Substitution Strategies & Green Chemistry

Tools for Sound Chemicals Management

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An overarching concept in chemicals legislation such as REACH, CLP and the Biocidal Product Regulation (BPR), is that the substitution of chemicals with those having less hazardous properties is desirable and has potential to be economically advantageous. For this reason, substitution strategies play an important role in these regulations and other similar legislation around the world.

“The whole system of REACH, CLP and the new Biocidal Products Regulation (BPR) is built towards substituting dangerous chemicals with safer ones,” says Jack de Bruijn, ECHA’s Director for Risk Management.

**REACH legislation & Substitution**

The main use of substitution strategies within REACH is seen in the authorisation section of the process, in which companies have to apply to ECHA for continued use of their hazardous substance beyond the sunset date deadline. Annex XIV of REACH, known as the ‘Authorisation List’ contains substances defined as Substances of Very High Concern (SVHC’s) and it is the uses of these substances that would need authorisation.

The identification of alternatives within the substitution strategy must be thorough and comprehensive. The proposed alternatives are evaluated against the Annex XIV substance via three different aspects:

*Comparison of Risk* - This involves the direct comparison of the risks of both the alternative and Annex XIV substance. The alternative substance would also be used in the original exposure scenario in order for direct comparison, resulting in the definition of a new exposure scenario for the alternative.

*Technical Feasibility* - This factor considers whether the alternative performs in the same manner as the Annex XIV substance and whether there would need to be any infrastructure changes needed in order to adopt this alternative.

*Economic Feasibility* - A judgement of any changes in cost between the alternative process and the original process needs to be made and considered if it is acceptable. Increased costs for the alternative process may arrive from changes in infrastructure and energy costs and training and regulatory costs. A socio-economic analysis may also be implemented for assistance.

Along with these factors, an overall substitution strategy for the implementation of the alternative should be completed which contains timelines for required activities, responsibilities and uncertainties/mitigation.

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BPR legislation & Substitution

In a similar nature to that of the REACH legislation, the study and use of alternative or substitute substances is prevalent in the approval of active substances within the BPR legislation. In order for the authorisation of a biocidal product to be granted, the active substance contained within must first be approved.

An active substance will be considered as a candidate for substitution if any of the following criteria are met:

- It meets at least one of the exclusion criteria.
- It is classified as a respiratory sensitiser.
- Its toxicological reference values are significantly lower than those of the majority of approved active substances for the same product-type and use.
- It meets two of the criteria to be considered as Persistent, Bioaccumulative or Toxic (PBT).
- It causes concerns for human or animal health and for the environment even with very restrictive risk management measures.
- It contains a significant proportion of non-active isomers or impurities.

The associated competent authority will judge the active substance by these criteria and if identified as a potential candidate for substitution, ECHA will initiate a public consultation. This public consultation (60 days) includes the submission of information on available safer alternatives from third parties. Alongside the public consultation there will also be a comparative assessment of the alternatives currently available on the market. If safer alternatives are available and they are effective, the biocidal product use can be prohibited or restricted.

Substitution strategies & links to Green Chemistry

Alongside REACH & BPR legislation and the associated drive towards replacing hazardous substances with those of a superior health and safety standard, there has been a simultaneous increase in prominence of an academic and industrial research field known as Green Chemistry.

Green Chemistry is based upon 12 principles, as defined by Anastas and Warner: (Figure 1) that cover a variety of different aspects but place a focus on topics such as the use of alternative solvents, the use of renewable feedstocks and the avoidance of hazardous chemical synthesis. Another important focus of Green Chemistry is to understand the full lifespan and use of a chemical substance (life cycle assessment) to ensure an appropriate end-of-life for the substance and to prevent the generation of hazardous waste streams.

Figure 1: The 12 Principles of Green Chemistry

In a way, Green Chemistry has emerged due to the fact that if people continue to synthesise and use existing hazardous chemicals in the same manner, they will face an increasing number of issues concerning legislation such as REACH and the associated regulatory costs. Therefore, funding has been made increasingly more available for the research into the efficacy and feasibility of the use of less hazardous alternatives.

Substituting chemicals based on hazard not only provides a competitive advantage to companies with respect to marketing greener, safer products, it also helps to avoid potential future impacts of regulations such as REACH and BPR that might impose a ban or restriction on chemicals.

Substitution – a key aspect of sound chemicals management

Monitoring chemicals legislation (e.g. Candidate List/Annex XIV (Authorisation List) within REACH and the new active substances under evaluation list within the BPR) and other activities that drive the regulatory process (such as substance evaluation, harmonised classification under CLP, and NGO activities) will help prioritise your substitution strategies. Checking current substances and possible future alternatives against these lists is a valuable tool for effective chemicals management, and can be achieved through the use of software, such as Yordas Hive.
Yordas Hive Core Functions

Substances
Gain access to global regulatory data on over 250,000 substances, actively maintained by our team of experts to ensure you always have the latest updates at your fingertips.

Regulations
Determine what the regulatory barriers to any market may be for your business with clear information on over 1000 global regulations.

Materials
Evaluate and manage the risk of non-compliance for your complex articles, through our comprehensive database of materials and the regulated or hazardous substances that they might contain.

Products
Create your own in-house database of products to help you manage and maintain your compliance data. Works with Hive Notifier to deliver notifications for regulatory changes affecting your substances and formulations.

Safety Data Sheets
Protect your workers by managing and distributing reliable safety information across multiple sites.

Getting in touch is easy!
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