EU Monitoring Report
14–20 August 2020

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EUROPEAN CHEMICALS AGENCY

CLP

- **CLH intentions Potassium chlorate and other substances**

  Source: European Chemicals Agency

The following three substances were added to or updated in the Registry of intentions for classification and labelling harmonisation (CLH):

- **Tert-butyl 2-ethylperoxyhexanoate** is known for widespread applications, such as a general antifouling agent, sometimes applied to paint, but also in general uses related to the building or construction process for buildings or boats (includes activities such as plumbing and electrical work, bricklaying, etc), an additive for products, plastics, and other manufacturing processes.

- **Potassium chlorate** knows widespread use, including as a disinfectant.

- **2,3-epoxypropyl neodecanoate**, which is used in coating products, adhesives and sealants, in the areas of building and construction work ; and for the manufacture of plastics and other chemicals.

The registry of classification and labelling (CLH) intentions until outcome lists the intentions and proposals received by ECHA for a new or revised harmonised classification and labelling of a substance. The proposals are submitted by Member State competent authorities, manufacturers, importers or downstream users.

Interested parties can follow the progress of a proposal through the CLH process, from the notification of the intention to the adoption of the opinion of the Committee for Risk Assessment (RAC). The advance notice enables interested parties to plan and prepare for commenting later on.

More information:
https://echa.europa.eu/fr/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e18526a376
https://echa.europa.eu/nl/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e184309041
https://echa.europa.eu/nl/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e1835aa465

EUROPEAN COMMISSION

CLP

- **EU Commission publishes update of Annex VI of CLP Regulation**

  Source: European Commission

The EU Commission published on 11 August 2020 an update of Annex VI to the EU Regulation on the classification, labelling and packaging of substances and mixtures (EC) No 1272/2008.

The update is contained in Commission Delegated Regulation (EU) 2020/1182 of 19 May 2020 and amends, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI. The updated substances and regulatory information regarding their classification and labelling can be viewed by following the link below.

More information:
https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:32020R1182

POLYMERS

- **Downstream chemical users' lobby group comments on polymer subgroup**

  Source: European Commission

The Downstream Users of Chemicals Coordination Group (DUCC) published comments on the mandate for the new CARACAL sub-group on the registration of polymers under REACH. DUCC is a joint platform representing eleven industry sectors that use chemicals to formulate mixtures (as finished or intermediary products) for professional and industrial users, as well as for consumers (see box below for more information). Most of these sectors are downstream users of polymers and as such rely on their suppliers for a more detailed understanding of the properties of the polymers they use.

However, some companies in DUCC sectors manufacture or import polymers (made from registered monomers and reactants); many of these companies would be placed in the role of registrant for the first time.

Furthermore, it should also be emphasised that some DUCC member companies customise polymers to the requirements of their mixtures and applications, which results in further new polymers that are currently exempt from REACH and not covered by their upstream suppliers.

A potential need to register every one of such 'customised polymers' will completely change the situation for these sectors, as it would shift their position from mere downstream users of substances to manufacturers of polymers.

Furthermore the registration of polymers under REACH will lead to other impacts in the downstream supply chain, which should be taken into account in these discussions. For a more detailed consideration of the downstream user perspective please see the annex to this document.

Relevant comments were also published by the following groups:

- FEICA, the Association of the European Adhesive & Sealant Industry
- European Centre for Ecotoxicology and toxicology of chemicals
- International Association for Soaps, Detergents and Maintenance Products

More information:
https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/d6fe593a-a5de-4c82-8acc-9af1b0de89f1/details

EXPOSURE TO CHEMICALS

- **CARACAL discusses regulation of exposure risk to combinations of chemicals**

  Source: European Commission

KEMI (Sweden) and the Netherlands hosted on 5 and 6 March 2020 a workshop in Leiden, that was aimed at building a common understanding of possible pragmatic approaches to address the risk from combined exposure to chemicals.

The comments received by competent authorities and other involved stakeholder organisations were compiled in a synthesis paper, which in return received a new round of comments by the competent authorities but also feedback from European environmental NGOs and other stakeholder organisations.

A second workshop will take place on 27–28 October 2020, to follow up on the first discussions, named “2nd Workshop on a pragmatic approach to address the risk from combined exposure to nonintentional mixtures of chemicals – REACH as an example”. The link below refers to the synthesis paper including comments made by the Competent Authority of Germany.

More information:
https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/cfc3f819-f398-48b2-9c42-52739542b5e0/details

BIOCIDES

- **Europe: No push from disinfectants industry for further legal exemptions**

  Source: Chemical Watch

Europe’s cleaning products industry is showing little appetite for acquiring further legal exemptions for disinfectants, amid confidence that demand for the products can be met.

Most legal exemptions for disinfectants are edging closer to their expiry date. The derogations are made under a clause in Article 55 of the EU biocidal products Regulation (BPR) and last for a maximum of 180 days, but can be extended if needed.

European soaps and detergents trade body, Aise, reports remaining bottlenecks on some ingredients and packaging materials. "However, I think most have more or less adapted to the situation," according to the organisation's director-general, Susanne Zänker.

Aise itself is not pressing for an extension to the legal exemptions for disinfectants. This is up to individual companies and national associations, which have a better idea of the local supply and demand situation, Ms Zänker said.

But national trade bodies are not keen on another round of derogations, which allow rogue manufacturers easier access to the market.

The German Association of Hygiene and Surface Protection Industries (IHO) said it is advocating against further legal exemptions because they hinder the German competent authority, Baua, from properly regulating disinfectants.

Members of the IHO are concerned that the exemptions "are causing products for disinfection to spread in the German market which do not fully meet the requirements for safe products," the trade body said, referring to unsafe packaging, added fragrances and other chemicals that can influence effectiveness.

"The proof of efficacy according to European standards, which is available for established products on the market, is also often missing," the IHO said.

And IHO members have expanded their production capacities enough to meet demand themselves, the organisation said. They now "see themselves in a position to produce around 100,000 tonnes of disinfectant per year", compared to a capacity of 20,000 tonnes a year before the pandemic.

Denmark, meanwhile, was among the first European member states to extend its Article 55 derogation. Its environment ministry announced on 14 August that the new deadline for selling – to consumers – unregistered hand disinfectants with ethanol or a mixture of ethanol and propan-2-ol, is 31 December.

The Danish Association of Cosmetics and Detergents said this decision was the result of a recent increase in the number of Covid-19 infected persons in Denmark, which could lead to greater demand for disinfectants.

"By extending the sell-out period the ministry is seeking to meet this demand and, at the same time, avoid that effective hand disinfectants will have to be destroyed," said the association's managing director, Helle Fabiansen.

But Ms Fabiansen said the trade body "will not work actively for a further extension of these deadlines".

"Our members are at the moment able to supply the Danish market and the number of (BPR) Article 95 registered (substance) suppliers are now at a level where they can meet the demand for raw materials," she said.

Planning ahead

Meanwhile, the European Commission has asked member states to provide forecasts on their needs for disinfectants in the coming months. The feedback is coming in very slowly, because of August holidays on the continent, according to Ms Zänker.

And Aise is advocating for making disinfectants a part of the EU4Health programme, which aims to organise reserves or stockpiling of essential goods.

"Along with greater predictability for industry in case of second (and other) waves, we are working on ensuring improved planning for the fall," the trade body said.

More information (subscription needed):
https://chemicalwatch.com/145410/europe-no-push-from-disinfectants-industry-for-further-legal-exemptions

ENERGY

- **In focus: A new generation of EU energy labels**

  Source: European Commission

By using less energy to perform the same task, we can make significant energy savings and reduce waste. This is the basic principle of energy efficiency, and it is one of the most essential ways for the EU to move away from fossil fuels and achieve carbon neutrality by 2050.

Improving energy efficiency will benefit society by reducing emissions and our dependency on energy imports, while also lowering energy costs for citizens and businesses across the EU.

More information:
https://ec.europa.eu/info/news/focus-new-generation-eu-energy-labels-2020-aug-13_en

EUROPEAN PARLIAMENT

SULPHURIC ACID

- **Parliamentary question on restrictions on availability and use of sulphuric acid**

  Source: European Parliament

On 15 June 2020, Member of the European Parliament Maria Spyraki submitted a question for written answer to the European Commission, asking whether the

Commission would consider to impose restrictions on the availability and use of sulphuric acid by citizens and propose harmonised regulatory measures for all Member States.

The question was answered in writing on 17 August by Ylva Johansson, European Commissioner for Home Affairs:

Highly concentrated sulphuric acid is indeed misused in acid attacks, as referred to by the Honourable Member. Regulation (EC) No 1907/20061 does not regulate criminal uses of chemicals. However, with a view to prevent the illicit manufacture of explosives, the European Union adopted a regulation on the marketing and use of explosives precursors, Regulation (EU) 2019/11482 , in August 2019. Sulphuric acid is such an explosives precursor. With the adoption of this new regulation, the sale to the general public of sulphuric acid is restricted. Members of the general public can only be sold sulphuric acid up to the limit value of 15% by weight. Member States can decide to implement a licensing regime. In that case, members of the general public could receive, after a careful assessment, a licence for acquiring, introducing, possessing or using sulphuric acid up to a limit value of 40% by weight.

More information:
https://www.europarl.europa.eu/doceo/document/E-9-2020-003571-ASW_EN.pdf

STAKEHOLDERS

STANDARDISATION

- **CEN/TC 136 publishes work on safety standards for pool ladders**

  Source: European Committee for Standardisation

CEN/TC 136, the technical body of the European Committee for Standardisation that works on Sports, playground and other recreational facilities and equipment, added two new entries to its work programme:

- Swimming pool equipment - Part 2: Additional specific safety requirements and test methods for ladders, stepladders and handle bends

This part of EN 13451 specifies safety requirements for ladders, stepladders and handle bends in addition to the general safety requirements of EN 13451-1. The requirements of this specific standard take priority over those in EN 13451-1.

This part of EN 13451 is applicable to manufactured ladders, stepladders and handle bends used for pool access and egress for use in classified swimming pools as specified in EN 15288-1 and EN 15288-2.

More information:
https://standards.cen.eu/dyn/www/f?p=204:7:0::::FSP_ORG_ID:6118&cs=140D1E450C7DC51CB3C0584A5BE0EEB78

REACH

- **Proposed PFCA restriction 'substantially weakens' action on PFASs**

  Source: Chemical Watch

The European Commission's plans to tackle per- and polyfluorinated substances (PFASs) have been "substantially weakened" by its new restriction proposal on PFCAs – a subset of the chemicals – NGO network International Pollutants Elimination Network (Ipen) has said.

In its draft regulation, notified to the WTO on 3 August, the EU executive plans to restrict perfluorocarboxylic acids containing 9 to 14 carbon atoms in the chain (C9-C14 PFCAs), their salts and related substances under REACH.

The proposed regulation, the Commission said, intends to prevent industry from using the chemicals as a potential "regrettable" substitute for perfluorooctanoic acid (PFOA), which was restricted under the EU Regulation on persistent organic pollutants (POPs) from 4 July, to fulfil the same role in the end products.

But, according to Ipen science advisor Dr Sara Brosché, the draft's high concentration limits, long phase-out times and range of derogations render recent moves to tighten controls on PFASs "a waste of time and resources".

In addition to the PFOA ban, the Commission is proposing separate restrictions of PFAS subsets perfluorohexane-1-sulphonic acid

(PFHxS) and perfluorohexanoic acid (PFHxA). Dr Brosché says multiple restrictions show that action on PFASs "needs to be taken through a wider grouping approach" to limit substitution and ensure consistency.

It is unclear how these separate restriction proposals will fit into the Commission's forthcoming chemicals strategy for sustainability. DG Environment has proposed a PFAS action plan in its draft communication, which would limit the substances to "essential use" only, but DG Grow has since suggested heavy edits.

Derogations

A key sticking point in the proposed PFCA restriction is the number of derogations listed in its annex.

The public consultation for the proposal took place in 2018, but when PFOA was added to the persistent organic pollutants (POPs) regulation, industry submitted new requests for derogations for longer chain PFCAs. Echa issued another call for information between May and June 2020.

In the proposal, the general concentration limit for the sum of C9-C14 PFCAs, their salts and related substances is 25 parts per billion (ppb), or 260ppb for the sum of C9-C14 PFCA-related substances. However, exceptions are listed for:

- PTFE fine powders, used in a variety of non-stick products including Teflon;
- fluoroelastomers, or synthetic rubbers; and
- aqueous dispersions of PTFE fine powders, used in lubricants and fabric coatings.

These products are given a limit of 2,000ppb for the first 36 months and 400ppb afterwards.

Dr Brosché says that these limits are based on current contamination limits reported by industry, rather than on health and environmental risk factors. "This bad practice has to end to make the restrictions truly effective," she says, recommending a limit of 3ppb or less.

Although the limits in the proposal should generally apply 18 months after it is adopted, exceptions will be made for certain:

- textiles, sealants and gas filters, which will be restricted from July 2023;

- medical devices, fire-fighting foams and photolithography, which will be restricted from July 2025;
- semiconductors, which will be restricted from December 2023 or December 2030;
- coatings for some inhalers, which will be restricted from seven years after the restriction comes into force; and
- articles already on the market until 18 months after the restriction's entry into force, which are exempt from the restriction.

Of particular concern, Dr Brosché says, is the long transition period for some uses of fire-fighting foam when non-fluorinated alternatives exist. Fire-fighting foams, she adds, are "one of the most dispersive uses" of PFASs.

The derogations for semiconductors, she says, were introduced in response to one non-EU company that requested a derogation at a late stage for import of semiconductors. "It seems that this derogation not only is unnecessary but has the potential to disadvantage EU industry actors that have already phased out PFCAs".

Next steps

Echa's Committees for Risk Assessment and Socio-Economic Analysis (Rac and Seac) announced on 4 August that they will prepare a supplementary opinion on additional derogations requested by industry and will review some current ones to ensure consistency with the POPs regulation.

Once it has assessed the WTO comments, the Commission will present the draft proposal to the REACH committee. If approved, the European Parliament and the Council of Ministers will then have three months to scrutinise the proposal. The Commission expects to adopt the regulation in the first half of 2021.

More information (subscription required):
https://chemicalwatch.com/144092/proposed-commission-pfca-restriction-substantially-weakens-action-on-pfass

- **Mandatory REACH dossier update deadlines could apply by year-end**

  Source: Chemical Watch

The European Commission is set to adopt new EU-wide deadlines on updates to REACH registrations in the autumn, which will begin to apply two months

later. It will mean that, for the first time, industry is legally obligated to add any new relevant information to their dossiers within a set time period.

The measure comes after persistent issues with dossier non-compliance. It fortifies legal provisions under REACH Article 22 which, until now, has required registrants to update "without undue delay". This has resulted in companies interpreting the rules differently and, in some cases, failing to execute updates unless requested by Echa.

The path to adoption for the implementing regulation – which does not require scrutiny by the European Parliament and the Council of Ministers – was cleared on 28 July by unanimous approval from member states in a written procedure following the REACH Committee meeting earlier that month.

Pressured by industry, the Commission has extended certain deadlines within the proposed draft regulation – in some cases, the time period has doubled.

Deadlines

Registrants will have three months to complete updates of a "more administrative nature" and, if updates include the generation of data, to fulfil requirements of REACH Annex VII or VIII following receipt of the study report.

Deadlines of six, nine or 12 months will be given to companies undertaking "more complex" updates, such as those requiring the generation of data based on a testing proposal, changes to the chemical safety report (CSR) or the guidance on safe use.

And where a member of a joint submission cannot make a particular update until the lead registrant has first updated, that member will have nine months for the update of a CSR and three months for any other update.

Deadlines are set under 13 articles detailing reasons for updates, including:

- changes in a registrant's status or identity;
- changes in the composition of the substance;
- changes in tonnage band;
- new identified uses and new uses advised against;
- new knowledge of the risks to human health and/or the environment;
- changes in the classification and labelling of the registered substance;
- testing proposals prior to conducting a test listed in Annex IX or X;
- changes in the access granted to information in the registration; and
- updates involving further testing.

Cefic said it welcomes the "clarifications" set out by the implementing regulation which, it added, will "help to align" registrants and other REACH actors on update needs and actions to be taken.

The trade body confirmed that Article 22's mandatory dossier updates are "independent" from the voluntary work it is spearheading via its seven-year action plan on dossier improvement.

This plan provides a template for registrants to evaluate the safety data submitted under REACH and decide whether their dossiers need to be updated with additional information. This may mean companies having to navigate through 2,000 entries per dossier on the REACH-IT tool.

"The voluntary work continues and is not affected by the new implementing regulation. This means that, in practice, synergies will have to be sought to make dossier updates as efficient as possible, where possible. This is all the more important given the pressure the [Covid-19] pandemic and Brexit are putting on resources."

Once adopted, the regulation will apply 60 days after its publication in the EU's *Official Journal*.

More information (subscription needed):
https://chemicalwatch.com/143538/mandatory-reach-dossier-update-deadlines-could-apply-by-year-end

EVENTS

- **REACH, RoHS, medical devices and hazardous substances in the EU**

  Source: Chemical Watch

The purpose of this webinar is to provide an overview of how chemicals are regulated under REACH, RoHS and the MDR. It looks at the intersection of these three regulatory instruments in the control of human and environmental exposure to hazardous effects derived from the use of certain chemicals. This webinar will cover:

- how hazardous substances are regulated in the EU (REACH, RoHS, MDR);
- who the key players are under the main pieces of EU hazardous chemicals legislation;

- what the obligations of the key players are what happens at the iIntersection of REACH, RoHS and MDR when it comes to the restriction of chemical substances.

Who should attend

- Regulatory affairs managers
- Compliance managers
- Government regulators
- Product stewards
- Lawyers
- Consultants
- Trade associations
- Service providers
- NGOs
- Academics

More information:
https://events.chemicalwatch.com/145646/reach-rohs-medical-devices-and-hazardous-substances-in-the-eu-9-october-2020