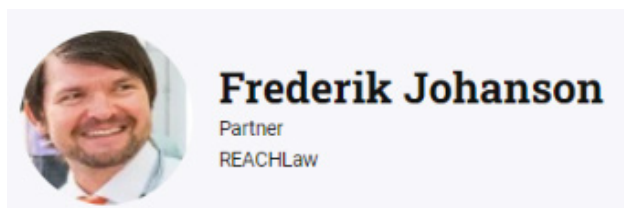
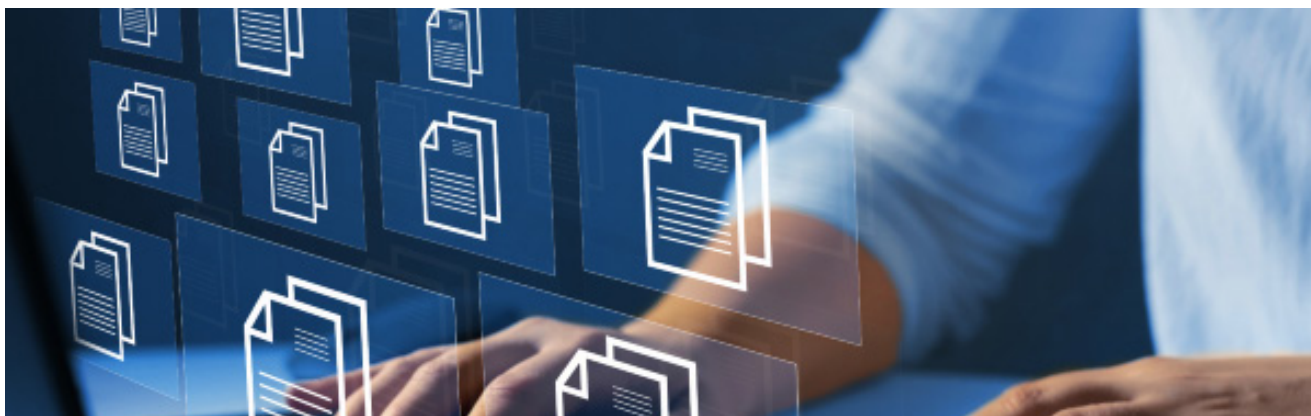


What are the data-sharing issues for jurisdictions with REACH-like regulations?

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Frederik Johanson, a partner with REACHLaw, looks at the regulatory implications facing the EU, Turkey and the UK



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The most significant aspect of the EU REACH Regulation for industry – which has just passed its fifteenth birthday – is without a doubt the registration requirements. And a key element of this is the joint submission of information on a substance. As part of this process the lead registrant may have to submit data on a substance's physico-chemical, toxicological and ecotoxicological properties.

Almost 23,000 substances have been registered and lead registration dossiers submitted, providing a wealth of information for anyone to view on Echa's dissemination platform.

To reach the point of having a final dossier ready to submit, companies registering a substance have had to cooperate in sharing, generating, and assembling the data that is required as well as dividing up the costs. This data and cost sharing is an integral part of REACH's one substance, one registration (Osor) principle.

Data sharing

Under this principle, companies registering a substance are required to share any existing and relevant data they have for the purpose of developing the joint dossier submission.

One of the aims of REACH is, as far as possible, to utilise existing data and only perform additional testing for endpoints where there are gaps.

The data-sharing process is governed by an implementing Regulation that came into force on 26 January 2016. Curiously, it also applies retroactively on already submitted joint registrations. Commonly known as the data sharing Regulation, it defines more clearly what REACH means when it says data sharing should be fair, transparent and non-discriminatory.

In essence, the 2016 regulation sets rules for making sure that data-sharing agreements are clear and comprehensive and that potential registrants are given the right to request a breakdown of the costs of a joint registration.

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The data sharing Regulation is a key part of the registration process, governing much of the principles associated with data-sharing activities in the EU. As an implementing Regulation, it does not cover data sharing across jurisdictional borders.

REACH-like chemicals regulations

Besides EU REACH, there are other REACH-like regulations either in development or already in force.

The two most similar regulations are Turkey's KKDIK (also known as Turkey REACH) which entered into force on 23 December 2017, and UK REACH, which did so on 1 January 2021. Both are based heavily on EU REACH's regulatory text. The KKDIK was introduced to align Turkish national law with that of the EU. The UK regulation comes as a result of Brexit.

The KKDIK and UK REACH are currently copies of the EU REACH Regulation with the same processes and methods carried over. The UK also enacted the data sharing Regulation under the withdrawal act that saw its departure from the EU. In Turkey it is yet to enter into force.

Turkey/UK deadlines

The KKDIK's registration deadline is 31 December 2023. And many of the approximately 18,000 pre-registered substances are currently starting to undergo, or are already undergoing, a joint registration effort whereby existing data is collected and compiled into the lead registration dossier. Because its data requirements are the same as for EU REACH, all the data is essentially already available albeit its ownership sits predominantly outside Turkey.

The situation in the UK is more complicated. In December 2021, its government announced that the environment ministry (Defra) "has committed to exploring alternative arrangements for UK REACH transitional registrations in order to support chemical businesses whilst upholding the highest standards to safeguard public health and the environment".

Together with industry and other stakeholders, the UK government is developing a new approach to the registration of most substances placed on Great Britain's (England, Scotland, Wales) market. This would only require a full registration for substances of high concern for the UK market. Substances of lesser concern would require only the submission of publicly available information to the UK Health and Safety Executive (HSE) as part of a so-called substance hazard information profile (SHIP).

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SHIPs aim to significantly reduce or even fully negate the need for the purchasing of existing data.

The mooted new approach will also propose diverging from the current chemical safety report (CSR) requirement by having companies submit a registrant specific risk assessment focusing on use and exposure in Great Britain. Based on current information, this could also apply to substances in the 1-10 annual tonnage band. The UK government says the reason for proposing this change is that it considers the EU REACH CSR too general.

The new approach also proposes postponing UK REACH registration deadlines. Based on currently available information, the first registration deadline of 27 October 2023 would move to 27 October 2026, the second deadline – 27 October 2025 – to 27 April 2027 and the last one put back a year to 27 October 2028. This would mean that they remain in this decade.

This is still under discussion and details scarce. But a public consultation will open this summer, with more information to follow in the autumn, with an aim of having an amending Regulation in force in 2024.

Data sharing

When working on joint registrations, the similarities of the legal texts mean that certain data- and cost-sharing principles apply across the EU, UK and Turkey.

And one of the key principles is that data and costs need to be shared in a "fair, transparent and non-discriminatory way".

However, this does not apply across jurisdictions and, for example, sharing data is not mandatory between the EU and Turkey. And if data is shared, the costs do not have to be either fair or transparent.

However, experience shows that most EU REACH data holders do tend to share their data at a fair price with their Turkish counterparts. One can assume that EU REACH data holders are motivated by a wish to avoid divergence

between jurisdictions and the chance to generate revenue. Any divergence in data quality and related dossier assessment could lead to questions from the authorities in Turkey and the EU and/or by NGOs – something registrants would wish to avoid.

The 12-year rule

As a means of reducing data costs, the EU/Turkish/UK regulations all contain a so called 12-year rule.

This says that compensation payments for data last only for 12 years and they apply only to (robust) study summaries submitted as part of a registration (for example, in EU REACH Article 25(3)).

The 12-year rule applies from the moment a particular study is submitted as part of a registration dossier, regardless of when it was performed.

Additionally, if a new study is submitted as part of a dossier update, the 12-year timeline starts from the time of submission of the updated dossier, not the original submission date for the registration. Therefore, if the data was submitted by the first EU REACH registration deadline – 31 November 2010 – the compensation period ends on 31 November 2022 and can be used without charge for EU REACH registration purposes the next day. For those excited by this prospect, it is important to note that compensation only applies to data, not to work that has been done preparing a joint registration and other related costs. Consequently, letters of access will still be needed.

It is also important to understand that, as with the general data-sharing provisions, the rule does not apply across jurisdictions. This means that a registrant under Turkey KKDIK cannot benefit from a 12-year old EU REACH robust study summary without payment.

Therefore, cross jurisdictional data sharing is not subject to any EU REACH, Turkey KKDIK or UK REACH rights or obligations but works on a purely voluntary and commercial basis.

Publicly available information

For UK REACH, the form of the final registration approach in the UK will have a significant impact on data sharing. The proposed SHIPs will require registrants of substances of lesser concern to compile and submit information based on publicly available information. As the 12-year rule will not help registrants achieve this, the question of what constitutes such information arises. Much of the information on various chemical databases is publicly available but its use can be subject to limitations.

Therefore, in itself, determining the availability of free information may prove a burdensome exercise and not be the blessing many are hoping for. The UK government will need to clarify the matter and give industry practical solutions.

Conclusions

The data-sharing concept, although simple in theory, can quickly become complicated and potential registrants should not underestimate it. The added complexity of issues around cross-jurisdictional data sharing between EU REACH, Turkey KKDIK and UK REACH exacerbates the difficulty.

In summary, joint registrants of dossiers in the three jurisdictions should keep the following in mind:

- all data and costs must be shared in a "fair, transparent and non-discriminatory way" but this only applies in isolation per jurisdiction, not between them;
- assume getting the required access to the data that you need for your registration will take longer and cost more than expected. This will not always apply but as a precaution, it is better to prepare for a worst-case scenario;
- when sharing data, act according to the data sharing Regulation – even though not in force everywhere yet – and itemise every data and administrative cost and document the cost-sharing model, including a reimbursement mechanism that considers future costs of the joint submission;
- for UK REACH, the new registration approach under discussion will, if it goes ahead, require less information for certain lower concern substances. However, this does not mean that companies will be immune from data-sharing considerations and their related complexities; and
- be aware that in some cases, data holders may require individual registrants to purchase part of the data packages needed for registration directly from them. This complicates the sharing process further and potentially puts liabilities on lead registrants that they do not control.

As with all potentially complicated compliance efforts, the final piece of general advice is to start early, plan ahead, seek advice if needed and prepare for sometimes significant costs.

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](#).