

Box 1. Extract from Annex XVI of REACH Regulation – Socio-Economic Analysis

**ANNEX XVI**

**SOCIO-ECONOMIC ANALYSIS**

*This Annex outlines the information that may be addressed by those submitting a socio-economic analysis (SEA) with an application for authorisation (...) or in connection with a proposed restriction (...). An SEA may include the following elements:*

- impact of a granted or refused authorisation on the applicant(s), or, in the case of a proposed restriction, the impact on industry (e.g. manufacturers and importers). The impact on all other actors in the supply chain, downstream users and associated businesses in terms of commercial consequences such as impact on investment, research and development, innovation, one-off and operating costs (e.g. compliance, transitional arrangements, changes to existing processes, reporting and monitoring systems, installation of new technology, etc.) taking into account general trends in the market and technology,*
- impacts of a granted or refused authorisation, or a proposed restriction, on consumers. For example, product prices, changes in composition or quality or performance of products, availability of products, consumer choice, as well as effects on human health and the environment to the extent that these affect consumers,*
- social implications of a granted or refused authorisation, or a proposed restriction. For example job security and employment,*
- availability, suitability, and technical feasibility of alternative substances and/or technologies, and economic consequences thereof, and information on the rates of, and potential for, technological change in the sector(s) concerned. In the case of an application for authorisation, the social and/or economic impacts of using any available alternatives,*
- wider implications on trade, competition and economic development (in particular for SMEs and in relation to third countries) of a granted or refused authorisation, or a proposed restriction. This may include consideration of local, regional, national or international aspects,*
- in the case of a proposed restriction, proposals for other regulatory or non-regulatory measures that could meet the aim of the proposed restriction (this shall take account of existing legislation). This should include an assessment of the effectiveness and the costs linked to alternative risk management measures,*
- in the case of a proposed restriction or refused authorisation, the benefits for human health and the environment as well as the social and economic benefits of the proposed restriction. For example, worker health, environmental performance and the distribution of these benefits, for example, geographically, population groups,*
- an SEA may also address any other issue that is considered to be relevant by the applicant(s) or interested party.*

Box 2. Cost-benefit analysis and cost-effectiveness analysis

**Cost-benefit analysis (CBA)** supplies a comparative framework of the costs and benefits of a management measure. The type of analysis can range from one that is mainly qualitative to one that is totally quantitative (and monetised). Traditionally, a CBA is used to establish whether an investment is desirable in terms of economic efficacy. The aim of the method is to measure as many impacts as possible using the same monetary unit in order to enable easier comparison, especially when a number of management measures are possible. In this case, the different options compared are presented in terms of cost advisability and the decision-maker will choose between them. A strong CBA provides justification for public decision-making to the extent that the benefits to society exceed the costs. The main methodological limits of a CBA result from uncertainties over the availability and reliability of the data needed to carry it out.

**Cost-effectiveness analysis (CEA)** is used to identify a measure that will enable the achievement of a goal decided in advance (a certain volume of reduction of atmospheric pollution, for instance) and do so as inexpensively as possible. The comparative costs of each measure are assessed using the same monetary unit and expressed per unit of pollutant reduced (tonne of CO<sub>2</sub>, for example). In the simplest cases, a CEA enables identification of the least expensive option of a number of choices liable to achieve the goal. In more complex cases, a combination of measures may be suggested. Compared to CBA, CEA has the advantage of not requiring monetisation of the benefits of achieving the target goal, but its drawback is that it must precisely determine that target beforehand. Moreover, in order to compare a number of options, the assessor must ensure that they are capable of achieving the same level of risk reduction and have costs based on similar methods of calculation.

Figure 1. Iterative approach of impact analysis related to a REACH Restriction

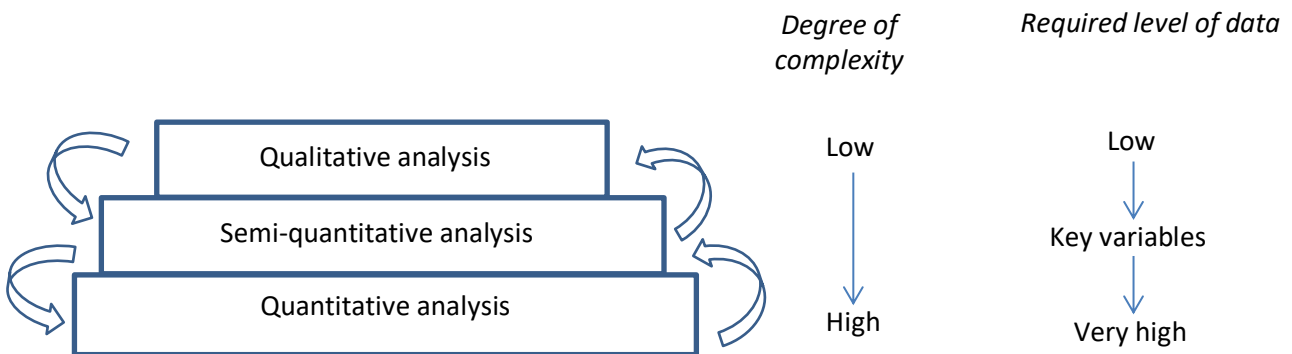


Figure 2. Composition of thermal paper and printing technique

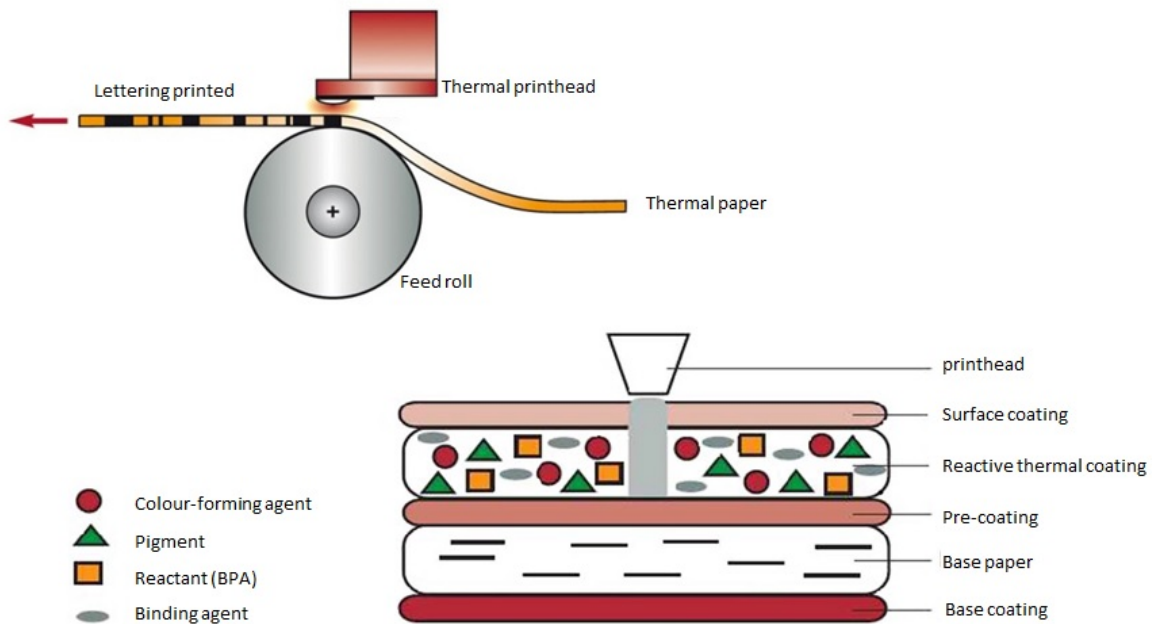
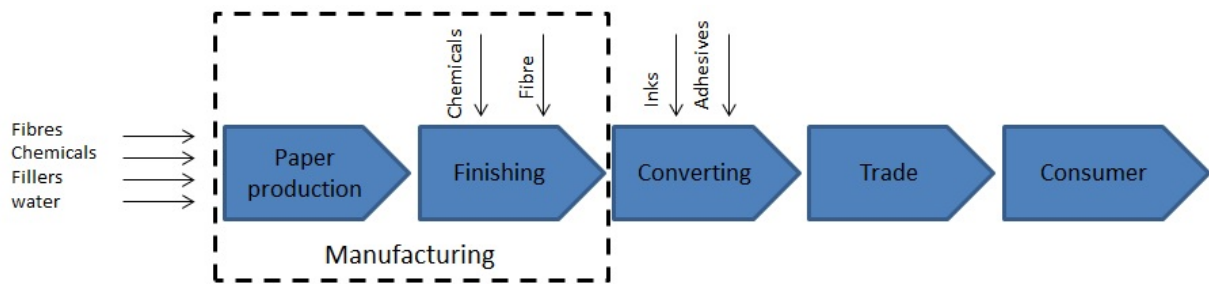


Table 1. Health impact and impacts related to the restriction of BPA in thermal paper

Critical effects	Pathologies	Impact assessed	Excess risk		Aggregated annual benefits (million €)
			workers	consumers	
female reproductive system	Endometriosis	Increase in the incidence of endometrial hyperplasia (future females only) Quantitative analysis	0.07%	0.0064%	0.5
	Ovarian cycle disruption	Qualitative analysis	-	-	>0
	Ovarian cysts	Qualitative analysis	-	-	>0
metabolism and obesity	Increase in cholesterol	Hypercholesterolemia	0.73%	0.07%	[ 0.04; 0.5]
	Increase in bodyweight	Increase in Body Mass Index (BMI)	0.33%	0.032%	2.1
mammary gland	Mammary hyperplasia (increase in hyperplastic ducts and/or lobules)	Increase in the incidence of breast cancer (future females only)	0.61% (BT) 0.55% (CT) 0.055% (CH)	0.059% BT 0.053% (CT) 0.055% (CH)	[ 2; 16.5] (BT) [ 1.8; 14.8] (CT) [ 0.2; 1.4] (CH)
brain and behaviour	Impaired spatial memory	Qualitative analysis	-	-	>0

	Impaired learning abilities	Qualitative analysis	-	-	>0
Annual aggregated benefits for 2013 (million €)					> [ 2.8; 19.6]
Discounted aggregated benefits (at 4%) for 2019-2030 (million €)					> [ 1.8; 12.6]

Figure 3. Supply chain of the thermal paper market in Europe



(Source: Jeffs, 2011)