Pre-emptive risk management option analysis (PRMOA) under REACH

As part of the European Commission's SVHC Roadmap to 2020, the risk management option analysis (RMOA) has been introduced as a step in the decision-making process for the authorities, although there is no legal obligation for it. Associated with it, the Public Activities Coordination Tool (PACT) was published by ECHA, listing the substances for which a RMOA or an informal hazard assessment for PBT/vPvB (persistent, bioaccumulative and toxic/very persistent and very bioaccumulative) properties or ED (endocrine disruptor) properties is either under development or has been completed since the implementation of the SVHC Roadmap commenced in February 2013.

An RMOA is a case-by-case analysis conducted by authority to conclude for an identified substance of concern, whether and which additional regulatory instrument(s) should be proposed to manage the risks from its use to human health or the environment. The main conclusions that will be drawn are one or multiple choices of the following:

- Identification as SVHC (entering the Candidate List before prioritised for REACH authorisation)
- REACH restriction
- REACH substance evaluation
- CLP harmonized classification and labelling
- Other EU-wide measures
- No need for follow up regulatory action at EU level

From companies' point of view, there is an imminent need to actively manage the regulatory risks, because any of the regulatory actions being decided can mean considerable investment for improving current operation conditions, significant obsolescence management and/or replacement cost, potential supply chain disruption, as well as dramatic market reactions. Therefore a strategy-level analysis and action plan is recommended to determine the potential risk management options that the authorities may apply and how to act accordingly. This exercise can be described in roughly four steps:

1. Monitoring
2. Analysing
3. Intervening
4. Strategic planning

MONITORING

The PACT list is the main list to be followed, which gives the first signal of which substances the authorities are working on, and whether there may be impact on the business. Knowing which authority is working on what subject is also important for potential intervention activities.

ANALYSING

Companies can try to put themselves into the authorities' shoes and make the RMOA themselves. It should be important to understand, that RMOAs for potential SVHC are normally looking at the full range of uses for a given substance. For individual companies or sector trade associations, it may be difficult to know this big picture. However, it should be understood that the main data source for the authorities, namely the registration information, is mostly available to the general public through ECHA's dissemination tool as well. In addition, it is important for the companies to understand the decision criteria and the related timelines.

The goal of the analysing step is to make a realistic prediction of the RMOA outcome and the associated timetable, which will be the input for the intervention and the strategic planning steps.

INTERVENING

The idea of intervention is to provide the right information to the right party at the right time. There are a few things that companies can do:

1. Keep the registration dossier up to date and reflecting the reality

   Updating the registration dossier to reflect the most current understanding is particularly important for information that is used as selection criteria, such as information on hazardous properties that may change the classification or qualification as PBT, vPvB and/or ED, as well as information on the uses and volumes. It is also important to coordinate this work with the Substance Information Exchange Forum under REACH, because every registrant needs to update in order for the change to be taken into consideration.

2. Participate in the public consultations with the most useful information

   The public consultation is the only official route to provide the decision makers with information that is not available in the registration dossier. The information concerning the use conditions, volumes, alternatives, as well as the socio-economic effects are all issues that may help authorities to make the most proportionate regulatory decisions.

In addition to individual companies' activities, the trade associations often play important roles in lobbying for a more appropriate regulatory option. For example, a use already regulated by specific EU laws aiming at the protection of human health or the environment may have the grounds for claiming inclusion of an exemption in Annex XIV based on REACH Article 58(2).

STRATEGIC PLANNING

In addition to the intervention activities, companies should develop a regulatory roadmap as part of their strategic planning. Such roadmap may address key issues such as

- processes to be designed or optimised on the substance and use information collection,
- mitigation of regulatory risks along the supply chain,
- timely obsolescence management,
- cost-effective replacement plan,
- portfolio optimisation,
- effective public communication.

As a conclusion, industry has now more possibilities than earlier to interact with the authorities during the RMOA and the subsequent regulatory decision making processes. Companies are advised to take a proactive approach to safeguard their future business in the best possible way. The pre-emptive risk management option analysis and strategic planning offers a structured concept to implement this approach.

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