NEWSLETTER OCTOBER 2018

REACH Regulation. Still open matters.

A brief summary
Substances subjected to the Reach regulation:
- **15.000 full substances**
- **8.000 intermediate substances**

Number of dossiers submitted: **82.586**
Number of companies involved in the registration process: **14.000**

Restrictions adopted: **18 in total**
Authorization process:
- **191 substances** listed in the Candidate List
- **43 substances** included in Annex XIV

As said many times in the last Chemsafe Newsletters, Reach regulation application is not finished. There's a number of still open matters. Let's see them a bit more in details:

Nanomaterials

Nanotechnology has gained a great deal of public interest due to the needs and applications of nanomaterials in many areas of human activities including industry, agriculture, business, medicine and public health. Environmental exposure to nanomaterials as well as exposure to human health is inevitable as these materials are becoming part of our daily life, and as a result, their toxicity research is gaining attention.
Any toxic effects of nanomaterials will be very specific to the type of base material, size, ligands, and coatings. One of the earliest observations was that nanomaterials, also called ultrafine particles (<100 nm), showed greater toxicity than fine particulates (<2.5 um) of the same material on a mass basis.
Many scientists consider nanotechnology as the next logical step in science, integrating engineering with biology, chemistry, medicine, and physics. When the dimensions of a material become very small, its physical and chemical properties can become very different from those of the same material in bulk form. Current nanotechnology is building devices of microscopic or even molecular size, which will potentially be of benefit for medicine, environmental protection, energy, and space exploration. With our ever increasing knowledge of nanoscience and the ability to engineer new products and services, it would not be far before the entire history can be compressed inside our pockets or the system extended by specially designed molecules that mimic the living systems. In the last couple of years, the term "Nanotechnology" has been inflated and has almost become synonymous for things that are innovative and highly promising. Nanotechnology enables us to create functional materials, devices, and systems by controlling matters at the atomic and molecular scales and to exploit novel properties and phenomena.
The exposed population to nanomaterials continues to increase as their application expands. Despite obvious benefits of the power of small materials, there are open questions about how the nanoparticles used for day-to-day life may affect the environment and human health. One of the crucial issues that have to be addressed in the near future, before massive fabrication of nanomaterials, is their toxicity to humans and impact on the environment. There are considerable debates regarding how the novel properties of nanomaterials could lead to adverse biological effects, with the potential to cause toxicity. One needs to understand when nanoparticles undergo biodegradation in the cellular environment, what will the cellular responses be? For example, biodegraded nanoparticles may accumulate within cells and lead to intracellular changes such as disruption of organelle integrity or gene alternations.
Some of the crucial questions are:
1) Are nanomaterials more toxic than their non-nano counterparts?
2) Will nanoparticles transform in the environment into more toxic forms?
Before nanomaterials are allowed to be used in daily life activities, it is important for nanotoxicology research to uncover and understand how nanomaterials influence the environment so that their undesirable properties can be avoided.
The Reach regulation mentioned nano-sustances in some sections but the original text (2007) did not go into details due to lack of extensive scientific experience at that time.

During the REACH MS Committee on 26 April, Member States voted for the draft Commission Regulation amending several Annexes to REACH. The proposed amendments will clarify REACH registration requirements with regard to nanomaterials and address the knowledge gap on which substances registered under REACH are placed on the market as nanomaterials and in which quantities.
The amendments will enable both companies and authorities to know more about the characteristics of nanomaterials, how they are used, how they are handled safely, what risks they potentially pose to health and the environment and how these risks are controlled. The Draft Commission Regulation is now subject to scrutiny by the Parliament and Council for a period of three months before being adopted by the Commission. ECHA will already start to assess the need to update existing, or issue new guidance to support registrants in complying with the new requirements. As soon as the proposal is formally adopted, ECHA encourages registrants of nanoform substances to familiarize themselves with the amendments and assess what action they need to take to comply.
We are still waiting for final approval and publication on EU Official Journal. It is expected that the clarification given in the such a special regulation will drive criteria to be adopted also in other fields (and regulation) like biocides, agrochemicals etc.

Art 138 review

CSA/CSR for substances < 10 tpa

By **1 June 2019**, the Commission shall carry out a review to assess whether or not to extend the application of the obligation to perform a **CSA** (Chemical Safety Assessment) and to document it in a **CSR** (Chemical Safety Report) to substances not covered by this obligation because they are not subject to registration or subject to registration but manufactured or imported in quantities of **less than 10 tonnes per year**. However, for substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction, category 1 or 2, in accordance with Directive 67/548/EEC, the review shall be carried out by 1 June 2014. When carrying out the review the Commission shall take into account all relevant factors, including:

1. the costs for manufacturers and importers of drawing up the chemical safety reports;

2. the distribution of costs between actors in the supply chain and the downstream user;

3. the benefits for human health and the environment.

On the basis of these reviews, the Commission may, if appropriate, present legislative proposals to extend this obligation.

POLIMERS

The Commission may present legislative proposals as soon as a practicable and cost-efficient way of selecting polymers for registration on the basis of **sound technical and valid scientific criteria can be established** and after publishing a report on the following:

1. the risks posed by polymers in comparison with other substances;

2. the need, if any, to register certain types of polymer, taking account of competitiveness and innovation on the one hand and the protection of human health and the environment on the other.

FIVE YEARS REPORT by THE COMMISSION, possible revision of information requested for 1-10 tpa substances

The report, referred to in Article 117(4), on the experience acquired with the operation of this Regulation shall include a review of the requirements relating to registration of substances manufactured or imported only in quantities starting at one ton but less than 10 tons per year per manufacturer or importer. On the basis of that review, the Commission may present legislative proposals **to modify** the information requirements for substances manufactured or imported in quantities of one ton or more up to 10 tons per year per manufacturer or importer, taking into account the latest developments, for example in relation to alternative testing and (quantitative) structure-activity relationships ((Q)SARs).

SUBSTANCES IN ARTICLES

By 1 June 2019, the Commission shall carry out a review to assess whether or not to extend the scope of Article 33 (Duty to communicate information on substances in articles) to cover other dangerous substances, taking into account the practical experience in implementing that article. On the basis of that review, the Commission may, if appropriate, present legislative proposals to extend that obligation.

TESTING REQUIREMENTS

In accordance with the objective of promoting **non-animal testing** and the replacement, reduction or refinement of animal testing (**3R's Principle**) required under this Regulation, the Commission shall review the testing requirements of Section 8.7 of Annex VIII by 1 June 2019. On the basis of this review, while ensuring a high level of protection of health and the environment, the Commission may propose an amendment in accordance with the procedure referred to in Article 133(4).

BREXIT, an overview

Brexit milestones and expected timelines

23 June 2016 : the UK voted to leave the EU

29 March 2017 : UK's notification to leave the EU sent; 2 year negotiation period started

November 2018: Brexit negotiations to be finilised. EU Council to agree UK's EU Withdrawal Agreement and political declaration on future relationship framewor

By March 2019: EU and British Parliaments to ratify Withdrawal Agreement

29 March 2019: UK leaves the EU at 11pm (UK time)

30 March 2019: Transition period starts (if ultimately agreed) – UK remains in EU REACH

31 December 2020: Transition period ends. EU and UK to start a new economic and political relationship.

Practical considerations to ensure continued validity of existing REACH registrations in the EU

1. It is important to identify substances/mixtures impacted by Brexit and your company's role in the supply chain;

2. If a substance is manufactured by a UK legal entity as well as by an EU legal entity of the same company and both hold valid registrations, the EU entity could act as importer of the UK product. In this case, the EU legal entity's existing registration would need to be updated to indicate that some volume is imported and reflect the additional volume in the dossier. Please be mindful that higher tonnage bands may be reached and further testing required as a consequence. An OR would not need to be appointed in this case and transfer of registrations would not be required. Such a scenario however would not be available to companies who have sites in the UK only.

3. The scenario of transferring of registrations is already envisaged under specific circumstances that are not necessarily related to Brexit, e.g. for changing OR, partial total asset transfer, mergers, spin-offs, splits (please see ECHA guidance for further information.

4. UK manufacturers and importers will need to maintain their registrations in the UK to be able to continue to manufacture/import in the UK until REACH stops to apply to the UK.

5. The ECHA website currently states that a possibility to transfer existing registrations "immediately" before the withdrawal date will be put in place in the case of registrations hold by UK manufacturers and practical steps will be clarified in due course. As part of your contingency planning, please assume that in a worst case scenario REACH IT UK accounts may have to be deactivated from the date REACH stops applying in the UK, so transfer of registrations should be completed before the UK leaves the EU REACH regime. Companies are advised to follow ECHA news alerts as new information will emerge in due course.

6. ECHA is currently advising to set up a contractual agreement to appoint an OR, which contains a suspensive conditional clause stipulating that the appointment takes effect on the date when the UK withdrawal from the EU takes effect.

7. In the case of UK importer registrations according to ECHA "it is not possible to transfer a registration of a UK importer to a newly appointed Only Representative. In this case, non-EU manufacturers may appoint an EU-based Only Representative of the substance. However, the EU-based Only Representative would then need to submit a new registration for the substance". No information is available at present on whether UK traders will be able to transfer individual registrations to EU legal entities that would act as importers post Brexit. This point needs clarification before the UK leaves REACH.

8. If not already done, please review your contractual conditions of SIEF/consortia agreements in order to prepare for the potential future transfer of dossier rights to an EU subsidiary or representatives so they can take over the EU registration. The CEFIC SIEF agreement template, for example, allows for the right to transfer company's rights without the consent from the SIEF but with an obligation to notify the Lead registrant of the assignment. This is the case of transfer of rights to a company's affiliate (please check definition of affiliate), or to a successor/third party in the event of a sale, merger of the business relevant to substance. In other cases you may have to check with the lead registrant before the transfer can take place.

9. Registrations that are transferred in REACH IT usually require a subsequent dossier update to include the legal entity's details where registrations are transferred to. Our current assumption is that EU legal entities would then need to complete an update of the dossier for all the registrations it receives from the UK.

10. In the case of mixtures, UK formulators may need to track raw materials imported from the EU to confirm future "re-import" to EU status (REACH registration exemption).

NOTE : UK based companies should also bear in mind that under a "UK out of REACH scenario" manufacturing and import will be subject to UK legislation in future

Considerations for EU-based companies with UK supply and trade relationship

Post Brexit, imports into the EU will continue to be subject to REACH. Once the UK leaves the EU REACH regime, EU27/EEA businesses relying on REACH registrations from UK suppliers will become **importers** under EU REACH and may therefore be subject to registration requirements, unless covered by EU-based ORs appointed from UK companies.

1. Check the list of your actual suppliers and approved suppliers of your substances and mixtures;

2. Identify substances and mixtures that are sourced from UK suppliers;

3. Please bear in mind that registrations are per legal entity, not per company;

4. Check whether UK suppliers plan to appoint an EU legal entity that will act as EU based OR post Brexit to ensure continued supply in the EU or if they can use a legal entity that has registered in the EU27/EAA countries and that can become EU importer;

5. If you are yourself already importing a substance and at the same time you have a registration under your company name, you can continue to be supplied from the UK source as you can be covered by your own registration. Your dossier would need to be updated in due course once the UK leaves REACH to indicate that some volume is imported and reflect the additional volume in the dossier. Please be mindful that higher tonnage bands may be reached and further testing required as a consequence.

6. If there are other suppliers in the EU-27/EEA countries, or other non-EU suppliers covered by an OR in the EU/EEA, they may be able to support you. If they are not approved yet by your company, you may have to initiate the process of approval of a new supplier, which may be rather cumbersome and time consuming in some cases (finding another supplier for a catalyst as an example will be more cumbersome than finding a replacement for a solvent like acetone).

7. If the other options are not available or you are not sure, you have to reflect on whether registering substances on their own or in mixtures as EU importer post Brexit may be a way forward (if import into the EU reaches 1 ton or more

per year). A registration as importer would allow to import from different non-EU sources if the substance is the same and if allowed by your quality system and your requirements for approving new suppliers.

8. Please remember that in the case of mixtures, an EU27 supplier of a mixture may also be dependent from a UK supplier for a substance or for a mixture in a mixture.

9. If your supplier of a mixture can confirm you that he is not using mixtures in mixtures and that all his suppliers of the substances used for the mixture are situated in the EU27 then no problems are expected. In all other cases there may be a risk of potential supply chain disruption if no action is taken in future.

NOTE : If your company sells chemical products in the UK, please take into consideration that imports into the UK from the EU will be subject to UK legislation in future

Rumors on possible scenario for **UK companies** if no deal will be in place with EU

- Existing UK registrations will be grandfathered
    - Validate their existing registration within 60 days
    - 2 years to provide the UK authorities with the full data package (March 2021)
- Former UK DU users (now UK Importers) will be given 180 days (Sept. 2019) to submit 'basic data' (not yet defined); transitional light-touch notification process
    - "UK pre-registration"
    - Eventually a UK registration will be required
- New chemicals being placed on the EEA and UK markets would now have to make 2 separate registrations. Data package would be the same for both though.

Member States to evaluate 96 substances in 2019-2021

ECHA proposes 96 substances for evaluation by Member States under the Community Rolling Action Plan (CoRAP) for 2019-2021. If you have registered any of these substances, you should coordinate actions with your co-registrants and contact the evaluating authority.

Helsinki, 10 October 2018 – 28 substances are planned to be evaluated in 2019, while 43 are currently listed for evaluation in 2020 and 25 for 2021. Registrants of a listed substance should start coordinating their actions and contact the evaluating Member State authority. Downstream users of a listed substance should review the information they have available and share it with the registrants.

In particular, it is important that the use and exposure scenarios as well as the exposure estimations are up to date and clearly documented within the registrants' chemical safety reports. For the 28 substances planned to be evaluated in 2019, the relevant dossier updates should be made before March 2019.

The draft plan includes the non-confidential substance names, the CAS and EC numbers, the tentative year of evaluation, the contact details of the proposed evaluating Member State, and an indication of the initial area of concern. This year, the groups of structurally similar substances that could potentially be evaluated together are also marked in the plan.

The draft plan has been prepared together with the Member States, taking into account risk-based criteria for selecting the substances. At this draft stage, some changes to the plan are still possible. The final updated plan will be adopted in March 2019.

Registrants will soon be able to get an overview of substance-specific activities (including substance evaluation) using the updated Public Activities Coordination Tool (**PACT**). It offers companies one entry point to information about substances that are on an authority's radar and which are potentially going for regulatory risk management. ECHA's Member State Committee will discuss the draft CoRAP this week and will prepare an opinion on the draft plan in February 2019. Based on the opinion, ECHA will adopt and publish the CoRAP update for 2019-2021 in March 2019. From the date of publication onwards, the Member States have one year to prepare a draft decision requesting further information from the respective registrants to clarify potential concerns identified during evaluation.

Two restriction dossiers submitted

On 5 October, **Italy** submitted a proposal to restrict **N,N-dimethylformamide** (EC 200-679-5, CAS 68-12-2) and ECHA submitted a proposal to restrict **five soluble cobalt salts**. ECHA's scientific committees are currently performing a conformity check on the dossiers. The dossiers will be published on ECHA's website within two weeks to increase transparency and to help stakeholders prepare for the six month public consultations on the dossiers, which are expected to be launched in mid-December if the dossiers pass conformity.

Chromates authorization applications

A group of NGOs is calling on EU member states to vote against applications to authorize various uses of chromates or back shortening the review period. This should be a maximum of four years, they said, to allow for the availability of alternatives to be "properly assessed" as soon as possible based on REACH Article 61(2b). Members at the REACH Committee meeting on 25 October will discuss whether to endorse separate applications by Hansgrohe, Lanxess Deutschland and REACHLaw (acting as an only representative) for use of chromium trioxide in decorative plating. In a letter ahead of the meeting, NGOs including ClientEarth, the European Environmental Bureau and the Health and Environment Alliance (HEAL) said that societal benefits of the uses, especially decorative ones, are "highly questionable". And alternatives are "clearly available" on the market as alternative providers have stated. According to the manifesto of the Alliance of PVD Providers submitted to the REACH Committee last September, they said, alternatives for decorative plating already exist and have been "*economically and technically feasible for at least the last two years*".

Functional chrome plating with decorative character is an industrial process widely used in applications including:
- automotive;
- cosmetics;
- furniture and household appliances.
- Wool

Member states will also discuss and possibly vote on an application by Ilario Ormezzano Srl for use of sodium dichromate:
- in repackaging for supply as a mordant in the dyeing of wool as sliver and/or yarn with dark colors in industrial settings;
- as a mordant in the dyeing of wool as sliver and/or yarn with dark colors in industrial settings.

The NGOs said that as shown last year during the discussion of a similar application for authorization submitted by Gruppo Colle, "*safer alternatives made by Huntsman and Dystar are available on the market*".
The applications "do not demonstrate that alternatives are unavailable", and therefore, they said, do not comply with authorization requirements as established by REACH.
The group repeated calls for ECHA's Socio-economic Analysis Committee (SEAC) assessment of alternatives "*to be improved urgently in order to ensure a level playing field for companies providing safer alternatives*".
Granting these authorizations, they added, "will fuel a growing problem" of toxic chemical exposure – the leading cause of occupational cancers. "Eighty-five per cent of cases come from exposure to only ten chemical agents, including chromium. With more than 100,000 deaths per year, occupational cancers are the leading cause of death in the EU."

Chemsafe attendance as speakers to next events

A. Conto:, invited speaker
Endocrine Disruptors
CONFERENCE: Detergent Product in the light of Polish and EU regulation – Future challenges
Warsaw, Poland, November 7, 2018

F. Fasano, Invited speaker
Grouping for in-situ biocides? Regulatory considerations/practical issues
Biocide Europe 2018, Vienna, November 27-28, 2018

A. Conto, Invited speaker
Endocrine Disrupting Substances: a new challenge for companies in the frame of EU Reach and other Regulations
EU-ASIA Chemical Regulation workshop, Dublin, December 6, 2018

Latest events

CHCS Training "EU CLP (GHS) Classification for Supply - Mixtures" (Module 18)
31 October 2018, Chemical Hazards Communication Society (CHCS), London, United Kingdom

CHCS Training "EU CLP (GHS) Labeling for Supply" (Module 19)
1 November 2018, Chemical Hazards Communication Society (CHCS), London, United Kingdom

CHCS Training "Advanced Preparation of Safety Data Sheets" (Module 15)
6 November 2018, Chemical Hazards Communication Society (CHCS), London, United Kingdom

CHCS Training "Risk Characterisation and the Chemical Safety Report" (Module 53)
12 December 2018, Chemical Hazards Communication Society (CHCS), Manchester, United Kingdom

CHCS Training "The Extended SDS - Understanding Exposure Scenarios" (Module 20)
13 December 2018, Chemical Hazards Communication Society (CHCS), Manchester, United Kingdom

End of the Newsletter