances released.**
- **QHRA can be used in complement to LCA for the purposes of eco-design (QHRA provides a means by which to manage health risks and to identify limits for the LCA practitioner).**
- **LCA can be used in complement to a process of toxic molecule substitution to identify any potential transfer of impacts to indicators other than human toxicity.**
- **Care should be taken when used for environmental labelling purposes.**

This report tackles the delicate subject of the communication of results for the toxicity impact in LCA. **The communication of results is a crucial step** for companies because it is the way to highlight the benefits of the study. It is therefore important to follow the communication recommendations proposed in the study and to **maintain transparency about the results regarding their uncertainty**. Finally, as this topic is in constant evolution and is the subject of numerous scientific researches, the report concludes by taking stock of the work currently being carried out by ProScale, of JRC, in the scope of the PEF project of the European Commission or the UNEP-SETAC flagship project. It is essential that the LCA practitioner keeps up to date with future methodological evolutions as well as any European recommendations to come.