OMNIITOX: EU Chemicals Regulation

The Potential Role of Life Cycle Assessment in Regulation of Chemicals in the European Union

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Abstract

Scope and Background. This paper presents the preliminary results from an ongoing feasibility study, investigating potential application of elements from the life cycle assessment (LCA) framework in European chemicals' policy. Many policy areas affect manufacturing, marketing and use of chemicals. This article focuses on the general chemical legislation, especially issues related to regulatory risk assessment and subsequent decisions on risk reduction measures.

Method. Current and upcoming chemical regulation has been reviewed and empirical knowledge has been gained from an ongoing case study and from dialogues with various stakeholders.

Results and Discussion. LCAs are comparative and more holistic in view as compared to chemical risk assessments for regulatory purposes[1]. LCAs may therefore potentially improve the basis for decisions between alternatives in cases where a risk assessment calls for risk reduction. In this process, LCA results might feed into a socio-economic analysis having similar objectives, but some methodological aspects related to system boundaries need to be sorted out. Life cycle impact assessment (LCIA) of toxic effects has traditionally been inspired by the more regulatory-orientated risk assessment approaches. However, the increasing need for regulatory priority setting and comparative/cumulative assessments might in the future convey LCIA principles into the regulatory framework. The same underlying databases on inherent properties of chemicals are already applied in both types of assessment. Similarly, data on the use and exposure of chemicals are needed within both risk assessments and LCA, and the methodologies might therefore benefit from a joint 'inventory' database.

Outlook. The final outcome of the feasibility study will be an implementation plan suggesting incorporation of core findings in future chemical regulation and related policy areas.

Keywords: EU chemicals regulation; OMNIITOX; REACH; risk assessment; socio-economic analysis (SEA)

[1] In the remaining part of this paper, the term 'risk assessment' will be used in the meaning of regulatory risk assessment of chemicals as, for example, set down in the EU Technical Guidance Document on Risk Assessment (EC 2003a).

Introduction

Potential application of LCA methodologies, tools and concepts in chemical policy is one of five main objectives in the OMNIITOX project[2]. This objective is addressed in a 'regulatory feasibility study' conducted by the European Chemicals Bureau (ECB) in close collaboration with the OMNIITOX project partners and external stakeholders. This article presents the preliminary feasibility study results, including some knowledge which has been obtained from an ongoing case study.

The relevance and need for the feasibility study is supported by other current activities related to the regulation, marketing and handling of chemicals in the European Union, as well as internationally. From a European viewpoint, much attention is directed towards the proposed new policy on chemicals known as REACH (Registration, Evaluation and Authorisation of CHemicals), which was suggested by The European Commission in October 2003 (CEC 2003b) based on the 'White paper – strategy for a future chemicals policy' (CEC 2001a)[3]. The REACH proposal, which is currently being negotiated in the European Parliament and in the Council of Ministers, contains some life cycle thinking elements that are addressed in this paper. At the Organisation of Economic Cooperation and Development (OECD), the need for a more direct link between LCA and chemical policy was acknowledged as one of the main conclusions in the 'OECD Environmental Outlook for the Chemicals Industry' (OECD 2001). The report concluded the need for: " ... creating a holistic approach to chemical safety that not only addresses the risks to man and the environment resulting form the production of individual substances, but also the risks posed by products made from these substances and by the use of natural resources and energy to create these substances and products". The report has resulted in an OECD Chemicals Product Policy (CPP) programme (OECD 2002), which is being initiated with a study on barriers and opportunities for information exchange in chemical supply chains.

[2] OMNIITOX: Operational Models aNd Information tools for Industrial applications of eco/TOXicological impact assessments. See Molander et al. (2004) for more information about the OMNIITOX project.
[3] Interested readers are referred to the homepages of the European Commissions' Directorate General for Environment and Directorate General for Enterprise for the latest developments on REACH: <http://www.europa.eu.int/comm/environment/index_en.htm> and <http://www.europa.eu.int/comm/enterprise/index_en.htm>

1 Scoping

Many policy areas affect manufacturing, marketing and use of chemicals in the European Union, including:

- Chemicals in general, e.g. the upcoming REACH legislation substituting about 40 pieces of current legal text
- People at work, e.g. the chemical agent at work directive (Council Directive 98/24/EC)
- Consumer Product Safety, e.g. the general product safety directive (GPSD) (Council Directive 92/59/EEC) and specific directives related to toys, food additives, pharmaceuticals, cosmetics, etc.
- Emission reduction from manufacturing facilities, e.g. the IPPC (Integrated Pollution Prevention and Control) directive (Council Directive 96/61/EC)
- Producer responsibility, e.g. the end-of-life vehicles directive (Directive 2000/53/EC)
- Eco-labelling (Regulation (EC) No 1980/2000)
- Air and water quality
- Standardisation of product/processes containing or releasing chemicals
- Integrated product policy (IPP)[4]

The OMNIITOX regulatory feasibility study has, so far, put most effort into analysing potential linkages between LCA and the general chemical regulation, especially the current and foreseen risk assessment activities. This will be the starting point and main issue in this article. 'Linkages' here means that LCA might feed data or methodological elements into regulatory risk assessments, *and* vice-versa, which is actually already the case when considering the assessment of toxic impacts (see e.g. Udo de Haes et al. (2002)).

The assessment of toxic impacts is considered one of the most complex areas in LCIA due to an extremely large number of substances that potentially contribute to this impact, encompassing a wide array of different effect mechanisms and with a very different fate in the environment. There has been a debate on the value and scientific soundness of assessing toxic impacts in LCA for a long time, e.g. Tukker (1998 and 1999), Pennington (1999) and Owens (1997), as more recently summarised in Udo de Haes et al. (2002), for instance, based on the uncertainties and unavailability of the necessary substance properties, aggregating different effect mechanisms, and many other issues. Such issues may be causes for different outcomes of LCIAs of toxic impacts of the same system, as was demonstrated by Tukker (1998), for example, and this introduces complications in the interpretation of the results. However, in this paper, attention is given to how elements of LCA might improve chemical policy. This is a different focus that also differentiates this study from several previous studies that have looked into similarities and discrepancies between risk assessment and LCIA, e.g. Olsen et al. (2001) and Owens (1997).

The article will discuss how LCA can be used in the decision-making process in parallel with, or as part of, other assessment outcomes, once a regulatory chemical risk assessment has shown the need for risk reduction. This will be followed by a discussion of possible interactions at the methodological and data level. Preliminary knowledge from an ongoing case study is included in these discussions.

[4] The EU initiative on an Integrated Product Policy (IPP) has recently been strengthened by a Communication on 'Integrated Product Policy – Building on environmental life-cycle thinking' from the European Commission (CEC 2003c) as a follow up to the 'Green Paper on integrated product policy' (CEC 2001b).

2 The Case Study in Brief – Comparative LCA of Potentially Banned Chemicals

A case study was set up to give some empirical knowledge on the feasibility of applying parts of the LCA framework in the EU chemical risk assessment framework, and vice versa. As the case study is still in progress, only a brief introduction will be given as a background for the preliminary conclusions drawn later on in the article.

A number of risk assessments have been, and are being, carried out under the 'existing chemicals legislation[5]. These risk assessments are conducted for individual substances, or for groups of substances, with similar properties such as medium-chained chlorinated paraffin's (MCCP), the choice for the current case study. MCCPs are used in a variety of formulations such as leather finishing products, sealants, paints and metal working fluids. The draft risk assessment of MCCP (HSE 2002, EA 2002) identifies a need for risk reduction for some applications of these substances, among others their use in metal working fluids. Various options for risk reduction are currently being investigated and a risk reduction strategy on MCCP is expected by the end of 2004. The legal action to be taken might, or might not, be similar to the actions taken as the result of a similar risk assessment of the structurally related, short-chained, chlorinated paraffin's (SCCP) (CEC 2000), which were banned for certain uses, including metal working fluid applications (Directive 2002/45/EC).

The case study includes a comparative LCA of metal working fluids, with and without MCCP delivering the same function. The function studied is pilgering[6] of the same length and dimensions of stainless steel tubes for application in heat exchangers. The process and a representative alternative metal working fluid – mainly based on oil and synthetic/sulphured esters – were chosen in co-operation with a manufacturer of stainless steel tubes (identity of manufacturer confidential).

One main objective of the case study is to see whether LCA can increase the knowledge about the environmental consequences of such a substitution. One issue of interest is the energy consumption related to the actual application of the metal working fluid. MCCP acts as an extreme pressure additive and one could expect that alternative metal working fluids would result in considerably increased energy consumption. Another important objective of the case study is to give empirical knowledge on workability issues such as data availability and accessibility when conducting an LCA as potential decision support in the risk reduction process.

3 LCA as a Decision Support in the Risk Reduction Process

In cases where the conclusion from an 'existing chemical' risk assessment shows concern for one or more uses, a risk reduction strategy is developed. This strategy is fed into the legislative decision-making process, which may e.g. end up with inclusion of the substance in the restriction directive (Council Directive 76/769/EEC). Current regulatory practice is to include a socio-economic analysis (SEA) in the risk

[5] According to Council Regulation (EEC) 793/93 of 23 March 1993 on the evaluation and control of the risk of existing substances.

[6] Pilgering is a high performance metal forming process shaping tubes between two rolls and an internal mandrel under high pressure.

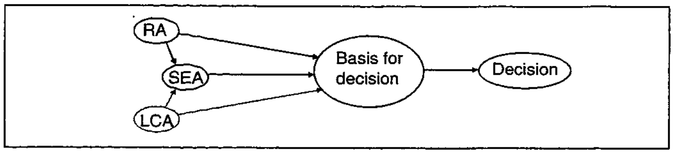

Fig. 1: Risk assessment (RA), socio-economic analysis (SEA) and potentially life cycle assessment (LCA) delivering input to the decision-making process associated with risk reduction decisions for chemicals

reduction strategy in order to make a more balanced basis for decision-making by assessing other impacts on society than the risk reduction itself. LCA might potentially play a role as a direct, or indirect, input to the basis for decision, as illustrated in **Fig. 1**.

There are some obvious benefits – not covered within the risk assessment – associated with applying LCA results for decision support in the decision-making process:

- LCA is a comparative tool
- LCA includes – in theory – all interventions in the product life cycle (resource consumption and emissions)
- LCA assesses several potential environmental consequences in the impact assessment stage

Due to these issues and due to the fact that the LCA methodology aims at assessing the 'average' or 'best estimate' situation[7], it might be possible to feed LCA results into an SEA as a more 'holistic' assessment of the environmental consequences as compared to the more narrow risk assessment results[8]. However, it equally calls for caution, for example that default system boundaries might easily vary between the methodologies and that LCAs could be used to challenge other assessments that have identified unacceptable levels of risk. An example of the boundary discrepancies was seen in recent Danish experiences from an SEA study comparing incineration versus recycling of scrap paper and using results from an LCA study. The study clearly illuminated the diverging outcome of the SEA considering national system boundary, in contrast to the geographical system boundaries for the LCA, which covered activities outside Denmark, incl. forestry (Teknologirådet 2003). Another issue that calls for further thought is the application of discounting rates in economic analyses. Applying discounting to the global warming potential outcome of an LCA, for example, would result in essentially no weight being allocated to long-term effects (see e.g. Hellweg et al. 2003 for a discussion on discounting). A more formal application of SEAs is foreseen under REACH. Some of the above issues could be addressed during development of guidelines on how to conduct SEAs under REACH.

It is also interesting to take a comparative look at the technical system boundaries of LCA versus 'regulatory risk assessment'. The risk assessment covers all downstream uses of the chemical on its own, in preparations/formulations and in products/articles; i.e. including all steps in the chemicals' life cycle from manufacturing to the final disposal of the substance or the preparations/articles containing the substance. **Fig. 2** shows that MCCP is applied in several formulations, which might each feed into several uses (professional as well as consumer uses, etc.).

A more conceptual illustration of this is given in **Fig. 3a**. Similarly, **Fig. 3b** illustrates the system boundaries for the core constituents in a product assessed by LCA (ancillary materials, e.g. chemicals crossing the life cycle indicated, are left out). From this figure, it is clear that one LCA only covers one of several 'use scenarios' assessed in the risk assessment. Consequently, if the risk assessment concludes that

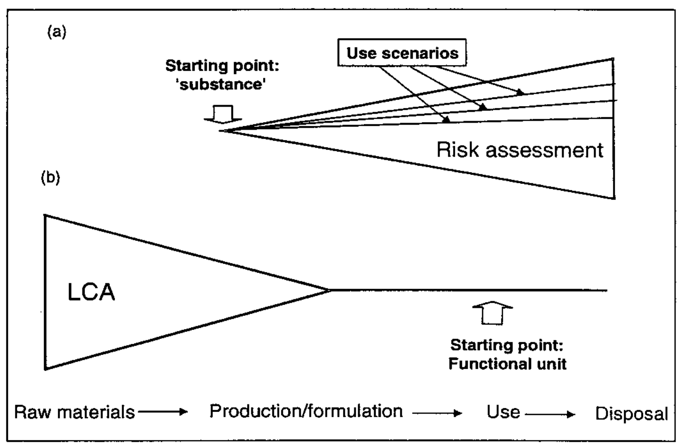

Fig. 3: Conceptual illustration of the technical system boundaries for a regulatory chemical risk assessment (a) and life cycle assessment (b)

[7] Quantitative and qualitative investigation of uncertainties should of course always be addressed in an LCA.

[8] It should be acknowledged that the underlying objective of risk assessment, i.e. to minimise risks from chemicals to environment and humans, must not be jeopardised through the additional use of other tools such as LCA that may have larger inherent uncertainties. These should only be used to arrive at more informed decisions. In addition, such studies should, of course, be peer reviewed.

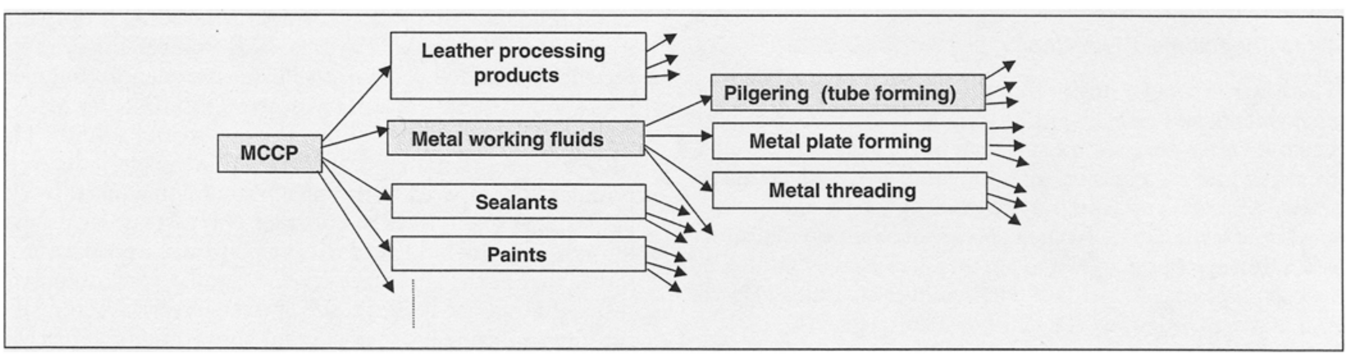

Fig. 2: Medium-chained chlorinated praffins (MCCP) are used in several formulations, which are each used for several applications, and the MCCP is eventually disposed of (if not already emitted to the environment in the previous life cycle stages). All of these chemical life cycle phases are covered in a regulatory chemical risk assessment. The grey toned path has been assessed in the MCCP case study

there is concern for several uses of a substance, several LCAs would be needed in order to cover the entire risk reduction strategy. Also here, thoughts should be given to the geographical system boundaries. EU regulatory risk assessments usually only cover impacts in the EU area (and surrounding waters), whereas most LCAs, as a starting point, take the entire world as the default geographical boundary.

Altogether, it seems theoretically possible to include LCA as a decision support for regulatory risk reduction decisions, either directly or indirectly via an SEA (see Fig. 1), although some further development/research is needed especially concerning coverage of the various tools in terms of system boundaries.

Other relevant issues to consider are the resources (time and costs) needed to conduct these LCAs and the availability of (inventory) data. Concerning the latter, the case study experiences have given rise to some concern. The preliminary LCA results show virtually no difference between the alternatives (metal working fluid with and without MCCP). One main reason for this is difficulties in finding key inventory data on the consequences for the energy consumption at the metal working process level (so far, similar inventory data have been applied for the two alternatives as no stakeholders seem to possess this kind of data, or to have an interest in/ability to provide such data). Another main difficulty is related to assessing consequences of emissions of the metal working fluid components. MCCP emissions would obviously give rise to a high eco-toxicity potential, but problems in obtaining or measuring exact recipe information on the MCCP free metal working fluid did so far prevent a fair comparison of these emissions. These findings should not be over-interpreted at this stage, as efforts are still being made to fill these data gaps and because the preliminary experiences are based on one case study only. However, it seems obvious that industry, and not governmental bodies, should have the responsibility of conducting these kinds of studies. Such an approach would be in line with one of the overall intentions of REACH, namely to shift responsibility for providing assessments from authorities towards industry. The cost and time constraints of conducting LCAs as a decision support for risk reduction decisions still needs to be investigated further, particularly in the context of small and medium-sized enterprises. The previously mentioned issue, that several LCAs might be needed in order to cover several 'concern uses' from the risk assessment, will be one element of these investigations.

4 Methodological Elements

There are obviously many overlaps between regulatory risk assessments and assessments of toxic impacts in LCA – both when it comes to assessment of fate of chemicals in the environment and to assessing the (potential) toxic effects themselves. Many life cycle impact assessment (LCIA) methodologies for assessing toxicity were developed based on regulatory risk assessment principles and are therefore heavily influenced by such a practice; e.g. EDIP (Hauschild et al. 1998a, 1998b) and USES-LCA (Guinée et al. 1996, Huijbregts 2001).

Several compromises are needed when going from a substance risk assessment approach to comparative/cumulative risk assessment approaches, such as those applied in LCIA. Risk assessments aim to protect humans and the environment and therefore tend to be conservative, e.g. by application of (reasonable) worst case exposure estimates and the use of safety factors in the effects' assessment, whereas LCAs should aim for average/best estimate assessments being a comparative tool (see e.g. Olsen et al. 2001). Efforts have been made to achieve this in more recent LCIA methods (see e.g. Udo de Haes et al. 2002 and Pennington et al. 2004). Some of the (inherent) assumptions made when assessing accumulated toxicity in current LCIA methodologies were highlighted by Owens (1997), Crettaz et al. (2002) and Pennington et al. (2002), including dose-response extrapolation to zero exposure for biological threshold effects, the assumption of additivity of risks across different effect end-points as well as the inherent assumption of additivity of exposures regardless of the fact that these take place in different places and at different times.

Another issue differentiating risk assessments of chemicals and LCIA is the low data availability on substance properties, as pointed out by Tukker (1998). Regulatory risk assessment is a stepwise approach in which it is possible to use relatively little data in a screening tier because a conservative assessment is made requiring only enough data to provide evidence that a substance is unlikely to pose unacceptable risks. Only those substances, for which an unacceptable risk cannot be excluded, need to be fully assessed. LCIA, on the other hand, needs best estimate data for all substances. Due to the low data availability for many chemicals this can result in high uncertainties in LCIA due to the use of poor data or default values (Tukker 1998). It should be noted that the scope of various policy support assessments can also be restricted to chemicals of high policy concern, in which case data availability issues may be of low importance. The LCIA methodology under development in OMNIITOX aims to take some of these issues as well as uncertainties into account (Guinée et al. 2004).

Current and future LCIA methodologies may, bearing in mind that their level of detail and aim are not that of a traditional risk assessment, assist future regulatory decision-making in situations where comparative/cumulative risks are to be addressed. The interest and potential need for comparative risk assessment is illustrated by some of the OMNIITOX case studies. Pant et al. (2004) compare the potential impacts from the use phase emissions of several washing powders by applying risk assessment and LCIA tools, respectively, with the aim of investigating different methodologies for product comparison. Some knowledge from the regulatory MCCP case study point to the need for product-orientated comparative risk assessment techniques. It was found that there is not a 'drop in' substitute for MCCP as an extreme pressure additive in metal working fluids. The MCCP free alternative is therefore a completely different product as compared to the MCCP containing metal working fluid. If one wishes to compare risk assessment results, the assessment would need to take place at the product level rather that at the substance level. A similar conclusion was reached by Lohse et al. (2003) in their investigation of the substitution principle, namely that substitution alternatives must be compared at the functionality level, approaching the well known functional unit concept at the foundations of the LCA framework.

Further into the future, risk assessment and LCA might for some comparative purposes be combined into one 'Life cycle risk assessment' tool. That could improve the assessment of chemicals by giving a more holistic assessment of the consequences of shifting from one chemical to another by covering all environmental interventions (also upstream), many impact categories and, in essence, being comparative. However, for other purposes such as e.g. assessing the risk of the use of a specific substance at a specific site, the tools in themselves are likely to remain in demand.

5 Data on Inherent Chemical Properties

Assessment of toxicity in risk assessments, as well as in LCA, rely to a great extent on the same inherent property data available for chemicals, such as physicochemical properties and dose-response information. Many of these data are initially established for risk assessment purposes. This fact has been one of the cornerstones in the work with developing a new state-of-the-art LCIA methodology for chemicals in other parts of the OMNIITOX project (Guinée et al. 2004), where much attention is given to the type and amount of data that are expected to be available once REACH is implemented. Most of the inherent property data established under REACH will become publicly available via the Internet and joint infrastructure options with the OMNIITOX Information System should be investigated for mutual benefits (see Molander et al. 2004).

6 Data on Use, Emission and Exposure

Practical experience from the existing chemicals programme (Council Regulation (EEC) 793/93), taking the chemical as the starting point (cf. Fig. 3a), has revealed severe difficulties in identifying downstream uses of chemicals and consequently downstream emissions and exposures. Implementation of REACH is expected to improve this situation by encouraging information exchange on use and exposure of chemicals in chemical supply chains (see e.g. Christensen et al. 2003 for further details). Downstream information may also be obtained from LCA studies, which in contrast to risk assessments take a downstream product (or more correctly the function of the product) as the starting point (cf. Fig. 3b). LCA practitioners, on the other hand, are often faced with a lack of upstream inventory data, as well as data for the numerous ancillary material/chemicals crossing the boundaries of a product life cycle system. Altogether, regulatory risk assessments and life cycle assessments rely on tracking the flow of substances and materials in society and, by having different starting points, joint benefits are obtained when bringing data and practitioners from the two fields closer together (see e.g. Olsen et al. 2001). Some of these approaches might take place under, for example, the OECD Chemical Product Policy (CPP) and the EU Integrated Product Policy (IPP) programmes mentioned in the beginning of this paper.

7 LCA will Continue to be a Methodology Primarily Applied within Industry

Despite the ideas of bringing LCA results, as well as data and methodological elements, into the context of the regulation of chemicals, LCA will probably continue to primarily be a methodology applied within industry. It is doubtful whether LCA will by used extensively to challenge the general principle of several current legislations, which require that risks be adequately controlled. Risks to workers, for example, are regulated through workers' legislation and risks to the environment surrounding a facility are regulated via emission-related legislation like the IPPC directive (Council Directive 96/61/EC), production permits and other local regulations. Furthermore, demonstration of safety throughout the chemical supply chain will be the starting point under REACH. In this connection, LCA can be seen as a tool which can work within these 'safety boundaries' in search for further improvement of the chemical or product manufactured.

8 Conclusions

LCA might in the future become an important tool in regulatory decision-making for risk reduction from chemicals. This facilitates a more holistic view of the environmental consequences of alternative ways to reduce unacceptable risks, for instance by substitution. LCA results might feed into the decision-making process either directly or indirectly via socio-economic analyses (SEA). Interaction between LCA and SEA seems theoretically possible due to some similarities in structure and objective of the methodologies, although some important issues related to system boundaries and assessment criteria need to become addressed further. Our experiences from a case study have revealed difficulties in obtaining core inventory data for such LCAs by a governmental body. It therefore seems logical that LCAs in the context of chemical policy should be the responsibility of industry. Such studies should, of course, be peer reviewed and applied critically in the decision-making process. Methodologies for regulatory risk assessment of chemicals have for some time inspired the development of life cycle impact assessment (LCIA) of toxicity. However, recent developments indicate that some future regulatory needs for assessing or setting priorities between cumulative emissions/exposures from several chemicals can learn from the LCIA in its ability and intention to assess average or best estimate aggregated impact. Such needs were also indicated by the case study and a recent study on the substitution principle suggested that many substitutions will not only cause changes at the substance level, but rather at the product or even at the functionality level. An even further step, perhaps also reflecting some recent LCIA developments, could be to develop a methodology bringing the benefits of the two tools together in a 'life cycle risk assessment' methodology.

Regulatory risk assessment and LCA already use the same type of underlying property data for the assessment of toxic impacts. There also seems to be good potentials for joint application and complementary generation of data on the use and exposure of chemicals. The starting point for regulatory risk assessments is the substance (upstream), but information on downstream uses and exposures are often limited. Contrarily, LCA starts with the product (or function of the product), but often lacks upstream information. Data sharing therefore remains obvious and might become further propagated by bringing the LCA and regulatory risk assessment communities further together, which is also to some extent taking place under the OECD chemical product policy (CPP) programme and might become an issue in the Integrated Product Policy (IPP) activities in the European Union.

Despite the above insights on integration of LCA elements into the regulation of chemicals, LCA will continue to be an important tool for the improvement of products and processes within industry.

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