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Annual Summary Report 2022

European Union

Background

REACH stands for **Registration, Evaluation, Authorization and Restriction of Chemicals**. EU-REACH entered into force on 1 June 2007. REACH aims to improve the protection of human health and the environment from the risks that can be posed by chemicals. Registration is required for chemicals imported or produced with tonnage over 1 tpa. However, other aspects of the REACH regulation such as restrictions, authorizations, and SDS apply to all chemicals placed on the EU market no matter the tonnage.

This report summarizes key news regarding EU REACH from 2022.

Key news from 2022

Safe and Sustainable by design

The Safe and Sustainable by Design (SSbD) is a design, development, production, and use strategy for chemicals and materials that emphasizes delivering the desired function (or service) while avoiding or minimizing detrimental effects on human health and the environment.

In December 2022, the European Commission published a "Recommendation" and an "Annex" that together constitute the long-awaited SSbD framework. The SSbD framework contains methods for assessing safety and sustainability features of chemicals. The European Commission encourages all market stakeholders to use the "Recommendation" in their research and innovation activities. The "Recommendation" is launched at a testing phase with voluntary reporting.

[Read more.](#)

News regarding EU-REACH revision

Alternatives for REACH reform and the essential use concept

The revision of the REACH Regulation is one of the key ongoing processes when it comes to chemicals legislation. It is expected to address current shortcomings concerning the regulation's implementation. The revision also seeks to bring the regulation in line with the EU's ambition for a pollution-free environment under the European Green Deal and the EU Chemicals Strategy for Sustainability. Comprehensive chemical management and the phase-out of substances of concern is an essential part of the said vision and many of the ongoing changes point in that direction. On 6 July 2022 the European Commission presented some of the options it is currently considering for the reform.

[Read more.](#)

European Commission publishes a roadmap for restrictions under REACH

In April 2022 the European Commission published a Restrictions Roadmap under the Chemicals Strategy for Sustainability. The roadmap provides an overview of the different substances that are considered for restriction. It establishes a Rolling List of substances for restriction, which categorizes proposals into three groups:

- Restrictions for which formal procedures have already started
- Restrictions for which preparatory work has been done, but haven't been formally proposed yet
- Restrictions (or revisions of restrictions) that are being discussed as one among other management options

[Read more.](#)

REACH revision further delayed

As presented in the "EU Strategy on Sustainable Chemicals" in 2020, the EU-REACH regulation was about to be revised and updated by end of 2022 to better correspond to the sustainability plans of the EU. However, the expected revision of REACH did not happen as expected in 2022. This indicates that the reform might now be delayed to 2024.

[Read more.](#)

News regarding EU REACH registrations & authorizations

Change in the dossier evaluation process regarding tonnage bands

ECHA announced that they will take into consideration any changes for tonnage bands made by companies in their dossiers. Companies that downgrade the tonnage band after ECHA's draft decision on the dossier, will have to show proof of the new tonnages to ECHA. When the adopted dossier evaluation decision is communicated to companies no further changes are allowed and the companies are expected to fulfil all information requirements as per the decision.

[Read more.](#)

REACH Authorization Decisions for Chemicals' Use

The European Commission adopted REACH authorization decisions for the use of four chemicals that are listed in Annex XIV of the law. [Read more.](#)

News regarding EU Toxicity testing

ECHA proposes changes for determination of dose levels in toxicity testing

In January 2022 ECHA published new guidelines on how to determine and apply dose selection for dose and reproductive toxicity. This is important for companies when performing toxicity tests of their chemicals' safety as stipulated in the amended REACH annexes. The guidelines help to establish the correct substance dose for the testing purposes. Furthermore, the guidelines are in alignment with OECD guidelines.

[Read more.](#)

EU REACH updated lists

Substance added to the SVHC list:	CAS number
N-(hydroxymethyl)acrylamide	924-42-5
tris(2-methoxyethoxy)vinylsilane	1067-53-4
S-(tricyclo(5.2.1.0' ² ,6)deca-3-en-8(or 9)-yl O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate	255881-94-8
6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol	119-47-1
(±)-1,7,7-trimethyl-3-[(4-methylphenyl)methylene]bicyclo[2.2.1]heptan-2-one covering any of the individual isomers and/or combinations thereof (4-MBC)	-
(±)-1,7,7-trimethyl-3-[(4-methylphenyl)methylene]bicyclo[2.2.1]heptan-2-one	36861-47-9
(3E)-1,7,7-trimethyl-3-(4-methylbenzylidene)bicyclo[2.2.1]heptan-2-one	1782069-81-1
(1R,3E,4S)-1,7,7-trimethyl-3-(4-methylbenzylidene)bicyclo[2.2.1]heptan-2-one	95342-41-9
(1S,3E,4R)-1,7,7-trimethyl-3-(4-methylbenzylidene)bicyclo[2.2.1]heptan-2-one	852541-30-1
(1R,3Z,4S)-1,7,7-trimethyl-3-(4-methylbenzylidene)bicyclo[2.2.1]heptan-2-one	852541-21-0
(1R,4S)-1,7,7-trimethyl-3-(4-methylbenzylidene)bicyclo[2.2.1]heptan-2-one	741687-98-9
(1S,3Z,4R)-1,7,7-trimethyl-3-(4-methylbenzylidene)bicyclo[2.2.1]heptan-2-one	852541-25-4

Substances added to *Recommendations for inclusion in the Authorisations list*:

Name	Cas Number	SVHC-relevant intrinsic property
2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers:	-	
(2R)-3-(4-tert-butylphenyl)-2-methylpropanal	75166-31-3	Toxic for reproduction
2-(4-tert-butylbenzyl)propionaldehyde	80-54-6	Toxic for reproduction
(2S)-3-(4-tert-butylphenyl)-2-methylpropanal	75166-30-2	Toxic for reproduction
2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	119313-12-1	Toxic for reproduction
2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	71868-10-5	Toxic for reproduction
Diisohexyl phthalate	71850-09-4	Toxic for reproduction
Ethylenediamine	107-15-3	Respiratory sensitising properties
Glutaral	111-30-8	Respiratory sensitising properties
Lead	7439-92-1	Toxic for reproduction
Orthoboric acid, sodium salt (group)		
Boric acid, sodium salt	1333-73-9	Toxic for reproduction
Orthoboric acid, sodium salt	13840-56-7	Toxic for reproduction
boric acid (H ₃ BO ₃), sodium salt, hydrate	25747-83-5	Toxic for reproduction
boric acid (H ₃ BO ₃), sodium salt (1:1)	14890-53-0	Toxic for reproduction
Boric acid (H ₃ BO ₃), disodium salt	22454-04-2	Toxic for reproduction
Trisodium orthoborate	14312-40-4	Toxic for reproduction

Substances added to the authorisation list 2022:

Substance	CAS number	Latest application date	Sunset date	Intrinsic property
Tetraethyllead	78-00-2	01-Nov-2023	01-May-2025	Toxic for reproduction (Article 57c)
4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol	561-41-1	01-Nov-2023	01-May-2025	Carcinogenic (Article 57a)
Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP)		01-Nov-2023	01-May-2025	Endocrine disrupting properties (Article 57(f) - environment)
Formaldehyde, reaction products with phenol heptyl derivs. and 1,3,4-thiadiazolidine-2,5-dithione	1471311-26-8			
Formaldehyde, reaction products with branched and linear heptylphenol, carbon disulfide and hydrazine	93925-00-9			
2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate	15571-58-1	01-Nov-2023	01-May-2025	Toxic for reproduction (Article 57c)
Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)		01-Nov-2023	01-May-2025	Toxic for reproduction (Article 57c)



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