

EAERE representation and the Socio-Economic Assessment Committee under the EU's REACH Regulation

Mike Holland, mike.holland@emrc.co.uk

Purpose of this note

EAERE has observer status at meetings of the Socio-Economic Assessment Committee (SEAC) convened at the European Chemicals Agency (ECHA) in Helsinki, under the REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) Regulation. This note provides some background to REACH and the work of SEAC. EAERE's representatives are Mike Holland (EMRC/Imperial College) and Roy Brouwer (University of Waterloo, Canada).

REACH

REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) is a regulation of the European Union, designed to improve the protection of human health and the environment from the risks that can be posed by chemicals. It is also intended to enhance the competitiveness of the EU chemicals industry by removing barriers to innovation.

The Committee for Socio-Economic Analysis (SEAC)

The processes of most relevance to SEAC concern the evaluation of:

- Dossiers proposing Restriction of specific chemicals, either in the form of an outright ban, or subject to use; and
- Applications for Authorisation, where companies seek permission to use specific substances in specific applications where they would otherwise be banned.

SEAC's role is primarily to assess information on socio-economic aspects of the dossiers/applications, to assess whether a restriction or authorisation would serve the best interests of society taking account of the avoided risks to health and the environment from additional controls on chemicals, costs to businesses and wider costs to society. SEAC collaborates closely with another technical committee under REACH, the Risk Assessment Committee (RAC), which has specific expertise in the risks to health and the environment of chemicals and in risk management.

Members of RAC and SEAC are nominated by most EU Member States and Norway. They are required to act independently of national or other external influences in their evaluation of dossiers and applications. The committees then present their opinions to ECHA. The final decision on whether to accept or reject a restriction or application for authorisation are taken by the European Commission through a regulatory committee procedure. Stakeholders, including EAERE, organisations representing European industry and NGOs, are present as observers to the committees. They are free to contribute to the debate but have no role in the formal adoption of an opinion by either committee.

The role of EAERE representation

SEA under REACH is a very dynamic area of applied environmental economics in Europe. EAERE's representation provides independent advice to SEAC on a variety of questions, reflecting the challenges recognised above. This role is especially important given the limited number of experienced practitioners in the field. Mike Holland is also on the steering committee of NeRSAP (Network on REACH Socio-economic assessment and Analysis of Alternatives Practitioners). This is a loosely affiliated group that brings together ECHA, members of the REACH Committees, analysts and consultants to discuss new challenges and discuss ways forward. It meets once or twice each year.

Following Brexit, the UK is no longer fully subject to REACH (though British companies exporting to the European Economic Area can clearly be affected), but is developing its own regulatory framework, UK REACH. As the name suggests, this has many similarities with the EU equivalent. However, the UK can now independently decide which chemicals should be prioritised for possible control and conclude on action following evaluation. The Health and Safety Executive will act as the lead agency for UK REACH and has appointed several environmental economists including EAERE members to RISEP, the UK's REACH Independent Scientific Expert Panel. There is, however, no specific role for EAERE in UK REACH.

Key elements of SEA for chemicals, and challenges faced

Guidance has been published by ECHA for undertaking SEA in the context of both restriction and authorisation. Key elements from that guidance are as follows. The challenges highlighted are drawn from experience of evaluating dossiers and from discussions with industry as they start to prepare applications for authorisation.

- *Knowledge of the market for chemicals and related products.* Associated supply chains can be long and involve numerous actors. In some cases final products may contain very little or none of the chemical under investigation, for example where substances are used to catalyse reactions.
- *Quantification of impacts of chemicals on health.* This is most straightforward for assessment of occupational health impacts, given the strength of epidemiological literature and the availability of exposure data. Assessment of effects on public health is more complex. Exposure models are needed and there is greater potential for thresholds to affect impact. Greater potential for interactions between chemicals in the environment should also be considered. ECAH has funded research on valuation of health impacts to extend the list of effects for which values are otherwise available. This includes valuation of cancers, skin sensitisation and fertility. It has also considered valuation of lost employment.
- *Quantification of impacts of chemicals on ecosystems.* Traditional methods for ecological risk assessment do not provide data in a form amenable to economic appraisal. This issue is becoming increasingly important as attention turns to substances that are considered hazardous

largely through being bioaccumulative and/or persistent. For some, but not all, there is evidence of toxicity. One rather preliminary study (focused on siloxanes in personal care products) has been carried out to investigate WTP to remove such substances from the market.

- *Analysis of alternative substances, techniques, products, etc.*, that would be required if a restriction is put in place or an application for authorisation is refused. This can range from simple substitution of one chemical by another with no alteration to process, to major changes in final products. A further possibility is that manufacture moves out of the EU.

Another challenge concerns informational asymmetry. Regulators must inevitably rely on the industries likely to be affected by their decisions for much of the data required for assessment. Examples of recent restrictions include:

- Use of an organic solvent, dimethylformamide (DMF), which is used in the production of goods containing polyurethane and of man-made fibres (MMF, including carbon fibres, critical in the production of large wind turbines)
- Polycyclic aromatic compounds that are present in rubber crumb applied to sports pitches and play facilities.
- Substances used in tattoo inks and permanent make-up.
- The use of cobalt salts for the manufacture of chemicals, catalysts, battery production, surface treatment, fermentation processes, health applications, feed grade materials, biogas, etc.

EAERE representation has provided input to all of these issues. Some of these measures raise little debate: the restriction on tattoo inks, for example, brought legislation into line with cosmetics. Some, however, are more problematic. The assessment for DMF, for example, extrapolated a valuation of chronic liver disease to 'alcohol intolerance' (a condition mediated through the liver, but not chronic or seriously debilitating at existing exposures) to justify the proposals presented to the Committee. EAERE members highlighted the fact that this extrapolation was inappropriate. EAERE members also questioned the extent to which the societal value of the products of the MMF industry such as supplies to the renewable energy and healthcare industries had been accounted for.

For authorisation, where SEAC assesses proposals by individual companies for continued use of otherwise banned substances, EAERE input is on methodological issues only, reflecting the rules on the role of stakeholder participation.

Upcoming activities of SEAC

In the coming year a proposal for a 'universal' restriction on PFAS (per- and polyfluoroalkyl substances) will be submitted to ECHA by 5 member states for evaluation by RAC and SEAC. This proposal is particularly challenging as it covers a very large number of substances (in the order of 10,000) which are used in a wide range of activities (refrigeration, heating, air conditioning, foam blowing, ski waxes, non-stick coatings, packaging, cosmetics, oil and gas

industry, etc). The focus of the restriction will be on the persistence of PFAS substances and (where appropriate) their degradation products –which cannot be valued using an impact pathway approach that establishes a clear impact (e.g. aquatic toxicity, change in cancer incidence) and which by definition need to be evaluated over protracted timescales. Earlier work has shown that the costs of getting legislation on PFAS wrong are extremely high in terms of clean up alone. The proposal will raise several issues extremely relevant to the interests of EAERE.

Mike Holland
mike.holland@emrc.co.uk

Roy Brouwer
rbrouwer@uwaterloo.ca

8/9/2021