NEWSLETTER MAY-JUNE 2019

20 new testing proposals consultations open

ECHA has launched 20 new public consultations on testing proposals. The deadline for comments is **11 July 2019**.There are currently 36 open public consultations on testing proposals.

New intention to identify a substance of very high concern

A new intention has been received for **diisohexyl phthalate** (EC 276-090-2, CAS 71850-09-4).

Authorization granted for uses of bis(2-methoxyethyl) ether (diglyme)

The European Commission has granted authorization for **bis(2-methoxyethyl) ether (diglyme)** (EC n. 203-924-4, CAS n. 111-96-6) for one use to Roche Diagnostics GmbH and one use to Life Technologies AS with a review period expiring on **22 August 2029**.

Key vote on REACH registration Implementing Regulation early July

Clarity on SIEF provisions expected, one year after legal obligation expired

A European Commission Draft Implementing Regulation that aims to clarify the state of play for REACH registrants following the final deadline, will face a key vote in early July.
The REACH committee of EU member states is due to vote at its 9 July meeting on a draft, that, according to the Commission, will deliver "concrete conclusions" and "ensure equal treatment between phase-in and non-phase-in substances after the transitional period" that ended on last year in June 1st.

In order to achieve this goal, the Commission draft sets out four main courses of action.

- setting a cut-off date of December 31, 2019 for tonnage calculation, based on the last three consecutive years;
- keeping registration requirements for certain low volume phase-in substances (those meeting Article 12(1)b) "untouched";
- clarifying that data-sharing obligations for registrants of phase-in substances continued after 1 June 2018;
- aligning the inquiry process and data-sharing dispute procedures for phase-in and non-phase-in substances after the final registration deadline.

The Implementing Regulation would also address substance information exchange FORA (SIEFs), which ceased to exist legally after last year's final REACH deadline. Industry has sought further guidance on the issue.
The Regulation will make it clear that the data-sharing obligations of registrants "should be reinforced and registrants should be encouraged to use similar informal communication platforms to enable them to meet their continuing registration and data-sharing obligations", the Commission said.

The Commission is also considering drafting another Implementing Regulation to boost the frequency of updating registration dossiers, amid concerns over high levels of non-compliance in REACH dossiers.

Some EU member states and Norway have called for an implementing Act to clarify Article 22 of REACH, to ensure companies regularly review and update dossiers. The Commission's second REACH Review called for actions to encourage this. Last September ECHA announced a major revamp of compliance processes.

In the meantime, last month CEFIC, ECHA and the Commission have made a commitment to take more action on REACH dossier non-compliance, following a widely publicized NGO report on data gaps. A joint action plan is due by the end of June.

ECHA's committees conclude on one restriction and 10 harmonized classification and labeling opinions

The Committee for Risk Assessment (RAC) adopted its opinion on the restriction proposal on granules and mulches used as infill material in synthetic turf pitches or in loose forms on playgrounds. The Committee for Socio-economic Analysis (SEAC) agreed its draft opinion on the same proposal.

RAC and SEAC supported the restriction proposal by the Netherlands to not place the granules and mulches in question on the market if the sum of the listed polycyclic aromatic hydrocarbons (PAHs) in the materials is more than 20 mg/kg. A public consultation on the SEAC opinion will begin soon and the committee is expected to adopt an opinion in its September meeting.

RAC also adopted 10 opinions for harmonized classification and labeling, including opinions on seven active substances used in biocidal products and/or plant protection products and three in industrial chemicals.

RAC and SEAC agreed on eight draft opinions on uses of chromium trioxide. Furthermore, RAC and SEAC discussed key issues in 11 applications for authorization, which were received by ECHA in February 2019. More information about the opinions is available on the ECHA web site.

Changes to the inquiry process

ECHA has re-organized the processing of inquiries. Inquirers for most already registered or successfully inquired substances will now be quickly directed to the relevant **Co-Registrants** page in REACH-IT, based on the numerical identifiers they provide.
For substances with ambiguous identifiers or where registrants or potential registrants do not exist, ECHA verifies the substance identity information.
Nevertheless, previous and potential registrants are still responsible for discussing substance sameness and deciding whether their substances can be registered together.

Opinion on substances in tattoo inks and permanent make up now available

The final opinion of the Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) to restrict substances in tattoo inks and permanent make up (EC -, CAS -) is now available on ECHA's website.

Controlling exposure to harmful chemicals at work

Since January 2019, ECHA has been supporting the European Commission in establishing occupational exposure limits (OEL) for selected chemicals to improve the protection of workers' health and safety. They explain what occupational exposure limits are, how the EU implements them through legislation, and what role ECHA has in their preparation.

An occupational exposure limit (OEL) is a regulatory value setting a safe concentration level of a chemical substance in the air of a workplace. They are set at EU and national level by regulatory authorities and help employers protect the health of workers from possible risks when using chemicals at work.

The Commission and ECHA agreed in January 2019 that the Agency will start providing recommendations for priority OELs under occupational safety and health (OSH) legislation. The agreement followed a pilot project run from 2017 to 2018 concerning five carcinogenic substances. ECHA expects to carry out OEL assessments for four to five substances per year. The scientific evaluations carried out by ECHA underpin the legislative proposal for EU occupational exposure limits for specific chemicals or substances, whether they are indicative or binding. Having a sound scientific basis is indispensable to any occupational safety and health action, particularly in relation to dangerous chemicals.

OSH – managing occupational risk

OSH legislation aims to protect Europeans at work, regardless of whether they are exposed to noise, bad workplace ergonomics, psychological stress or chemicals. Taking action on harmful chemicals forms a significant part of OSH policy in the EU and is a priority area for worker protection.

OSH requires employers to carry out a wider workplace risk assessment, while REACH requires them to implement a chemical-specific risk assessment. Under REACH, manufacturers and importers have to communicate safe use information for chemical substances down the supply chain in safety data sheets and exposure scenarios. OSH, on the other hand, covers the wider use of chemical agents and their emissions, also considering the waste stage. REACH and OSH are mutually exclusive pieces of legislation that operate without prejudice to each other, meaning that companies might have obligations under both and need to comply with each of them. Together, the two sets of legislation provide a high level of worker protection.

RAC to prepare recommendations to the Commission

The Commission decides the substances for which OELs are needed. "Concerning our work on chemicals, decisions on priority substances are supported by discussions in the tripartite Working Party on Chemicals. This working group comprises experts from Member States together with representatives of employer and worker organisations," Mr Morris tells.

When the Commission has assigned a substance for ECHA to assess, the Agency will prepare a scientific report for RAC based on the available scientific data and any relevant information collected through a call for evidence. The report will then be open for a public consultation, after which RAC will discuss and then adopt its opinion on the report and send it to the Commission. "The decision for setting an occupational exposure limit is always based on extensive consultations, including employers, workers and Member State authorities. Full support and ownership of social partners and governments is essential for ensuring effective implementation and enforcement of the limit values," Mr Morris points out.

Indicative or binding?

OELs can either be indicative or binding. Indicative OELs are adopted directly by the Commission. For binding OELs, the Commission adopts a legislative proposal based on RAC's opinion and discussion between the Member State authorities and social partners. The proposal is then sent to the Council and the European Parliament for the final adoption.

Indicative occupational exposure limits are health-based limits established for substances for which it is possible to set a level where there should be no risk to workers' health. This is typically the case under the Chemical Agents Directive. Member States must establish a corresponding national occupational exposure limit value in accordance with national legislation and practice, taking the EU value into account.

In some cases, it may not be scientifically possible to identify a safe level of exposure. This is typically the situation for substances under the Carcinogens and Mutagens Directive where it may not yet be realistically feasible to achieve an identified safe level due to technical considerations in some or all sectors of employment. It will then be necessary to set a binding occupational exposure limit to provide a minimum level of protection for all workers in the EU. In such cases, Member States must set a corresponding binding limit that does not exceed the EU value.

BIOCIDES

Latest news

China's National Health Commission has published a draft positive list of 94 biocidal active ingredients. If approved, only the substances listed can be used as antibacterial and bacteriostatic agents in liquid products intended for direct contact with skin, oral or vaginal mucous membranes. The list is open for public comment until 25 May.

Another public consultation is currently open in South Korea, on the Ministry of Environment's proposed criteria for identifying biocide substances as technically equivalent, or biocide products as similar, under the K-BPR. Comments are accepted until 22 May.

In the US, the EPA has published its proposed draft guidelines for the efficacy testing of some tick and flea products. It has scheduled a meeting on these for 11 June and will accept written comments, to be discussed at this meeting, until 17 May.

Guidance on biocidal product family approach, draft available

The May 3rd the DRAFT note for guidance about implementing the concept of biocidal product family has been published for the first time. In this draft note is explained how the concept of biocidal product family may change from the past. The concept of similarity of composition within varied composition was clarified introducing the concepts of the backbone composition and the grouping of co-formulants.

A decision tree reporting the criteria to assess similarity of uses was developed Similar level of risk and efficacy goes through the definition of the core assessment (one for a significant portion of the family) which represents the worst case of risk assessment and of efficacy for every use. Some extension of the core may exceptionally be possible as the presence of some subset. It seems that the guidance will apply in the 2021. This guidance is still under discussion, and may be approved late 2019 The May 3rd the DRAFT note for guidance about implementing the concept of biocidal product family has been published for the first time. In this draft note is explained how the concept of biocidal product family may change from the past.

Biocides industry warns of BPR's '*silent effect*' on market

Costs too high and reviews take too long *(from Chemical Watch)*

Biocides stakeholders are calling for a rethink of the biocidal products Regulation's (BPR) authorization processes, claiming concerns that the law's costs and complexity are pushing biocidal products off the European market.

Representatives from biocides manufacturers, ECHA and consultancies reflected on the five and a half years since the BPR entered into effect, at the Chemical Watch Biocides Symposium in Rome last week.

While the experts agreed that the law has introduced structure and harmonization to the regulation of biocides in Europe, concerns over the BPR's impact on industry overshadowed its achievements.

"*Industry and regulators are struggling under the weight of this regulation*," said Ian Watt from Dupont Microbial Control. "*The costs are too high for the size of the market and the active substances and products reviews take too long*."

This is having a "*silent effect*" on the number and variety of biocides on the EU market.

Businesses are put off from supporting biocidal active substances through a BPR authorization due to the cost and resources required, according to some opinion.

It takes at least five years to bring a new active substance to market, it was said. Coupled with a minimum cost of €750,000, the return on investment comes too late for many businesses.

Reckitt Benckiser decided against supporting carbendazim for use in vermicides (product-type 16) for this very reason. The substance – which is classified as reprotoxic and mutagenic – is used as a fungicide in agriculture. But it has also been used to control earthworms on golf greens, cricket squares and other grounds that are affected by uneven soil.

However, the company estimated the chemical's retail value for this use at less than £250,000 per year. "How do you justify supporting a substance like this?", "That's not a profit."

Without carbendazim there are no longer any biocidal earthworm control products on the EU market, he said. "This is one example of a niche product that has disappeared from the market under the BPR."

While the law appears to be discouraging companies from investing in substance authorization, so far 95% of biocidal active substances that have gone through the process have been approved, said Erik van de Plassche, chair of ECHA's Biocidal Products Committee (BPC).

Mr. Van de Plassche asked whether this means that substance assessments could be less rigorous. "There must be a possibility for reducing complexity and doing things in a simpler and more balanced way," he told delegates.

He added that regulators and industry should focus on finishing the biocides review program to free up resources to work on "actually achieving the objectives of the Regulation".

Currently, stakeholders are forced to cope with all of the law's authorization processes at the same time. This includes the biocides review program, active substance renewals, as well as the authorization of biocidal products at the national and EU level.

Mr. Watt agreed on the need to bring balance to the regulatory system, pointing to overly conservative risk assessments as a guilty behind the cost and time involved in the processes.

"Appropriate protection goals are important…….but can we take a step back and ask whether it all makes good sense?"

Interesting arguments to be developed in other occasions.

Chemsafe events and participation

Chemical Watch Conference on biocides (Rome), May 2019
Francesca Fasano had a talk during the last "*Biocide Symposium*" in Rome.
She spoke in session 5: Biocides in the supply chain, the talk title was: ***Comparison use of biocides or not – end of supply chain case study***. The idea behind the talk was that regulatory people and CA, are focused on setting up dossier that fulfill all the regulatory requirements, but they forgot the final aim of the authorization process which is to make available the product on the market for consumers. She made a pilot survey in order to understand which is consumer perception about the differences between detergent and disinfectants, between PT2 and PT4 and between different applications of PT2. The outcome of the survey was that Italian consumers have no idea of the differences between PT2 and PT4 and between different PT2 applications. The final hypothesis was that if we do not find a way to make claims easier to understand for consumer the risk is to have products correctly authorized but that may be completely misused by consumer. Such an interesting survey needs to be implemented at EU level…. We will try to do our best to enlarge such evaluation at least at European level.

Chemsafe attendance to the AFI Symposium, Rimini, Italy, June 2019
An important attendance of Chemsafe people occurred this year during the 59° Annual AFI Symposium in Rimini, ITALY.
A workshop on June Wednesday 5, morning was organized by Chemsafe. ***"Le nuove frontiere regolatorie dei Dispositivi Medici: come affrontarle in un contesto Europeo ed Internazionale"***. The workshop was aimed to give a overview on EU Regulation on Medical Devices from a scientific/regulatory perspective and having a glance at the USA and Chinese regulation respectively. International guests were hosted by Chemsafe during workshop. Chemsafe people involved were Mr. Paolo Rossi as Chairman, Alessandra Iavello and Tiziana Nardo of Chemsafe Medical Device Business Unit, as speakers. The workshop was attended by around 50 people.

The following day, our Managing Director Antonio Conto, had a speech in the GMP session regarding the quality of API (Active Principle Ingredients) entitled "***Toxicology evaluation in the quality of API***". The session was attended by around 150 persons. Many interesting questions were posed by the audience.

On June 7, the Conference session dedicated to the Medical Devices was chaired by Alessandra Iavello, Head of the Chemsafe Medical Device Business Unit. The session was attended by around 200 persons with interesting round table at the end and many questions regarding the future new Regulation implementation starting from May 26, 2020.

Chemical Watch Expo 2019, Global Chemical regulation, Bruxelles June 12, 13
Chemsafe attended such event with its booth and a talk entitled ***"THE EDC criteria and impact on different regulations (REACH, BPR, AGRO and DRUGS)"***. Francesca Fasano replaced Antonio Conto due to a sudden impossibility to attend.

CHEMSAFE attendance 2019

Milan (ITALY) February 26-2
Regulatory Toxicology, IKN workshop
Teachers: Antonio Conto (Chemsafe), Marco Rodda (Chemsafe)

Baltimore (USA), March 10-14
USA SOT (Society of Toxicology), Exhibition booth + two poster presentations, 4 people

London (USA), March 20-21
BCPA PESTEX, 1 people attending

Nurnberg (GE), May 21-23
MEDTECHLive, Exhibition booth + 3 people

Basel (CH), May 7-9
VITAFOODS 2019, Exhibition booth + oral presentation, 4 people

Rimini (ITALY) June 5-7
AFI 59° SIMPOSYUM, Exhibition booth + MD workshop organization, 6 people + talk in the Quality of API session

Bruxelles, June 12-13
CHEMICAL WATCH EXPO: GLOBAL CHEMICAL REGULATION, Exhibition booth + oral presentation, 2 people

Helsinki (FI), September 8-11
EUROTOX 2019, Exhibition booth + two poster presentations, 3 people

End of the newsletter