



EU Monitoring Report

9–16 July 2020

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EUROPEAN CHEMICALS AGENCY

BIOCIDES

- **Chlorine from sodium chloride electrolysis: opinion for approval**

Source: European Chemicals Agency

The European Chemicals Agency has published the opinion for approval of the Biocidal Products Committee on active chlorine generated from sodium chloride by electrolysis.

The opinion on the application for approval of the active substance was adopted on 16 June 2020.

Due to the entry into force of Regulation (EU) 2017/2100 the Commission returned the BPC opinion to ECHA on 18 June 2018 with the request to revise the opinion already adopted by the Biocidal Products Committee (BPC), related to the application of the criteria for endocrine disrupting properties as laid down in this regulation.

In addition, the Commission requested to ECHA for an opinion on sodium chloride specifications and water quality for the generation of active chlorine by electrolysis pursuant to Article 75(l)(g) of Regulation (EU) No 528/2012. This request was based on the industry's concerns that they would not be able to meet the specification for sodium chloride and water as adopted in BPC opinion on 25 April 2018. The BPC opinion was adopted by consensus. The opinion is published on the ECHA webpage at: <http://echa.europa.eu/regulations/biocidal-products-regulation/approval-ofactive-substances/bpc-opinions-on-active-substance-approval>.

More information:

https://echa.europa.eu/documents/10162/21680461/active_cl_generated_sodium-chloride_electrolysis_pt2_opinion_en.pdf/83c753e7-92eb-e42d-f4bf-85c993740586

CHEMICALS

- **Sweden submits SVHC intention for Dioctyltin dilaurate**

Source: European Chemicals Agency

Dioctyltin dilaurate has widespread uses, including Plastic products, industry for plastics, manufacturing of plastics, plastic additives. The registry of SVHC intentions until outcome aims to make interested parties aware of the substances for which an SVHC dossier is planned to be submitted to ECHA.

Member States, or ECHA at the request of the European Commission, may propose a substance to be identified as a substance of very high concern (SVHC) by preparing a dossier in accordance with the requirements set out in Annex XV to REACH.

Interested parties can follow the progress of a proposal through the SVHC identification process, from the notification of the intention until the outcome.

The advance notice gives interested parties time to prepare for commenting later in the process. Interested parties with relevant information on the identity or hazard properties of the substance may submit such information during the consultation.

More information:

<https://echa.europa.eu/nl/substance-information/-/substanceinfo/100.308.020>

- **PFAs restriction | Call for evidence deadline 31 July 2020**

Source: European Chemicals Agency

Five European countries are preparing a joint restriction proposal on the manufacture and use of a wide range of PFAs. Interested parties can send in any information they may have and evidence by 31 July 2020.

PFAs are a group of chemicals that are widely used, included in textiles, leather; Cosmetic products; Food contact materials; Paper and board; Firefighting foams; Household articles and consumer mixtures; Construction products; Lubricants and greases; Chrome plating;

Semiconductors; Mixtures for treatment of skis; Medical devices; Applications within oil, gas and mining industry; F-Gases; Uses of C1 perfluorinated

carboxylic and sulfonic acids; Transportation (automotive, aviation etc.); Photographic surface layers etc.

More information:

<https://www.reach-clp-biozid-helpdesk.de/DE/REACH/Verfahren/SVHC-Verfahren/Stoffliste-EN/Stoffliste-EN.html>

- **Substance evaluation conclusion on di-tert-butyl peroxide (dTBP)**

Source: Netherlands Institute for Public Health

Di-tert-butyl peroxide (dTBP) is characterised by widespread use in the production of various materials (including plastics) and also serves as a base for the production of other chemical substances. The Netherlands Institute for Public Health has recently published its substance evaluation conclusion and report as required by REACH Article 48. Substance evaluation is an evaluation process under REACH Regulation (EC) No. 1907/2006. Under this process the Member States perform the evaluation and ECHA secretariat coordinates the work.

More information:

<https://echa.europa.eu/documents/10162/e253dcc7-4e30-7f2e-a345-e1100d2ab678>

EUROPEAN PARLIAMENT

SUSTAINABILITY

- **European Parliament adopts resolution on future EU chemicals strategy**

Source: European Parliament

The upcoming new EU chemicals strategy for sustainability must better protect our health and the environment, says Parliament in a resolution adopted on Friday.

Following Wednesday's debate, where MEPs requested the Commission to close loopholes in EU chemicals legislation to help REACH to function more efficiently, Parliament adopted a resolution by 579 votes to 18 and 84 abstentions. It calls on the Commission to come up with a new chemicals

strategy that effectively ensures that health and the environment are well protected, by minimising exposure to hazardous chemicals. Further regulatory measures are needed to protect vulnerable groups in particular such as children, pregnant and breastfeeding women and the elderly.

According to MEPs, the new chemicals strategy must fully reflect the precautionary principle and the polluter-pays principle, and ensure more transparent approval processes. It should also stimulate competition for developing safe and sustainable alternatives, e.g. by committing to securing funds for research.

MEPs believe in the ‘one substance – one hazard assessment’ principle: substances should be reviewed by only one EU agency to speed up the process and make chemicals regulation more consistent.

Reduce exposure to endocrine disruptors and pesticides

The resolution calls for a comprehensive EU framework on endocrine disruptors (EDCs) to effectively minimise the extent to which humans and the environment are exposed to EDCs. Specific provisions on toys, food contact materials and cosmetics should be inserted into legislation to treat EDCs in the same way as substances that are carcinogenic, mutagenic or toxic for reproduction.

It also calls on the Commission to heed the various calls of the European Parliament to improve the EU’s authorisation procedure for pesticides and accelerate the transition towards low-risk pesticides.

Encourage green innovation and end toxic recycling

MEPs call on the Commission to develop EU criteria for Sustainable Chemicals to provide incentives for sustainable chemistry, materials and technologies, especially non-chemical alternatives that are safe. Harmful chemicals also end up in recycled products and should therefore be covered by the same rules as new products. The EU must also minimise and progressively replace animal testing by using more new approach methodologies and intelligent testing strategies.

Next steps

The resolution is Parliament's input to a new EU chemicals strategy for sustainability to be presented by the Commission this autumn. A draft roadmap was open for feedback until 20 June. It is part of the European Green Deal.

More information:

<https://www.europarl.europa.eu/news/en/press-room/20200706IPR82729/parliament-calls-on-eu-commission-to-step-up-action-against-dangerous-chemicals>

EUROPEAN COMMISSION

BIOCIDES

- **Dutch biocides authority open to extending dossier deadlines**

Source: Chemical Watch

The Dutch competent authority (CA) for biocides (Ctgb) has become the first member state authority to agree to extend the deadlines for dossiers in light of the Covid-19 crisis.

In an announcement published on 1 July, the CA acknowledged that there could be associated delays in compiling dossiers for biocidal substances and product authorisations. It suggests companies apply for an extension to the submission deadlines for their dossiers if the reasons are "thoroughly substantiated and related to Covid-19".

The applicant must explain why and how much extra time they need, "preferably" with supporting documentation from testing laboratories, and what actions they have already taken to prevent or limit the delay.

Ctgb's announcement follows concerns that data collection may come up against full capacity at testing laboratories, which are prioritising Covid-19 work, including testing disinfectants for their efficacy against the virus. Extensions will be granted "only once and for a short period" of one or a few months, the CA said.

The Netherlands is the first member state authority to have come forward with an official statement on extending deadlines for biocides dossiers, Chemical Watch understands.

Consultancy Arche says its attempts to apply for deadline extensions with other member state authorities have been unsuccessful, although it expects CAs could be open to accommodating applicants that have proof that their chosen laboratory cannot finish testing in time because of capacity constraints.

"It might be case-specific, but we are happy to see Ctgb putting out a formal statement and hope that others will follow," said Arche consortium manager, Katinka Renoult and senior project scientist, Barbara Dhoop. "There is clearly a need for it, especially with labs being busy testing disinfectants."

An overarching approach for deadline extensions from the European Commission has, so far, not been developed. However, Echa announced in March that it would extend some deadlines to help companies.

More information (subscription needed):

https://chemicalwatch.com/134667/dutch-biocides-authority-open-to-extending-dossier-deadlines_2

SUSTAINABILITY

- **Chemicals Strategy for Sustainability: stakeholder feedback published**

Source: European Commission

We informed you in recent monitoring reports of the EU Commission's Chemicals Strategy for Sustainability as well as the upcoming opportunity for stakeholders to provide their feedback on the Strategy. Several stakeholders have done so, and their feedback has been published on the Commission's consultation portal. You can find a number of these listed below:

- [European Biocidal Products Forum, Cefic Sector Group](#)
- [European Association of Chemical Distributors \(Fecc\)](#)
- [Downstream Users of Chemicals Co-ordination Group \(DUCC\)](#)
- [European Chemical Industry Council](#)

- [The Association of Dutch Water Authorities and Association of Dutch Water Companies](#)
- [EurEau - European Federation of Water Services](#)
- [European Biocidal Products Forum, Cefic Sector Group](#)

You can find the roadmap and the (now closed) consultation by clicking the link below. The consultation period closed on 20 June 2020.

More information:

[https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12264-Chemicals-strategy-for-sustainability-toxic-free-EU-environment-](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12264-Chemicals-strategy-for-sustainability-toxic-free-EU-environment)

- **DG Grow draws battlelines on draft EU future chemicals strategy**

Source: Chemical Watch

A leaked high-level European Commission internal document shows early health and environmental protection commitments for an ambitious new EU chemicals strategy for sustainability are far from approved, and likely to be significantly amended.

The document, produced by industry directorate DG Grow and seen by Chemical Watch, proposes significant changes to a draft strategy communication from the environment directorate, saying the latter includes actions and concepts "without prior discussion or assessment".

The overall tone and approach of DG Environment's draft is "prohibitive and very negative, creating unnecessary fear among citizens", the DG Grow document says. The "self-criticising" tone should be changed and its language should be "less definitive and committing".

As well as scaling back some of DG Environment's proposals, DG Grow's document links the chemicals strategy to other Commission initiatives, such as its industrial strategy. It sets out measures to improve the competitiveness of Europe's chemicals sector in areas such as funding, skills, digitalisation and, in response to the impact of the Covid-19 crisis, the reshoring of chemicals production.

The document, dated 23 June, could be a major setback for DG Environment's ambition to transform chemicals legislation with a 'game-changer' strategy – a key pillar of president Ursula von der Leyen's new Green Deal.

While DG Environment spearheads the strategy, it has to win the approval of other Commission services, in particular DG Grow, which champions the interests of industry.

DG Environment's proposals, also seen by Chemical Watch, include a raft of measures to increase health and environment protection from hazardous chemicals and stimulate the use of safer alternatives, delivering on many of the measures long sought by NGOs and members of the European Parliament.

The envisaged proposals included:

- a poly- and perfluoroalkyl substances (PFAS) action plan;
- a comprehensive framework on endocrine disrupting chemicals;
- new hazard classes to fully address environmental toxicity, persistency, mobility (PMT and vPvM); and
- the introduction of a mixture assessment factor (MAF) in Annex I of REACH to account for unintentional mixtures of chemicals.

Some of these will be key battlegrounds over the coming months.

No prior discussion

The document criticises DG Environment for introducing concepts and committing to actions without any prior discussion or assessment.

These include a six-point PFAS action plan set out in the draft communication to phase out all but "essential" uses, without spelling out the criteria. NGOs have called for a strict definition to prevent industry exploiting "loopholes".

"It has not been discussed or agreed yet what such uses would be, let alone the question whether the Commission is at all to decide on dividing society and economy in matters that are essential and non-essential," the DG Grow document says. "The concept of essentiality needs further assessment, as well as to be agreed upon, based on objective criteria."

It also opposes DG Environment's proposal to include a MAF in REACH as a "step too far", adding that there is no agreement or consensus on this approach.

DG Grow wishlist

The chemicals strategy should include actions to alleviate the burden on the industry, in particular SMEs, to comply with new and complex legislative requirements proposed by DG Environment, the document adds.

Particularly important is "predictability and transparency", so that industry knows what they have to plan for and invest in, echoing recent comments by Cefic.

The legislative focus should be "on the bigger risks" and regulating those chemicals, instead of being dependent on individual member states' "random decision" to tackle a particular chemical. This should be done by "formalising and enhancing" the risk management options analysis (RMOA) process.

Substitution of hazardous chemicals should be implemented in a "realistic way", the document says, and there must be a "good balance" between generic and specific risk approaches. The document also says a hazard-based approach is "not justified".

Chemical Watch contacted Cefic for reaction but it declined, saying its policy is "not to comment on draft opinions, speculations or internal exchanges between various Commission services".

In its reaction to Chemical Watch, NGO the European Environmental Bureau (EEB) said it was "extremely worried" about DG Grow's stance on the strategy. "They don't seem to realise that the political weather has changed and environment and health are core to the new Commission's mission."

More information (free subscription required):

<https://chemicalwatch.com/135486/dg-grow-draws-battlelines-on-draft-eu-future-chemicals-strategy>

- **Draft EU chemicals strategy outlines plans to add 'mixtures factor' to REACH**

Source: Chemical Watch

The European Commission is planning to introduce a mixture assessment factor (MAF) in Annex I of REACH to account for unintentional mixtures of chemicals. The plan raises the possibility of thousands of registrants having to update their dossiers to accommodate the additional factor, which will cause nominal risk values to rise.

The Commission's intention is set out in an unpublished draft communication document on the upcoming EU chemicals strategy for sustainability, circulated in June and recently seen by Chemical Watch. It is not final and is subject to change before publication, expected in the autumn.

"The Commission will introduce adequate legal provisions to take account of combination effects in other relevant legislation ... bearing in mind the benefits of a MAF approach," the document says.

The first of the "other relevant legislation" will be the water framework Directive and the food contact materials Directive, "continuing with other legislation whenever this is revised".

Earlier this year, Sweden and the Netherlands asked other EU member states for feedback on the idea of implementing a MAF under REACH. Risk assessment under REACH does not currently account for an individual substance's potential to form part of an unintentional mixture and thereby pose a greater risk compared with the substance on its own. The Swedish-Dutch proposal aims to change this situation by requiring registrants to incorporate a MAF into their chemical safety assessments (CSAs).

The MAF would be a number by which a key value in the risk calculation should be multiplied to nominally increase the final result. As proposed by Sweden and the Netherlands, it would be a generic, fixed value in all cases, although this is still open to discussion. Furthermore, the MAF would be relevant to all substances requiring a CSA, which are those manufactured or imported in quantities of ten tonnes a year or more.

Austria, Bulgaria, Denmark, France, Norway and Spain have said that they support the Swedish-Dutch proposal.

The German Federal Institute of Occupational Safety and Health (Baua), one of the competent authorities for REACH and CLP for Germany, has said that it is pragmatic and feasible – as well as "scientifically justified" – for protection of the environment. However a MAF is not necessary for occupational settings, and the "scientific data basis" for the assumption that unintentional mixtures pose a risk to consumers or the general population "appears rather weak".

In contrast, five industry associations – Concawe, Cefic, Eurometaux, the European Crop Protection Association (ECPA) and the Association of Chemical Industry of the Czech Republic – have been critical of the proposal.

Concawe has said that a MAF of ten or higher would affect all relevant REACH registration dossiers for petroleum substances. "We need to ensure a simple and efficient consideration of mixture toxicity in the risk assessment of substances by means of a mixture assessment factor, so that policy action is not further delayed," the Commission's unpublished draft communication document says. Commission services and EU agencies will work together on addressing the combination effects of chemicals across legislation through "an ad hoc working group", it adds.

However, there are no details about key issues in the MAF debate, such as where in the risk calculation the factor should be applied and how big the factor should be.

Ninja Reineke, head of science at CHEM Trust, said that combination effects should have been addressed already under the previous Commission and now represent an "urgent issue" for the chemicals strategy. "If this is a draft, it's a start and should not be weakened," she added.

"We understand the need to tackle this complex and long-lasting issue," said Violaine Verougstraete, chemicals management director at Eurometaux. "But we would caution against the application of a generic mixture assessment factor applied across substances and uses. This should be seen as a default solution and should allow – and be overruled by – refinements based on robust data, for example, what we know on natural background of metals."

The Commission and Cefic declined to comment for this article.

More information (subscription needed):

<https://chemicalwatch.com/133337/draft-eu-chemicals-strategy-outlines-plans-to-add-mixtures-factor-to-reach>

- **CEFIC stance on workability issues of CLP, poison information requirements**

Source: European Commission

Cefic (the European Chemical Industry council) welcomes the second amendment of Annex VIII of CLP, aimed to solve the workability issues identified in the original text.

We strongly support the inclusion of Interchangeable Component Group (ICG) concept and the standard formulas concept (for cement, gypsum, petroleum and concrete). It is Cefic's view that the Standard formulas could be considered

in a generic manner for other industrial sectors and we ask the EU Commission for their consideration.

Cefic would like to highlight the serious concerns we have related to the timelines and application dates, namely the adoption and publication in the Official Journal of the European Union is expected in November 2020, giving the chemical industry just two months to submit the necessary notifications according to the amended Annex.

As of 1 January 2021, the notification requirements according to Annex VIII of CLP (Regulation (EC) No 1272/2008) will apply. The Annex is being amended to solve certain workability issues identified in a study carried out during 2018-2019.

The adoption and publication in the Official Journal of the European Union is expected in November 2020, giving the chemical industry just two months to submit the necessary notifications according to the amended Annex. The changes in the legal text include essential solutions for the notification process to be workable. However, Cefic believes that a two-month window makes it extremely difficult for the chemical industry to fulfill the new requirements.

More information:

<https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/fa1c65b0-d6e9-4491-8f1e-fdae551ad885/details>

- **Framework for REACH polymer data requirements set out in EU study**

Source: Chemical Watch

A major study on the possible registration of polymers under REACH suggests a framework for data sharing whereby groups of co-registrants come together through 'inquiry-like' processes to establish the 'sameness' of their substances.

The European Commission has revived efforts to bring polymers within the scope of REACH registration, a mammoth task given significant data gaps and the complexity of such substances – factors that thwarted similar attempts in the past.

After some delay, this week the EU executive published a 345-page final report from consultancy groups Wood and Peter Fisk Associates (PFA). The study is seen as setting the building blocks of a possible proposal on polymer registration, expected by 2022.

A summary of its key findings, including criteria for selecting polymers for registration, were outlined to the Competent Authorities for REACH and CLP last week.

The final report, also submitted to Caracal, provides detailed options for data requirements on some 33,000 polymers of concern for which it says the benefits of registration outweigh the costs. It proposes adapting REACH registration obligations to accommodate them, but doing so "within a model of minimum divergence".

While the fundamentals of REACH registration are "broadly applicable" to polymers, it says, the establishment of sameness and groups to enable one registration per substance will be "very demanding".

Therefore, the report adds, bringing co-registrants together to manage a joint submission and the formation of groups of polymers with potential for registration should be tackled together. And "every effort" should be made to encourage data sharing, subject to compensating owners and minimising animal testing.

Guidance specific to polymers will be required to steer the registration process, data requirements or derogations, it says. After that, inquiry-like processes similar to those performed already for non-polymeric substances would be "a familiar and sensible first step" toward the establishment of co-registrant groups. Groups could be formed by two different procedures:

- companies that know they manufacture or import the same polymer based on composition or market use; or
- in certain cases, co-registrant groups based on specific hazard, as expressed by compositional or physical data alone. This could include different, mainly non-bioavailable polymers but which could contain the same constituents or functionalities which possess a particular hazard.

And they should agree on:

- whether closely related members could be registered together;
- the lead registrant;
- the name of the substance under Echa guidance; and
- a description that would include certain criteria, for example molecular weight range, solubility and biodegradability.

Noting that polymers can exhibit differences even when composition appears very similar on first examination, the report says the approach to sameness will need further work, "probably through guidance development".

Confidentiality

With a huge variety of polymers currently on the market, each tailored for different uses and changes carried out down the supply chain, manufacturers are apprehensive about sharing what they see as business confidential information.

The Wood-PFA report says this aspect and compensation for use of data will need to be "managed". And a mechanism respecting confidentiality may require "additional considerations" beyond the typical current practice for non-polymers. The report proposes polymer identification criteria based on molecular weight (MW), prioritising those with lower MW, and sets out data requirements that are tonnage dependent.

The simplest option, it says, is registration based on the whole substance tonnage. Polymers could be considered as similar to multi-constituent substances or those of unknown or variable composition, complex reaction products or of biological materials (UVCB), which use this.

Some data requirements may not be relevant, however, particularly for higher molecular weight polymers, the report says. Therefore, a series of testing strategies are proposed that enable an initial assessment. The results will indicate which further tests are relevant to derive a meaningful chemical safety assessment based on the polymer properties.

More information (subscription needed):

<https://chemicalwatch.com/133345/framework-for-reach-polymer-data-requirements-set-out-in-eu-study>

COUNCIL OF THE EUROPEAN UNION

INSTITUTIONAL AFFAIRS

- **Germany details its priorities during its 6-month EU presidency**

Source: German Presidency of the EU

The priorities of Germany's presidency are driven by its motto: "Together for Europe's recovery". The German presidency of the Council of the EU will focus directly on overcoming the COVID-19 pandemic. Fighting the spread of the virus, supporting the European economy to recover and reinforcing social cohesion in Europe. In order to achieve this, Germany is committed to joint approved action, European solidarity and common values.

The agenda contains a number of items that could be of interest to the European Swimming Pool and Spa sector, and are listed below.

(Page 9) "The single market should be strengthened with improved security provisions for the platform economy and digital services, as well as in the area of consumer protection. We intend to adopt Council conclusions on the issue of ecodesign."

"In the Council we also intend to adopt conclusions on the Commission's new Circular Economy Action Plan and its implementation. During our Council Presidency we plan to commence negotiations on the EU's 8th Environmental Action Programme."

"During our Council Presidency we want to work towards concluding the deliberations on the draft of a European Climate Law which will specifically write into law the goal for the European Union to become climate-neutral by 2050."

(Page 17) "We are calling for the Council to be involved from an early stage in drafting the new Consumer Agenda, which the Commission wants to present in the second half of 2020. The Agenda must help consumer protection in the European Union to adapt to the current digital and environmental challenges, protect consumers and be more effective in enforcing existing consumer rights."

More information:

<https://www.eu2020.de/blob/2360248/978a43ce17c65efa8f506c2a484c8f2c/pdf-programm-en-data.pdf>

STAKEHOLDERS

PFAs

- **PFASs: Avoiding the streetlight effect**

Source: European Environmental Bureau

Per- and polyfluoroalkyl substances, commonly known as PFASs, are receiving increased regulatory attention because of their persistence and (eco)toxicological profile, as well as their widespread use and resulting ubiquitous presence.

In this report, we have used REACH registrations of PFASs, independent literature, technical information from producers and general chemical knowledge to sketch the landscape of which types of PFASs are most prevalent in products and likely lead to highest environmental pressures.

We conclude that the types of PFASs one should most care about are: fluorotelomer substances (FTs) and the side-chain fluorinated polymers (SCFPs) they give rise to, as well as fluorinated (poly)ethers. This report is also meant as an introduction to the world and chemistry of PFASs.

More information:

<https://eeb.org/library/pfass-avoiding-the-streetlight-effect/>

WATER

- **OECD report addressing the social consequences of tariffs for water services**

Source: EurEau.org

Where they exist, tariffs for water supply and sanitation services face a tension between different policy objectives, such as ensuring the financial sustainability of service provision and ensuring access to all, including vulnerable and poor social groups. Governments (local and national) resort to a range of measures to reconcile these objectives and address social consequences of tariffs: tariff levels and structures, nudging, budgetary transfers, targeted social measures.

This paper revisits most common practices and discusses their pros and cons, and requisites to make them work. It provides up-to-date analyses on a series

of related issues, such as definitions of affordability, principle for cost recovery, benefits and costs of metering, elasticity of domestic water use to prices, fiscal transfers to water services. The paper is informed by recent academic research, data on selected countries, and interactions with OECD bodies.

More information:

https://www.oecd-ilibrary.org/environment/addressing-the-social-consequences-of-tariffs-for-water-supply-and-sanitation_afede7d6-en?