# Drawing valuable lessons from the SEA route

## What did REACHLaw learn from its first authorisation applications?



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21 November 2013 was not only the latest application date for diarsenic trioxide (EC 215-481-4, CAS 1327-53-3), but also when authorisation applications were filed for the first time under the socio-economic analysis (SEA) route. Under the REACH authorisation framework, companies seeking to keep a "non-threshold" substance (those for which an acceptable exposure threshold has not been set) on the market for a particular use, or uses, must apply for authorisation under the SEA route. This means that, in addition to proving that there are no feasible alternatives available, the applicant needs to demonstrate that the socio-economic benefits of continued use of the substance outweigh the health and environmental risks. REACHLaw prepared and submitted two applications for its clients for the use of diarsenic trioxide in the production of zinc, and this article summarises the main lessons learned during the process.

It is true that the application for authorisation through the SEA route comprises three main documents: the chemical safety report (CSR); the analysis of alternatives (AoA) and the SEA. It is also the case that in order to prepare the three documents, very different competences are required: toxicology, ecotoxicology, exposure scenario and risk assessment competences for the CSR; industry-specific know-how in the AoA; and socio-economic competence in the SEA.

However, the three parts should not be developed independently, because they are deeply interlinked and dependant on each other. The CSR has data for both the risk reduction assessment in the AoA and the analysis of human health and environmental impacts in the SEA. The AoA requires SEA expertise for the economic feasibility analysis. At the same time, the AoA often determines the SEA's non-use scenario by establishing which alternative the applicant would most likely switch to if the authorisation was not granted. As such, the experts preparing the three reports should be working closely together throughout the process, continuously exchanging input.

### Early supply chain consultation

Consultation with the supply chain is often necessary, both to collect data and to define the scope of the analysis. Downstream users possess valuable information on substance usage, exposure, alternatives and potential socio-economic impacts if the authorisation is not granted. However, the identification of, and engagement with, supply chain actors is often difficult and time-consuming. The companies' relationships have rarely been mapped out in detail before and previous communication between them has often been limited. They may not have a good understanding of the authorisation process, or how it affects them. Therefore, the exercise should be undertaken early on in the process, and the effort required should not be underestimated.

It is a common myth that an application for authorisation requires extensive amount of confidential business information (CBI), especially with regard to the AoA and SEA. But our experience tells a different story.

Concerning the AoA, it should be understood that it doesn't equal the replacement programme a company conducts internally. The AoA is an examination of the suitability of the publically-known potential alternatives. If a company has a top secret replacement programme, it is likely that the rest of the world doesn't know about it. But there is no need to reveal it, because you will probably not be challenged during the public consultation.

The aim of the SEA is to demonstrate that the socio-economic benefits of continued use of the substance outweigh the human health and environmental risks. The idea is not to conduct a comprehensive analysis of the

business and social environment surrounding a company. If the arguments are clear, and the case is strong with publically available information, then just stop there.

After the submission, the applicant will be asked further questions concerning its application by ECHA's Risk Assessment and Socio-economic Analysis Committees. In our case, more than three pages of very detailed questions were asked, requiring over 40 pages of written answers and supporting documents. The time given to come up with such a document was less than two weeks. The committees were asking for more supporting evidence and wanted to know the detailed methodology/considerations behind the conclusions made. The questions were relevant, but they required a significant effort in terms of communication and organisation of data. Therefore, you need to do your homework well. Don't leave any stones unturned, because the committees are likely to ask about them, and you will have very limited time to do the work properly.

### It is not an exact science

Applicants should also remember that this is not an exact science. On the contrary, it is more like an educated guess, because the SEA is an analysis of possible future scenarios and therefore inherently involves a degree of uncertainty. Values should be estimated conservatively on both sides - underestimating socio-economic impacts and overestimating potential health and environmental impacts. As they are speculative, it may be best to describe them qualitatively rather than quantitatively. An analysis that shows that the benefits outweigh the costs even with conservative estimates is likely to be a convincing case.

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