Regulatory Toxicology and Pharmacology 68 (2014) 438–446

Contents lists available at ScienceDirect

Regulatory Toxicology and Pharmacology

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

Regulatory decision-making under uncertainty: Are costs proportionate to benefits when restricting dangerous chemicals on European markets?

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ARTICLE INFO

Article history:
Received 23 June 2013
Available online 8 February 2014

Keywords:
REACH
Decision-making under uncertainty
Dangerous chemicals
Proportionality
Economic feasibility

ABSTRACT

Since 2007 regulation 1907/2006/EC concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) is in force in Europe to reduce the adverse effects of hazardous chemical substances on human health and the environment. Implementation of the regulation by the European Chemicals Agency (ECHA) is supported by a Socio-Economic Analysis (SEA) Committee, consisting of European experts who help prepare ECHA's opinion on proposals for either restricting or authorizing dangerous substances. This paper presents the outcomes of the SEA underlying the first restriction proposals. Member states proposing a restriction have to show that it will reduce the risks to an acceptable level at a cost which is proportionate to the avoided risk. What is considered proportionate is not clearly defined in REACH. The opinion making process is characterized by many uncertainties: the expert group had no previous experiences to fall back on and limited information about the expected costs and benefits of the proposed restrictions. The study provides insight into expert opinions on environmental and health risks under uncertainty in the specific context of REACH. Particular attention is paid to the confidence experts place on the estimated socio-economic benefits of the avoided risks compared to the estimated compliance costs.

1. Introduction

Environmental regulatory decision-making in the European Union (EU) has led to the existence of a wide variety of directives and regulations. In conjunction with many of these European directives and regulations, a number of European committees and working groups have been formed, usually consisting of representatives from national regulatory authorities, experts and stakeholder groups in individual member states, to discuss, advise on, and take decisions regarding joint implementation of these directives and regulations in the member states. Regulation 1907/2006/EC concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) is an example of such European legislation. REACH aims to reduce the hazards and likely harm inflicted on human health and the environment of chemical substances manufactured, placed on the market and used, on their own or in articles. Implementation of REACH is managed by the European Chemicals Agency (ECHA) in Helsinki. Since its establishment in 2007, ECHA supervises the various REACH processes, ensuring consistency at EU level, and providing individual member states with expert advice on chemicals which fall under REACH.

Within ECHA, a Socio-Economic Analysis Committee (SEAC) exists, in which experts nominated by individual member states, are responsible for preparing the opinion of the Agency on applications for authorization to use certain substances of very high concern, or proposals from individual member states for restricting certain dangerous substances. Socio-economic analysis (SEA) forms an important part of these regulatory processes, and aims to provide support to decision-making as to whether it is a good idea for society as a whole to either impose a restriction (compared to continued use or using other risk management options) or grant an authorization (compared to refusing the authorization) for a hazardous substance. Authorization will only be granted if the applicant can prove 'adequate control' of the substance, or if it can show that the socio-economic benefits outweigh the associated risks to human health or the environment and if there are no suitable alternative substances or technologies. In the case of a restriction, the costs of complying with the restriction, including any shift to alternatives, are compared to the benefits from the reduced level

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http://dx.doi.org/10.1016/j.yrtph.2014.01.016
0273-2300/

of risk to either the environment or human health. The individual member states proposing a restriction on a substance (or ECHA if they are the proposer) will have to show through the SEA that the restriction is capable of reducing the risks to an acceptable level within a reasonable period of time and at a cost which is proportionate to the avoided risk. In the case of authorization, the burden of proof that the benefits outweigh the risks from the authorization application being granted lie with the industry wishing to use the substance within Europe (Angerer et al., 2008).

What is considered proportionate is not clearly defined in REACH and open to discussion and interpretation, in a manner similar to ongoing discussions regarding the concept of 'disproportionate costs' for example in the European Water Framework Directive adopted in 2000 (Brouwer, 2008). Furthermore, one of the key challenges in the socio-economic analysis underpinning any restriction proposal is the lack of socio-economic information about their impact on producers, users and other third party beneficiaries (including the environment) (see, for example, also Pearce and Koundouri, 2004). This is partly related to the limited scientific knowledge and information about the underlying dose–response relationships (e.g. exposure level to a chemical and corresponding impact on human health and the environment). However, it is also the case that there is often very limited available information about the direct and indirect costs of using alternatives.

In this paper we consider the way in which the SEA has operated in practice as a decision-support tool within the REACH restrictions regulatory process. In particular, we present and examine the outcomes of the SEAC's official opinions on the first four restriction proposals under REACH, which have been made on the basis of limited data and information about the associated costs and benefits, as well as little guidance on what is considered proportionate for a restriction and what not (see, for instance, Postle et al., 2004). No such experiences exist yet with authorization proposals. The main objective is to shed more light on the nature of expert opinions made under uncertainty in the specific context of dangerous substances. Particular attention will be paid to the confidence experts place on the estimated socio-economic benefits of the avoided risks compared to the estimated compliance costs given the limited information. Following a participatory research approach and using semi-structured interviews with SEAC experts, the cross-comparison of the first four opinions provides detailed insights into the expert decision-making process regarding what are considered acceptable or proportionate cost levels to restrict the use of different hazardous substances on European markets.

The remainder of the paper is organized as follows. Section 2 presents the methodological approach employed in the study. Section 3 briefly introduces the concepts of proportionality and feasibility under REACH, followed by a description of the procedure followed in the SEAC to prepare official opinions on the socioeconomic analysis in Section 4. Section 5 introduces the four restriction proposals, together with the available information about their costs and benefits. The cost levels of the four restriction proposals in the opinions, traded off against the benefits of reduced risk exposure levels, are summarized in Section 6. This is followed in Section 7 by a presentation and discussion of the outcomes of the expert interviews, focusing on expert confidence in the available data and information related to the restriction proposal and the uncertainty assessment underlying the opinion of the restriction. Finally, Section 7 concludes.

2. The definition of proportionality under REACH

This section first briefly describes the process of initiating a restriction proposal up to its adoption within Annex XVII of REACH. This is then followed by a discussion of the concept of proportionality.

Once a proposal is submitted, the process is coordinated by ECHA and involves consideration of the proposal by both the Committee for Risk Assessment (RAC) and the SEAC of ECHA. The restriction process is bound to legal deadlines within which the process must be completed. This timeframe puts limits on the development of the committee opinions, which can be quite constraining. A restriction can be initiated either by member states or ECHA by request of the European Commission. The starting point of the process is the notion that there is an unacceptable risk to human health or the environment caused by the manufacture, use or placing on the market of a substance. In such a case, a member state can notify to ECHA their intention to submit a restriction proposal. The restriction proposal then needs to be submitted within 12 months after this notification. After submission of the proposal the RAC and the SEAC have to screen it within 30 days to see whether it conforms with the official REACH Annex XV requirements ('conformity check'). If a dossier fails this conformity check, the proposal submitter has 60 days to modify the proposal so it meets the official requirements. As soon as a dossier is found to conform to the Annex XV requirements, it is published on ECHA's website for public consultation, lasting a period of six months. After publication, the RAC has nine months to formulate an opinion reviewing the relevant parts of the proposal and evaluating whether the proposed restriction is appropriate in reducing the risk to human health and/or the environment. SEAC has twelve months to publish its final opinion reviewing relevant parts of the proposal and the socio-economic impact. Both RAC and SEAC need to take into account, where appropriate, comments received in the public consultation on the dossier in their opinion making. SEAC has to publish its draft opinion after nine months, after which an additional public consultation of 60 days takes place on the draft opinion. After adoption, the opinions are published by ECHA and submitted to the European Commission. If there is an unacceptable risk to human health or the environment, the Commission shall then prepare a draft amendment of Annex XVII within three months after receiving the opinions. The final decision on the amendment will be made by the Commission through voting of the member states.

For the opinion development, RAC and SEAC members can volunteer to work as a so-called rapporteur or co-rapporteur on an opinion. One rapporteur and one co-rapporteur take the lead in the assessment and opinion development process and prepare the writing of drafts of the opinions in the available time based on an extensive review of the relevant parts of the proposal. The drafts of the opinions are sent to all SEAC members for comments (approximately 30 experts from different EU Member States are officially listed as SEAC members) and are also discussed in the different meetings of the committee. On average, a restriction proposal will be discussed over five separate SEAC plenary meetings, and additionally at a number of proposal specific working group meetings. Besides the opinion, also a Background Document is prepared, which includes the original proposal complemented with updated information, depending on the discussions in the SEAC. The rapporteurs are supported in their work by the ECHA secretariat, who provides logistical, administrative and where appropriate technical assistance, as well as the submitter of the proposal, who provides responses to the public consultation comments and other clarifications to the committees as necessary. Both RAC and SEAC produce their own respective opinions. However, as the committees depend on each other for several related aspects (e.g. technical feasibility), there is close collaboration in the opinion development process.

One of the key concepts in SEAC's opinion is the concept of 'proportionality'. Proportionality refers to both the risk reduction