DEVELOPMENTS WITH BORATES

Workshop on 2 August 2023

OVERVIEW OF BORATES ISSUE

The borates issue began in 2014-2015 with the 6th recommendation proposal from ECHA for the inclusion of borates in Annex XIV.
https://echa.europa.eu/documents/10162/742d3150-ef77-9cf6-d50d-060301739eba

Everything remained frozen until 2022, when the EBA (European Association of Borates) had unblocked the situation by proposing a restriction instead of inclusion of borates in Annex XIV.
Attached is the 2022 document that Gianluca told you about (2022_02_23_verbale CT)

Then ECHA published the roadmap on the restrictions that fall within the scope of the so-called Chemicals Strategy for Sustainability.
Link: https://ec.europa.eu/docsroom/documents/49734 (attached SWD_2022_128_F1_STAFF_WORKING_PAPER_EN_V3_P1_1918809)
At the same time, in parallel, there was the 17th ATP with the new limit of borates for the danger.

In the Roadmap, you can observe that the Borate family is among those under potential restriction.
In this regard, ECHA points out that the development of an RMOA, or regulatory management options, is still in progress.

Last Update: You will find some preliminary results on the RMOA in the presentation of the EBA (European Borates Association) attached.
(EBA-IT ministry of Health_Final)

Objectives of the Restrictions Roadmap

The Restriction Roadmap has **three main objectives**:

1. Ensure that the commitments under the strategy can be fulfilled in a transparent and timely manner. The Rolling List included in the Annex (see below) sets out the **restrictions that have been planned and prepared, and those that have progressed**, in particular for the most harmful substances (i.e. those that meet the criteria for **CMRs, PBTs, vPvBs, endocrine disruptors (ED), immunotoxicants, neurotoxicants, respiratory sensitisers** and **STOT substances** (Specific target organ toxicity). It will be the cornerstone for the multiannual planning under Article 68 of REACH on introducing new and amending current restrictions and Article 69 of REACH on preparing proposals for the period up to 2025-2027, until the new rules on the generic approach are put in place.

2. Provide an overview, through its Rolling List, of we are **using the available authority resources**. The Rolling List contains (groups of) substances which are being considered for a risk management measure or for which an entry in the Registry of Intentions (RoI) has been submitted.

3. Provide **transparency** to stakeholders on the restriction work by authorities and allows companies to anticipate (potential) upcoming restrictions, e.g. by already beginning substitution activities[6].

In this context, and as part of the implementation of the strategy, the Commission is also working with industry on the co-creation of a transition pathway for chemicals.

In any given year, ECHA uses around 10-13 FTEs (Full Time Equivalents) for developing restrictions and for the opinion-making phase. This means ECHA can normally prepare between 3-4 restrictions a year (depending on complexity). ECHA's scientific committees can currently manage 4-5 restrictions per year. As more restrictions are likely to be processed, this would require Member States to adequately resource including with experienced rapporteurs the Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC).

1. The Rolling List will be **regularly reviewed**. Further investigations may lead to changes in the anticipated regulatory risk management action. Therefore, it is 'rolling' in nature and substances covered by the Restrictions Roadmap may finally not be restricted in practice and may be taken off the list while other substances may be added.

2. The Roadmap, including the Rolling List, will be established without affecting **Member State prerogatives under REACH**. Thus, the Roadmap does not affect the Member States' right to propose new restrictions[8], including those for substances not (yet) included in the Roadmap.

The Roadmap should therefore provide for a balance between the need for flexibility on when and how to act while securing the necessary commitment to ensure progress on restricting the most harmful (groups of) substances as set out in the strategy. The roadmap will further guide the prioritisation of substances for which safe and sustainable alternatives should be developed according to the criteria on Safe and Sustainable by Design (SSbD) announced in the chemical strategy for sustainability and to be published by the Commission in 2022.

Implementing the Roadmap will require the **joint commitment** and collaborative efforts of Member States, the Commission and ECHA (European Chemicals Agency (ECHA). Achieving the Roadmap's objectives requires ECHA and the Member States to have adequate resources to work on further RMO (Risk Management Option) analysis (if needed), hazard confirmation (if needed) and restriction work.

The Rolling List will be discussed periodically at CARACAL and in principle be updated once per year.

3. Identifying (groups of) substances for the Restrictions Roadmap Rolling List

This section describes the processes that the Commission has used for identifying the substances proposed in this version of the Roadmap and those that may be added in future. The Roadmap is primarily addressing the hazard endpoints specified for the generic approach to risk management. However, restrictions covering other endpoints, such as skin sensitisers, are also addressed by the Roadmap to ensure resources are used in a consistent manner.

4. The Rolling List of (groups of) substance(s) for restriction

The Rolling List consists of three pools of (groups of) substances currently pointing towards the regulatory hypothesis of restriction. These pools are included in Annex I, which also provides an indicative timing, if available. Information available on 20 October 2021 was used to prepare the Rolling List.

The Annexes present the state of play on 18 March 2022.

Pool 0: Restrictions already on the RoI for restrictions[10], mandate provided to ECHA or restriction dossier recently submitted

This pool contains those substances in the current pipeline for restrictions, i.e. where the substance or group of substances are i) already subject to opinion-making procedure in the ECHA Risk Assessment and Socio-Economic Assessment Committees (with attributed resources), or ii) are included in the RoI for submission in 2021/2022, or iii) where the Commission has requested ECHA to prepare a restriction dossier.

Pool 1: Planned restrictions not yet on the RoI for restriction

This pool contains substances for which work is already very advanced and that are under consideration by ECHA, Member States or the Commission for a restriction proposal. For some of these substances, preparatory work towards a planned restriction proposal has already started. Furthermore, for some (groups of) substances classification under the CLP Regulation or SVHC-identification under REACH is discussed a as the next regulatory action.

Pool 2: Potential restrictions

This pool contains:

− (Groups of) substances where restrictions are discussed as a potential regulatory management option, e.g. in working groups involving Member States, the Commission and ECHA. No decision has yet been taken on the potential restrictions nor on who submits the dossier (a Member State, or ECHA on behalf of the Commission). Similar as for pool 1, for some (groups of) substances classification under the CLP Regulation or SVHC-identification under REACH is discussed a as the next regulatory action.

− Substances for which review reports or previous assessments indicate that revising a restriction could be necessary (e.g. lead in consumer articles; nickel in in articles intended to come into direct and prolonged contact with the skin).

Pool 2: Potential restriction, ***[TBD = the potential submission date of the mandate to ECHA still needs to be decided]***

	Subject of restriction proposal	Numbers of substances in group for regulatory action (if applicable)	Hazards in scope	Uses				Additional information	(Anticipated) year of submission of mandate to ECHA
			Confirmed or suspected hazards	Industrial	Professional	Consumer	Article service life		
Potential restrictions under discussion (dossier submitter TBD)									
1.	Formaldehyde and formaldehyde releasers	Group	C				x	Potential occupational risk to workers not covered by the Binding Occupational Exposure Limits (BOEL) e.g. professional and self-employed. Follow-up to review report to be considered.	TBD
2.	Lead in consumer articles	Group	R				x	Follow-up to review report not a priority due to current state of play with alternatives.	TBD
4.	Borates	Group						Assessment of regulatory needs ongoing.	TBD
5.	Skin sensitisers in consumer mixtures	Group	Skin Sens			x		Investigative work has begun by group of Member States and ECHA.	TBD
6.	Substances containing 4-tert-butylphenol (4-TBP), 4-nonylphenol and other alkylphenols	Group	ED ENV					Discussions are ongoing on how to address the wider group of alkylphenols. The scope of a potential restriction needs to be further clarified. ECHA, Member States and the Commission are currently assessing the need for further regulatory management measures for substances containing alkylphenols, and the possibilities for grouping. A decision on (a) potential	TBD

For each group of substances, authorities deliberate whether there is a need for further regulatory risk management activities for the whole group, for a subgroup or for individual substances within the group. Since December 2021, conclusions on the need for regulatory risk management activities for the assessed (groups of) substances have been available in the Activities Coordination Tool (ACT) for Member State authorities and the Commission, and have been published on the ECHA's website in the Public Activities Coordination Tool (PACT) onwards.
When information shows that the manufacture, use or placing on the market of a substance poses an unacceptable risk to human health (HH) or the environment (Article 68(1) of REACH), the Commission or Member States begin the restriction procedure. The Commission provides a mandate to ECHA to prepare a restriction dossier (Article 69(1) of REACH). Member States can begin the restriction procedure as laid down in Article 69(4) of REACH. Furthermore, Article 68(2) of REACH empowers the Commission to propose restrictions for consumer uses as regards CMR substances, whether they are used on their own, in mixtures or in articles.

Assessment of risk from the use in articles of substances on the Authorisation List under Article 69(2) of REACH

Article 69(2) of REACH aims to ensure that risks from the use of substances which are listed on the Authorisation List and used in articles, are adequately controlled via a restriction introduced by ECHA after the sunset date. All substances on the Authorisation List will continue to be investigated over the Restrictions Roadmap's lifetime, following the latest application date, to ascertain whether using them in articles poses a risk to the environment or human health. If there is such a risk, ECHA will propose a restriction on such use. Whenever Annex XIV substances are to be screened, ECHA should assess whether the use of substances with a similar molecular structure, if present in articles, poses a risk and it should recommend to the Commission whether a broader restriction is needed. Such a restriction covering substances other than those on the Authorisation list should be based on one of the scenarios already mentioned in Section 3a.

According to Article 69(2) of REACH, where the assessment concludes that a restriction proposal may be needed, this will be indicated in the Restrictions Roadmap. Annex II provides an overview of how the assessments of Article 69(2) of REACH are progressing.

Annex II - Overview of Article 69(2) assessments

Entry No	Substance(s)	Intrinsic property(ies) referred to in Article 57	Latest application date	Sunset date	Expected date of completion of ECHA assessment	Current progress[13]	Conclusion
01	5-tert-butyl-2,4,6-trinitro- m-xylene (Musk xylene) EC No: 201-329-4 CAS No: 81-15-2	vPvB	21/02/2013	21/08/2014	Completed	Screening report published on ECHA website.	No need for restriction.
02	4,4'-Diaminodiphenylmethane (MDA) EC No: 202-974-4 CAS No: 101-77-9	Carcinogenic (category 1B)	21/02/2013	21/08/2014	Completed	Screening report published on ECHA website.	No need for restriction.
03	Hexabromocyclododecane (HBCDD) EC No: 221-695-9, 247-148-4, CAS No: 3194-55-6 25637-99-4 alpha-hexabromocyclododecane CAS No: 134237-50-6, beta-hexabromocyclododecane CAS No: 134237-51-7 gamma-hexabromocyclododecane CAS No: 134237-52-8	PBT	21/02/2014	21/08/2015	Completed	Screening report published on ECHA website.	No need for restriction under REACH, as included in the list of POPs[14] in the Stockholm convention[15]

Entry No	Substance(s)	Intrinsic property(ies) referred to in Article 57	Latest application date	Sunset date	Expected date of completion of ECHA assessment	Current progress[13]	Conclusion
46	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters or mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5) [12]	Toxic for reproduction (Article 57c)	27/08/2021	27/02/2023	2022	Call for evidence over. Screening report in finalisation.	To be considered in the restriction proposal on ortho phthalates (C4-C6) (Restrictions roadmap).
47	Trixylyl phosphate EC: 246-677-8 CAS: 25155-23-1	Toxic for reproduction (Article 57c)	27/11/2021	27/05/2023	2022	Draft screening report in preparation.	To be assessed.
48	Sodium perborate, perboric acid, sodium salt Sodium perborate EC No.: 239-172-9 | CAS No.: 15120-21-5 Perboric acid, sodium salt EC No.: 234-390-0 | CAS No.: 11138-47-9	Toxic for reproduction (Article 57c)	27/11/2021	27/05/2023	2022	Draft screening report in preparation.	To be assessed.
49	Sodium peroxometaborate	Toxic for reproduction (Article 57c)	27/11/2021	27/05/2023	2022	Draft screening report in preparation.	To be assessed.

THANK YOU