**Socio-economic analysis in the framework of REACH Regulation: a case study of the restriction of Bisphenol A in thermal paper**

Author: Karine Fiore, ANSES, 14 rue Pierre et Marie Curie, 94701 Maisons-Alfort, Cédex 01, France karine.fiore@anses.fr; Telephone: +33 (0)1.56.29.52.17

**Abstract:**

REACH Regulation introduced socio-economic analysis as a decision-making tool for the management of risks generated by chemicals. With its formalized and scientific-based features, it aims at supporting public action as a complement to risk assessment. Within this framework, socio-economic analysis consists of evaluating impacts for human health and environment, as well as economic and social impacts expected from the management measures for the different players affected in Europe. The assessment performed to underpin the French restriction proposal of Bisphenol A in thermal paper stands as an instructive example. Developed on the basis of a semi-quantitative cost-benefit analysis, it reflects both a methodological challenge due to uncertainty, and a useful analysis to assist public decision-making.

***Keywords:*** economic evaluation, cost-benefit analysis, REACH Regulation, human health impact assessment, Bisphenol A

***

## Context

In force since 1 June 2007, the aim of European REACH regulation (Registration, Evaluation, Authorisation, Restriction of Chemicals) no. 1907/2006/EC is to ensure a high level of protection of human health and the environment from chemical-substance risks while promoting alternative methods for the assessment of hazards of substances, as well as the free movement of substances,

competitiveness and innovation in the common market. That is the gist of the first article of the introduction to REACH regulation.

In particular, REACH has formally approved socio-economic analysis as a tool to assist decision-making, complementing the assessment of health and environment risks. Socio-economic analysis is a well-established approach used to assess the advantages and drawbacks of initiatives related to public policy in various areas. In the specific context of REACH, its aim is to objectively analyse the anticipated impacts of regulation in health, environmental, economic and social terms. In other words, it enables scientifically-based analysis of the positive and negative consequences for different players of a risk-management measure under consideration. Socio-economic analysis also applies to the assessment of substitution feasibility – i.e. the possibility of replacing the toxic and/or eco-toxic substances concerned with technological solutions or substances that are less hazardous and technically and economically viable. In its formalisation and scientific approach, REACH socio-economic analysis has a clear objective: to provide the public decision-maker, the European Commission, with as clear a picture as possible of the impacts of regulation.

## REACH Authorisation vs. Restriction

REACH uses socio-economic analysis in two procedures: the authorisation and restriction of chemical substances.

The authorisation procedure is related to the most disquieting substances[1] and requires an industry that uses or markets a substance to apply for formal authorisation from the ECHA (*European Chemicals Agency*) to continue to use or distribute that substance. Authorisation will only be granted if the risks related to use are properly managed or, where appropriate, if it can be shown that the socio-economic

[1] SVHCs (*Substances of Very High Concern*) listed in Annex XIV of REACH Regulation. Categorisation of substances as SVHCs reflects the following criteria of hazard: substances classified as carcinogens, mutagens or toxins with regard to reproduction (CMR) in categories 1A or 1B by CLP regulation (related to classification, labelling and packaging regulation no. 1272/2008); substances that are persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) for the environment, according to Annex XIII of REACH; other substances on a case by case basis, which instigate a level of concern equivalent to that raised by the use of CMR or PBT/vPvB substances.

advantages of using the substance outweigh the risks, and if there is no appropriate replacement solution that is economically and technical feasible. The assessment of socio-economic advantages and the benefit-risk ratio is the responsibility of the applicant themselves, and is conducted on the basis of their own expertise or with the assistance of specialist consultants (the most common solution). The procedure must follow the recommendations of REACH regulation, laid down in Annex XVI (see Box 1) and a number of methodological guidance documents published by the ECHA[2] [1, 2] and be supplied in the required format. The recommendations are not compulsory, but are intended to provide the assessor with guidance in drawing up their application. The assessment of the impacts of a possible denial of authorisation is made from the viewpoint of the applicant. So the type and extent of the impacts examined can vary greatly according to whether the applicant is a manufacturer, an importer or a downstream user of a substance or product. Certain applications (known as 'upstream applications'), submitted by a manufacturer for example, can cover the entire supply chain from start to finish. In that case, they must reflect all related impacts.

The restriction procedure[3] applies to all chemical substances falling with the field of REACH application and is intended to prohibit or restrict the manufacture, use or marketing of substances (alone or contained in mixtures or articles[4]) in certain cases, where they present a risk to human health or the environment which requires community action. Proposals for restriction are made by the Member States of the European Union or the ECHA (at the request of the European Commission). As in the case of applications for authorisation, they are accompanied by an assessment of the anticipated socio-economic impacts, including the economic feasibility of substitutes, on the basis of the recommendations of Annex XVI of REACH and the dedicated methodological guides of the ECHA [3; 4].

[2] Guides and formats are available on the site of the ECHA: https://echa.europa.eu/fr/guidance-documents/guidance-on-reach and https://echa.europa.eu/fr/support/guidance-on-reach-and-clp-implementation/formats

[3] Current restrictions are listed in Annex XVII of the REACH Regulation

[4] REACH Regulation defines an 'article' in the following way (Article 3-3): "an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition"

After submission, each application for authorisation and each proposal for restriction is the subject of public consultation and is examined by the committees of the ECHA for REACH: the RAC (*Risk Assessment Committee*) and the SEAC (*Socio-Economic Analysis Committee*), which subsequently produce a report for the European Commission.

## Assessment of the impacts of chemical substances: does everything have a cost?

As a guide, Annex XVI of the REACH regulations provides a list of impacts to be assessed as part of a socio-economic analysis to justify a restriction proposal (or authorisation application) (see Box).

***What impacts?***

In relation to a restriction proposal, the socio-economic impacts of the measure suggested must reflect the net advantages the restriction will represent for human health and (where relevant) the environment, compared to the net costs to the manufacturers of the substance or mixtures of articles containing it, importers, compounders, downstream users and distributors, as well as consumers and society as a whole. The anticipated impacts for each player are examined, measured and monetised where possible. The types of impact to be assessed are decided case by case. Annex XVI of REACH gives a list as a guide. Their assessment aims to demonstrate the efficacy of the restriction to the public decision-maker – i.e. its ability to reduce or eliminate the risk and its proportionality to the risk. A restriction is seen to be proportionate when the cost it represents for society is lower than the anticipated benefits and a reasonable time is given to market operators to comply. This aspect must be judged case by case according to the specific constraints of the markets concerned. If a restriction is not proportionate, it will in all likelihood be rejected.

- In terms of human health and environment, the impacts analysed correspond to pathologies prevented in the general population or in certain specific populations (workers, pregnant women, children) and the environmental externalities avoided by the restriction.
- In economic terms, the impacts are related to the cost for industry and the consequences for consumers.
- In social terms, job losses in the markets affected by the restriction are most frequently assessed, together with certain distributional effects. Other impacts are also examined, such as cost to the public authorities (cost of implementation and monitoring).

**What methods?**

In the domain of health and environment, the economic approach is particularly complex because of its actual aim, which involves scientific uncertainties. In both REACH procedures – restriction and authorisation – cost-benefit and cost-efficacy methods are most commonly used to assess impacts (Box 2).

**And in practice?**

In practice, the production of a socio-economic analysis in REACH (as in a general context) has two constraints: the goal of operationality and the availability of data. Firstly, the socio-economic analysis does not need to be exhaustive and measure all possible impacts. With limited resources, the assessor can decide to reduce the scope of their analysis and target the impacts they see as most significant for the market involved. Even with the assistance of methodological guides and recommendations, assessors working in relation to REACH are, in practice, free to decide to adapt their work within the limits of the aims of their demonstration. When the RAC and SEAC committees receive the restriction proposal or authorisation application, they can require the assessor to develop their analysis further if they judge the degree of detail to be insufficient.

Then the socio-economic analysis is dependent on the availability of data. Here, the assessor very often has to cope with a certain degree of uncertainty, in particular when they are using cost-benefit and cost-efficacy methods, which demand a great deal of measurable data. So the shortage of field exposure data, the confidentiality of certain economic data, uncertainty over the dose-response relationship between exposure to the chemical substance and a pathology, methodological limits in assessing environmental damage, etc. are all obstacles to quantification. In these circumstances, qualitative (non-monetised) analyses and sensitivity analyses[5] play a crucial role in developing a quantitative assessment.

In order to deal with these uncertainties, the ECHA recommends that REACH socio-economic analyses should take an iterative approach as illustrated in Figure 1, beginning with a qualitative impact analysis [3]. According to the volume and reliability of available data, and if the robustness of the conclusion depends on it, the authority recommending the restriction can add a greater or lesser amount of quantification to their analysis, stage by stage, beginning with general/major impacts and going on to specific/minor impacts. In a situation of radical uncertainty, only a qualitative analysis of impacts will be viable; inversely, a situation where information is complete will require as much quantification and monetisation as possible. In reality, socio-economic analyses fall somewhere between these two extremes.

## Restriction of Bisphenol A in thermal paper

Bisphenol A (BPA) is a chemical produced in large quantities. Its uses range from the synthesis of polymers (such as polycarbonates) and resins (such as epoxy resins) to the production of flame retardants, dental dressings and thermal paper. Since it is an endocrine disruptor, BPA is increasingly subject to regulation.

[5] A sensitivity analysis is a study of the way in which uncertainty related to certain parameters impacts or does not impact on the results of the assessment.

In 2013, the ANSES (Agence Nationale de Sécurité Sanitaire pour l'alimentation, l'environnement et le travail – National Agency of Health Safety for Food, the Environment and Work) conducted an assessment of the risks of BPA and concluded that there were unacceptable dangers for the future children of pregnant women (workers and consumers) caused by different sources of exposure, including the handling of thermal paper [5; 6]. Thermal paper is made up of a paper base to which at least one layer of chemical coating is applied (Figure 2). This layer is thermally reactive and contains, among other things, a binding agent, pigments and a reactant such as BPA. Thermal paper is used for till and other receipts, sticker labels and, to a lesser degree, fax paper. The ANSES report (2013) showed an unacceptable risk of 4 critical effects on unborn children:

- effects on the female reproductive system (ovarian cycle disruption, ovarian cysts, endometriosis) (future effects from puberty);
- effects on the metabolism and obesity (increased cholesterol level and bodyweight) (possible future effects from childhood);
- effects on the mammary gland (increased susceptibility to the future development of tumours when associated with exposure to a carcinogen, because of an increase in hyperplasic ducts and lobules) (future effects from puberty);
- effects on the brain and behaviour (deterioration of spatial memory and learning functions) (possible future effects from childhood).

Given the toxicity of BPA and particularly strong media and political interest in the substance, its substitution in thermal paper has already been going on in Europe for a number of years, decided by the industries themselves. Even so, in order to accelerate progress and ensure efficient risk reduction, in 2014, France suggested it be banned from use in thermal paper by a REACH restriction regulatory process. In relation to this proposal, ANSES carried out a socio-economic analysis on the anticipated health benefits and costs of the management initiative.

**Anticipated health impacts of the restriction**

The anticipated health benefits of the restriction correspond to pathologies prevented in the target population of unborn children in utero in Europe. These pathologies are multi-causal and, aside from exposure to BPA, can have other possible sources, such as heredity or co-exposure to other pathogenic chemicals or agents. So the first stage in the assessment of these pathologies required an estimation of the population exposed on the basis of occupational and demographic data (number of cashiers, number of women of childbearing age, rate of female and male births in Europe). The aim of the second stage was to estimate excess risk in order to infer a probability of the onset of a pathology that can be attributed to exposure to the BPA contained in thermal paper. This critical stage used toxicity research based on animal data employed in ANSES risk assessment in 2013. It aimed to adjust animal doses to equivalent human doses, then derive a starting point by adjusting a mathematical model to the data, and finally extrapolate from the starting point to weaker doses in a linear way. Through this approach, the probability (risk) that an individual would be exposed to an undesirably high dose could be estimated directly as a function of the dose. Because of a high degree of uncertainty, particularly with regard to extrapolation to humans, this stage could only be conducted in relation to certain pathologies. So, complying with the iterative approach recommended in REACH, the health benefits associated with non-quantifiable pathologies (disruption of ovarian cycles, ovarian cysts and effects on the brain and behaviour) were the subject of qualitative analysis. For quantifiable pathologies, the last stage consisted of attributing a value to them on the basis of the review of economic literature. Breast cancer, hypercholesterolemia, obesity and endometriosis are known pathologies whose costs to society are relatively well documented ([7; 8; 9; 10; 11; 12; 13; 14; 15]). According to the research, the economic assessment was based on a 'cost of treatment' approach (only taking into account the direct costs of care) or a 'cost of illness' approach (so also taking into account the indirect costs of the disease). The health benefits have been estimated to be worth between (at least) 1.8 million euros and 12.6 million euros a year in Europe (discounted at 4% for 2019-2030) (Table 1).

**Anticipated economic impacts of the restriction**

The anticipated costs of restriction correspond to the impacts suffered by four interconnected markets: the BPA market, the thermal-paper market and the substitute markets (alternative reactants and technical alternatives). Given the very limited use of BPA to manufacture thermal paper in Europe (0.2%), the impact of the restriction on the BPA market was considered to be negligible and was not quantified. The impacts on the thermal-paper market was assessed for the different segments of the supply chain: manufacturers, converters, distributors and final users, and importers of thermal paper (Figure 3). The assessment focused on the costs of substitution and the costs of compliance testing related to the analysis of BPA concentration in thermal paper. The data used in this assessment was gathered from industry and a review of available data ([16; 17; 18; 19; 20]).

The alternative chemical reactants examined were bisphenol S, bisphenol F, bisphenol AP, 1,2-diphenoxyethane, Pergafast (DP 201), D8[6], D90[7] and UU[8] on the basis of their technical feasibility. The substitution costs for these reactants to thermal-paper producers were calculated on the basis of their respective price, their concentration in the paper and the grammage of the paper. A number of scenarios were studied to take into account a certain degree of uncertainty. Alternative printing techniques examined were dot-matrix, inkjet and thermal-transfer. Replacing all the direct thermal-transfer printers at all points of sale in Europe was not seen as economically viable. With regard to the increasing use of paperless technology (e-tickets and payment by smartphone), it was seen as difficult to generalise in the short term.

The costs of compliance testing to European converters and distributors were estimated on the basis of the cost and frequency of BPA testing, the characteristics of the paper to be tested (grammage and surface) and the rate of growth of the volume of thermal-paper production.

Considered to be negligible, impacts on employment and consumers were qualitatively analysed.

[6] 4-(4-isopropoxyphenylsulfonyl)phenol, CAS no.95235-30-6
[7] Phenol, 4,4'-sulfonylbis-, polymer with 1,1'-oxybis[2-chloroethane], CAS no.191680-83-8
[8] Made up of urethane-urea, CAS no.321860-75-7

The anticipated cost of restriction was estimated on average as between 1.1 million euros and 39.2 million euros a year in Europe (discounted at 4%[9]).

On that basis, the anticipated benefits and costs of restriction, subject to uncertainty, had to be compared in order to assist decision-making. In contrast, the low value of the benefits exceeds that of the costs and the high value of the costs exceeds that of the benefits. Even so, the costs are low since they represent between 0.18% and 5.85% of the total value of the production of thermal paper manufactured for points of sale over the same period. Moreover, only some of the benefits were measured. Restriction was judged proportionate by the SEAC and approved by the European Commission in December 2016.

**Conclusion**

The production of a socio-economic analysis related to health and environment is an exciting, ambitious goal. The example of the REACH restriction of Bisphenol A in thermal paper illustrates both the methodological challenge of an exercise full of uncertainties and the operational utility of such analysis for public action. Generally, the application of socio-economic analysis in relation to REACH regulation is now backed by a certain amount of experience, confirming its status as a decision-making assistance tool.

**References**

1. ECHA*,* Guidance document on socio-economic analysis – authorisation*, 2011*
*2. ECHA,* Technical guidance document: application for authorisation, 2011
*3. ECHA,* Technical guidance document: annex XV for restrictions, 2007
*4. ECHA,* Guidance document on socio-economic analysis – *Restrictions*, 2008
5. Anses, 2011, Health effects of Bisphenol A, Maisons-Alfort
6. Anses, 2013, Risk assessment of Bisphenol A (BPA) on human health, Maisons-Alfort
7. Simoens S et al., 2012, The burden of endometriosis: Costs and quality of life of women with endometriosis and treated in referral centres. Human Reproduction 27 (5): 1292-1299

[9] Discounting is the application of rates known as discount rates to monetary flows that are not directly comparable and relating to periods and/or dates of occurrence, so as to compare or combine them in various ways.

8. Benner JS et al., 2005, Cost-effectiveness of rosuvastatin compared with other statins from a managed care perspective. Value in Health 8 (6): 618-628
9. Lachaine J et al., 2007, A Model for Assessing the Cost-Effectiveness of Atorvastatin and Simvastatin in Achieving Canadian Low-Density Lipoprotein Cholesterol Targets. Clinical Therapeutics 29 (3): 519-528
10. Grabowski DC et al., 2012, The large social value resulting from use of statins warrants steps to improve adherence and broaden treatment. Health Affairs 31 (10): 2276- 2285
11. Brown III HS et al., 2007, The cost-effectiveness of a school-based overweight program. International Journal of Behavioral Nutrition and Physical Activity 4
12. Radice D, Redaelli A, 2003, Breast cancer management: Quality-of-life and cost considerations, Pharmacoeconomics 21 (6): 383-396.
13. Marino P et al., 2003, Can sequential administration minimise the cost of high dose chemotherapy? An economic assessment in inflammatory breast cancer. Pharmacoeconomics 21 (11): 807-818
14. Campbell JD and Ramsey SD, 2009, The costs of treating breast cancer in the US: A synthesis of published evidence, Pharmacoeconomics, 27 (3): 199-209
15. Gruber EV et al., 2012, Breast Cancer Attributable Costs in Germany: A Top-Down Approach Based on Sickness Funds Data. ONE 7 (12)
16. Anses, 2013, Substitution of Bisphenol A, Maisons-Alfort
17. RPA, 2003, Interim Risk Reduction Strategy and Analysis of Advantages and Drawbacks for Bisphenol-A
18. US EPA, 2012, BPA Alternatives in Thermal Paper Partnership - Design for the Environment
19. INERIS, 2010, Données technico-économiques sur les substances chimiques en France: Le Bisphénol A (Technical-economic data on chemical substances in France: Bisphenol A), -200. Verneuil-en-Halatte
20. EPA Danois, 2013, Alternative technologies and substances to bisphenol A (BPA) in thermal paper receipts., 1-64

[source of Figure 3] Jeffs J. 2011. Bisphenol-free tickets - Länstrafiken Jämtland - Market analysis. publ. SSC Jegrelius