



EU Monitoring Report

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EUROPEAN COMMISSION

REACH

- **Discussion on inclusion of polymers under REACH**

Source: European Commission

We informed you on April 25 about the upcoming meeting of the Competent Authorities for REACH and CLP which is taking place online on 15 May. As mentioned before, the agenda includes discussions on a mandate for a CARACAL sub-group to provide advice on the need to register certain polymers under REACH. You can find more information about this point below.

In particular the potential scope of the inclusion of polymers under REACH is interesting for EUSA. Polymers include materials such as polyethylene – the most common plastic in the world, used in everything from shopping bags to storage containers – and are currently exempt from REACH registration or evaluation processes. However the European Commission is expected to publish a proposal by 2022 for these to begin.

Several documents have now been published that indicate the potential scope that the sub-group’s mandate would have. According to initial proposal, the CASG-

Polymers should provide advice to the Commission, in particular on the following regulatory and policy issues:

- Which type or classes of polymers may deserve registration under REACH for the benefit of further assessment and potential risk management;
- What information requirements should be proposed for polymers requiring registration under REACH;
- Provide options to be considered in the context of an impact assessment.

The Rules of Procedure of the CARACAL apply with regard to convening the subgroup meetings, the agenda and the documents. Subject to the needs identified by the Commission and advised by the members of the CASG-Polymers, two or three meetings per year will be organised.

The CASG-Polymers activities will start indicatively in June 2020. Subject to the delivery of the expected outputs, future needs and discussions in CARACAL, the CASG-Polymers will be disbanded on 31 December 2021.

More information:

<https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/53d0c4f9-39ab-4957-811b-0c4088dee5b8/details>

BIOCIDES

- **European Commission issues draft Regulation approving formaldehyde in disinfectants**

Source: Chemical Watch

The European Commission has published a draft implementing Regulation that would approve the biocidal active substance formaldehyde for use in disinfectants and algacides not intended for direct application to humans or animals (biocidal product-types two and three).

In December last year, Echa's Biocidal Products Committee (BPC) voted in favour of the move, despite formaldehyde's classification as a carcinogen and suspected mutagen. Normally, substances with these properties would meet the exclusion criteria under the biocidal products Regulation (BPR) and not be approved.

However, because the dossier was submitted before the BPR entered into operation – and was evaluated under the rules of the biocidal products Directive – it can get approval. But this will be limited to five years and reevaluations will then follow BPR rules.

The substance is used as a biocide in public health areas. In product-type two, professionals use it to disinfect surfaces and in fogging/fumigation where there is the danger of an epidemic. In product-type three, the substance is used to disinfect areas where animals are housed, kept or transported to prevent diseases.

The Commission proposes to adopt the Regulation in July. It will enter into force 20 days after publication in the Official Journal of the EU and apply from February 2022.

Access the documents:

[The draft proposal](#)

[The annex](#)

CLP

- **Commission's proposal to improve poison centre information requirements under CLP**

Source: European Commission

The European Commission has published a draft proposal for a delegated regulation to improve the workability of information requirements related to emergency health response, as described in Annex VIII of Regulation 1272/2008 on the classification, labelling and packaging of substances and mixtures.

Member States' appointed bodies are responsible for receiving information from importers and downstream users on the hazardous chemical mixtures they place on the market.

According to the proposal, to ensure that the emergency health response requirements can be complied with properly in practice, importers and downstream users should be allowed to group toxicologically similar components of a mixture together in an interchangeable component group and provide information on the

total concentration of those components present in the mixture, without having to specify their separate concentrations.

This proposed act introduces a general solution with the concept of an interchangeable component group, as well as more sector specific solutions for gypsum, ready mixed concrete, cement and fuels and bespoke paints.

More information:

<https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/9f5d7005-8755-42f8-9c0b-bd9b4bf22d4b/details>

Access CEFIC's position on the proposal:

<https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/3a768900-79e4-4994-a8c6-7b19b9aea795/details>

EUROPEAN CHEMICALS AGENCY

COVID 19

- **Extensions to company deadlines**

Source: European Chemicals Agency

ECHA is committed to helping industry meet its regulatory obligations during the COVID-19 pandemic. The Agency has decided on deadline extensions which will apply until the end of May 2020. The companies concerned have been informed directly about these extensions since the end of March.

More information:

<https://echa.europa.eu/fr/covid-19?panel=industry#industry>

CLP

- **Consultation on harmonised classification and labelling on sodium chlorate**

Source: European Chemicals Agency

The European Chemicals Agency is looking for comments on the harmonised classification and labelling proposal for several compounds, including **sodium chlorate**. Parties concerned are invited to comment on hazard classes open for consultation.

For sodium chlorate, feedback is asked on the substance's acute toxicity via oral route as well as its hazardous impact on the aquatic environment. The deadline for comments is 3 July 2020.

More information:

<https://echa.europa.eu/en/harmonised-classification-and-labelling-consultation/-/substance-rev/25603/>

- **Scientific committees in June – agendas available**

Source: European Chemicals Agency

The agendas of the upcoming meetings of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) are online. Interestingly, the Committee for Socio-economic Analysis is scheduled to discuss and possibly adopt its draft opinion on **formaldehyde** and formaldehyde releasers as part of its work on Restriction Annex XV dossiers.

Access the agendas:

https://echa.europa.eu/documents/10162/29022590/RAC-53_ProvisionalDraftAgenda.pdf/

https://echa.europa.eu/documents/10162/28948811/SEAC-47_ProvisionalDraftAgenda.pdf/

IUCLID

- **New IUCLID version introduces an extended and more complete web interface**

Source: European Chemicals Agency

IUCLID (International Uniform Chemical Information Database) is a software application to record, store, maintain and exchange data on intrinsic and hazard properties of chemical substances. It is a key software application for both regulatory bodies and the chemical industry where it is used in the implementation of various regulatory programmes

The new release, published on 4 May 2020, also completes all IUCLID inventories (for example: contacts, category, and literature references), the advanced search for datasets, the derived no-effect level (DNEL) calculator, the bulk copy of records, and the management of user preferences.

More information:

https://iuclid6.echa.europa.eu/view-article/-/journal_content/title/iuclid-6-april-2020-release

EUROPEAN PARLIAMENT

ENDOCRINE DISRUPTORS

- **Parliamentary questions on endocrine disruptors answered by the Commission**

Source: European Parliament

In response to parliamentary questions asked by MEP Maria Arena back in February, the European Commission confirms its work on endocrine disrupting chemicals is ongoing.

The zero-pollution ambition and the ‘chemicals strategy for sustainability’ have already been included in the communication on the European Green Deal, which preceded the 2020 Commission Work Programme.

The European Commission reiterates that its services are working on a proposal to update the data requirements of the REACH Regulation in order to improve the identification of endocrine disruptors.

This means that industry will be required to include information on endocrine disrupting properties of the chemicals they place on the EU market in their REACH registration dossiers.

The Commission foresees that the fitness check on endocrine disruptors is expected to be finalised by the third quarter of 2020. Based on its results the Commission will decide on any further steps.

Access the question:

https://www.europarl.europa.eu/doceo/document/E-9-2020-001039_EN.html

Access the answer:

https://www.europarl.europa.eu/doceo/document/E-9-2020-001039-ASW_EN.html

SUSTAINABILITY

- **Report on chemicals strategy for sustainability**

Source: European Parliament

The European Parliament’s Committee on the Environment, Public Health and Food Safety is currently working on a resolution on a European chemicals strategy for sustainability.

Although the report is not legislative, it will give a strong indication of the position of the European Parliament in the future regarding the expected proposals of the European Commission.

We will analyse the report once it has been adopted by the ENVI committee and inform the members of EUSA of its most relevant parts, if any.

- **Parliament and Commission to discuss Circular Economy Action Plan**

Source: European Parliament

The European Parliament's Environment Committee is scheduled to discuss on 12 May the recent Circular Economy Action Plan with Virginijus Sinkevičius, the Commissioner for Environment, Oceans and Fisheries. The draft agenda of Tuesday's meeting also indicates that the Commission's 'Biodiversity Strategy for 2030' will be discussed.

AlienorEU will follow the livestreamed discussions and inform you of any relevant information that may come up during the meeting.

More information:

https://www.europarl.europa.eu/doceo/document/ENVI-OJ-2020-05-12-1_EN.html

BREXIT

- **Environment Committee of the EU Parliament urges 'dynamic alignment' of future UK-EU chemicals laws**

Source: Chemical Watch

The European Parliament's environment committee (Envi) has stressed the importance of the UK remaining "dynamically aligned" with the EU on chemicals regulations after Brexit.

Envi was requested to provide its opinion on recommendations on the negotiations for a new partnership by the EU's committees on foreign affairs and international trade.

At its meeting on 4 May Envi decided on suggestions for them to incorporate into their motion for a resolution.

It said that in particular, alignment is needed on rules concerning endocrine disrupting chemicals, REACH, medical devices and pharmaceuticals. With such convergence, it added, UK companies would still be subject to the same obligations that apply to non-EU companies outside the European Economic Area.

Additionally, the committee said it supports the UK's continued participation as a third-country observer with no decision making role in non-regulatory agencies, such as the European Environment Agency.

Envi also encouraged the UK and the EU to consider establishing cooperation agreements with peer regulatory agencies, such as Echa, "in order to exchange information, best practice and scientific knowledge".

Last month, the UK's Chemical Industries Association reiterated its call for Brexit negotiators to explore the option of permitting UK regulatory authority access to Echa's database in the future.

In February, a UK government white paper on the country's approach to the negotiations said it "will not agree to any obligations for our laws to be aligned with the EU's".

The third round of UK/EU negotiations on the future relationship will take place from 11-14 May. The transition period is currently expected to end on 31 December.

Access the article (subscription needed):

<https://chemicalwatch.com/114726/envi-urges-dynamic-alignment-of-future-uk-eu-chemicals-laws#overlay-strip>

OTHER STAKEHOLDERS

BREXIT

- **MPs restate post-Brexit chemicals strategy concerns after Covid-19 delay**

Source: Chemical Watch

The new chair of a UK parliamentary committee has expressed his concerns over the government's post-Brexit chemicals strategy, after its development was suspended due to the coronavirus Covid-19 pandemic.

In a letter to minister of state George Eustice, Environmental Audit Committee chair Philip Dunne said that given the delays already incurred, the decision to pause work on it in order to prioritise the government's response to the pandemic was "regrettable".

The Department for Environment, Food and Rural Affairs (Defra) has not said whether the strategy, currently due in 2022, would be delayed.

Mr Dunne's letter, dated 30 April, raises a number of questions over Defra's approach to chemicals regulation after Brexit, reiterating persistent anxiety among stakeholders about the UK's future relationship with Echa and access to chemicals data.

It requests clarity on how the government is using the Brexit transition period to prepare businesses for a new regulatory framework, and guidance on whether a two-year window for UK registrants to submit full data packages would be extended.

The committee is concerned, it says, that ongoing uncertainty for the sector could damage access to vital chemicals for business after the transition period. This will expire at the end of the year, unless an extension is agreed with the EU by the end of June.

While the government has made "top-line announcements" on UK REACH and its competent authority, the Health and Safety Executive (HSE), that endeavour to mirror Echa, the committee adds it "remain[s] unclear how these will work in practice".

Mr Dunne was elected as chair of the committee at the end of January, replacing Mary Creagh.

Data woes

His letter outlines grievances aired by experts and business groups during two parliamentary inquiries – one in 2016-17 on post-Brexit chemicals regulation and another last year on the impact of toxic chemicals in everyday products.

Then in a parliamentary debate in February, Defra undersecretary of state Victoria Prentis caused further unease by signalling possible divergence from EU rules

through an independent UK REACH – a shift from the government's previously stated objective to pursue associate membership of Echa.

The letter asks what relationship the government envisages with Echa that would provide sufficient access to data, flagging the need for businesses to have reassurance on future arrangements "now"

"If the full data package is necessary but impossible to gain, this could render the entire UK database unusable," it says.

Access to data has been a constant worry for UK industry. Last month, the Chemical Industries Association (CIA) repeated a call for Brexit negotiators to explore the option of permitting UK regulatory authority access to Echa's database as part of a trade agreement.

Recommendations

Elsewhere, the letter says that the committee had previously recommended that the HSE should outline a formal role in the substance evaluation process for two UK committees – the Committee on Toxicity and the Hazardous Substances Advisory Committee.

It had also recommended that HSE establish a forum for engaging with stakeholders and suggests specialists feed into decision making for chemicals policy.

The letter asks for an update on progress and how the HSE model will ensure consistency to maintain environmental protection.

Mr Dunne has requested a response from Defra by 25 May.

Access the article (subscription needed):

<https://chemicalwatch.com/114110/mps-restate-post-brexite-chemicals-strategy-concerns-after-covid-19-delay#overlay-strip>

COVID 19

- **Europe eyes further legal exemptions as disinfectant demand changes**

Source: Chemical Watch

Potential shortages of disinfectants, other than hand and surface sanitisers, could trigger another wave of legal exemptions in Europe, regulators have said.

Speaking at the Chemical Watch webinar, Covid-19 related derogations under the EU's biocidal products Regulation (BPR), Olivier Gras from the French Ministry for Ecology said the authority is seeing growing demand for some materials disinfectants and other biocidal products.

The ministry has had a request for an exemption from the BPR authorisation requirements for biocidal products used to sanitise face masks for their reuse, said Mr Gras, who heads the ministry's office of chemical products.

And it has already decided to grant a derogation for Biobor JF, a biocidal product for the preservation of aircraft fuel.

Leaving aircraft unused for long periods of time increases the risk of oil-degrading microorganisms contaminating the fuel tank – a risk that has increased with the reduction in global air traffic caused by the pandemic.

Other member states, such as Germany and Sweden, have granted the same derogation. And Echa is in talks with the EU's Aviation Safety Agency (Easa) and the European Commission on how to meet the increased demand for aircraft fuel additives, the agency's Hugues Kenigswald told the webinar.

As it stands, exemptions from the BPR's legal requirements in Europe have centred primarily on hand sanitisers and some surface disinfectants. France, for instance, has issued one ministerial decree covering hand sanitisers with four formulations, based on ethanol or propan-2-ol. The derogation is due to end on 1 September.

France has not given any legal exemptions to products falling under the BPR's product-types two (disinfectants and algaecides not intended for direct application to humans or animals) or four (food and feed area).

But Mr Gras said regulators should "anticipate and be reactive to respond to new potential shortages ... We know the market is tense and we are monitoring the situation closely."

Evolving demand

Meanwhile, the European Commission is holding weekly meetings with Cefic sector group, the European Biocidal Products Forum (EBPF) and cleaning products trade body, Aise, to monitor evolving supply issues in the biocides sector.

Head of the Commission's pesticides and biocides unit, Klaus Berend told the webinar that the supply and demand for hand disinfectants is "returning to balance".

But the regulators and industry are keeping a close eye on how demand for disinfectants develops as the bloc begins to ease lockdown measures.

The European Commission's roadmap to lifting coronavirus containment measures notes a reliance on "intensified and regular cleaning and disinfection of transport hubs and vehicles, shops and workplaces, instead of entirely prohibiting services, and provision of adequate measures or equipment to protect workers or customers".

Ian Watt, chair of the EBPF, said industry and regulators need to consider this when deciding on whether to introduce new legal exemptions or extend current derogations for disinfectants.

"We are now starting to look at how [the situation] will evolve as Europe comes out of lockdown and to a more mobile state that will require ongoing reliance and possibly an increased reliance on disinfection," Mr Watt said.

At the same time, Mr Gras said industry and authorities are beginning to ponder how to transition out of the derogations when they expire. This will involve informing disinfectant producers that are new to the BPR on what their legal obligations are when normal rules apply again, he said.

Access the article (subscription needed):

<https://chemicalwatch.com/113753/europe-eyes-further-legal-exemptions-as-disinfectant-demand-changes#overlay-strip>

- **Covid-19 and disinfectants – what active substances can I use?**

Source: Chemical Watch

As the rapid spread of the coronavirus Covid-19 pandemic has put hand and surface disinfectants in extraordinarily high demand, manufacturers are setting all wheels in motion to get products to market and replenish supplies. Not only are biocidal product producers working around the clock but chemical companies, as well as downstream businesses from cosmetics to distilleries, are undertaking a mass shift in production to sanitiser products or the key substances, such as alcohols, needed to produce them.

But the unprecedented demand itself, coupled with limited production capacities, lack of personnel at factory-level, and intermittent supply chain problems is continuing to cause difficulties.

Fatty alcohols, ethanol and isopropyl alcohol, benzyl chloride, ethyl benzyl chloride and methyl chloride are among the widely used disinfectant ingredients that are in danger of shortages. European cleaning products industry association, Aise, has also noted challenges in sourcing some co-formulants, as well as packaging materials for hand and surface disinfectants.

Meeting demand regardless of these disruptions requires a degree of flexibility, not least in tweaking formulations and changing sources when a link in the supply chain comes to breaking point.

Although governments are opening doors in the form of exemptions and derogations to chemical laws, the rules for legally supplying disinfectants are fragmented around the world and differ in their systems so much they are hard to compare. Few jurisdictions provide a straight-up positive list of biocidal active substances permitted for use in hand and surface sanitisers. Others employ negative lists of banned chemicals, or approve products individually, based on efficacy test data and an assessment of their risk to human health and the environment, regardless of the biocidal substances in them.

There are, however, resources available in some countries that give an insight into what manufacturers, whether they are seasoned in or new to the biocides industry, can use to expand the range of products they bring to a pandemic-stricken market.

Europe

The EU biocidal products Regulation (BPR) has separate authorisation procedures for biocidal active substances and the biocidal products they are used in. When substances are approved, they are split into categories that define the uses they are approved for. Chemicals allowed for use in hand sanitisers, for instance, fall under product-type one: human hygiene disinfectants. Chemicals for use in surface disinfectants, on the other hand, have to be approved for product-type two: disinfectants and algacides not intended for direct application to humans or animals.

This list published by a trio of European trade associations – Aise, the European Association of Chemical Distributors (Fecc) and Cefic sector group European Biocidal Products Forum – gives an overview of the biocidal active substances that are currently approved or under review for these two product-types.

Normally, companies could use any of these substances to produce a disinfectant product, but the product would have to be approved itself, separately, under the BPR. In light of the current crisis, however, certain products have been exempted from this rule. These exemptions are being put in place by European member states individually, painting a rather uneven picture of what products can quickly and easily reach which markets. Chemical Watch provides an evolving resource (available to Advance members) that records these exemptions, with details on the substances and product-types they apply to.

There are also rules to keep in mind for changing the supplier of a biocidal active substance. All suppliers have to be registered according to the BPR's Article 95 and be included on the list of the same name.

Some member states are excluding disinfectant products from this requirement at the moment. There is no list of countries doing this and few official announcements from national authorities promising a full exemption from the rule. But national helpdesks have invited companies to contact them for information.

For manufacturers looking to use a new source of propan-1-ol or propan-2-ol, Echa will fast-track the technical equivalence procedure that assesses the new source of an active substance.

Some individual European countries, like the Netherlands and Switzerland, have lists of hand and surface disinfectants that are generally approved as safe and effective against pathogens.

Note that companies established outside of the EU are not bound by the obligations of the BPR, even if they export their products there. The responsibility for fulfilling its requirements, such as the approval of active substances or authorisation of biocidal products, lies with the importers established in the EU.

Access the article (subscription needed):

<https://chemicalwatch.com/114109/feature-covid-19-and-disinfectants-what-active-substances-can-i-use#overlay-strip>

EU CHEMICALS STRATEGY

- **Europe eyes further legal exemptions as disinfectant demand changes**

Source: Chemical Watch

Supporting industry frontrunners and speeding up the regulatory processes are among five goals NGO ChemSec has set for the EU's new chemicals strategy being developed under its Green Deal.

ChemSec said the upcoming chemical strategy for sustainability must give incentives for companies to phase out substances of concern and limit derogations to restrictions to "essential use".

The European Commission should also set clear political targets and timeframes to speed up the identification and phasing out of substances of concern, it says. Additionally, the EU executive should use the precautionary principle to avoid "paralysis by analysis", regulate groups of substances and strengthen the 'no data, no market' principle.

The other three aspects it recommends that the strategy include are:

- strengthening the balance between generic and specific risk assessment in all EU chemicals regulations;
- transparency and traceability, which are important for a circular economy; and

- closing the existing gaps in EU chemicals regulation. These concern imported articles, endocrine disrupting chemicals, mixtures, persistent chemicals (including PFASs) and enforcement.

'Business as usual' is no longer an option, ChemSec says, calling on the Commission to present "clear commitments, deadlines and deliverables, as well as a more ambitious chemicals legislation".

Last month, the European Environmental Bureau also stated its ambitions for the Green Deal, calling on leaders to safeguard environmental standards in the face of the coronavirus Covid-19 pandemic.

The Commission should develop the Green Deal as a "greenprint" for a better future, the EEB said. As part of this, it should give "due priority" to its zero pollution ambition for a toxic-free environment, while the chemical strategy should include swift action to identify and phase out EDCs and other harmful substances.

The EU should address exposure to toxic chemicals horizontally in all related sectors and strategies, and prioritise implementation of its circular economy action plan, the EEB added.

The Commission is set to unveil its chemicals strategy later this year and has not said whether it would be delayed due to the pandemic.

Access the NGO article :

<https://chemsec.org/publication/reach/5-aspects-that-the-chemical-strategy-must-include/>