Socio-economic assessment

as part of regulatory risk management

Hans Marquart of **Triskelion** discusses the options for companies to provide socio-economic input into regulatory risk management processes for chemicals.

Multiple Regulations and Directives regulate chemical products in the EU. A general aim of this type of legislation is to protect human health and the environment. Therefore, the legislation offers various options for action by authorities to limit or prevent risks. These fall under the general term 'regulatory risk management.'

It is clear that we need chemicals in our daily life and that every risk that is mitigated comes with a price, as the implementation of risk management measures (RMMs) often requires large investments. To balance risks and costs, many of the aforementioned regulations take into account socio-economic aspects before taking decisions, as shown in Figure 1.

Some regulatory risk management options are directly invoked by the legislation, as shown in Figure 2. For example, the Biocidal Products Regulation (BPR) requires the approval of biocidal products to ensure that there will be no risks from them. Other options occur after an evaluation of hazard or risk has been made. The use of restrictions or authorisations under REACH depends on evaluated hazards or risks of substances to be regulated.

What can we do?

Our future is at stake - can we do something about it? What if your product is in the line of fire of the authorities? Is there anything you can do to limit the negative consequences?

Sometimes our clients from outside the EU ask us, whether we can put pressure on someone in government to 'make this go away.' And perhaps someone who knows a prime minister or a European commissioner might get things done that others cannot achieve. But the direct influence a consultant can usually exert via his network on decisions in the scope of EU legislation is rather limited.

However, that does not mean, that nothing can be done. Quite often, an assessment of the impacts of decisions including socio-economic impacts, is an integral part of the decision making process. Affected companies can provide input into such processes – and such opportunities should not be wasted!

If you leave it up to the authorities to assess your situation, they may overlook important aspects or not value them as much as you would do. Giving input on the socio-economic aspects of proposed RRMs can therefore be very important. Table 1 includes a couple of possibilities from different pieces of legislation.

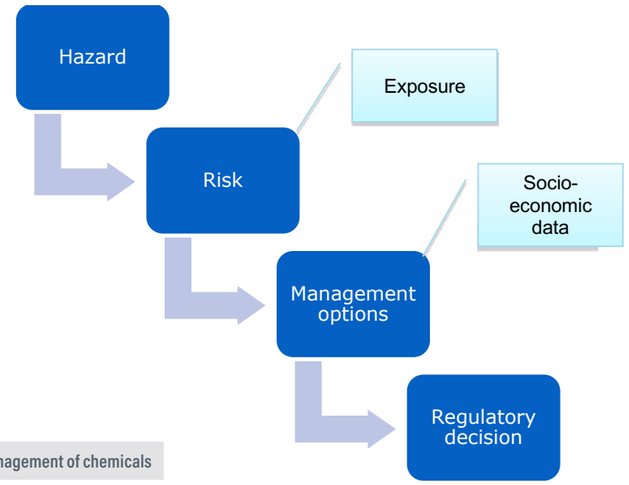

Figure 1 – Role of socio-economic data in regulatory risk management of chemicals

In developing **REACH restrictions**, an EU member state or ECHA reports the justification for the proposed restriction. This includes information on alternatives and costs, as well as benefits of the restriction.

An intention to prepare a restriction proposal is published beforehand. That is a moment for companies to gather and send socio-economic information to the authority drafting the proposal.

Further on in the process, the Socio-Economic Assessment Committee of REACH will give its opinion on the socio-economic aspects. A draft report is published and stakeholders can respond to that draft in the public consultation.

In the **REACH authorisation** process, it is up to the applicants for authorisation to prepare a dossier. This dossier must include a socio-economic assessment if it cannot be shown that there will be no risk when the authorisation is granted.

Even where there is no risk, it is advisable to supply a socio-economic assessment to support the application as well. Specific guidance and formats are available for this application.

BPR exclusion criteria can likewise arise, even though substances that are considered too hazardous, such as carcinogens or substances toxic to reproduction, are in principle not acceptable under the BPR.

In some cases they can be accepted, specifically if the benefits for society are larger than the expected negative impacts. This can be shown by the applicant by justifying that non-approval will lead to serious dangers to human health, animal health or the environment, or by showing a disproportionate negative impact on society.

Occupational exposure limits (OELs) are derived under the rules of the **CAD** or the **CMD**. This is the responsibility of DG Employment, Social Affairs & Inclusion. The full process is a seven-step process from the selection of chemicals for evaluation to the adaptation of the Directive with the OEL and publication in the Official Journal.

Step four is the impact assessment. This is also the responsibility of the DG, but in practice is carried out by consultants. Part of the process is gathering information from stakeholders, basically the producers and users of the substance, usually via (internet) questionnaires. Socio-economic aspects are a crucial part in the information to be provided.

How to provide information

The ways in which information can be provided on the socio-economic impact of a regulatory proposal are variable. This can be via a format described by a guidance document, or via a free-text e-mail. In some cases, questionnaires are used to gather information from stakeholders.

Whatever the format, actual convincing information is crucial for input to be taken seriously. Simply stating 'This is too expensive' will have little or no effect on the process.

Almost all formats and processes allow for a proper analysis to be submitted, either within the given format or as an appendix. A proper study of the impact with calculated costs for different sectors in Europe, without neglecting the benefits, should not be simply neglected.

For example, based on a socio-economic assessment of possible OEL values of 1,3-butadiene, made on behalf of a number of affected sector groups, the Socio-Economic Council ➤

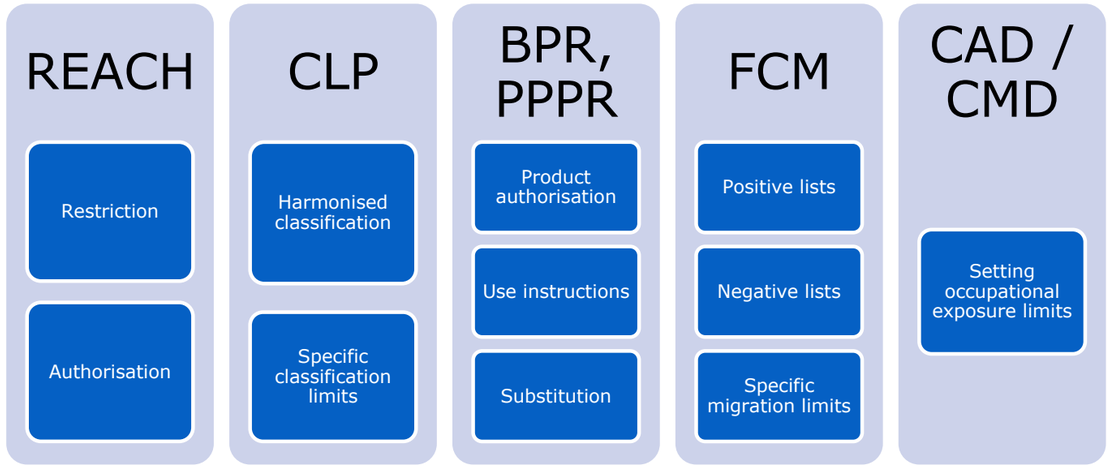

Figure 2 – Examples of regulatory risk management tools for chemicals

Regulation	Process and phase	Phase	Activity	Performed by	Socio-economic input possible
REACH	Restriction	Preparation of proposal	Information on alternatives; Assessment of costs and benefits	Authorities	No formal process; socio-economic input can be sent to evaluating member state or ECHA
	Restriction	SEAC draft opinion	Public consultation	Authorities	Provide feedback on SEAC opinion
	Authorisation	Application	Prepare application	Industry applicants	Provide analysis of alternatives and socio-economic analysis
BPR	Candidates for substitution	Defining potential candidates	Public consultation	Authorities	Provide information on alternatives, technical feasibility, economic feasibility
	Exclusion criteria	Derogation to exclusion criteria	Public consultation	Authorities	Indicate essential to control serious danger; disproportionate negative impact on society of disapproval
	Derogation in emergency	Application	Prepare application	Industry applicants	Justify the (socio-economic) need
PPPR	Derogation in emergency	Application	Prepare application	Industry applicants	Provide economic evidence that socio-agronomic system cannot be changed within a year
CAD/CMD	Setting of OEL	Deriving limits	Impact assessment	Authorities	Provide input on socio-economic impact of new OEL

Table 1 – Options for providing input on socio-economic aspects of regulatory risk management

➢ of the Netherlands recommended in 2014 that a limit of 0.1 mg/m^3 was not feasible and that a 2 mg/m^3 limit be set instead.[1]

While such a clear relation between input from industry and resulting authority positions is unfortunately not always visible, it does show that a good study can have an important impact on a regulatory decision.

Summary & conclusion

In the decision-making process on RRMs for chemicals, socio-economic aspects can play an important role. Several regulatory processes provide options for stakeholders to submit information on such aspects. The formats and processes can differ and, in some cases, a formal option to provide such information has not been foreseen.

In all cases, if you are a stakeholder who expects to be impacted seriously by the proposed RRM, it is up to you to ensure that the authorities are aware of that (unwanted) impact. You should not miss the opportunity to make your points clear and the best way to do it is to provide convincing calculations and data, supporting your position. ●

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Reference:

1: *SER. Grenswaarde voor 1,3-Butadieen. Advies 14/08, September 2014, ISBN 978-94-6134-066-5*