How can automated systems help mitigate the risks of obsolescence caused by REACH?

INSIGHT EXPERT FOCUS | 12 September 2022

Oliver Reiff-Musgrove, regulatory consultant, REACHLaw UK, looks at how to stay ahead of the challenges the regulation presents

© Jade adobe stock.com

Materials obsolescence is the process by which a material becomes unavailable to the market, typically due to external pressures. REACH has become a driver of obsolescence as it aims to phase out substances of very high concern (SVHCs). This is, of course, a positive in terms of human health and environmental protection but presents major risks, especially to highly sophisticated end-user industries.

In its current form, unless it has an authorisation, inclusion of a substance on the REACH Regulation's candidate list of SVHCs can result in it being banned from the European Economic Area within five years.

But industry frequently works to different schedules – in the space sector, for example, project timelines often range upwards of 15 years, with decisions regarding materials taken early in the process.

> Industry frequently works to different schedules – in the space sector, for example, project timelines often range upwards of 15 years, with decisions regarding materials taken early in the process

Such a discrepancy between the regulatory and project timelines can result in materials becoming obsolete and require companies to go through a costly material requalification process. Hence there is a need to closely monitor REACH regulatory intentions from the early stages.

However, somewhat counterintuitively, compliance with chemical regulations is not the largest materials obsolescence risk factor for such sectors. In fact, a greater cause is from the secondary effects relating to the commercial viability, and therefore availability, of critical materials. This, coupled with a lack of suitable alternative materials, means commercial obsolescence can pose significant risks to projects in niche low-volume sectors.

When monitoring for the risk of obsolescence caused by REACH, the basic method is to cross-reference the substances contained in a bill of materials against the Regulation's relevant substance lists, most notably:

- the candidate list;
- the authorisation list (Annex XIV); and
- the restriction list (Annex XVII).

Such cross-referencing was possible in the early days of REACH. However, the candidate list and Annex XIV have expanded to the extent that manual processing would be extremely time-intensive for even moderately sized

material portfolios. With the candidate list being updated twice a year, and the irregular updates to the authorisation and restriction lists, the task has become complex, heightening the need for an automated solution.

Automation

Some in industry argue that a spreadsheet-based solution would be fit for purpose, but there are a host of reasons why such an approach could not be used in place of an optimised database, including:

- performance with large datasets;
- version control; and
- concurrency.

Web apps are an excellent low-cost alternative, offering high levels of customisation and cross-platform compatibility, which can be enhanced when used in combination with application programming interfaces (APIs) to access real-time REACH list data.

In its simplest form, the way that automated cross-referencing happens is that materials obsolescence management systems connect to a source of REACH list data and check against a database containing the bill of materials to be assessed. Crucially, this database must be chemically indexed, allowing the substances contained in a material to be recognised. Such systems can dramatically reduce the burden of manual input down to solely the indexing of chemicals in a material portfolio. Should the algorithm and dataset used be sufficiently robust, REACH obsolescence risks can be assessed on the fly through automated cross-referencing against the latest REACH substance lists.

By focusing on risks derived from SVHC identification, the predictability of the REACH candidate list can be leveraged, owing to its role as a regulatory precursor. Inclusion in the recommendations for authorisation should raise further alarm bells within a REACH risk management system, although many SVHCs that take this path have culminated in a holding pattern, potentially never entering Annex XIV. Regulatory forecasting can be taken further by including the Echa community rolling action plan (Corap) list, which – decision dependant – offers foresight of one potential route into the candidate list. Automated systems can benefit from the shorter-term predictability of the registry of SVHC intentions, typically, a six-month warning of candidate list inclusion.

Finally, Echa's chemical universe list has recently become a useful resource for risk monitoring at a substance level as it makes visible ongoing or considered regulatory actions.

Challenges

Automated obsolescence risk management where the REACH restrictions list is concerned is a less straightforward affair. As each entry in Annex XVII has a unique legal text stipulating the scope of the substance restriction, one cannot assume the whole list to be of equal regulatory risk. Instead, the restriction text for each entry must be analysed independently, allowing for individual conclusions.

One solution is to assess each restriction through the lens of a company or whole sector, declaring the entry as relevant or irrelevant. However, this is subjective and can change when novel materials are used in a sector. It is also possible for a restriction entry to be relevant to certain industrial uses but not to others. This could lead to the generation of false positives in an automated system if this context cannot be purveyed.

While not specific to the restriction list, group entries also pose a challenge for automated REACH obsolescence risk management systems. Where a non-exhaustive list of Cas/EC numbers has been provided by Echa, it is often necessary to complement this with further manual entry of the missing numbers. This can add uncertainty to the supply chain as differing versions of exhaustive lists could be generated. Cross-referencing using a chemical name is discouraged due to the increased risk of human error. Automated systems should seek to utilise the in-built checksum of Cas and, although not perfect, EC numbers. Where the chemical indexing numbers have not been provided the task becomes very challenging, hampering regulatory compliance.

Future

On the horizon there is the prospect of having to track further REACH obsolescence risks. The planned upcoming general use PFAS restriction would present a major challenge for materials portfolio mapping. Estimates for the number of PFAS Cas numbers range from 4,500 to potentially more than 12,000 – by far the most numerous in REACH to date. Mapping exposure to such a wide scope restriction will almost certainly require an automated tracking solution, without which the ambitious aim of eliminating non-essential PFAS use will be difficult to achieve. Uncertainty surrounding the number of Cas numbers Echa will provide remains. However, due to the magnitude of the possible restriction, it is likely that companies will need to draw chemically indexed PFAS data from multiple sources to both stay compliant and fully assess the obsolescence risks.

> On the horizon there is the prospect of having to track further REACH obsolescence risks. The planned upcoming general use PFAS restriction would present a major challenge for materials portfolio mapping

In addition, with the ongoing REACH revision plans under the European Commission's chemicals strategy for sustainability (CSS), the number of substances to be tracked is likely to ramp up. The considered enhanced regulatory obligations for candidate list entries would increase the need for forecasting. As a result, automated risk management systems may need to hold the candidate list registry of intentions and CLP Annex VI in a higher regard. However, a further obsolescence monitoring challenge could arise from the proposed Ecodesign for Sustainable Products Regulation (ESPR), with its new category of substances, nominally 'substances of concern' (SoCs). Should there be regulatory obligations imposed upon product groups containing these, it may require a far larger pool of substances to be continually assessed against material portfolios.

Conclusions

The need for automated REACH obsolescence risk management systems has never been more acute. Complex article manufacturers and importers must not only be able to automatically assess their large bill of materials to maintain REACH compliance but also to mitigate against the risk of materials obsolescence. Without utilising the ability for systems to rapidly and accurately cross-reference chemically indexed materials against continually updating REACH (and possibly ESPR/SoC) substance lists, the risk of human error or a missed obsolescence event will be higher. Utilising software solutions facilitates better risk comprehension through improved visualisation, and when designed well can reduce the need for REACH obsolescence training.

While a certain level of manual monitoring of possible regulatory options and political priorities must remain, inevitably there will be a requirement to track more substances in the future. Nevertheless, the practicalities of how they can be integrated with automated systems must not be overlooked. After all, mitigating REACH obsolescence risks creates market forces to effectively remove toxic substances from circulation ahead of the regulatory schedule. Therefore, efforts to improve the availability and exhaustiveness of REACH substance list data and their integration into automated risk management software should be prioritised.

The views expressed in this article are those of the author and are not necessarily shared by Chemical Watch. The author transparency statement can be seen here.

FURTHER INFORMATION

Candidate list
Echa registry of SVHC intentions
Chemical universe