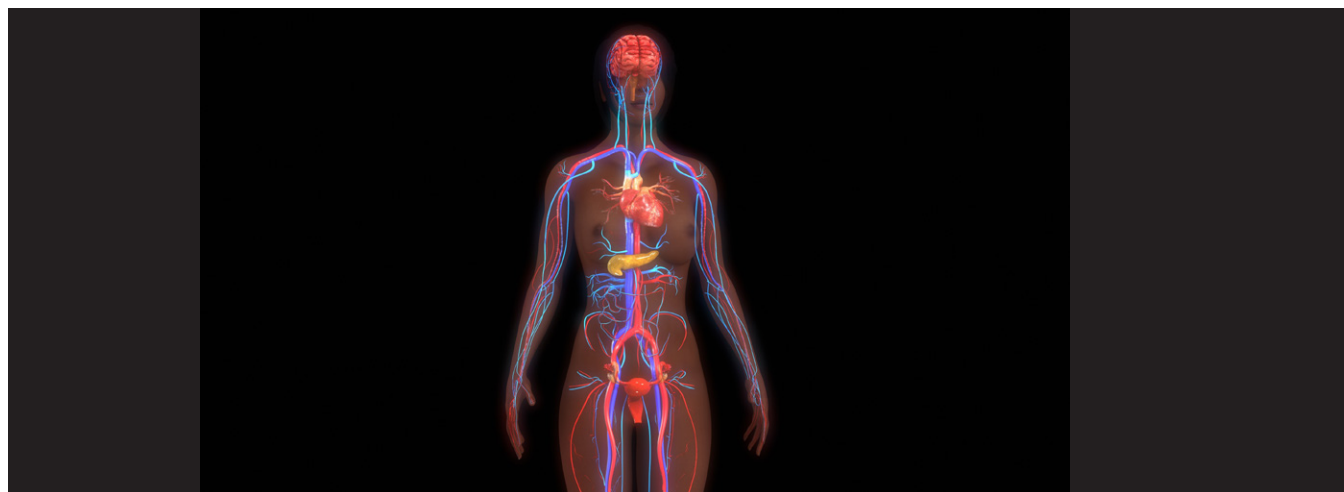


Endocrine disruptors are changing the socio-economic analysis

Quantification methods and the monetisation of environmental impacts are huge challenges for the 2019 applications for authorisation



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Endocrine-disrupting chemicals (EDCs) have been a hot topic in REACH authorisation lately. Two substances of very high concern (SVHCs) with this property have been added to Annex XIV, since when the industry has struggled with the question of how risks arising from the use of EDCs should be monetised in the socio-economic analysis (SEA). This is a major issue, since one of the most crucial tasks of an application for authorisation (AfA) through the SEA route is to demonstrate that the economic benefits of using the substance outweigh the risks.

Previously, it was relatively straightforward to monetise the risks of using substances classified as carcinogenic, mutagenic or toxic to reproduction (CMR), because the relationship between individual exposure and the incidence of a defined health effect was estimated quantitatively via willingness-to-pay estimates. The authorities have used the ratio resulting from comparing the monetised risk and benefit of continued use as a basis for deciding on whether to

grant an authorisation, and the length of the review period.

Persistent, bioaccumulative and toxic (PBT) substances and very persistent, very bioaccumulative (vPvB) substances are also subject to authorisation. Like EDCs, these both lack a clear quantification method and the monetisation of environmental impacts is not currently feasible. This makes it challenging to evaluate whether the benefits of use outweigh the risks.

The Committee for Socio-economic Analysis (Seac) published a brief guidance for the risk assessment of PBT and vPvB substances in 2016. Now, with the latest application date for the EDCs in Annex XIV looming, Echa and Seac have shed some light on monetising them.

This article introduces the risk assessment method Seac endorsed in its **latest comments**: semi-quantitative assessment with a cost-effectiveness analysis (CEA). CEA is a form of economic analysis which compares the monetary costs and non-monetary effects of different courses of action. This is where the cost of, for example, the non-use scenario is related to some non-monetary parameter, like kilograms of avoided emissions. The ratio

of this is then derived to achieve the cost in terms of euros/tonne.

Impact on SEA assessment

Assessing the benefits of continued use of environmentally hazardous substances does not differ from other AfAs. This assessment is based on the non-use scenario, where the substance is no longer available for use, and its impacts on society and the applicant. These impacts (costs) are ordinarily unemployment and business losses in monetary terms.

With these groups of substances, however, it is very difficult to monetise the environmental risk arising from their use. Firstly, they can remain and accumulate in the environment over long periods of time. In the long-term, the effects of this accumulation are unpredictable, and exposure is difficult to reverse because ending releases will not necessarily result in a measurable reduction in exposure.

Secondly, deriving thresholds or dose-response relationships is extremely difficult for these substances. With current methods, it is problematic to establish a no-effect concentration for the environment. It is also quite difficult to estimate reliably how they behave in the environment and what the consequences of releases are.

Even without full quantification of risks, however, it is still possible to assess environmental risks. As the **relevant guidance documents** show, it is possible to use qualitative and semi-quantitative approaches, with the approach being case-specific. When the benefits of the continued use are significant and the emissions are properly controlled, a qualitative assessment may be enough.

In a more complex case, in-depth semi-quantitative analysis may be needed. This would include an assessment of the monetised benefits of continued use and quantified release estimates, complemented by qualitative information.

In practice, this means that a SEA assessing EDCs and PBT/vPvB substances would need to include several elements, including, among others:

- » quantified releases;
- » a qualitative description of the location of the releases;
- » a qualitative description of the potential impacts of the releases; and
- » a qualitative comparison of the benefits and risk of the continued use.

Applicants will also need to undertake a CEA, based on the emissions reduction and compliance costs related to the substance. To assess the proportionality of policy measures based on a CEA, there is a need for a benchmark: the decision maker wants to know if a specific level of cost (for example, per unit of emission reduction) should be considered as proportional or not.

The cost-effectiveness ratio can then be compared to a benchmark like previous studies on abatement or avoidance costs, or existing data on remediation or clean-up costs, etc., in order to conclude on the proportionality. From this, an opinion can be derived as to whether the regulatory action results in net benefits to society.

However, there are currently no standard benchmarks for evaluation that would lead to an acceptable level of cost-effectiveness or other indicator of benefits applicable to all EDCs and PBT/vPvB substances. As a result, Seac stated that the information provided in the application for authorisation will be assessed on a case-by-case basis.



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Monetising the environmental impact of certain hazardous chemicals is very difficult

Ways forward

If standard benchmarks could be established for each EDC and PBT/vPvB substance, it would greatly clarify how the SEA assessments and evaluation should be developed. There have already been investigations, but these are, currently, only initial attempts.

For example, the Free University of Amsterdam conducted a project to develop a benchmark for regulatory decision making-under REACH for PBT and vPvB substances. However, this resulted in a substantial evidence base in terms of cost-effectiveness data rather than any specific suggestion for benchmarks.

Another future possibility might be exploiting the United Nations System of Environmental-Economic Accounting (SEEA) as an environmental risk monetisation method, since it compiles accounts in physical and monetary terms. This is a statistical multi-purpose conceptual framework for understanding the interactions between the environment and the economy.

The SEEA system generates a wide range of statistics, accounts and indicators with many different potential analytical applications, and can be adapted to policy needs while at the same time providing a common framework, concepts, terms and definitions. In theory, it can give a monetary value for a physical unit of emissions to the environment.

In relation to EDCs, it is theoretically possible to monetise pollutants discharged into water bodies using the SEEA.

Unfortunately, this framework is still in the conceptual and data collection phase. Finalising this approach before usable data is available could take years.

Conclusion

Substances with endocrine-disrupting properties are changing the conventional way of thinking how the SEA for AfAs should be prepared. In risk assessment, the main focus should be on environmental rather than human health impacts.

With the aforementioned deficiencies in full quantification of the environmental risk of using EDCs and PBT and vPvB substances, the proposed analysis method is a semi-quantitative assessment with a cost-effectiveness analysis.

With a euro/tonne ratio derived from CEA, it is in theory possible to assess the proportionality of an authorisation decision but in practice this depends on valid and robust benchmarks, which do not yet exist.

Despite not being definitive, Seac's latest clarifications will help SEA practitioners unify authorisation application dossiers. Industry and the authorities should carry on investigating and developing more robust monetisation methods for the risk assessment of EDCs and PBT/vPvB substances. However, in the short-term it will also be necessary to develop robust benchmarks for these substance groups to allow transparent risk-benefit comparisons.

The views expressed in this article are those of the expert author and are not necessarily shared by Chemical Watch