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CHEMSAFE ACTIVITY DURING COVID19 EMERGENGY

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Dear Customers, Suppliers, Partners, Authorities,

Chemsafe Srl implements and supports Italian Government actions in order to restrain Covid19 outbreak and related social and sanitary effects. In such a difficult period for our Country, it's important to avoid any unnecessary contacts and, in the meantime, to protect the supply chain of chemical and medical products, so needful items.

Chemsafe have re-organized its operations in order to keep available to its customers all offered regulatory services (Consultancy, SDS, Dossier, Feasibility Studies, Experimental Studies Monitoring, etc). Our Regulatory Experts, even if not physically in the office, will be able to manage the inquiries by Customers via e-mail, skype calls and phone calls.

REACH

Product sold online: Inspectors to check products sold online that contain harmful substances

January 20, 2020

Inspections for the Eighth Forum Enforcement Project have started. The project will check whether companies selling hazardous substances, mixtures, biocide products and articles online in Member States and EEA countries comply with REACH, CLP and the Biocide Products Regulation.

The chemical products sold online represent a huge problem in terms of safety information supply chain. From recent information about 80% of all the products sold on interned are lacking of safety data for consumers. How to manage this problem?

The Eighth Forum Enforcement Project (REF-8) concentrating on the online sale of substances, mixtures and products has entered its operational phase and will run until 31 December 2020. 29 countries will participate in the project.

The project will target products for the general public and professionals, available in private companies' web-shops and in marketplace platforms, such as Amazon and eBay.

Inspectors will check if buyers are informed about the existence of hazardous substances before the purchase is completed and if particular aspects of the regulations are fulfilled. This can be checked by controlling the advertisement of a chemical product or by purchasing products and subsequently evaluating them. For example, inspectors will look into restricted substances found in products commonly sold online such as toys and textiles and check against the requirements laid down in the REACH Regulation.

Inspectors will also check whether the advertisements for hazardous chemical substances sold online adequately inform consumers about the hazard class and the applicable hazard categories of the substance or mixture as required by the CLP Regulation.

For the Biocide Products Regulation, the project covers both authorized biocide products and those available under the transitional regime. The transitional regime is the period of time where biocide products are still governed by national provisions in each Member State.

The project will focus on the online product information and online advertisements but inspectors may visit the companies for on-site inspections, whenever they consider it relevant.

The project also aims to raise awareness of the duties related to online sales of substances, mixtures and products among companies and marketplace platforms as well as strengthening the communication and cooperation between enforcement authorities from different Member States.

The results of the project are expected to be published at the end of 2021.

New intentions to identify substances of very high concern

New intentions to identify substances of very high concern have been received for:

- dibutylbis(pentane-2,4-dionato-O,O')tin (EC 245-152-0, CAS 22673-19-4),
- 2-methylimidazole (EC 211-765-7, CAS 693-98-1), and
- 1-vinylimidazole (EC 214-012-0, CAS 1072-63-5).

Submission of lead chromates restriction report postponed

The submission of the Annex XV restriction report on lead chromate; lead sulfochromate yellow (C.I. Pigment Yellow 34) and lead chromate molybdate sulphate red (C.I. Pigment Red 104) by ECHA has been postponed until 3 April 2020.

Authorisations granted for use of chromium trioxide

The European Commission has granted an authorisation for **chromium trioxide** (EC n. 215-607-8, CAS n. 1333-82-0) for one use to Doosan Electro-Materials Luxembourg SARL and Doosan Energy Solution Kft. The review period expires on 10 January 2032.

Authorisation List updated

The European Commission has added **11** new substances to the Authorisation List. It contains now **54** substances in total.

Consultations launched for applications for authorization

ECHA is looking for comments on alternative substances or technologies on eight applications for authorization covering 10 uses of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (EC-, CAS-). It is used to produce various medical devices and medicinal/biopharmaceuticals.
The deadline for comments is **8 April 2020**

New version 4.4 of the OECD QSAR Toolbox available now

This new version offers a simplified user interface for new users to the Toolbox. Data, profiler and metabolic results, as well as potential analogues for a chemical of interest can be retrieved and exported with just one click. Furthermore, the new Toolbox Repository allows third parties to develop their own extensions and make them available to the whole Toolbox community. The Toolbox is a free software application developed by ECHA and the OECD that supports reproducible and transparent chemical hazard assessment.

From ECHA Newsletter (February 2020)

Make sure your Chemical Safety Report (CSR) is complete. ECHA will start checking in April 2020

Once you have submitted your registration dossier, ECHA checks that all the necessary information is included. In April 2020, ECHA will expand its checks to cover, among other things, chemical safety reports.
From April 2020, ECHA will check that use and exposure information as well as risk characterization is included in your chemical safety report (CSR). This information has to be there because it forms the basis for risk management measures that companies communicate through their supply chains and need to follow to protect their workers and the environment. The checks of the chemical safety report will be based on the uses you have reported in your registration dossier.

ECHA will be checking the completeness of chemical safety reports for any registrations where the substance tonnage band is more than 10 tonnes/year and the substance is classified as hazardous to the environment or human health, or has persistent, bioaccumulative and toxic properties. The registration dossier will not be checked for the CSR if you are part of a joint submission and you rely on the chemical safety report submitted in the Lead Registrant dossier.
The new checks on the chemical safety report will only verify that the required elements are present and will not look at the adequacy of the information submitted. The checks will be carried out for both initial dossiers and their updates. If the chemical safety report cannot be opened or is written in a language other than one of the official EU languages, it will be considered incomplete and your submission will fail.

Why the change is needed
ECHA previously improved the completeness check rules in 2016 when some automated, computer-based checks were revised and some manual checks were added. Based on this experience, we expect that additional manual checks on chemical safety reports will further improve the data availability in REACH registrations.
For authorities this means that they will have a better basis for prioritizing substances that need further regulatory action, whereas companies will be in a better position to communicate appropriate information to their customers. Information on uses is also published on ECHA's website if they have not been claimed confidential.
The new rules do not mean that any of the legal requirements in REACH would change, we simply improve the way ECHA checks that the requirements have been met.

Use Chesar to prepare your chemical safety report
Since chemical safety reports are text documents attached to IUCLID dossiers, a computer-based verification of that information is not possible. A group of ECHA staff will carry out the checks manually following standard instructions to guarantee that each check is performed using the same principles. As the checks are manual, the validation assistant available in IUCLID will not be able to report on completeness issues found in your chemical safety report.
When preparing your CSR, we recommend using the Chemical Safety Assessment and Reporting tool, Chesar. Chesar contains a workflow that guides you in filling in the necessary information consistently. It helps you address all reported uses, routes of exposure and environmental compartments, in line with the outcome of the hazard assessment. Once you have finalized your chemical safety assessment, you can automatically create a chemical safety report that you can attach to your IUCLID dossier. As Chesar exchanges data with IUCLID, the information recorded in your IUCLID dossier will be consistent with that in your chemical safety report. Although ECHA recommends to use Chesar, this is not mandatory. Any chemical safety report format is accepted as long as you have included all information listed in REACH and the reader can clearly identify all the main elements.

Other improvements
There will be some changes to the computer-based completeness checks, too. To make sure that the standard information requirements described in REACH Articles VII-X are met, we are improving the way the elements for key hazard endpoints are checked. More explicit checks will be carried out for the following endpoints: mutagenicity, reproductive toxicity and degradation.
Information related to the substance life cycle will also be checked as part of the computer-based verification. This means that the checks will detect if, based on the use description, the registration should also include information about article service life.
Since these changes will become part of the computerized checks, they will also be included in the updated IUCLID Validation assistant which is recommended to be used before submitting the data to ECHA.

New rules apply from end of April 2020

The improved completeness check will start to apply at the end of April 2020 following the release of a new version of IUCLID.

It is good to keep in mind that the new rules apply both to new registrations and registration updates. This means that your update may not pass the completeness check anymore, even though your previous registration did. However, if your update would be considered as incomplete, it does not directly impact your current registration. It means that the information you intended to submit to ECHA needs to be amended and resubmitted before it applies to your registration and can be taken into account by authorities.

In order to ensure that you have included all required information in your registration dossier, start by checking it with the validation assistant before submitting anything to ECHA. The tool is being updated and the latest version will be included in the April release of IUCLID. In addition, an updated version of the document supporting users in the areas of manual verification is expected to be available on the ECHA website by the end of February 2020. If you are not yet doing so, consider using Chesar for your chemical safety assessment and report as this will decrease the chance of incompleteness.

New substance evaluation conclusion published

A new substance evaluation conclusion document is now available on ECHA's website for:

- Medium-chain chlorinated paraffins/alkanes, C14-17, chloro (EC 287-477-0, CAS 85535-85-9), added to the CoRAP list in 2012 and evaluated by the United Kingdom.

Five proposals to identify new substances of very high concern (SVHCs)

The substances and examples of their uses are:

1-vinylimidazole (EC 214-012-0, CAS 1072-63-5) - used in formulations and as a monomer in the production of polymers;

2-methylimidazole (EC 211-765-7, CAS 693-98-1) - used as a catalyst and in the production of coating products;

dibutylbis(pentane-2,4-dionato-O,O')tin (EC 245-152-0, CAS 22673-19-4) - used as a catalyst and as an additive in the production of plastics;

butyl 4-hydroxybenzoate (EC 202-318-7, CAS 94-26-8) - used in cosmetics, personal care products and pharmaceuticals; and

resorcinol (EC 203-585-2, CAS 108-46-3) - used to manufacture rubber compounds, resins, coatings, adhesives and sealants, and cosmetics.

The deadline for comments is **17 April 2020**.

CLP

Poison centre notification postponement now official

The recent proposal for the first amendment to Annex VIII to CLP, which includes postponing the first compliance date, was published in the Official Journal on **10 January 2020** and will enter into force on **30 January 2020**. The amendment also introduces a few changes on how information should be provided.

New proposals and intentions to harmonize classification and labeling

New intentions have been received for:

2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino)acetamide (EC 261-043-0, CAS 57966-95-7)

2-chloro-N-(2,6-dimethylphenyl)-N-(2-methoxyethyl)

Acetamide (EC n. 256-625-6, CAS n. 50563-36-5)

dimethyl propylphosphonate (EC 242-555-3, CAS 18755-43-6),

nitroethane (EC 201-188-9, CAS 79-24-3),

1-nitropropane (EC 203-544-9, CAS 108-03-2), and

nitromethane (EC 200-876-6, CAS 75-52-5).

Consultation on harmonized classification and labeling

The proposal for the harmonised classification and labelling (CLH) of N-(5-chloro-2-isopropylbenzyl)-N-cyclopropyl-3-(difluoromethyl)-5-fluoro-1-methyl-1H-pyrazole-4-carboxamide; isoflucypram (EC -, CAS 1255734-28-1) was submitted by the United Kingdom and subject to a consultation, which ended on 26 July 2019. As, in the meantime, new studies have been made available, ECHA is looking for comments related to the modes of action data to investigate liver and thyroid effects observed in studies.
The deadline for comments is already passed on **20 February 2020**.

<u>New intentions have also been received for</u>:

2,2'-ethylenedioxydiethyl dimethacrylate (EC 203-652-6, CAS 109-16-0),

3,6,9-trioxaundecamethylene dimethacrylate (EC 203-653-1, CAS 109-17-1),

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate (EC 276-957-5, CAS 72869-86-4),

tetramethylene dimethacrylate (EC 218-218-1, CAS 2082-81-7),

glyoxal (EC 203-474-9, CAS 107-22-2), and

hexyl salicylate (EC 228-408-6, CAS 6259-76-3).

14°ATP (Adaptation on the Technical Progress published)

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2020/217

of 4 October 2019

amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting that Regulation

(Text with EEA relevance)

The 14°ATP will modify Annex VI of the CLP regulation which includes the list of substances with harmonized classification. Such Delegate Regulation will be under application from September 9, 2021 on substances and mixture. Anticipated voluntary adoption is possible.

Titanium dioxide (CAS n. 13463-67-7)

The amendment also includes the long-disputed Annex VI entry for Titanium dioxide (CAS no 13463-67-7); the entry applies to respirable TiO2 particles and the minimum classification of Carcinogenic Category 2, H351 (inhalation) will need to be applied to the substance when it is in powder form containing 1% or more of particles with aerodynamic diameter ≤ 10 µm. In accordance with the newly added note 10, for mixtures containing the substance, the classification as a carcinogen would apply when the mixture itself is in powder form and contains 1% or more of Titanium dioxide which is in the form of or incorporated in particles with aerodynamic diameter ≤ 10 µm.

As some hazardous dust may be produced during the use of some mixtures that contain TiO2, Annex II to CLP introduces the requirement to warn users via the product label using supplemental label statements:

- For liquid mixtures containing 1 % or more of Titanium dioxide particles with aerodynamic diameter equal to or below 10 µm: EUH211: 'Warning! Hazardous respirable droplets may be formed when sprayed. Do not breathe spray or mist.'
- For solid mixtures containing 1% or more of titanium dioxide: EUH212: 'Warning! Hazardous respirable dust may be formed when used. Do not breathe dust.'

Titanium dioxide is used widely across multiple industries in a range of product types, including paints, coatings, printing inks and plastics, and concerns remain over the potential negative impact that the harmonized classification and required label warnings will have, in particular with regards to misleading the general public and loss of consumer trust.

Inconsistent classification and labeling of mixtures – companies need to improve

When inspectors in 29 countries checked to see if companies are classifying and labeling their mixtures correctly, they found that almost **half of the checked mixtures** were not compliant with the law.

Chemical products used by consumers are mixtures of different substances. All products on the EU market that contain hazardous chemicals have to be appropriately classified and labeled so that those using them have the information they need to do so safely. The mixtures inspected during the sixth Enforcement Forum project included washing and cleaning products, paints and paint removers, adhesives and sealants, room fragrances, air fresheners and biocide products.

Altogether 3.391 mixtures and 1.620 companies were inspected. *"For me, the most important finding was the high level of non-compliance. There was at least one non-compliance in 44 % of the checked mixtures and the project showed us the reality of the situation on the market. Since I am working as an inspector myself, I wasn't surprised because we regularly see similar results in our national inspections,"* says Henrik Hedlund, Swedish Forum member and the Chair of the Forum working group that ran the project.

Since the scope of the project was very wide – the checks covered classification and labeling of mixtures, exemptions for labeling small packaging, harmonized classification, liquid laundry detergent capsules and biocides – it is not easy to pinpoint how severe the non-compliance is. *"Some of the cases might refer to formalistic errors whereas others directly affect risk management measures or hazard communication*," Mr Hedlund explains.

Some of the mistakes are easy to fix

Some of the inconsistencies observed during different inspections are not difficult to correct – but they might require some work particularly if the company has many products in their portfolio. One example relates to the classification of substances in the mixture under Section 3 of the Safety Data Sheet. *"We often see in Swedish inspections that the classification of substances in mixtures in the safety data sheet doesn't correspond with the one in the registration dossier. These two need to match and it is quite easy to make sure they are aligned."*

Another mistake commonly seen in Sweden relates to how mixtures are classified. Although companies are allowed to use concentration ranges in their safety data sheets, they need to calculate mixture classifications using exact concentrations. *"This is problematic since inspectors often only have access to concentration ranges in safety data sheets and make their calculations based on the 'worst case scenario', so they might end up with a different classification than the owner of the data."* In order to prevent this effect, companies should use concentration ranges in such a way that they do not span over several hazard classes and categories.

The third important point is related has with IT tools designed to help create safety data sheets. *"When looking for a reason why a classification in the safety data sheet doesn't match with the information given in the corresponding registration, we've noticed that in many cases, the company has used an IT tool to create the safety data sheet and this tool already contains some classification and labeling data. Using this ready data from the IT tool, instead of asking for the real data from your supply chain, may cause the classification not to match with what you have reported in your registration dossier."* Therefore, it is strongly recommended to carefully check that the data adds up if they are getting this information directly from an IT tool.

Consumers and downstream users lacking correct information

The high levels of deficiency observed during the checks affect both consumers and downstream users. *"Since 17 % of reported mixtures were incorrectly classified, this means that not all downstream users and consumers are getting correct and sufficient information on the hazards of mixtures to enable safe use*," Mr Hedlund explains.

Having incorrect or insufficient information on the label may have serious consequences. While professional users have other pieces of legislation they can rely on, such as the occupational safety and health (OSH) legislation that aims to protect them and improve their safety and health at work, consumers only have the information from the label. Professional users also have access to safety data sheets and in some cases, their employers may provide additional advice and material, too.

BIOCIDES

Action plan agreed to speed up the Biocides Review Program

ECHA, national authorities and the European Commission have agreed on an action plan to speed up the reviewing of active biocidal substances. The Review Programme of existing active substances should be completed by the end of 2024. So far, almost 250 active substance and product-type combinations have been evaluated from more than 700. The Review Programme aims to achieve a high level of safety for citizens and the environment and a level playing field for companies.

Consultation launched for a potential candidate for substitution

ECHA has launched a consultation for alpha-bromadiolone as a new potential candidate for substitution under the Biocidal Products Regulation. The deadline to comment is **14 April 2020**.

End of the newsletter