

## What's new for EU REACH and the two most REACH-like regulations?

REACHLaw's Frederik Johanson assesses the ongoing evolution of EU REACH, plus implications for industry of the latest developments concerning REACH-like regulatory schemes in Turkey and the UK

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Besides EU REACH, there are several similar regulations either in development or already in force. The two that most resemble it are [Turkey KKDİK](#) (also known as Turkey REACH) and UK REACH. Unlike the regulations in the EU and Turkey, UK REACH is not yet in force and there is no legal text in existence for a scenario where the UK, currently in 'transition' having left the EU on 31 January, secures a deal with the union. The part of this article dealing with the UK therefore assumes that the main content of its statutory instrument developed for a no-deal Brexit will be adopted in the UK from 1 January 2021.

### EU REACH latest developments

In 2017, a report for Echa on the drivers, barriers, costs and benefits of updating registration dossiers showed that approximately 64% of those submitted to Echa since 2008 had never been updated. This, together with the findings of the second review of EU REACH by the European Commission, triggered discussion on the need for mandatory updates.

There are already requirements under Article 22 of EU REACH for registrants to keep their registration dossiers up to date. However, the legal wording is seen as too vague to properly motivate registrants to meet this requirement. New regulatory measures have therefore been proposed to ensure that companies update their EU REACH registration dossiers at regular intervals.

A draft implementing Regulation was published in December 2019 by the European Commission, defining fixed deadlines for updates currently listed under Article 22. Updates of a more administrative nature need to be completed within three months while more complex updates, such as those requiring the generation of new data or changes to the safety assessment, need to be completed within six or 12 months. For example, in the case of updates to a joint submission, co-registrants will have three months to update their registrations after the lead registrant has submitted its update.

A consultation on this draft implementing Regulation, which closed in January 2020, has received a large amount of feedback from industry and stakeholders, including concerns regarding the tight timelines. Currently, the European Commission is reviewing the feedback and considering potential adaptations prior to publication of a [final implementing Regulation](#) possibly later this year. This development constitutes one of the most significant updates yet to the practical implementation of EU REACH. There will be direct implications in the near future for the compliance activities of registrants who should continue to follow this development closely.

Other smaller procedural updates to EU REACH have also been implemented. The Echa registration dossier completeness check now encompasses the chemical safety report (CSR) when a new or updated registration

dossier is submitted. This is likely to slow down the process a little as the CSR check is manual.

Meanwhile, this June, a [regulation](#) was published amending Annex II of EU REACH, which governs safety data sheets (SDS). Updated requirements include changes to the quality of the content of the SDS. The legal text states that the “safety data sheet shall be written in a clear and concise manner” and that “the language used in the safety data sheet shall be simple, clear and precise, avoiding jargon, acronyms and abbreviations”. Where an SDS relates to nanoforms, this will need to be indicated in the SDS using the word “nanoform” and information on the characteristics of the nanoform particle(s) will need to be included. The requirements came into force from 1 January 2020 for new SDSs, while existing SDSs can be used until 31 December 2022.

Due to Covid-19, Echa, together with the European Commission, is considering flexibility for some companies in meeting certain deadlines. While this mostly applies to biocides, flexibility with regards to registration and authorisation for example will be considered on a case-by-case basis. Companies are instructed to contact member state competent authorities and Echa for further information with regards to their specific case.

Finally, the eighth REACH enforcement [project](#) (Ref-8) has been targeting articles sold online during 2020. The Echa Enforcement Forum developed a training project for the national enforcement coordinators last year and the enforcement project is operational this year.

### Turkey KKDİK updates

On 23 June 2017, Turkey published its REACH-like [regulation](#) on registration, evaluation, authorisation and restriction of chemicals, the KKDİK Regulation (Kimyasalların Kaydı, Değerlendirilmesi, İzni ve Kısıtlanması). Like EU REACH, the KKDİK Regulation requires companies to register all substances manufactured in Turkey or imported into Turkey with a volume above 1 ton/year before a given deadline. A key difference is that the KKDİK requires that only trained and qualified experts sign off on part of the registration work as well as SDSs.

The deadline for the current pre-registration phase is 31 December, hence most companies manufacturing substances in Turkey, or importing substances into the country, are currently occupied with KKDİK compliance. Any company that misses the pre-registration deadline for substances already on the Turkish market must stop manufacturing or importing those substances from 1 January 2021 until a joint registration is available (unless

derogations are defined by the Turkish authorities). However, according to the latest information from Turkey, late pre-registration will be allowed for substances manufactured in Turkey, or imported into the country, for the first time by a company at one t/a or more.

Some organisations have pushed for an extension to the pre-registration deadline. But according to the latest information from the Ministry of Environment and Urbanisation (MoEU), there will be no extension and companies should be ready to pre-register all their substances for Turkey by the end of this year.

By the time the registration period begins next year, the online chemical registration system KKS (Kimyasal Kayıt Sistemi) is expected to have been updated to better accommodate the process. The update will also bring the current system, launched back in 2013, more into line with current usability expectations.

One of the main registration hurdles under the KKDİK Regulation will be access to existing EU REACH data. The authorities in Turkey are aware of the need but have stated that this is an issue for companies registering substances that rely on data produced for EU REACH to solve. Acquiring legitimate access to data needed for the KKDİK joint registration will be key for successful registration and industry should tackle this without delay.

Although in its adolescence, KKDİK is gradually incorporating EU REACH restrictions into its scope. It is reasonable to expect that sooner or later most amendments to EU REACH will be adopted by KKDİK. Therefore, being aware of EU REACH regulatory developments will help companies anticipate regulatory changes to Turkey’s REACH-like regulation.

### UK REACH – work in progress

The UK left the EU on 31 January 2020, at which point an 11-month transition period began during which both sides have held talks with the aim of reaching an agreement on the terms of their future relationship, including trade. The transition period ends on 31 December 2020 and it is therefore very likely that the UK REACH regime will enter into force on 1 January 2021.

During this transition period, EU law, including REACH and CLP, continues to apply in the UK. If no agreement is reached, the UK will leave the EU regime, including REACH and CLP, by the end of the transition period and only basic WTO rules will govern trade between the EU and the UK. Northern Ireland will retain a special status whereby it will continue to be part of the EU REACH regime, at least for some years to come. As a result, all UK-held EU REACH

registrations, except those held by companies based in Northern Ireland, will become void once the transition period ends. Companies that are in the UK and supply chemical substances to the EU need therefore to take steps to ensure continued compliance with EU REACH beyond the end of the transition period. Furthermore, companies located in the EU that are reliant on chemical supplies from, or through, the UK need to evaluate alternative supply arrangements to secure their future supply of chemicals.

UK REACH is currently almost identical to EU REACH with the main difference, besides jurisdiction, to be found in compliance timelines and how substances are to be registered. All companies manufacturing chemicals in the UK or importing chemicals into the UK, including former downstream users under EU REACH, will be directly affected by UK REACH. Non-UK manufacturers or formulators may appoint a UK REACH only representative (OR) to take care of UK REACH importer obligations. The importer in the UK will be seen as a downstream user covered by the compliance of the OR.

While the current status of the final text of the UK REACH regulation is unknown, it is fair to assume that most of the text from the “no-deal” UK REACH statutory instrument will be carried forward to the final UK REACH legal text. This would be in line with the call from some chemical associations for [close alignment](#) on chemical regulation and standards. However, so far, very little practical information has been made available as to what a final UK REACH text might look like and how it might compare with the original “no-deal” statutory instrument text. The next few months should see development in this area and a tangible UK REACH legal text made available by the end of the year. All stakeholders are encouraged to follow the developments and once they are finalised, take action to comply with any requirements.

*The views expressed in this article are those of the expert author and are not necessarily shared by Chemical Watch.*

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