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Restrictions Roadmap under the Chemicals Strategy for Sustainability

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1. Context

On 14 October 2020, the European Commission published its chemicals strategy for sustainability towards a toxic-free environment¹ (the 'strategy') as part of the European Green Deal². The strategy highlights that chemicals are fundamental for society and a robust framework is needed to make Union legislation stronger and more coherent. It presents several actions to bring about a toxic-free environment and to protect people and the environment from hazardous chemicals.

In particular, the Commission is considering extending the 'generic approach to risk management', i.e. restricting certain substances in products for certain users while allowing limited exemptions under conditions clearly defined in law.

Until the proposed changes have been assessed and introduced in Regulation (EC) No 1907/2006³) (REACH Regulation), the strategy aims to 'prioritise carcinogenic, mutagenic and reprotoxic substances (CMRs), endocrine disruptors, persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances, immunotoxicants, neurotoxicants, substances toxic to specific organs and respiratory sensitisers substances for (group) restrictions' for all uses. To facilitate this action, the Commission has prepared a **roadmap** to **prioritise** these substances for (group) restrictions under REACH (the 'Restrictions Roadmap').

In its Conclusion on the strategy⁴ (in para. 21), the Council stated that it:

• *'supports the prioritisation of restrictions for the most harmful chemicals to be covered by the generic approach for all uses and through grouping* as an interim solution until the extension of the generic approach to risk management is fully implemented

¹ <u>COM(2020) 667</u>

² <u>COM(2019) 640</u>

³ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396 30.12.2006, p. 1.

⁴ <u>https://www.consilium.europa.eu/media/48827/st06941-en21.pdf</u>

• stresses that the Member States should also be able to initiate restrictions based on this approach'.

A first exchange on a draft Restrictions Roadmap took place at the Risk Management and Evaluation (RIME+) meeting on 22 April 2021 and the Restrictions Task Force meeting on 29 April 2021. Revised drafts were subsequently discussed at the CARACAL (Competent Authorities for REACH and CLP⁵) meetings of 28 and 29 June 2021 and on 17 and 18 November 2021.

This document is a staff working document prepared by the Commission services and does not necessarily represent the views of the European Commission. It is in no way legally binding.

2. 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 activities⁶.

Those restrictions aim to maximise the reduction of unacceptable chemical risks with all available resources⁷, by means of broader restrictions, through both grouping of substances, and addressing a wider range of uses (industrial, professional, consumer uses and uses in articles). This should lead to better cooperation and shared work to ensure that authority resources are helping to fulfil the overall aim of the Roadmap in an optimal way.

In this process, two important conditions are to be underlined:

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

⁵ Regulation (EC) No 1272/2008 on the Classification, Labelling and Packaging of chemicals and mixtures, OJ L 353, 31.12.2008, p. 1, as revised.

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.

⁷ 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).

Restrictions Roadmap may finally not be restricted in practice and may be taken off the list while other substances may be added.

 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 restrictions⁸, 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.

a. Sources of information for Commission and Member States to begin restrictions

The Commission, Member States and ECHA receive information on (groups of) substances via various procedures under REACH, such as substance evaluation and identification of substances of very high concern (SVHC), as well as by means of classification and labelling provided for under the Classification, Labelling and Packaging (CLP) Regulation⁴. Information available on (groups of) substances is contained in REACH registration dossiers and can be complemented by means of data generation or collection via different processes under REACH, such as dossier or substance evaluation. Hazardous properties can be confirmed by identifying SVHC, as well as under harmonised classification and labelling provided for under the CLP Regulation. The Commission, Member States and ECHA use this information when assessing regulatory needs, e.g. in the context of regulatory management option analyses, to conclude whether a restriction is the most appropriate way to address the identified concerns.

The Commission, Member States and ECHA carry out additional assessments on their own initiative. For instance, the Commission regularly funds studies leading to restriction proposals (e.g. per and polyfluoroalkyl substances (PFAS in firefighting foams). Member States assess (groups of) substances (e.g. PFAS in general)

⁸ This includes Norway, Liechtenstein and Iceland since REACH is part of the Agreement on the European Economic Area (EEA).

using own resources.

Since 2019, ECHA has been assessing the need for regulatory action on groups of substances under the umbrella of its integrated regulatory strategy⁹. One of the strategy's main goals is to identify, and prioritise, groups of substances which require EU regulatory risk management. By October 2021, over 3 000 substances in more than 125 groups have been investigated. This has resulted in over 400 substances being identified as needing further regulatory risk management (which mainly involves harmonised classification and labelling (CLH)/authorisation/restriction or setting occupational exposure limits (OEL)). For over 200 of these substances, restriction or a combination of restriction and authorisation has been recommended as a risk management measure. In addition, for around 200 substances, harmonised classification and labelling is proposed. For many of these substances further data generation will be the next required step. It could happen that following further assessment by authorities, the regulatory action considered could change from restriction to another (a combination of) regulatory risk management action(s) (under REACH or another Union legislation) or that other actions like harmonised classification or SVHC-identification are recognised as necessary preceding steps. In some cases, it may be also uncertain whether a restriction is the most appropriate way to address the identified concern.

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.

Annex I of this document provides information on whether Member States or the Commission have initiated restrictions, are planning to do so or whether discussions on a restriction as a regulatory management option are ongoing.

b. 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.

⁹ <u>https://echa.europa.eu/substances-of-potential-concern</u>

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 Rol for restrictions¹⁰, 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 Rol 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 <u>restrictions</u> 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 <u>revising a restriction</u> could be necessary (e.g. lead in consumer articles; nickel in in articles intended to come into direct and prolonged contact with the skin).

¹⁰ Registry of restriction intentions until outcome - ECHA (europa.eu)

Annex I - Rolling List of (groups of) substances for restriction

	Subject of restriction proposal	Group restriction or number of	Hazards in scope	Uses	in sc	ope		Additional information	(Envisaged) Date of Annex XV
		substances to be restricted	Confirmed or suspected hazards	Industrial	Professional	Consumer	Article service life ¹¹		restriction dossier submission
	1. ECHA-Commission request								
1.	Per- and polyfluoroalkyl substances (PFAS) in firefighting foams	Group	PBT, vPvB, PMT, R	x	x	x		Firefighting foams.	14/01/2022
2.	Medium-chain chlorinated paraffins (MCCPs)	Group	PBT, vPvB	x	х	х	x	Restriction proposal due to the nomination of MCCP to the Stockholm Convention.	15/7/2022
3.	Substances containing polycyclic aromatic hydrocarbons (PAHs) (including pitch, coal tar, high temp (CTPHT)) used in clay pigeons	Group	CM, PBT, vPvB				x	Mandate ex Art. 69(1) given to ECHA based on an extended assessment according to Art. 69(2).	13/10/2021
4.	Lead in ammunition and in fishing tackle	Group	R		x	x	х	Lead and its compounds in ammunition (for firearms and airguns), and in fishing sinkers and lures for outdoor activities.	15/01/2021
5.	Lead compounds in polyvinyl chloride (PVC; revision)	Group	R	x	x	x	х	Revision of the 2019 restriction proposal following the binding objection of the European Parliament (EP) in 2020. Scope limited to lead compounds in PVC.	16/12/2016

Pool 0: Restrictions already on the Registry of Intention (RoI), mandate provided to ECHA or restriction dossier recently submitted

¹¹ Article service life means the period of time an article remains in service or in use.

	Subject of restriction proposal	Group restriction or number of	Hazards in scope	Uses	in so	соре		Additional information	(Envisaged) Date of Annex XV restriction
		substances to be restricted	Confirmed or suspected hazards	Industrial	Professional	Consumer	Article service life		restriction dossier submission
	2. ECHA-69.2								
1.	<u>2,4-dinitrotoluene</u>	1	СМ	x	x	x	x	Restriction proposal ex Art. 69(2) for consumer and professional uses. No AfAs (Applications for Authorisation) received	16/07/2021
	3. Member States								
1.	PFAS DE, NL, SE, NO, DK	Group	PBT, vPvB, PMT, R	x	х	x	x		13/01/2023
2.	N,N-dimethylacetamide (DMAC) and 1-ethylpyrrolidin-2-one (NEP) NL	2	R	x				Follow-up to 1-methyl-pyrrolidone (NMP) and dimethyl formamide (DMF) restrictions.	08/04/2022
<u>3.</u>	1,6,7,8,9,14,15,16,17,17,18,18- Dodecachloropentacyclo[12.2.1. 16,9.02,13.05,10]octadeca-7,15- diene ('Dechlorane Plus'™) covering any of its individual anti- and syn-isomers or any combination thereof NO	Group	vPvB	x	x	x	x	Nominated to Stockholm Convention.	09/04/2021
4.	4,4'-isopropylidenediphenol (bisphenol A) and structurally related bisphenols (including derivatives) of similar concern for the environment DE	Group	ED for ENV	x	x	x	x	See also 'Bisphenols, risks for human health'.	07/10/2022

	Subject of restriction proposal	Group restriction or number of	Hazards in scope	Uses	in sc	ope		(Envisaged) Date of Annex XV
		substances to be restricted	Confirmed or suspected hazards	Industrial	Professional	Consumer	Article service life	restriction dossier submission
5.	Terphenyl, hydrogenated(substance used as hightemperature heat transfer fluids)IT	1	PBT/vPvB				х	08/04/2022
6.	Substances in single-use baby diapers (PAHs, furans, dioxins, formaldehyde and polychlorinated biphenyls (PCBs)) FR	Group	CR, PBT, vPvB			x		9/10/2020
7.	Undecafluorohexanoic acid (PFHxA), its salts and related substances DE	Group	P/vP	x	x	x	Х	20/12/2019
8.	Creosote FR	1	СМ			x		1/2/2022

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

[TBD = the potential submission date of the mandate to ECHA still needs to be decided]

	subst group		mbers of Hazards in scope stances in up for					Additional information	(Anticipated) year of submission of mandate to
		regulatory action (if applicable)	Confirmed or suspected hazards	Industrial	Professional	Consumer	Article service life		ECHA
1.	ECHA-Commission request								
1.	PVC and its additives	Group	Multiple hazard properties				х	Additional follow-up to the binding EP resolution on the 2019 Lead in PVC restriction proposal. Scope would be a broad assessment of the risks posed by PVC and its additives.	2022
2.	CMRs in child care articles	Group	CMR				х	CMR substances including some organophosphate flame retardants (TCEP, TCPP, TDCP; see pool 1 entry 3) in childcare articles. Restriction proposal ex Art. 68(2).	2022
3.	Organophosphate flame retardants (OPFRs) (tris(2-chloroethyl) phosphate (TCEP), tris(2-chloro-1-methylethyl) phosphate (TCPP), tris[2-chloro-1- (chloromethyl)ethyl] phosphate (TDCP)) ECHA(DK)	3	CR				х	Proposal to restrict TCEP ex Art. 69(2). ECHA Recommendation to restrict in a group with TCPP and TDCP (restriction proposal ex Art. 69(1)). See also pool 1, entry 8 on 'flame retardants' and pool 1, entry 2 on 'child care articles'.	TBD
4.	Ortho-phthalates (C4-C6)	Group	R, ED		x	x	x	From ECHA's assessment of regulatory needs on phthalates. Originally 69(2) restriction extending the existing restriction on 4 phthalates	2023

								in articles. Restriction ex Art. 69(1) may cover some other ortho-phthalates currently under the group work in ECHA. Ongoing study for developing the dossier for CLH and/or SVHC identification for around 40 C4-C6 ortho-phthalates could be used to complement the restriction.	
5.	Lead chromate; Lead sulfochromate yellow (C.I. Pigment Yellow 34); Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	3	CR				x	Art 69(2) proposal on hold until discussions/restriction proposal on lead in PVC is completed (see entry 1 of pool 1).	TBD
6.	Substances in thermal paper	Group	R, ED (maybe others)		x	X	x	Follow-up to restriction of bisphenol A in thermal paper, which asked to monitor the use of bisphenol S as a potential substitute in thermal paper. The possible restriction might target bisphenols but also other substances. Hence, the scope of substances might partly overlap with those in pool 1, entry 7.	2022/TBD
7.	Bisphenols (4,4'-isopropylidenediphenol (bisphenol A) and structurally related bisphenols (including derivatives)	Group	R, ED HH	x	x	X	X	COM and ECHA are currently assessing the need for further regulatory action, including restrictions, SVHC- identification or CLH for bisphenols. Depending on the outcome of these discussions, COM could request ECHA to prepare a restriction dossier that may complement the restriction of some bisphenols for environmental risks (pool 0, entry 4) due to concerns for human health as well as to cover additional bisphenols.	2022/TBD
8.	Flame retardants	Group	TBD	Х	х	х	х	ECHA, Member States and COM are currently assessing the need for further	2023

	regulatory management measures on flame retardants. ECHA will prepare an overall strategy on flame retardants by 2022, which will support COM when it decides to request (a) restriction dossier(s). The substances in scope are in principle all flame retardants, and there will be particular focus on brominated flame retardants and their prioritisation for restrictions. The work on flame retardants may involve assessments of substances in pool 1
	assessments of substances in pool 1 (entry 3) and pool 2 (entry 4).

	Subject of restriction proposal	Numbers of substances in group for regulatory action (if	Hazards in scope	Use	25			Additional information	(Anticipate d) year of submission of mandate to ECHA
		applicable)	Confirmed or suspected hazards		Professional	Consumer	Article service life		
2.	ЕСНА 69.2								
-									
3.	Member States								
-									

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	Hazards in scope	Us	es			Additional information	(Anticipated) year of submission of mandate to ECHA
		applicable)	suspected hazards		Professional	Consumer	Article service life		
Р	otential restrictions under discussion (doss	ier submitter TBD							
1.	Formaldehyde and formaldehyde releasers	Group	С				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			х		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

	Subject of restriction proposal	Numbers of substances in group for regulatory action (if	Hazards in scope	Us	es			Additional information	(Anticipated) year of submission of mandate to ECHA
		applicable)	Confirmed or suspected hazards	Industrial	Professional	Consumer	Article service life		
								restriction(s) will be taken once this work is finalised.	
7.	Petroleum substances used in consumer and/or professional mixtures	Group	PBT, CMR		x	x		Work ongoing in PetCo. Scope to be further clarified taking into account the need for data generation, CLH, SVHC- identification or candidate listing.	TBD
8.	Other substances in infill material	Group	СМ				x	Depends on outcome of the proposal on microplastics restriction.	TBD
9.	Substances in fertilisers ¹²	Group	TBD	x	x	x		Pending discussion on the results of COM study. Substances in scope will be further discussed, and could include contaminants in phosphate fertilisers and possibly other substances intentionally used in fertilisers such as pyrazoles (see section 'Groups where CLH or candidate listing to be carried out' in pool 2).	2023
10.	PAHs in granules for children playgrounds and other domestic applications	Group	СМ, РВТ		x	x	x	As a follow-up to the restriction of PAHs in granules or mulches, discussions are ongoing whether stricter limits are required on granules and mulches used in	TBD

¹² The new Fertilising Products Regulation identifies the REACH Regulation as the appropriate legislation to manage the chemical risks from fertilisers (unless they are PPP/biocides).

	Subject of restriction proposal	Numbers of substances in group for regulatory action (if	Hazards in scope	Us	es			Additional information	(Anticipated) year of submission of mandate to ECHA
		applicable)	Confirmed or suspected hazards	Industrial	Professional	Consumer	Article service life		
								children playgrounds and other domestic application.	
11.	Formamide	1	R			x		Addressing the release from ethylene vinyl acetate (EVA) based consumer articles and glues.	TBD
12.	Nickel in articles intended to come in direct and prolonged contact with the skin	Group	Skin sensitiser				X	In 2019, the ECHA and COM decided to discontinue the work on a guideline on restriction entry 27 on nickel and its compounds. At CARACAL 29, COM instead expressed its intention to assess the possibility to request ECHA to review the current restriction as regards points b) and the associated point c). The risks posed by nickel in contact with the skin should be reassessed, in particular with a view to potentially modifying the scope by removing reference to direct and prolonged contact with the skin. The potential review of nickel and its compounds is regarded as being a low priority.	TBD

	Subject of restriction proposal	Numbers of substances in group for regulatory action (if applicable)	Hazards in scope Confirmed or suspected hazards	Use Industrial	 Consumer	Article service life	Additional information	(Anticipated) year of submission of mandate to ECHA
ECHA	6 9.2							
1.	1,2-dichloroethane (EDC)		C				Uses of the substance in articles. An Annex XV restriction dossier will be prepared if appropriate.	TBD
2.	Anthracene oil		C, PBT, vPvB			x	Uses of the substance in articles. An Annex XV restriction dossier will be prepared if appropriate.	TBD
3.	Pitch, coal tar, high temp. (CTPHT)		C, PBT, vPvB			x	Uses of the substance in articles (other than clay targets, see pool 0). An Annex XV restriction dossier will be prepared if appropriate.	TBD

	Subject of restriction proposal	of restriction proposal Numbers of substances in group for regulatory action (if		Hazards in scope Uses				Additional information	(Anticipated) year of submission of mandate to ECHA
		applicable)	applicable) Confirmed or suspected hazards		Professional	Consumer	Article service life		
Groups	where CLH or candidate listing to be ca	rried out with restr	iction as suggested	risk	mai	nage	ment		
1.	Pyrazoles	Group (6)	R, ED HH, PM		x	х		The need for further regulatory risk management measures (e.g. restriction) is under discussion, focusing on their use as a fertiliser and potential reproductive, and ED HH properties as well as possible persistency and mobility.	TBD
2.	Simple manganese compounds	Group (15)	R, STOT RE, Neurotox.		x	x	X	The need for further regulatory risk management measures (e.g. combination of authorisation and restriction) is under discussion, focusing on subgroups 'Simple inorganic salts, oxides and manganese metal' and 'Permanganates'. Might apply to other substances in the group following steps taken to generate data in order to clarify the hazard.	TBD
3.	Simple vanadium compounds	Group (24)	CMR, STOT RE	x	x	x	x	Potential need for an exposure limit for workers under OSH (occupational health and safety) or restriction under discussion as well as potential group CLH proposal mainly for carcinogenicity.	TBD

	Subject of restriction proposal Numbers or substances group for regulatory action (if		Hazards in scope U		Uses		Additional information	(Anticipated) year of submission of mandate to ECHA
	action (if applicable) Confirmed or suspected hazards	suspected	Protessional Industrial	Consumer	Article service life			
4.	Acrylates and methacrylates	Group	Skin Sens				The need for further regulatory risk management measures (e.g. restriction) under discussion for all acrylates and methacrylates in the group that can be identified as skin sensitisers. May be covered by the 'skin sensitisers in consumer mixtures' entry above.	TBD

Annex II - Overview of Article 69	(2) assessments
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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	νΡνΒ	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

¹³ In each case, it is stated whether a restriction report development/restriction report needs to be prepared and submitted, or whether a screening report is being/has been prepared and published. Note that in some cases the screening report in preparation may conclude that a restriction is needed. For some cases, the screening work has not started yet.

¹⁴ Persistent Organic Pollutant

¹⁵ SC-6/13: Listing of hexabromocyclododecane: <u>http://chm.pops.int/TheConvention/ThePOPs/AllPOPs/tabid/2509/Default.aspx</u>

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
04	Bis(2-ethylhexyl) phthalate (DEHP) EC No: 204-211-0 CAS No: 117-81-7	Toxic for reproduction (category 1B) ¹⁶	21/08/2013	21/02/2015	Completed	Annex XV restriction report submitted. Restriction adopted.	Risk identified for EU produced and imported articles.
05	Benzyl butyl phthalate (BBP) EC No: 201-622-7 CAS No: 85-68-7						
06	Dibutyl phthalate (DBP) EC No: 201-557-4 CAS No: 84-74-2						
07	Diisobutyl Phthalate (DIBP) EC number: 201-553-2 CAS number: 84-69-5						
08	Diarsenic trioxide EC No: 215-481-4 CAS No: 1327-53-3	Carcinogenic (category 1A)	21/11/2013	21/05/2015	Completed	Screening report published on ECHA website.	No need for restriction.
09	Diarsenic pentaoxide EC No: 215-116-9 CAS No: 1303-28-2						
10	Lead chromate EC No: 231-846-0 CAS No: 7758-97-6	Carcinogenic (category 1B) Toxic for reproduction (category 1A)	21/11/2013	21/05/2015	TBD	Annex XV restriction report in preparation. Awaiting decision on lead in PVC restriction.	Need for restriction.

¹⁶ In addition, the candidate list has the following properties: For EC No: 204-211-0. Endocrine disrupting properties (Article 57(f) - environment) and endocrine disrupting properties (Article 57(f) - human health) were introduced later. For EC No: 201-622, EC No: 201-557-4 and EC No: 201-553-2, Endocrine disrupting properties (Article 57(f) - human health) was introduced later.

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
11	Lead sulfochromate yellow (C.I. Pigment Yellow 34) EC No: 215-693-7 CAS No: 1344-37-2						
12	Lead chromate molybdate sulphate red (C.I. Pigment Red 104) EC No: 235-759-9 CAS No: 12656-85-8						
13	Tris (2-chloroethyl) phosphate (TCEP) EC No: 204-118-5 CAS No: 115-96-8	Toxic for reproduction (category 1B)	21/02/2014	21/08/2015	2022?	Annex XV restriction report in preparation. the availability of new critical data is pending (awaiting the US NTP final studies on the carcinogenicity of TCPP).	Need for restriction in articles, grouped with TCPP and TDCP. COM request according to Article 69(1). Possibly incorporated with a restriction on childcare articles.
14	2,4-Dinitrotoluene (2,4-DNT) EC No: 204-450-0 CAS No: 121-14-2	Carcinogenic (category 1B)	21/02/2014	21/08/2015	07/2021	Annex XV simple restriction dossier submitted. Under opinion development.	Need for restriction.
15	Trichloroethylene EC No: 201-167-4 CAS No: 79-01-6	Carcinogenic (category 1B)	21/10/2014	21/04/2016	2022	Screening report published on ECHA website	No need for restriction.
16	Chromium trioxide ¹⁷ EC No: 215-607-8 CAS No: 1333-82-0	Carcinogenic (category 1A) Mutagenic (category 1B)	21/03/2016	21/09/2017	2022	Call for evidence over. Screening report in finalisation.	No need for restriction at present.

¹⁷The chromium substances will all be taken as one group.

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
17	Acids generated from chromium trioxide and their oligomers Group containing: Chromic acid ¹¹ EC No: 231-801-5 CAS No: 7738-94-5 Dichromic acid EC No: 236-881-5 CAS No: 13530-68-2 Oligomers of chromic acid and dichromic acid EC No: not yet assigned CAS No: not yet assigned	Carcinogenic (category 1B)	21/03/2016	21/09/2017	2022	Call for evidence over. Screening report in finalisation.	No need for restriction at present.
18	Sodium dichromate ¹¹ EC No: 234-190-3 CAS No: 7789-12-0 10588-01-9	Carcinogenic (category 1B) Mutagenic (category 1B) Toxic for reproduction (category 1B)	21/03/2016	21/09/2017	2022	Call for evidence over. Screening report in finalisation.	No need for restriction at present.
19	Potassium dichromate ¹¹ EC No: 231-906-6 CAS No: 7778-50-9	Carcinogenic (category 1B) Mutagenic (category 1B) Toxic for reproduction (category 1B)	21/03/2016	21/09/2017	2022	Call for evidence over. Screening report in finalisation.	No need for restriction at present.

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
20	Ammonium dichromate ¹¹ EC No: 232-143-1 CAS No: 7789-09-5	Carcinogenic (category 1B) Mutagenic (category 1B) Toxic for reproduction (category 1B)	21/03/2016	21/09/2017	2022	Call for evidence over. Screening report in finalisation.	No need for restriction at present.
21	Potassium chromate ¹¹ EC No: 232-140-5 CAS No: 7789-00-6	Carcinogenic (category 1B) Mutagenic (category 1B)	21/03/2016	21/09/2017	2022	Call for evidence over. Screening report in finalisation.	No need for restriction at present.
22	Sodium chromate ¹¹ EC No: 231-889-5 CAS No: 7775-11-3	Carcinogenic (category 1B) Mutagenic (category 1B) Toxic for reproduction (category 1B)	21/03/2016	21/09/2017	2022	Call for evidence over. Screening report in finalisation.	No need for restriction at present.
23	Formaldehyde, oligomeric reaction products with aniline (technical MDA) EC No: 500-036-1 CAS No: 25214-70-4	Carcinogenic (category 1B)	22/02/2016	22/08/2017	2022	Draft screening report in preparation.	To be assessed.
24	Arsenic acid EC No: 231-901-9 CAS No: 7778-39-4	Carcinogenic (category 1A)	22/02/2016	22/08/2017	2021	Screening report published on ECHA website.	No need for restriction.
25	Bis(2-methoxyethyl) ether (diglyme) EC No: 203-924-4 CAS No: 111-96-6	Toxic for reproduction (category 1B)	22/02/2016	22/08/2017	2022	Draft screening report in preparation.	To be assessed.

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
26	1,2- dichloroethane (EDC) EC No: 203-458-1 CAS No: 107-06-2	Carcinogenic (category 1B)	22/05/2016	22/11/2017	2022	Call for evidence ended on 16/03/2022.	Restriction probably need
27	2,2'-dichloro-4,4'- methylenedianiline (MOCA) EC No: 202-918-9 CAS No: 101-14-4	Carcinogenic (category 1B)	22/05/2016	22/11/2017	2022	Draft screening report in preparation.	To be assessed.
28	Dichromium tris(chromate) ¹¹ EC No: 246-356-2 CAS No: 24613-89-6	Carcinogenic (category 1B)	22/07/2017	22/01/2019	2022	Call for evidence over. Screening report in finalisation.	No need for restriction at present.
29	Strontium chromate ¹¹ EC No: 232-142-6 CAS No: 7789-06-2	Carcinogenic (category 1B)	22/07/2017	22/01/2019	2022	Call for evidence over. Screening report in finalisation.	No need for restriction at present.
30	Potassium hydroxyoctaoxodizincatedichromate ¹¹ EC No: 234-329-8 CAS No: 11103-86-9	Carcinogenic (category 1A)	22/07/2017	22/01/2019	2022	Call for evidence over. Screening report in finalisation.	No need for restriction at present.
31	Pentazinc chromate octahydroxide ¹¹ EC No: 256-418-0 CAS No: 49663-84-5	Carcinogenic (category 1A)	22/07/2017	22/01/2019	2022	Call for evidence over. Screening report in finalisation.	No need for restriction at present.
32	1-Bromopropane (n-propyl bromide) EC No: 203-445-0 CAS No: 106-94-5	Toxic for reproduction (category 1B)	4/01/2019	4/07/2020	2022	Screening report published on ECHA website on 2nd/03/2022.	No need for restriction at present.

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
33	Diisopentylphthalate ¹⁸ EC No: 210-088-4 CAS No: 605-50-5	Toxic for reproduction (category 1B)	4/01/2019	4/07/2020	2022	Call for evidence over. Screening report in finalisation.	To be considered in the restriction proposal on ortho phthalates (C4-C6) (Restrictions roadmap).
34	1,2-Benzenedicarboxylic acid, di-C6- 8-branched alkyl esters, C7 rich ¹² EC No: 276-158-1 CAS No: 71888-89-6	Toxic for reproduction (category 1B)	4/01/2019	4/07/2020	2022	Call for evidence over. Screening report in finalisation.	To be considered in the restriction proposal on ortho phthalates (C4- C6) (Restrictions roadmap)
35	1,2-Benzenedicarboxylic acid, di-C7- 11-branched and linear alkyl esters ³ EC No: 271-084-6 CAS No: 68515-42-4	Toxic for reproduction (category 1B)	4/01/2019	4/07/2020	2022	Call for evidence over. Screening report in finalisation.	To be considered in the restriction proposal on ortho phthalates (C4-C6) (Restrictions roadmap).
36	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear ³ EC No: 284-032-2 CAS No: 84777-06-0 -	Toxic for reproduction (category 1B)	4/01/2019	4/07/2020	2022	Call for evidence over. Screening report in finalisation.	To be considered in the restriction proposal on ortho phthalates (C4-C6) (Restrictions roadmap).
37	Bis(2-methoxyethyl) phthalate ¹² EC No: 204-212-6 CAS No: 117-82-8	Toxic for reproduction (category 1B)	4/01/2019	4/07/2020	2022	Call for evidence over. Screening report in finalisation.	To be considered in the restriction proposal on ortho phthalates (C4-C6) (Restrictions roadmap).

¹⁸ Ortho phthalates (C4-C6) will all be taken as one group. To be considered in the restriction proposal on ortho phthalates (C4-C6) (Restrictions roadmap).)

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
38	Dipentylphthalate ¹² EC No: 205-017-9 CAS No: 131-18-0	Toxic for reproduction (category 1B)	4/01/2019	4/07/2020	2022	Call for evidence over. Screening report in finalisation.	To be considered in the restriction proposal on ortho phthalates (C4- C6) (Restrictions roadmap).
39	N-pentyl-isopentylphthalate ¹² EC No: – CAS No: 776297-69-9	Toxic for reproduction (category 1B)	4/01/2019	4/07/2020	2022	Call for evidence over. Screening report in finalisation.	To be considered in the restriction proposal on ortho phthalates (C4- C6) (Restrictions roadmap).
40	Anthracene oil EC No: 292-602-7 CAS No: 90640-80-5	Carcinogenic (category 1B) (***), PBT, vPvB	4/04/2019	4/10/2020	2022	Call for evidence over. Screening report in finalisation.	Restriction probably needed.
41	Pitch, coal tar, high temp. (CTPHT) EC No: 266-028-2 CAS No: 65996-93-2	Carcinogenic (category 1B), PBT, vPvB	4/04/2019	4/10/2020	Annex XV restriction report in/10/2021. Screening report in 2022.	Annex XV restriction report proposed for use in clay targets. RoI in Q2 2021. Submitted on 1/10/2021. Other uses: Call for evidence over. Screening report on other uses in finalisation.	Clay targets: Restriction on the placing on the market and use of substances containing (PAHs) in clay targets for shooting. Submitted (covers CTPHT and other substances - group restriction). Other uses: Restriction probably needed.

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
42	4-(1,1,3,3-Tetramethylbutyl)phenol, ethoxylated (covering well-defined substances and UVCB ¹⁹ substances, polymers and homologues) EC No: – CAS No: –	Endocrine disrupting properties (Article 57(f) – environment)	4/07/2019	4/01/2021	2022	Draft screening report in preparation.	To be assessed.
43	4-Nonylphenol, branched and linear, ethoxylated (substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB ¹⁸ - and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof) EC No: – CAS No: –	Endocrine disrupting properties (Article 57(f) – environment)	4/07/2019	4/01/2021	2022	Draft screening report in preparation.	To be assessed.
44	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear ¹² EC: 271-093-5 CAS: 68515-50-4	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).
45	Dihexyl phthalate ¹² EC: 201-559-5 CAS: 84-75-3	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).

¹⁹ Substance of unknown or variable composition, complex reaction product or of biological origin

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 \ge 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.

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
50	5-sec-butyl-2-(2,4- dimethylcyclohex-3-en-1-yl)-5- methyl-1,3-dioxane [1], 5-sec-butyl- 2-(4,6-dimethylcyclohex-3-en-1-yl)- 5-methyl-1,3-dioxane [2] covering any of the individual stereoisomers of [1] and [2] or any combination thereof	vPvB (Article 57e)	27/002/2022	27/08/2023	-	Screening work has not started.	-
	1,3-Dioxane, 2-(2,4-dimethyl-3- cyclohexene-1-yl)-5-methyl-5-(1- methylpropyl)- EC No.: 413-720-9 CAS No.: 117933-89-8						
	2-(2,4-Dimethylcyclohex-3-ene-1- yl)-5-methyl-(1-methylpropyl)-1,3- dioxane EC No.: 601-499-3 CAS No.: 117933-89-8						
	5-sec-Butyl-2-(2,4- dimethylcyclohex-3-en-1-yl)-5- methyl-1,3-dioxane EC No.: 700- 927-7 CAS No.: -						
	5-sec-butyl-2-(2,4- dimethylcyclohex-3-en-1-yl)-5- methyl-1,3-dioxane EC No.: - CAS No.: -						
	5-sec-butyl-2-(4,6- dimethylcyclohex-3-en-1-yl)-5- methyl-1,3-dioxane EC No.: - CAS No.: -						

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
51	2-(2H-benzotriazol-2-yl)-4,6- ditertpentylphenol	PBT (Article 57d) vPvB (Article 57e)	27/05/2022	27/11/2023	-	Screening work has not started.	-
52	2,4-di-tert-butyl-6-(5- chlorobenzotriazol-2-yl)phenol	vPvB (Article 57e)	27/05/2022	27/11/2023	-	Screening work has not started.	-
53	2-(2H-benzotriazol-2-yl)-4-(tert- butyl)-6-(sec-butyl)phenol	vPvB (Article 57e)	27/05/2022	27/11/2023	-	Screening work has not started.	-
54	2-benzotriazol-2-yl-4,6-di-tert- butylphenol	PBT (Article 57d) vPvB (Article 57e)	27/05/2022	27/11/2023	-	Screening work has not started.	-