

ECHA focuses on REACH compliance for 2019



Dr Thomas Berbner of Knoell Germany looks at the actions needed to meet tightening REACH dossier update requirements

THE FINAL REACH registration deadline for phase-in substances passed on 31 May 2018. At first glance, it might have appeared that the main part of REACH was over then. However, although this was the biggest single effort that industry had to put into REACH, the reality is quite different.

So far, data have been collected and evaluated with regard to the hazards and risks of chemical substances used in Europe. This resulted in one of the world's largest databases of information on chemicals, including their physical and chemical properties, their toxicological and ecotoxicological impact and their uses.

The introduction of extended safety data sheets, a new way of communicating about the safe use of a chemical substance, adds valuable information about substances and especially their safe use in the supply chains. In short, today we know more than ever before about chemicals and how they are used in Europe.

The chemicals market is not and has never been in a steady state. Every year, new ones enter the market, while others leave it. Their market shares, production volumes and manufacturing processes can change. New uses are introduced or new scientific knowledge about a substance might become available.

Keeping up to date

Whereas manufacturers and importers of new substances are generally aware about the registration obligations they have to fulfil to place a substance on the market legally, awareness of the importance of keeping substance information up to date

is lower. Article 22 of REACH requires a registration to be updated without undue delay if there are any change(s) in: the status of the registrant; the composition of the substance; the annual or total quantities manufactured or imported; or, its classification and labelling.

The introduction of new uses – and uses advised against – or the identification of new risks to human health or the environment all require an update to the registration dossier and the chemical safety report (CSR)

Updates are also required if there are amendments or updates to the CSR or Annex VI, Section 5, and in cases where a test for which a testing proposal is necessary must be performed, or where changes in data access are granted. Finally, ECHA may also request updates for various reasons, such as decisions on a completeness check.

At ECHA's Safer Chemicals Conference in Helsinki on 22 May, the authorities made it clear that

the compliance of REACH dossiers has to improve. An implementation regulation that requests registrants to update a dossier is currently in preparation.

The regulation will clarify some terms like 'undue delay'. This might be defined as over three months for a dossier update in cases of changes in substance identity, tonnage band or new uses, or 12 months where an updated CSR becomes available or new scientific data is found with regard to intrinsic properties and risks of a substance.

Keeping substance-related information up-to-date is a key element of the sound management of chemicals and their safe use. Hence, there are many reasons why companies should review their registrations regularly, even if there has not been a change. Performing a literature search for new information regularly is also highly recommended.

Another key issue, often highlighted by the press and NGOs, is that many companies

do not comply with the legal requirements for substance registration. According to the first report from a recently completed REACH compliance project by the German Federal Institute for Risk Assessment, only 31% of the dossiers for substances at >1,000 tonnes/year and 44% of those at 100-1,000 tonnes/year are compliant.

Why is data missing?

For the rest of the dossiers, data were considered to be missing. Why is this? Since the authorities perform a technical completeness check for every registration, for every required data endpoint there has to be some information available – otherwise a registration number cannot be granted.

To understand the background better, it might be helpful to take a look back in time before 2009, when the first registration deadline was still in the future. Chemicals management in the European Economic Area based

on REACH was completely new, ECHA was very young and guidance documents still had to be developed or published.

Therefore, registration dossiers were submitted that had been generated to the best of the ability of all stakeholders at the time. They were happy to have overcome the registration burden and kept products on the market, and they considered registrations to be in a steady state. Some of the older dossiers might have been high quality when they were prepared but now they fall short of today's expectations of sound chemicals management.

After REACH entered into force, all stakeholders had to learn its requirements and the required study data was clearly missing for many intrinsic substance properties. Registrants often deviated from standard data requirements towards the optional use of alternative approaches like read-across or quantitative structure-activity relationships (QSARs). However, the





➔ justifications for using these are not considered sufficient when applying today's standards, which in turn leads to the impression of missing data and non-compliance. There are also cases where the robust study summaries lack a sufficient level of detail and hinder an independent assessment.

ECHA stated that REACH was built in a way such that industry does its job and the agency checks the results. Wherever data is missing, industry is encouraged to avoid animal testing and use alternative methods. Developing such methods proceeded too slowly and created a problematic situation.

New action plan

Industry addressed this problem by using the aforementioned options, like read-across, but did so to a far higher degree than ECHA expected. The pressure to use such approaches may, however, leave uncertainty about the hazard and thus the risk of a chemical substance. Hence, there is no other way than to tackle such uncertainties.

To improve the quality of registration dossiers in the future, ECHA is developing an action plan. This will address all substances and improve the clarity

of legal provisions. Reaction times have to improve. By the end of 2020, all registered substances at above 100 tonnes/year will be assigned to regulatory pools with different objectives and priorities. We also expect the compliance check target to increase from 5% of the dossiers to 20%.

A substance for which the registration dossier is non-compliant by today's standards does not necessarily pose a hazard or risk to human health and/or the environment, but there are worries, because one simply does not know for sure. Therefore, you should take Article 22 of REACH seriously and keep your dossier up to date.

Check the basic data about volumes and uses (and also uses advised against): are they still accurate? Remove uses that are not active any more. Keep an eye on the scientific data: is there something new with regard to hazards to humans and/or the environment? Check your justifications for read-across or QSAR data. Do they sufficiently and reliably explain why you chose this approach?

One final point about why it is so important to keep a registration up to date is the prioritisation of dossiers for further evaluation by

the authorities. They will probably be inclined to tackle hazardous substances that are produced in high volumes and have dispersive uses. Therefore, check these points in your dossier. Is the classification of the substance accurate and are the volumes still in the registered range? Check also whether the uses are all correct.

In the near future, the chance of receiving a compliance check decision from ECHA is likely to increase, so be prepared. Once you receive such a decision, your only options left are to react and fulfil the requested actions within a fixed period. Therefore, be proactive and develop your own time schedule and strategy for keeping your registration data accurate and up to date. ●

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