



EU Monitoring Report

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CONTENTS

EUROPEAN CHEMICALS AGENCY	2
REACH.....	2
• <i>New submission test environment to stop misleading data reaching Member States ...</i>	2
• <i>ECHA pressed to clarify 2020 chemical universe pool allocation deadline.....</i>	2
CLP.....	3
• <i>Updated guidance clarifies labelling requirements for poison centre notifications.....</i>	3
• <i>UPDATE: Proposal for harmonised classification and labelling of sodium chlorate.....</i>	4
COVID-19.....	5
• <i>UPDATE: ECHA recommends compositional requirements for disinfectants.....</i>	5
EUROPEAN COMMISSION	6
REACH.....	6
• <i>New EU group to spearhead REACH polymer registration work.....</i>	6
• <i>EEB calls for extension of precautionary principle under REACH review.....</i>	7
BREXIT.....	8
• <i>Newly released Brexit papers reveal UK chemicals cooperation wish list.....</i>	8
ENDOCRINE DISRUPTORS.....	9
• <i>EU authorities finalise data requirements for endocrine disrupting biocides.....</i>	9
CONSTRUCTION.....	9
• <i>Parliament and Commission discussions on Circular Economy Action Plan.....</i>	9
EUROPEAN PARLIAMENT	10
WATER REUSE.....	10
• <i>Parliament approves increased water reuse.....</i>	10
STAKEHOLDERS	11
CHEMICALS.....	11
• <i>SMEunited: Scip database could cost SMEs €48-€67bn a year.....</i>	11
• <i>Three times more chemicals on the global market than thought, scientists say.....</i>	11
COVID-19.....	12
• <i>Pool Technologie offers its sodium hypochlorite production in COVID-19 crisis.....</i>	12
CHEMICALS IN ELECTRONICS.....	12
• <i>Report on global regulatory developments on chemicals in electronics.....</i>	12
REGULATION.....	13
• <i>EVENT: Save-the-date for Key Regulatory Updates: Europe and Asia.....</i>	13
BIOCIDES.....	13
• <i>EVENT: Biocides Europe 2020.....</i>	13

EUROPEAN CHEMICALS AGENCY

REACH

- **New submission test environment to stop misleading data reaching Member States**

Source: European Chemicals Agency

The new test environment is available for companies submitting through the ECHA Submission portal and those using the system-to-system service.

Companies can now upload and submit notifications in the test environment as if they were in the official ECHA Submission portal. The full user experience allows different submission scenarios to be tested and full validation checks to be done for dossiers. Now with the test environment, companies can check how the portal works without appointed bodies and poison centres receiving misleading data.

The terms and conditions for using the ECHA Submission portal describe the commitment for the users to submit only true and accurate data. For poison centres, having access to correct and high-quality information is essential when providing advice to consumers or medical professional in an emergency situation. Submissions in the test environment are securely handled with no interference from other users.

If you want to run a test submission using the system-to-system service, you should follow the instructions available in the system-to-system integration for industry document.

More information:

<https://poisoncentres.echa.europa.eu/-/new-submission-test-environment-to-stop-misleading-data-reaching-member-states>

- **ECHA pressed to clarify 2020 chemical universe pool allocation deadline**

Source: Chemical Watch

ECHA's director of prioritisation and integration Jack de Bruijn has said the agency is "still looking into" the feasibility of its end-of-year deadline to allocate all substances above 100 tonnes a year to three distinct chemical universe 'pools' for potential regulatory action.

The agency's interim goal is to generate a "sufficient" understanding of all substances registered above 100 tonnes by the end of [2020](#). Using [grouping](#), it is aiming to assign each substance to one of three 'pools' within the chemicals universe – high priority for risk management, high priority for data generation and low priority. The goal falls under its integrated regulatory strategy, the second annual report for which was [published](#) on 13 May. The report revealed that last year, the agency and member states assessed 219 high tonnage chemicals. Some 2,400 are still to be assigned to a pool.

Reacting to the report, the European Environmental Bureau questioned whether doing this by the end of the year is possible. This will be a "challenge", the NGO's policy manager Tatiana Santos said. "Last year they had 2,700 left to screen and this year they still have 2,400 left. We wonder how Echa will manage to allocate 2,400 substances in six months while they only allocated 219 in one year?"

More information (subscription needed):

<https://chemicalwatch.com/118677/echa-pressed-to-clarify-2020-chemical-universe-pool-allocation-deadline>

CLP

- **Updated guidance clarifies labelling requirements for poison centre notifications**

Source: European Chemicals Agency

The Guidance on harmonised information relating to emergency health response – Annex VIII to CLP – has been updated (version 3.0) to include changes following the annex's first amendment, which entered into force on 20 January 2020. In addition, the Labelling and Packaging Guidance has also been updated.

ECHA is currently working on additional changes to the Guidance resulting from the second amendment of Annex VIII, which has been consulted with Competent Authorities for REACH and CLP (CARACAL) on 15 May 2020 and expected to be finalised and adopted by the Commission by the end of summer 2020.

The second amendment covers workability issues identified by certain industry sectors, such as for mixtures with high or unpredictable composition variability, where a disproportionate number of notifications and UFI's would be required.

More information:

<https://poisoncentres.echa.europa.eu/-/updated-guidance-clarifies-labelling-requirements-for-poison-centre-notifications>

- **UPDATE: Proposal for harmonised classification and labelling of sodium chlorate**

Source: European Chemicals Agency

We recently informed you (Monitoring report 30 April – 7 May) that ECHA is looking for comments on sodium chlorate regarding harmonised classification and labelling, following a notification by the Swedish Chemical Agency.

The procedure for a proposal for harmonized classification and labelling of sodium chlorate and the consultation are ongoing. The proposal is now included in the so-called 'registry of classification and labelling (CLH) intentions until outcome'. This registry lists the intentions and proposals received by ECHA for a new or revised harmonised classification and labelling of a substance.

The Swedish Chemicals Agency proposes to change the classification and labelling of the substance along the following lines:

	Classification		Labelling		Specific Conc. Limits, M-factors
	Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	
Current Annex VI entry	Ox. Sol. 1 Acute Tox. 4* Aquatic Chronic 2	H271 H302 H411	GHS03 GHS07 GHS09 Dgr	H271 H302 H411	
Dossier submitters proposal	Remove Aquatic Chronic 2 Modify Acute Tox. 3	Remove H411 Modify H301	Remove GHS09 Modify GHS06	Remove H411 Modify H301	Add oral; ATE = 100 mg/kg bw
Resulting Annex VI entry if agreed by RAC and COM	Ox. Sol. 1 Acute Tox. 3	H271 H301	GHS03 GHS06 Dgr	H271 H301	oral; ATE = 100 mg/kg bw

More information:

<https://echa.europa.eu/fr/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e183552bed>

COVID-19

- **UPDATE: ECHA recommends compositional requirements for disinfectants**

Source: European Chemical Agency

We informed you in the monitoring reports of 19–26 March and 9–16 April that ECHA is supporting competent national authorities to apply derogations from the normal authorisation requirement for biocidal products, in order to speed up the manufacture and supply of disinfectants in the context of the COVID-19 crisis.

The information below summarises ECHA's recently released Questions-and-Answers aimed at companies seeking to make available on the EU market disinfectants for the purpose of managing the Covid-19 pandemic.

ECHA's advice particularly aims to target biocidal products that are meant to be used in the following product types (PTs):

- PT 1: products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp.
- PT 2: products used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs. Usage areas include, inter alia, swimming pools, aquariums, bathing and other waters; and products used as algaecides for treatment of swimming pools, aquariums and other waters and for remedial treatment of construction materials.
- disinfection of surfaces in contact with food and feed (PT 4, including Used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed (including drinking water) for humans and animals).

Question: I represent a (non-)EU company that wishes to place on the EU/EEA/Swiss market products based on 'active chlorine generated from sodium chloride by electrolysis' for use in PT1. How can I quickly access the market?

Answer for non-EU based company: Firstly, note that companies established outside of the EU are not bound by the obligations of the BPR, even if they export

their products into the European Union. The responsibility for fulfilling the requirements of the BPR, such as the approval of active substances or the authorisation of biocidal products lies in principle with the importers established in the European Union. It is the EU based importer which needs to comply with the BPR obligations illustrated below.

Answer for EU based company: Biocidal products containing ‘new’ active substances can normally only be placed on the market, following approval of the substances and authorisation of the products. However, in exceptional situations (e.g. in case of danger to public health), a Member State may permit products on its market that do not comply with the BPR, under Article 55(1) of the BPR. This is valid for: (1) Biocidal products containing approved AS (such as propan-1-ol or propan-2-ol); or (2) Biocidal products containing new AS (not supported in the Review Programme).

More information

https://echa.europa.eu/documents/10162/28801697/q_a_covid_disinfectants_en.pdf/f380496a-d61a-1ff1-ee78-12d302c5d520

EUROPEAN COMMISSION

REACH

- **New EU group to spearhead REACH polymer registration work**

Source: Chemical Watch

The European Commission has mandated a subgroup of experts from EU member states to lead the work for a possible proposal for registration of certain types of polymers under REACH.

CASG-Polymers – a subgroup of the Competent Authorities for REACH and CLP (Caracal) – will start activities "indicatively" in June and be disbanded at the end of 2021 "subject to the delivery of the expected outputs, future needs and discussions", the Commission said in a recent paper to Caracal.

The Commission has rekindled efforts to bring some polymers within the scope of REACH registration and evaluation. In November, it [committed](#) to publishing a proposal by 2022 amid persistent calls from NGOs and MEPs and despite having decided against such a move twice before due to lack of data and the complexity of polymers.

The subgroup will draw on the conclusions of a major study the EU executive commissioned with consultancy groups Wood and Peter Fisk Associates for the development of criteria to identify and group polymers. The current approach is to target certain polymers that can "reasonably be assumed to display some hazardous properties".

More information (subscription needed):

<https://chemicalwatch.com/118956/new-eu-group-to-spearhead-reach-polymer-registration-work>

- **EEB calls for extension of precautionary principle under REACH review**

Source: European Commission

The committee of Competent Authorities for REACH and CLP is currently discussing the review of the EU REACH Regulation. A document was published that contains comments made by the European Environmental Bureau (EEB), which has observer status, on the ongoing review of REACH. The EEB is a prominent environmental NGO network of over 143 environmental citizens' organisations based in more than 30 countries, and often considered amongst the most influential NGOs in the field of European policy-making. The EEB commented the following:

The EEB regrets that ECHA and the Commission are not taking the opportunity to extend the application of the precautionary principle to other REACH risk management processes such as identification of SVHCs: e.g. applying the precautionary principle as regards the level of evidence required to assess the properties of the substances; during information generation phases such as classification of a substance (e.g. when uncertainties around the properties of the substance exist but a precautionary approach would recommend to suggest the classification while raising uncertainties), etc.

In no place is the 2018 REACH REFIT explicitly saying that the implementation of the principle shall be limited to the restriction procedure while the REACH regulation is underpinned by the precautionary principle (and that includes all processes). Although it does refer to ECHA and to the committees' decisions, but also to the Commission's involvement in the procedure as well as the REACH committee, the implementation of the principle is not limited to the restriction procedure. We suggest ECHA and the Commission extend these recommendations to other REACH processes as soon as possible, and to not limit these developments to the Restriction procedure.

More information:

<https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/7b8ac972-6873-46f5-b850-207e5aeccc18/details>
<https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/61e735b0-c4ab-4ae9-9b01-dd27af7a9685/details>

BREXIT

- **Newly released Brexit papers reveal UK chemicals cooperation wish list**

Source: Chemical Watch

The UK has published a series of policy papers on its plans for the future trade relationship with the EU, in which it proposes to cooperate on chemicals regulation, share data and align approaches towards classification and labelling.

The annexes to the draft UK-EU comprehensive free trade agreement (CFTA), one of the batch of documents released on 19 May, elaborate on the government's February [whitepaper](#). This included only two paragraphs on chemicals that outlined briefly what could potentially be agreed in future.

In their February negotiation mandate given to the European Commission, member states pushed for a future trade agreement that binds the UK to standards for goods, including chemicals, which correspond to those adopted by the trade bloc in the future.

However, the UK demanded the right to diverge from single market rules while at the same time securing frictionless trade with the EU. The draft annexes to the policy papers contain one on chemicals – annex 5-E, which outlines in eight articles what the UK is hoping to achieve.

On the subject of cooperation (article 8) the draft annex says that both parties would "agree to continue and strengthen their cooperation on chemicals regulation to facilitate trade in a way that benefits" consumers, businesses and the environment and provides for the protection of human and animal health.

More information (subscription needed):

<https://chemicalwatch.com/119044/newly-released-brexit-papers-reveal-uk-chemicals-cooperation-wish-list>

ENDOCRINE DISRUPTORS

- **EU authorities finalise data requirements for endocrine disrupting biocides**

Source: Chemical Watch

Industry and NGO requests for changes rejected — The EU competent authorities (CAs) for biocides have given the final nod to proposed data requirements for assessing endocrine disrupting (ED) properties in biocides, despite stakeholder concerns over their burden to industry and animal testing demands.

The data requirements are laid out in a delegated Regulation, amending the biocidal products Regulation's Annexes. A European Commission consultation on these amendments in February and March drew 11 contributions from five NGOs, two European industry associations, three individual companies and one testing laboratory.

Commenters voiced concerns over the complexity and costs of the proposed tests, as well as over their reliance on vertebrate animals. In order to assess a biocidal active substance for ED properties, industry will have to provide more data on reproductive toxicity, developmental neurotoxicity and developmental immunotoxicity than the BPR currently requires.

More information (subscription needed):

<https://chemicalwatch.com/118697/eu-authorities-finalise-data-requirements-for-endocrine-disrupting-biocides>

CONSTRUCTION

- **Parliament and Commission discussions on Circular Economy Action Plan**

Source: European Parliament

The European Parliament's Environment Committee discussed on 12 May the recent Circular Economy Action Plan with Virginijus Sinkevičius, the Commissioner for Environment, Oceans and Fisheries. AlienorEU followed the livestreamed discussions and would like to inform you of relevant comments made by the Commissioner regarding the role of the construction sector:

Regarding construction, Commissioner for Environment Sinkevičius insisted on the fact that "it is necessary to consider the entire life cycle and go beyond energy

9

efficiency alone, in order to look at the source of primary materials. The European Commission will therefore make a proposal to revise the Construction Products Regulation and table a new initiative to measure the environmental performance of construction products. The principles of the circular economy must also be applied to the construction sector.”

More information:

https://multimedia.europarl.europa.eu/en/envi-committee-meeting_20200512-1400-COMMITTEE-ENVI_vd

EUROPEAN PARLIAMENT

WATER REUSE

- **Parliament approves increased water reuse**

Source: European Parliament

To prevent water shortages in the EU, Parliament approved the Water Reuse Regulation. The new law defines minimum requirements at European level for the first time for reclaimed water (i.e. urban wastewater that has been treated in a reclamation plant) to be used for agricultural purposes in a safe way, protecting people and the environment. It was adopted without vote at the start of the Plenary.

The new rules aim to ensure that treated wastewater is more broadly reused in order to limit use from water bodies and groundwater. The fall in groundwater levels, due in particular to agricultural irrigation, but also industrial use and urban development, is one of the main threats to the EU water environment.

The adopted measures will enter into force on the twentieth day following its publication in the Official Journal of the European Union and shall apply three years after entry into force.

More information:

<https://www.europarl.europa.eu/news/en/press-room/20200512IPR78921/parliament-approves-increased-water-reuse>

STAKEHOLDERS

CHEMICALS

- **SMEunited: Scip database could cost SMEs €48-€67bn a year**

Source: Chemical Watch

The trade body representing small and medium sized enterprises in Europe has estimated that the reporting obligations associated with Echa's soon to be launched substances of concern in products ([Scip](#)) database will cost SMEs between €48bn and €67bn a year.

More information (subscription needed):

<https://chemicalwatch.com/117321/smeunited-scip-database-could-cost-smes-48-67bn-a-year>

- **Three times more chemicals on the global market than thought, scientists say**

Source: Chemical Watch

Scientists who found there are up to three times more chemicals on the global market than previously thought are hoping to transform their research database into a more user-friendly, publicly-available tool.

In research published in January, the team found that 350,000 chemicals or chemical mixtures have been registered for production and use globally, based on analysis of 22 chemical inventories from 19 countries or regions.

More information (subscription needed):

<https://chemicalwatch.com/117758/three-times-more-chemicals-on-the-global-market-than-thought-scientists-say>

COVID-19

- **Pool Technologie offers its sodium hypochlorite production in COVID-19 crisis**

Source: Euro Spa Pool News

As part of the health crisis linked to Coronavirus (Covid-19), the Pool Technologie company has rallied together and as a sign of solidarity is offering its sodium hypochlorite production.

Chlorine is known to be the most effective disinfectant on inert surfaces and is therefore used on materials to destroy coronavirus. This specialist in salt chlorination for private and communal swimming pools has therefore decided to use its expertise to help the community, despite its reduced operations. At its factory in Valergues (34), near to Montpellier, two Pure Chlore® units have been set up to produce 200 litres of sodium hypochlorite per hour (concentrated bleach).

All this production has been offered to communities, institutions, medical and paramedical workers, and any businesses that need it. Pool Technologie has also offered its storage capacity of 2,000 litres.

More information:

https://www.eurospapoolnews.com/actualites_piscines_spas-en/65134-covid,19,mobilization,pool,technologie,communités,sodium,hypochlorite,production.htm

CHEMICALS IN ELECTRONICS

- **Report on global regulatory developments on chemicals in electronics**

Source: Chemical Watch

As the world continues to grapple with the consequences of the ongoing Covid-19 pandemic, product safety professionals across the electronics industry are seeing no let-up in the momentum of regulatory activity affecting this critical sector.

The European Commission is currently reviewing RoHS2, while RoHS-style restrictions are making an appearance in regulations around the world. Meanwhile, activity continues apace in the US, where a number of substances used in

electronics are either undergoing risk evaluation under TSCA or have been designated as a high priority for risk evaluation.

More information (subscription needed):

<https://home.chemicalwatch.com/electronics-report-members/#>

REGULATION

- **EVENT: Save-the-date for Key Regulatory Updates: Europe and Asia**

Source: Chemical Watch

Chemical Watch plans to organise a virtual conference on key regulatory updates in Europe and Asia. The event will take place on 15–16 October 2020. Programme information will be made available in the coming months.

Register interest:

<https://events.chemicalwatch.com/118068/key-regulatory-updates-europe-and-asia-15-16-october-2020>

BIOCIDES

- **EVENT: Biocides Europe 2020**

Source: Chemical Watch

Chemical Watch will organise a conference entitled ‘Biocides Europe 2020’ in Copenhagen, Denmark on 1–2 December 2020. Programme information will be made available in the coming months.

Register interest:

<https://events.chemicalwatch.com/117964/biocides-europe-2020-1-2-december-2020>