Environmental Impact Assessment Review 65 (2017) 156–163

Contents lists available at ScienceDirect

Environmental Impact Assessment Review

journal homepage: www.elsevier.com/locate/eiar

Combination of life cycle assessment, risk assessment and human biomonitoring to improve regulatory decisions and policy making for chemicals

Tobias Walser*[,1], Réjane Morand Bourqui, Christoph Studer

Risk Assessment of Chemicals, Federal Office of Public Health (FOPH), Schwarzenburgstrasse 157, 3003 Bern, Switzerland

ARTICLE INFO

Keywords:
Life cycle assessment
LCA
Risk assessment
RA
Human biomonitoring
HBM
Nanotechnology
Nanomaterials
Chemical regulation
Policy making

ABSTRACT

Prior to market entry, new chemical substances are assessed for their risk to human health and the environment. Conventional risk assessment (RA) is limited in scope, i.e. it usually does not cover the entire life cycle of a substance, nor does it take into account sustainability aspects such as the amount of raw materials and energy required to produce the substance. Life cycle assessment (LCA) can provide this pivotal information to support an informed decision on the sustainability of a new substance. Unfortunately, LCA has had little regulatory application up to now. We believe that increasing the focus on combined use of LCA and life cycle-based RA could lead to improved regulatory long-term decisions for marketed chemicals. Inclusion of human biomonitoring could increase the robustness of such decisions even further. In addition, the combined use of the three methods allows a robust search for sustainable alternatives of currently marketed chemicals that have an unfavourable risk profile.

1. Introduction

Individuals are constantly exposed to emissions of chemical substances such as nitrogen oxides, formaldehyde and combustion-generated particles. Governments have regulatory measures in place to limit such emissions into the environment or the workplace, and also to minimize the release of substances from consumer products. To develop such measures, authorities require data on emission sources and exposure concentrations, as well as on adverse health effects and potential mitigation options. According to the present chemicals legislation a manufacturer or downstream user "shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses" if a chemical safety assessment is required (European Parliament and Council, 2006). Life cycle-based risk assessment (LC-RA) is the most appropriate term to describe such evaluations during the life cycle of chemicals and has been explicitly introduced by various researchers (Christensen and Olsen, 2004; Shatkin and Davis, 2008), though the concept can be implicitly also found in regulation (European Parliament and Council, 2006). LC-RA is used to assess the risks arising from a single substance for a particular use. Industry and regulators scrutinize these risks. However, it is difficult to assess the overall risk of a particular substance, as it may be incorporated into many products, and the total amount of the substance in all products on the market and the frequency of product use is unknown. LC-RA thus gives little to no information about the effective exposure of the population. Approaches that include cumulative exposure assessment and (sub)-populations instead of individuals can partly compensate for the information not provided by LC-RA. Two such approaches are life cycle assessment (LCA), which provides this information on a relative scale (International Organization for Standardization, 2006), and human biomonitoring, which provides concrete exposure values.

LCA evaluates products over their entire life cycle and includes all up- and downstream energy and material requirements with their respective emissions and potential impacts. LCA and LC-RA are often confused, leading to unproductive discussions about the same topic. For example, Life Cycle Analysis (also referred to as LC-RA in Europe) is often used to mean life cycle assessment in the United States. Both approaches have their own strengths, and complementary use of both could improve the regulatory assessment of chemical substances and products. Use of both methods in parallel was first published by (Owens, 1997) and seven years later by (Sonnemann et al., 2004). More recently, successful use of both methods was demonstrated for water quality management (Kobayashi et al., 2015), toluene(Walser et al., 2014) and soy-biodiesel (Milazzo and Spina, 2015). While LC-RA

* Corresponding author at: Vereala GmbH, Eyhof 34, 8047 Zürich, Switzerland.
E-mail addresses: tobias.walser@vereala.com (T. Walser), Rejane.MorandBourqui@bag.admin.ch (R.M. Bourqui), Christoph.Studer@bag.admin.ch (C. Studer).
[1] Permanent address: Vereala GmbH, Eyhof 34, 8047 Zürich, Switzerland

http://dx.doi.org/10.1016/j.eiar.2017.05.004
Received 8 December 2016; Received in revised form 28 March 2017; Accepted 12 May 2017

of chemicals has already found its way into various regulations, the role of LCA in regulatory decision making is still largely unexplored.

One challenge for regulatory decision making is limited knowledge on cumulative exposure and risk assessment of subpopulations. Regulators receive safety information from industry on individual substances and products, but with vague quantitative information on their use and expected production volumes. Consequently, neither industry nor the authorities have data on the exact use of the substances in the reported products, nor do they know the exact tonnage of substances in similar products. Therefore, estimates of material emissions (and consequently environmental and human exposure arising from industrial and consumer goods in general) are at best fragmented and usually non-existent. National and international initiatives for human biomonitoring (HBM) could fill this gap. In HBM, the concentration of biomarkers in biological samples is measured. Coupled to health data and detailed questionnaires about specific behaviors and potential sources (occupational settings, cosmetic use, lifestyle, dietary habits…), HBM allows to assess the effects resulting from exposure to known chemical substances, taking all sources and routes of uptake into account (Angerer et al., 2007). In contrast to the modelled results from LC-RA and LCA, which follow the pathway *emission – exposure – health impacts*, HBM follows the other direction: starting from observational data – health effects, concentrations in biological samples – the effective exposure can be measured and potential sources identified. Ideally they are quantified by statistical source apportionment (Pleil and Sheldon, 2010). HBM helps to determine critical uses of certain product categories or unsustainable industrial activities. Whereas cross sectional HBM studies give an overview of the chemical burden at a certain time, longitudinal studies that are sufficiently large enable an even more detailed understanding of e.g. potential impacts resulting from existing and emerging chemicals (Nieuwenhuijsen et al., 2006; Clewell et al., 2008). Such longitudinal studies require detailed data and long running times in order to have a value for risk assessment. Data from HBM could help to decide whether regulatory actions are necessary to protect the population or a vulnerable subpopulation from overall exposure.

The regulatory view of the safety or sustainability of a substance, product, or technology can improve with joint use of LCA, LC-RA, and HBM. However, a number of preconditions must be fulfilled prior to implementation and regulatory acceptance. In this article, we present the power of the mutual use of these methods with a focus on LCA, and identify the methodological developments necessary for future regulatory implementation. We illustrate the potential of the three methods with a case study on nanotechnology, which is an emerging industrial sector with a wealth of chemical substances and products for industrial and consumer use.

2. LC-RA in regulation

LC-RA is undoubtedly the principal tool for the regulatory risk assessment of chemicals, and a wealth of literature explains the use of RA in regulatory settings (Traas and Van Leeuwen, 2007). RA starts with hazard identification of the substance, which is subsequently combined with an exposure assessment that may include the environment, work places or households (Paustenbach, 2015). Emissions and transport processes of a hazardous substance must be known to determine the effects upon exposure (dose-response modelling) (Paustenbach, 2015). Responsible production, use and disposal of chemicals require a holistic view on the chemical. Therefore, life cycle aspects are mentioned explicitly in many regulations. A substance-specific risk assessment is a regulatory condition for market entrance in Europe (European Parliament and Council, 2006). The assessments (usually tiered) are determined according to the tonnage, use, and hazards of the new substance. Restrictions may be introduced and classification and labelling are specified for safe use (European Parliament and Council, 2008a,b). The regulations are in principle applicable to all chemicals. For certain chemicals, however, some test guidelines are adapted to capture specific properties. Therefore LC-RA is usually very precise for a specific substance and its use.

3. The added value of LCA

LCA is different to LC-RA and consists of four phases: (1) goal and scope definition, (2) life cycle inventory analysis, (3) impact assessment, and (4) interpretation of the results (Finkbeiner et al., 2006). The scope (1) of the study is usually an environmental and human health assessment of a product or service, either to detect hotspots of concern along the life cycle, or to compare the environmental and human health performance with those of a substitute. One of the outstanding strengths of LCA is that it can cope with a large number of substances being analyzed together and can incorporate transformations along the life cycle of a substance. LCA is good at incorporating models that are not overly detailed; this helps to generate comprehensive results from datasets of hundreds of substances that are not too complex to be handled by an informed person.

Do the environmental and health benefits of a new technology or product outweigh its negative impacts? LCA can provide decision makers with such information on the benefits and impacts over an entire life cycle: LCA considers all material and energy flows involved in the production, use, and disposal of the product, including downstream emissions from the various stages in the life cycle. This part of an LCA is referred to as life cycle inventory analysis (2). The following life cycle impact assessment (3) couples fate-exposure-effect models to quantify potential environmental and/or human health impacts. A distinctive feature of the impact assessment is the effect model, where the toxic effect of a single substance is either normalized to a single surrogate substance or presented as per-capita impact, in order to enable summation of effects from the emissions of all substances of the assessed product system (Guinee et al., 2002). Consequently, the impacts of a substance can be presented in various ways, such as Comparative Toxicity Units (Rosenbaum et al., 2008), or Chloroethylene-equivalents (Jolliet et al., 2003; Goedkoop et al., 2008). The values are relative (i.e. comparative values), since the fate and exposure models are generalized over time and space. The results depend strongly on system boundaries and the comprehensiveness of the inventory. They do not allow conclusions about the absolute safety of a product or process, something that can be done with LC-RA. However, LCA provides a comprehensive assessment of the effects on environmental or human health, with quantitative indicators such as human toxicity, ionizing radiation, ozone layer depletion, or photochemical oxidation.

4. LCA in regulation

The recently adopted action plan for the Circular Economy (European Commission, 2015) covers material flows for entire life cycles: from production and consumption to waste management, with the aim of creating a market for secondary raw materials and thus decreasing emissions and final deposits of unused materials. It shows the increasing political importance of closing material cycles with greater reuse and recycling, which ultimately benefits public health, the environment and the economy. It will lead to adapted regulatory regimes (primarily in the waste sector), which will incorporate life cycle considerations to a higher degree than at present. These life cycle considerations include LCA, which can help to decide on appropriate areas of application for regulatory restrictions of product categories or industrial activities, depending on environmental performance, benefits, and costs. A prime example of implementation into legislation is the requirement of LCA results to evaluate biofuels in Switzerland. The required LCA is an ISO standard and includes an adapted impact assessment method (Frischknecht et al., 2009). The key metrics of this method are eco-factors, which measure the environmental impact of