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Socio-economic analysis: a tool for assessing the potential of nanotechnologies

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Abstract. Cost-Benefit Analysis (CBA) has a long history, especially in the USA, of being used for the assessment of new regulation, new infrastructure and more recently for new technologies. Under the denomination of Socio-Economic Analysis (SEA), this concept is used in EU safety and environmental regulation, especially for the placing of chemicals on the market (REACh regulation) and the operation of industrial installations (Industrial Emissions Directive).
As far as REACh and other EU legislation apply specifically to nanomaterials in the future, SEA might become an important assessment tool for nanotechnologies. The most important asset of SEA regarding nanomaterials, is the comparison with alternatives in socio-economic scenarios, which is key for the understanding of how a nanomaterial « socially » performs in comparison with its alternatives. « Industrial economics » methods should be introduced in SEAs to make industry and the regulator share common concepts and visions about economic competitiveness implications of regulating nanotechnologies,
SEA and Life Cycle Analysis (LCA) can complement each other : Socio-Economic LCA are increasingly seen as a complete assessment tool for nanotechnologies, but the perspective between Social LCA and SEA are different and the respective merits and limitations of both approaches should be kept in mind.
SEA is a "pragmatic regulatory impact analysis", that uses a cost/benefit framework analysis but remains open to other disciplines than economy, and open to the participation of stakeholders for the construction of scenarios of the deployment of technologies and the identification of alternatives. SEA is "pragmatic" in the sense that it is driven by the purpose to assess "what happens" with the introduction of nanotechnology, and uses methodologies such as Life Cycle Analysis only as far as they really contribute to that goal. We think that, being pragmatic, SEA is also adaptative, which is a key quality to handle the novelty of economic and social effects expected from nanotechnology.

1. Introduction

The aim of this paper is to bring about some information regarding Socio-Economic Analysis and to discuss how to use it to help drive the development of nanotechnologies through a sustainable pathway.

It first describes Socio-Economic Analysis (SEA) and makes a brief overview of how it has been used in the past. More importance is devoted to discussing the current and future use of SEA in the context of the REACh regulation of chemicals in the EU, for two reasons: REACh (Regulation 1907/2006) is one of the most important piece of legislation currently requiring SEA to be used, and REACh might in the near future be a cornerstone of the regulation of nanomaterials in the EU.

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We also review the state-of-the-art of the use of SEA for nanomaterials. Finally, on the basis of our experience from chemicals management and EU Research projects on nanomaterials, we make some proposals to adapt and improve SEAs for nanomaterials, and we clarify the relations between SEA and Life Cycle Analysis.

2. An overview of Socio-Economic Analysis

Socio-Economic Analysis could be defined as a variant for Regulatory Impact Analysis (terminology used in the USA) of Impact Analysis (as used by the European Commission). (Regulatory) Impact Analysis is used by public authorities "to balance the potential benefits and costs of action or lack of action", as the EU Treaty reads. (R)IA is the term used for the pre-ante assessment and preparation of legislation, and the denomination "SEA" is more often used for implementation of legislation, but the methodology is the same in the two situations.

The conceptual framework of both (R)IA and SEA, as clearly expressed in the case of the EU by the above excerpt of the Treaty, is that of cost-benefit analysis (CBA). The concept of CBA and its first tentative uses seem to stem from France in the XIX century. CBA has been systematically developed, among others, in the USA by the US Army Corps of Engineers, then in other OECD countries and in the EU, at first for public infrastructure projects [1]. Since a number of years, CBA concepts use has expanded considerably to public policy preparation and implementation and included more frequently and systematically public health and environmental issues. Several European Directives or Regulations (Water Framework Directive, Industrial Emissions Directive, REACh Regulation…), even if they leave room to Member States for choosing the means to achieve objectives of public health and ecosystems protection, do impose or strongly encourage that the choice be based on such techniques as CBA that allow to take into account as a whole the impacts on health, the environment and the economy.

The ambition of SEA in our context is to get a rational, balanced and holistic view of advantages and drawbacks of the introduction of new products and new technologies in society. For instance, to assess the impacts of introducing a new material on the market, SEA makes an inventory of all impacts of the material and its alternatives. Since past failures of regulation of chemicals and materials was sometimes explained by lack of information or attention to the existence of alternatives, in SEA the issue of the market and non-market utility of innovation, and the comparison with alternatives, is regarded as a key issue [2,3]. SEA also considers collective risks and deals with their economical dimension, and in that respect goes beyond "risk reduction strategies" that were previously carried out for chemicals in the EU for the pre-REACh regulations [4]. For instance, risk assessments and reduction strategies for chemicals were focused on PEC[1]/PNEC[2] ratios for ecosystems or exposure/NEL[3] for human health impacts, whereas SEA will concentrate on collective impacts such as overall morbidity/mortality, ecosystems damage…

2.1. Use of SEA for chemicals under the framework of the REACh Regulation

In the framework of REACH, substances "of Very High Concern" cannot be put on the market unless risks for human health and the environment associated with their use are "adequately controlled". If not (no possibility to control the risk below a significant level), industry can still request an authorization to put the substance on the market, on the grounds that the advantages of using the substance outweigh the potential unwanted impacts, and that there are no economically and technically viable alternative substances or technology. Even if not mandated by the legal text, providing an SEA with the authorization Dossier in that case seems the logical procedure that should be followed in the future, when applications procedures under REACh will actually start.

[1] Predicted Effect Concentration
[2] Predicted Non-Effect Concentration
[3] No-Effect Level

Alternatively, Member States (and the European Chemicals Agency upon request of the European Commission), can ask for a total or partial "restriction" of the access of an existing chemical to the market, on the mandatory condition that a SEA shows that the benefits of the restriction outweigh its social and economic cost.

Even if conducting SEAs for chemicals presents great technical and scientific challenges, as we discuss later in this paper, the European Chemicals Agency in charge of the implementation of REACh has included SEA in its work programme: a guidance for SEA has been published [5], and a Socio-Economic Analysis Committee has started elaborating opinions on whether particular chemicals should be restricted in the EU. The guidance is limited to a general process, as summed up in Figure 1, and to general information about the techniques that are at the basis of SEA: costing methods for financial impacts, description of welfare impacts indicators, and techniques for cost/efficiency, cost/benefit and multicriteria analysis.

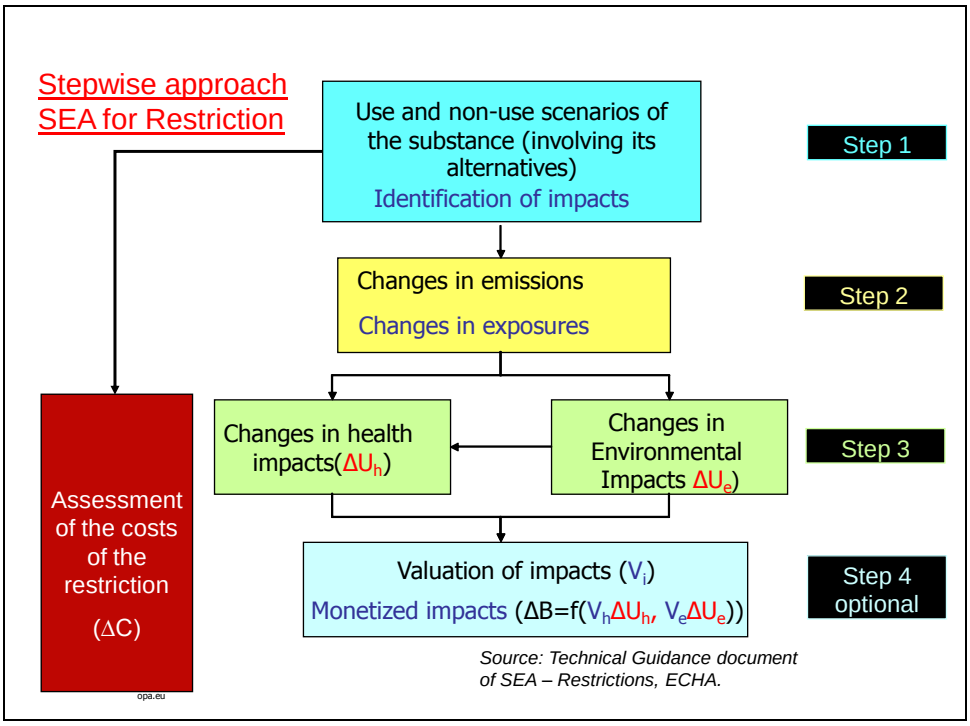

Figure 1. SEA Stepwise approach.

2.2. SEA in other environmental regulation in Europe

SEA is also used in the framework of the Directive on detergents (EC/648/2004): derogations to the prohibition of non-biodegradable surfactants in household detergents have to be based on a SEA comparing the socio-economic benefits of the surfactant to the damage caused by its release in the environment.

The future EU regulation on biocides (COM(2009) 267 final) does not request SEAs in the permitting process, but the "balance between advantages and risks" will be a criterion for decision (Article 21-3).

2.3. Nanomaterials and Safety Regulations in Europe

REACh applies to nanomaterials but currently ,without any specific provision, in particular there is no specific threshold for the registration of nanomaterials. Many nanomaterials are manufactured and imported in the EU below the thresholds applying to chemicals, and will not be registered nor assessed for their risks, unless the REACh regulation is revised and that particular aspect is changed in 2012.

Many difficulties also still exist for a definition and characterization of nanomaterials that would be effective and pragmatic under REACh, given the variety of nanomaterials and their functionalization. Other safety regulations in the EU do not either have specific provisions for nanomaterials: Directives for the protection of environmental media (air, water), Directives for Industrial Installations, Directives for biocides. In return, the new European Regulation on Cosmetics (EC 1223/2009) includes an obligation of pre-declaration and labeling of products containing nanomaterials, and the premises of a specific risk management system.

We can only at this stage conclude that SEA is just starting to play a role in risk management for nanomaterials under REACh and the cosmetic Regulations. But that this role is expected to raise significantly in the coming years, under both Regulations, and also under other environmental legislation.

3. The usefulness and the challenges of SEA for managing the risk of nanotechnology

In SEA, the central issue is the market (or consumer) and non-market (or societal) utility of nano-innovations, and its comparison with non-nano alternatives [3]. The functionality and utility of a material in relation to its alternatives will inform on the value of nanoinnovations, which can then be compared to the risks of the new nanomaterial (the comparison being also carried out for the alternatives).

The preoccupation in SEA to consider alternatives in the risk/benefit assessment and compare them with the new material under scrutiny is key to avoid some past failures of risk management. A lesson learnt for instance from the case of asbestos is that some actors might conceal available alternatives and narrow the debate on how to manage the risk of a material without questioning its social value [2]. In the current situation of high uncertainty and high stakes regarding risks of nanomaterials, utility is also a possible criteria to discriminate between promising nanomaterials and less valuable ones. Even when all risks (and a fortiori impacts) cannot be quantitatively and even qualitatively assessed, partial Socio-Economic assessments shed light on the relative merits of a nanomaterial versus its alternatives. The stake is to avoid to invest in low-value new materials (in a dense universe of competing value creation opportunities) that could consume limited financial of raw material resources or damage scarce environmental resource.

3.1. Current state-of-the art of SEAs for nanomaterials

Reviews [6] have highlighted that very few SEAs seem to have been conducted for nanomaterials or nanotechnologies until now. On the other hand, a considerably growing body of literature (scientific, grey, general public…) has noticed the high potential benefits (aquifer remediation, increased industrial safety, energy efficiency, substitution of hazardous chemicals, public health application…) and also potential risks from nanomaterials and call for socio-economic assessments.

These reviews also display the existence of a flourishing body of either optimistic or gloomy predictions regarding the future and the impacts of nanomaterials (in terms of a “nano-divide” between rich and poor countries, and in terms of employment or economic growth). These predictions are most often based on beliefs and not on evidence on the current state of our information. It is important that, as soon as feasible, as rational and transparent SEAs as possible start giving more robust basis for discussion and decision.

We give hereafter recent feedback from ongoing European Research Projects to which INERIS is taking part:

In the SAPHIR project on “Safe Manufacturing of Nanomaterials”, a sustainability assessment was demanded by the European Commission at the beginning of the project. However, now that the project is towards it ends, it appears that the focus of industrial stakeholders has been put more on process design, and only on process safety (accidents) and workers health than overall sustainability issues. In the most advanced SEA case study, the cost/benefit analysis was reduced to an assessment of the financial cost of exposure reduction for workers due to lack of information and visibility on the supply chain. From this project is it also clear that data availability and data access (emissions, consumptions,

description of supply and value chains...) are still a problem, probably because of confidentiality issues, and also because supply chains are not organized already at industrial scale.

In contrast, the NANOFOL project (Nanofolate biodevices for chronic inflammatory disease) started in 2009, with socio-economic impact and sustainability issues put at higher level in the project (WP). The need for a SEA of nanofolate devices, and to compare them with alternatives treatments, was identified by industry and scientists from the beginning. In this project there is therefore better hope to have useful SEAs for the nanobiodevices.

3.2. The Challenges of SEA for nanomaterials

The objective of this paper is not to discuss all the challenges and limitations of the cost/benefit, cost/efficiency or multicriteria analysis frameworks of SEAs, on which a vast body of economic literature already exists. We will just mention some features of SEA that are of importance in the case of nanomaterials:

- Many authors have highlighted the challenge of assessing the specific toxicological and ecotoxicological hazards linked to exposure to nanomaterials, and this is obviously a basic challenge for SEA.
- Going beyond "traditional" Risk Assessment (RA), SEA aims at predicting realistic estimates (and not "worst case" like in RA) of collective health and environmental impacts (and not of individual effects like in RA). Providing such impact estimates requires information on exposures along the lifecycle of nanomaterials, which is currently particularly scarce and difficult to access.
- The Cost Benefit paradigm underlying SEA supposes that benefits can provide a compensation for damages: in the case of (very) high and uncertain damages of emerging nanomaterials and technologies, such an assumption is controversial, because irreversible and long term damages could be impossible to be compensated by the benefits of the technology elsewhere.

Another less often underlined challenge is the existence of rather new impact pathways for nanomaterials, such as the ones proposed in the following examples:

- Nanosilver, given its strong and persistant biocidal activity, can impact waste water treatment works and biological activity in soils, leading to:
  - More degraded drinkingwater resource and treatment problems (because of deficiencies in waste watertreatment works upstream of surface water intakes).
  - Possible impacts on soil and food quality if nanosilver-containing sludge is spread on agricultural land.
- Some other nanomaterials (as carbon nanotubes) have a long persistence and high reactivity in the natural environment. Therefore they have been shown to adsorb chemicals like phytosanitary chemicals present in the environment, and transport them on very long distances, or to create new by-products of these chemicals [7].

3.3. Some new features of nanotechnologies and nanomaterials will make their socio-economic assessment more complex:

Rapidity: Nanotechnology is a fast-growing domain and socio-economic information on production and use is likely to become more rapidly outdated than in the case of usual chemicals.

Extensiveness: Nanotechnology is not a defined economic sector but is changing many basic technologies: the socio-economic implications of introducing a new nanotechnology or class of nanomaterials can be therefore very wide (across many economic sectors) and very deep (start at the beginning of the value/supply chain of a consumer product). Being « enabling technologies », nanotechnologies could change or create new functionalities among a wide array of industrial production sectors and consumer products. In such situations, SEA has a problem to compare the nanomaterial with alternatives that deliver the same functionality. The solution might be to adopt a

wider point of view for the definition of the functionality, less focused on the technical characteristics of the nanomaterial, or to conduct ad-hoc assessments of the value attached by society to new functionalities (through economic valuation studies).

The **Novelty** of nanotechnologies and nanomaterials raises concern about the real-life applicability of risk mitigation measures. Economic actors in nanotechnology are often new players in the field, and are often small companies. They could therefore lack resources and experience to understand and correctly apply risk management measures that are themselves more complex (sophisticated cleaning and isolation procedures and techniques, clean rooms…) [8]. Theoretically adapted risk management measures could in real-life be difficult to apply or require a learning process that means a higher cost than thought. To produce realistic assessments, SEAs for nanomaterials should identify these situations based on real-life experience. This novelty also applies to some extent to the technologies to manage the nano-risks: technologies for monitoring nanoparticles, or the removal of nanoparticles from diverse environmental media are under development and their cost is difficult to assess.

The **Variety** of nanomaterials is likely to surpass the number of chemicals that regulators and industry have ever had to handle. Solutions will have to be found, and it is clear that socio-economic analysis will have to be carried out only on a selection of most important nanomaterials. Prioritization activities, which are becoming increasingly important under REACh to target resources to the most critical chemicals, will probably be even more important for nanomaterials. Screening tools using some socio-economic information will have to be developed for that purpose.

The **interpenetration between socio-economic impacts, innovation dynamics, and risk management for nanotechnologies**.

For some nanomaterials, the financial economic stakes are high for businesses and society, and competitiveness impacts of granting or not granting access to the market should be taken into account. SEAs should therefore use industrial economics methods and ratios to assess these impacts, which are seldom used in practice for regulating emerging technologies or materials and substances in the EU at present.

Industrial economics, and methods to represent innovation dynamics will also prove useful to carry out SEAs with longer term time-horizons, when the socio-economic assessment is build on foresight scenarios, and when the expected outcome of SEAs are more to highlight the far-reaching consequences of critical choices in emerging technology development. In that case, methods to integrate socio-environmental and health risks along with business risks in stakeholders decisions and strategies regarding innovation, and their uptake by the market, need to be developed, and embedded in SEAs. The use of « industrial economics » methods in SEAs would also help industry and the regulator share common concepts and visions about economic competitiveness implications of regulating nanotechnologies

4. Interactions between Life Cycle Approach and Socio-Economic Analysis

There seem to be a consensus among stakeholders on the necessity to have a Life Cycle Approach for nanomaterials (see USEPA position for instance in [13]), but the added-value for SEA and also the limitations of LCA should be underlined.

First, the evident value of Life Cycle Approach is to assess risks and impacts wherever and whenever they occur, and to address some issues important for nanomaterials : fate of nanomaterials after end-of-life of products, cross-contamination of other products, modification of recycling potential of products, overall life-cycle energy profile of products with nanomaterials designed for energy-saving applications…

The second asset of LCA is the integrated approach of environmental and human health impacts. LCA-based supplement specific impact assessment of toxic and ecotoxic effects of nanomaterials dissemination by taking into account the other impacts, such as: the toxic effect of possible use of numerous auxiliary chemicals, energy and other utility consumption… Depending on the production route used, these “annex” impacts could actually be as important as nano-specific impacts [9].

Given these assets of LCA, should SEAs systematically rely on LCA?

LCA itself has methodological weaknesses, the most important being the toxic and ecotoxic impacts, particularly important in the case of nanomaterials. Information delivered in this field by LCA is limited to global indicators of potential impact and not actual and focused enough estimates of potential impacts [8]. To inform Socio-Economic Analysis, Specific Impact Assessment on (eco)toxicological issues need to be combined with more general information from LCA for other impacts.

LCA is often regarded as attractive also because it is international and normalized, well known from industry, consultants. It is coming with well-established databases and software, and at the same time based on "hard" science. However, the ability of LCA to inform so complex, uncertain and "trans-scientific"[4] [9] questions such as the impact or sustainability of nanotechnologies is limited. One limitation is that LCA compares products or technologies of equal functionality, without questioning the utility of a nanomaterial versus its alternatives, as SEA basically does. Another limitation is a bias from LCA that it seems to give better assessments because there are numerous quantitative indicators in LCA. Another consequence is that, being methodology-driven, LCA is less adaptative in essence that the objective-driven SEA, whereas nanotechnology requires adaptative assessment frameworks [10].

Finally it is also worth mentioning the interesting developments for a "Socio-Economic LCA" (or the many analogues) [11]. Socio-Economic LCA intends to integrate new socio-economic impact categories and extends the notion of functional units so that they reflect the socio-economic world. But again, the Social LCA is a methodology-driven approach and attempts to as exhaustively as possible quantify all impacts. This carries the risk to hide or at least decrease the visibility of the most important impacts, the "what happens" that SEA essentially tries to capture.

5. Conclusion

In this paper we described the potential of Socio-Economic Analysis, for a pragmatic and open assessment of nanomaterials and nanotechnology. SEA is a "pragmatic regulatory impact analysis" [12], that uses a cost/benefit framework analysis but remains open to other disciplines than economy, and open to the participation of stakeholders for the construction of scenarios of the deployment of technologies and the identification of alternatives. SEA is "pragmatic" in the sense that it is driven by the purpose to assess "what happens" with the introduction of nanotechnology, and uses methodologies such as Life Cycle Analysis only as far as they are really contributing to that goal. We conclude that, being pragmatic, SEA is also adaptative, which is a key quality to handle the novelty of economic and social effects expected from nanotechnology.

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