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Directorate-General for Environment Circular Economy and Green Growth Sustainable Chemicals



Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs Ecosystems I: Chemicals, food, retail

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Online

Concerns: Proposal for a Restrictions Roadmap under the Chemical Strategy

for Sustainability

Agenda Point: 8.1

Action Requested: Competent Authorities and observers are invited to comment on the

document and the discussion points put forward. Written comments

should be sent by 2 December 2021 to:

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Introduction

The EU Commission announced the Restrictions Roadmap in the Chemicals Strategy for Sustainability.

First exchanges on a draft Restrictions Roadmap took place at the RIME+ meeting on 22 April 2021 and the Restrictions Task Force meeting on 29 April 2021. A revised draft was subsequently discussed at the CARACAL meeting on 28 and 29 June 2021, and members were invited to submit written comments by 31 August 2021. Based on the input received, the Commission services in collaboration with ECHA services prepared an update version for further discussion at the CARACAL meetings on 17 and 18 November.

It is the intention of the Commission services to publish the Restrictions Roadmap by the end of 2021.

The members are invited to provide further comments on the draft Restrictions Roadmap below.



Restrictions Roadmap

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1. Context

On 14 October 2020, the European Commission published its Chemicals Strategy for Sustainability Towards a Toxic-Free Environment¹ (herein referred to as the "Strategy") as part of the European Green Deal². The Strategy highlights that chemicals are fundamental for society and that a robust framework is needed to make the EU legislation stronger and more coherent. It presents several actions for a toxic-free environment and to protect people and the environment from hazardous chemicals.

The Commission in particular considers 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 assessment of the proposed changes and their introduction in the REACH Regulation is in place, it is foreseen in the Strategy 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 restrictions for all uses and through grouping, instead of regulating them one by one". To facilitate this action, the Commission has prepared a Roadmap to prioritise these substances for (group) restrictions under REACH (herein "Restrictions Roadmap").

In the Council Conclusion on the Strategy³, it is stated (para 21) that the Council:

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

¹ Chemical Strategy for Sustainability

² EUR-Lex - 52019DC0640 - EN - EUR-Lex (europa.eu)

³ st06941-en21.pdf (europa.eu)

A first exchange on a draft Restrictions Roadmap took place at the RIME+ meeting on 22 April 2021 and the Restrictions Task Force meeting on 29 April 2021. Revised drafts were subsequently discussed at the CARACAL meetings on 28 and 29 June 2021 and at the CARACAL meetings on 17 and 18 November 2021.

2. Objectives of the Restrictions Roadmap

The Restriction Roadmap has three main objectives:

- 1. Firstly, it should ensure that the commitments under the Strategy can be achieved in a transparent and timely manner. The so-called "Rolling List" included in the annex (see below) sets out which restrictions are planned, prepared, and progressed, in particular for the most harmful substances (i.e. those that meet the criteria for CMRs, PBTs, vPvBs, Endocrine disruptors, immunotoxicants, neurotoxicants, respiratory sensitisers and STOT substances). It will be the corner stone for the multi-annual planning under REACH Article 68 on introducing new and amending current restrictions and REACH Article 69 on the preparation of proposals with a time horizon up to 2025-2027, until the new rules on the generic approach will become operational.
- 2. Secondly, the Roadmap through its Rolling List gives an overview of how we are **using the available authority resources**. The Rolling List contains (groups of) substances which are under discussion for a risk management measure or for which an entry in the Registry of Intentions (Rol) has been submitted.
- 3. Thirdly, the Roadmap provides **transparency** to stakeholders on the restriction work by authorities and allows companies to anticipate (potential) upcoming restrictions, e.g. by already now initiating substitution activities.

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

In this process, two important conditions should be underlined:

- 1. The Rolling List will be subject to **regular review**. 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 in the end not end up being restricted in practice and may come off the list while other substances may be added.
- 2. The Roadmap including the Rolling List will be established without prejudice to the prerogatives of the Member States under REACH. Thus, the Roadmap does not affect the Member States' right of initiative as regards proposing new restrictions also for substances that are 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 whilst securing the necessary commitment to ensure progress on restricting the most harmful (groups of) substances as established in the Strategy.

⁴ In any given year, ECHA has about 10-13 FTE to spend on 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 are likely to be processed this would require MS to resource RAC and SEAC adequately with experienced rapporteurs.

The implementation of the Roadmap will require the **joint commitment** and collaborative efforts of Member States, the Commission and ECHA. The achievement of its objectives requires adequate resources in ECHA and the Member States to work on further RMO analysis (if needed), hazard confirmation (if needed) and restriction work.

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

3. Identification of (groups of) substances for the Restrictions Roadmap rolling list

The objective of this section is to describe the processes by which the Commission has identified the substances proposed in this version of the roadmap and those substances that may be added in the future. The roadmap is primarily addressing the hazard endpoints specified for the Generic Approach to Risk Management but restrictions covering other endpoints, e.g. skin sensitisers, may also be covered to ensure a consistent use of resources.

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

The Commission, Member States and ECHA generate information on (groups of) substances via various procedures under REACH, including substance evaluation and identification of substances of very high concern (SVHC), as well as under classification and labelling according to the CLP Regulation. This information is used, e.g. in the context of Regulatory Management Option Analyses (RMOA), to conclude whether restriction is the best management option.

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

Since 2019, ECHA has been assessing the need for regulatory action on groups of substances under the umbrella of its Integrated Regulatory Strategy⁵. One of the main goals is to identify, and prioritise, groups of substances for which there is a need for EU regulatory risk management. So far (October 2021), over 3000 substances in more than 125 groups have been investigated. This has resulted in over 400 substances where needs for further regulatory risk management have been identified (which mainly covers harmonised classification and labelling (CLH)/Authorisation/Restriction or setting occupational exposure limits (OEL)). For over 200 substances, restriction or a combination of restriction/authorisation has been recommended as risk management measure. For about 200 substances, harmonised classification and labelling is proposed. Many of these will require further data generation as the next step. It could happen that following further assessment by authorities, the foreseen regulatory action could change from restriction to another (combination of) regulatory risk management action(s) (under REACH or another EU legislation) or that other actions like harmonised classification or SVHC-identification is recognised as a necessary preceding step. In some cases, it may be also uncertain as to whether a restriction is the most appropriate Regulatory Management Option.

For each group of substances, authorities consider whether there is a need to initiate further regulatory risk management activities for the whole group, for a subgroup or for individual substances within the group. The conclusions for each group are currently available in ACT for Member State authorities and the Commission, and will be made publicly available starting from late 2021.

When information shows that an unacceptable risk to human health or the environment arises from the manufacture, use or placing on the market of a substance (REACH Article 68(1)), the Commission or Member States initiate the restriction procedure. The Commission provides a mandate to ECHA to prepare a restriction dossier (REACH Article 69(1)). Member States can initiate the restriction procedure via REACH

⁵ https://echa.europa.eu/substances-of-potential-concern

Article 69(4). Furthermore, REACH Article 68(2) empowers the Commission to propose restrictions for CMR substances that could be used by consumers on its own, in mixtures or in articles.

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

b. Assessment of risk from the use in articles of substances on the authorisation list under REACH Article 69(2)

REACH Article 69(2) 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 initiated by ECHA after the sunset date. All substances on the Authorisation List will continue to be investigated during the lifetime of this Restrictions Roadmap, following the latest application date, to ascertain whether their uses in articles cause risks to the environment or human health. If there is such a risk, ECHA will propose to prepare a restriction for such uses. When screening of Annex XIV substances will be done, ECHA should assess whether the use in articles of similar types of substances (using Annex XIV substances as a "seed") poses a risk and it should recommend to the Commission whether a broader restriction would be needed. Such a restriction proposal covering other substances than those on the Authorisation list cannot be based on REACH Article 69(2) but on a procedure that is mentioned in section 3a. of this document.

Where the assessment according to REACH Article 69(2) concludes that a restriction proposal may be needed, this will be indicated in the Restrictions Roadmap. An overview of the current progress with REACH Article 69(2) assessments is provided in Annex II for information.

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 already available. Information available on 20 October 2021 was used to prepare the Rolling List.

Pool 0: Restrictions already on the Registry of Intention (RoI) for restrictions⁶, mandate provided to ECHA or restriction dossier recently submitted

This pool contains the substances in the current restrictions pipeline, i.e. where the (group of) substance(s) is already undergoing opinion-making in the ECHA Risk Assessment and Socio-Economic Assessment Committees (with attributed resources) or are included in the Registry of Intentions (RoI) for submission in 2021/2022, or where the Commission has sent a request to 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 much 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.

Pool 2: Potential Restrictions, CLH or candidate listing as part of regulatory management option

This pool contains:

(Groups of) substances where <u>restrictions</u> are discussed as a potential regulatory management option,
 e.g. in working groups with the participation of Member States, the Commission and ECHA. No decision

⁶ Registry of restriction intentions until outcome - ECHA (europa.eu)

has yet been taken on the potential restrictions nor on the dossier submitter (a Member State, or ECHA on behalf of the Commission).

- Substances for which review reports or previous assessments indicate that a <u>revision of a restriction</u> could be necessary (e.g. lead in consumer articles; nickel in in articles intended to come in direct and prolonged contact with the skin).



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

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

	Subject of restriction proposal	Group restriction or number of	Hazards in scope	Uses	in so	cope		Additional information	(Envisaged) Date of Annex XV
		substances to be restricted	Confirmed or [suspected hazards]	Industrial	Professional	Consumer	Article service		restriction dossier submission
	1. ECHA-Commission request	'							
1.	Per- and polyfluoroalkyl substances (PFAS) in Fire-Fighting Foams	Group	PBT, vPvB, PMT, R	х	х	X		Firefighting foams	14/01/2022
2.	Medium-chain chlorinated paraffins (MCCPs)	Group	PBT, vPvB	х	х	х	х	Restriction proposal due to nomination of MCCP to the Stockholm Convention.	15/7/2022
3.	Substances containing PAHs (including CTPHT) used in clay pigeons	Group	CM, PBT, vPvB				х	Mandate based on Art. 69(1) was 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
	2. ECHA-69.2								
1.	2,4-dinitrotoluene	1	СМ	Х	x	x	х	Restriction proposal acc. to Art. 69(2) for consumer and professional uses. No AfAs received	16/07/2021

	Subject of restriction proposal	Group restriction or number of	r of			cope		Additional information	(Envisaged) Date of Annex XV
		substances to be restricted	Confirmed or		Professional	Consumer	Article service		restriction dossier submission
	3. Member States				'				
1.	PFAS DE, NL, SE, NO, DK	Group	PBT, vPvB, PMT, R	х	x	х	х		15/07/2022
2.	N,N-dimethylacetamide (DMAC) and 1-ethylpyrrolidin-2-one (NEP) NL	2	R	Х				Also N-ethyl-2-pyrrolidone (NEP). Follow up to 1-methyl-pyrrolidone (NMP) and dimethyl formamide (DMF) restrictions. GMT ongoing on a wider group of substances.	08/04/2022
<u>3.</u>	1,6,7,8,9,14,15,16,17,17,18,18- Dodecachloropentacyclo[12.2.1.1 6,9.02,13.05,10]octadeca-7,15- diene ("Dechlorane Plus"™) covering any of its individual anti- and syn-isomers or any combination thereof NO	Group	vPvB	х	x	х	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	х	х	x	х	See also "Bisphenols, risks for human health"	08/04/2022

	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		restriction dossier submission
5.	Substances used as high temperature heat transfer fluids (terphenyl, hydrogenated and other substances) IT	3	PBT/vPvB				х		08/04/2022
6.	Substances in single-use baby diapers FR	Group	CR, PBT, vPvB			х			9/10/2020
7.	Undecafluorohexanoic acid (PFHxA), its salts and related substances DE	Group	P/vP	х	Х	Х	Х		20/12/2019
8.	<u>Creosote</u> FR	1	CM			х			1/2/2022

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

[TBD = potential submission date is not yet defined]

	Subject of restriction proposal	Numbers of substances in group for regulatory	Hazards in scope	Uses	;		Additional information	(Anticipated) year of submission of mandate to ECHA
		action (if applicable)	Confirmed or [suspected hazards].	Professional Industrial	Consumer	al ticle set vice		
1.	ECHA-Commission request	'						
1.	PVC and its additives	Group	Multiple hazard properties			x	Given the EP resolution on Pb in PVC restriction. 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 acc. Art. 68(2).	2022
3.	Organophosphate flame retardants (OPFRs) (TCEP, TCPP, TDCP) ECHA(DK)	3	CR			X	Proposal to restrict TCEP following Art. 69(2). Recommendation by ECHA to restrict in a group with TCPP and TDCP (restriction proposal acc. 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	From ECHAs assessment of regulatory needs' on phthalates. Originally 69(2) restriction extending the existing restriction on 4 phthalates in articles. Restriction via art. 69(1) may	2023

	Subject of restriction proposal	Numbers of Hazards in scope substances in group for regulatory		Use	es			Additional information	(Anticipated) year of submission of mandate to ECHA
		action (if applicable)	Confirmed or [suspected hazards].	Industrial	Professional	Consumer	Article service		
								cover some other ortho-phthalates currently under the group work in ECHA. On-going study for developing 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				х	A69(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	Follow-up to restriction of BPA in thermal paper. The scope of substances partly overlaps 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	х	COM and ECHA are currently assessing the need for further regulatory action, including restrictions, SVHC-identification or CLH for bisphenols. Depending the outcome of these discussions, COM could request to 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

	Subject of restriction proposal	Numbers of substances in group for	Hazards in scope	Us	es			Additional information	(Anticipated) year of submission of mandate to ECHA
		regulatory action (if applicable)	Confirmed or [suspected hazards].	Industrial	Professional	Consumer	Article service		
8.	Flame retardants	Group	TBD	X	x	х	х	ECHA, Member States and COM are currently assessing the need for further regulatory management measures on flame retardants. ECHA will prepare an overall strategy on flame retardantsby 2022, which will support COM when deciding to request (a) restriction dossier(s). Substances in scope are in principal all flame retardantsand there will be particular focus on brominated flame retardantsand their prioritisation for restrictions. The work on flame retardantsmay should incorporate assessments of substances in pool 1 (entry 3) and pool 2 (entry 4).	2023

	Subject of restriction proposal	Numbers of substances in group for regulatory action (if applicable)	Hazards in scope Confirmed or [suspected hazards].	Uses Professional Industrial	Consumer	Article service	Additional information	(Anticipated) year of submission of mandate to ECHA
ECHA 6	9.2							
-								
Membe	er States							
-								

Pool 2: Substances for which restriction, CLH or candidate listing is currently discussed (e.g. in working groups of Member States, Commission and ECHA), as regulatory risk management measure; [TBD = potential restriction under discussion]

	Subject of restriction proposal	Numbers of substances in group for regulatory action (if	scope		es			Additional information	(Anticipated) year of submission of mandate to ECHA
		applicable) C	Confirmed or [suspected hazards].	Industrial	Professional	Consumer	Article service		
P	otential restrictions under discussion (doss	ier submitter TBD)		<u>' </u>	-				
1.	Formaldehyde and formaldehyde releasers	Group	С				X	Potential occupational risk to workers not covered by the BOEL e.g. professional and self-employed. Follow up to review report to be considered	TBD
2.	Lead in consumer articles	Group	R				х	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 been initiated by group of MSs 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 defined. ECHA, Member States and the Commission are currently assessing the need for further regulatory management measures of substance containing alkylphenols and the	TBD

	Subject of restriction proposal	Numbers of substances in group for regulatory action (if	s in scope					Additional information	(Anticipated) year of submission of mandate to ECHA
		applicable)	Confirmed or [suspected hazards].	Industrial	Professional	Consumer	Article service		
								possibilities for grouping. A decision on (a) potential 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 defined taking into account the need for data generation, CLH, SVHC-identification or Candidate Listing.	TBD
8.	Other substances in infill material	Group	CM				Х	Depends on outcome of microplastics restriction proposal.	TBD
9.	Substances in fertilisers ⁷	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 entry 1 in pool 2, CLH,)	2023
10.	PAHs in rubber and plastic articles	Group	CM, PBT	х	х	х	х	Discussion ongoing on the review of entry 50 REACH XVII, after ECHA's investigation report.	TBD

⁷ The new fertilising products regulation specifically 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		
								ECHA published the investigation report on the review of article 8 of entry 50, Annex XVII restriction on PAHs in October 2020.	
11.	PAHs in granules for children playgrounds and other domestic applications	Group	CM, PBT		х	х	X	See also COM position in the REACH Committee of 20/11/2020. Discussion ongoing as follow-up to the restriction of PAHs in granules or mulches on whether stricter limits are required on granules and mulches used in children playgrounds and other domestic application.	TBD
13.	Formamide	1	R			X		Addressing the release from ethylene vinyl acetate (EVA) based consumer articles and glues.	TBD
14	Nickel in articles intended to come in direct and prolonged contact with the skin	Group	Skin sensitiser				х	ECHA and COM decided in 2019 to discontinue the work on a guideline on restriction entry 27 on nickel and its compounds. At CARACAL 29, COM expressed instead 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 and in particular with a view of	TBD

	Subject of restriction proposal	Numbers of substances in group for regulatory action (if	substances in scope group for regulatory					Additional information	(Anticipated) year of submission of mandate to ECHA
		applicable)	Confirmed or [suspected hazards].	Industrial	Professional	Consumer	Article service		
								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 of low priority.	



	Subject of restriction proposal	Numbers of substances in group for regulatory action (if	Hazards in scope		es			Additional information	(Anticipated) year of submission of mandate to ECHA	
5014		applicable)		Industrial	Consumer Professional		Article service			
ECHA										
1.	1,2-dichloroethane (EDC)		С	k				Uses of the substance in articles. An Annex XV restriction dossier will be prepared if appropriate.	TBD	
2.	Anthracene oil		C, PBT, vPvB				х	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	Numbers of substances in group for regulatory action (if	stances in up for ulatory					Additional information	(Anticipated) year of submission of mandate to ECHA
			Professional	Consumer	Article service				
Groups 1.	Pyrazoles	Group (6)	R, ED HH, PM	risk	x		emen	The need for further regulatory risk management measures (e.g. restriction) is under discussion, focusing on the use as 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 data generation steps to clarify the hazard.	TBD
3.	Simple vanadium compounds	Group (24)	CMR, STOT RE	X	x	Х	х	Potential need for an exposure limit for workers under OSH or restriction under discussion as well as potential group CLH proposal mainly for carcinogenicity.	TBD
4.	Acrylates and methacrylates	Group	Skin Sens					The need for further regulatory risk management measures (e.g. restriction) under discussion for all acrylates and	TBD

Subject of restriction proposal	Numbers of substances in group for regulatory action (if applicable)	Confirmed or [suspected hazards].	Industrial	မ Professional	Consumer	Article service	Additional information	(Anticipated) year of submission of mandate to ECHA
							methacrylates in the group that can be identified as skin sens. May be covered by the 'skin sensitisers in consumer mixtures' entry above.	



ANNEX II Overview of Article 69(2) assessments (14 October 2021)

Ent ry No	Substance(s)	Intrinsic property(ies) referred to in Article 57	Latest applicat ion date	Sunset date	Expecte d date of completi on of assessm ent by ECHA	Current progress ⁸	Conclusio n
01	5-tert-butyl-2,4,6-trinitro- m-xylene (Musk xylene) EC No: 201-329-4 CAS No: 81-15-2	vPvB	21 February 2013	21 August 2014	Complete d	Screening report published on ECHA website.	No need for restrictio n.
02	4,4'- Diaminodiphenylmethane (MDA) EC No: 202-974-4 CAS No: 101-77-9	Carcinogen ic (category 1B)	21 February 2013	21 August 2014	Complete d	Screening report published on ECHA website.	No need for restrictio n.
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 February 2014	21 August 2015	Complete d	Screening report published on ECHA website.	No need for restrictio n under REACH, as included in the list of POPs in the Stockhol m conventi on 9.
04	Bis(2-ethylhexyl) phthalate (DEHP) EC No: 204-211-0 CAS No: 117-81-7	Toxic for reproduction	21 August	21 Februar	Complete	Annex XV restriction report	Risk identified for EU produced
05	Benzyl butyl phthalate (BBP) EC No: 201-622-7 CAS No: 85-68-7	(category 1B) ¹⁰	2013	y 2015	d	submitted. Restriction adopted	and imported articles.

⁻

http://chm.pops.int/TheConvention/ThePOPs/AllPOPs/tabid/2509/Default.aspx

⁸ In each case it is stated whether there is a need for a restriction report development/restriction report prepared and submitted, or a screening report is in preparation/prepared and published. Note that in some cases the screening report in preparation may conclude that there is a need for a restriction. For some cases the screening work has not started yet.

⁹ SC-6/13: Listing of hexabromocyclododecane:

¹⁰ 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.

Ent ry No	Substance(s)	Intrinsic property(ies) referred to in Article 57	Latest applicat ion date	Sunset date	Expecte d date of completi on of assessm ent by ECHA	Current progress ⁸	Conclusio n
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	Carcinogen ic (category	21	21 May	Complete	Screening report published	No need
09	Diarsenic pentaoxide EC No: 215-116-9 CAS No: 1303-28-2	iA)	Novemb er 2013	2015	d	on ECHA website.	restriction.
10	Lead chromate EC No: 231-846-0 CAS No: 7758-97-6	Carcinogen				A TO SALVA	
11	Lead sulfochromate yellow (C.I. Pigment Yellow 34) EC No: 215-693-7 CAS No: 1344-37-2	ic (category 1B) Toxic for reproducti	21 Novemb er 2013	21 May 2015	TBD	Annex XV restriction report in preparatio n. Waiting decision	Need for restriction.
12	Lead chromate molybdate sulphate red (C.I. Pigment Red 104) EC No: 235-759-9 CAS No: 12656-85-8	on (category 1A)				on lead in PVC restriction.	
13	Tris (2-chloroethyl) phosphate (TCEP) EC No: 204-118-5 CAS No: 115-96-8	Toxic for reproducti on (category 1B)	21 February 2014	21 August 2015	2022?	Annex XV restriction report in preparatio n. Pending the availability of new critical data (waiting the US NTP final studies on the carcinogen icity of TCPP)	Need for restriction in articles, grouped with TCPP and TDCP. COM request according to Article 69(1). Possibly incorporat ed with a restriction on childcare articles.
14	2,4-Dinitrotoluene (2,4- DNT) EC No: 204-450-0 CAS No: 121-14-2	Carcinogen ic (category 1B)	21 February 2014	21 August 2015	July 2021	Annex XV simple restriction dossier submitted. Under opinion	Need for restriction.

Ent ry No	Substance(s)	Intrinsic property(ies) referred to in Article 57	Latest applicat ion date	Sunset date	Expecte d date of completi on of assessm ent by ECHA	Current progress ⁸	Conclusio n
						developme nt.	
15	Trichloroethylene EC No: 201-167-4 CAS No: 79-01-6	Carcinogen ic (category 1B)	21 October 2014	21 April 2016	2021	Call for evidence over. Screening report in finalisation . To be submitted to the CARACAL-41.	No need for restriction at present.
16	Chromium trioxide ¹¹ EC No: 215-607-8 CAS No: 1333-82-0	Carcinogen ic (category 1A) Mutagenic (category 1B)	21 March 2016	21 Septem ber 2017	2021	Call for evidence over. Screening report in finalisation	No need for restrictio n at present.
17	Acids generated from chromium trioxide and their oligomers Group containing: Chromic acid ² 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	Carcinogen ic (category 1B)	21 March 2016	21 Septem ber 2017	2021	Call for evidence over. Screening report in finalisation	No need for restrictio n at present.
18	Sodium dichromate ² EC No: 234-190-3 CAS No: 7789-12-0 10588-01-9	Carcinogen ic (category 1B) Mutagenic (category 1B) Toxic for reproducti on (category 1B)	21 March 2016	21 Septem ber 2017	2021	Call for evidence over. Screening report in finalisation	No need for restrictio n at present.
19	Potassium dichromate ² EC No: 231-906-6 CAS No: 7778-50-9	Carcinogen ic (category 1B)	21 March 2016	21 Septem ber 2017	2021	Call for evidence over. Screening report in finalisation .	No need for restrictio n at present.

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 $^{^{\}rm 11}{\rm The}$ chromium substances will all be taken as one group.

Ent ry No	Substance(s)	Intrinsic property(ies) referred to in Article 57	Latest applicat ion date	Sunset date	Expecte d date of completi on of assessm ent by ECHA	Current progress ⁸	Conclusio n
		Mutagenic (category 1B) Toxic for reproducti on (category 1B)					
20	Ammonium dichromate ² EC No: 232-143-1 CAS No: 7789-09-5	Carcinogen ic (category 1B) Mutagenic (category 1B) Toxic for reproducti on (category 1B)	21 March 2016	21 Septem ber 2017	2021	Call for evidence over. Screening report in finalisation .	No need for restrictio n at present.
21	Potassium chromate ² EC No: 232-140-5 CAS No: 7789-00-6	Carcinogen ic (category 1B) Mutagenic (category 1B)	21 March 2016	21 Septem ber 2017	2021	Call for evidence over. Screening report in finalisation	No need for restriction at present.
22	Sodium chromate ² EC No: 231-889-5 CAS No: 7775-11-3	Carcinogen ic (category 1B) Mutagenic (category 1B) Toxic for reproducti on (category 1B)	21 March 2016	21 Septem ber 2017	2021	Call for evidence over. Screening report in finalisation	No need for restrictio n at present.
23	Formaldehyde, oligomeric reaction products with aniline (technical MDA) EC No: 500-036-1 CAS No: 25214-70-4	Carcinogen ic (category 1B)	22 February 2016	22 August 2017	2022	Draft screening report in preparatio n.	To be assessed
24	Arsenic acid EC No: 231-901-9 CAS No: 7778-39-4	Carcinogen ic (category 1A)	22 February 2016	22 August 2017	2021	Call for evidence over. Screening report in finalisation . To be submitted to the CARACAL-41.	No need for restrictio n at present.

Ent ry No	Substance(s)	Intrinsic property(ies) referred to in Article 57	Latest applicat ion date	Sunset date	Expecte d date of completi on of assessm ent by ECHA	Current progress ⁸	Conclusio n
25	Bis(2-methoxyethyl) ether (diglyme) EC No: 203-924-4 CAS No: 111-96-6	Toxic for reproducti on (category 1B)	22 February 2016	22 August 2017	2022	Draft screening report in preparatio n.	To be assessed
26	1,2- dichloroethane (EDC) EC No: 203-458-1 CAS No: 107-06-2	Carcinogen ic (category 1B)	22 May 2016	22 Novem ber 2017	2022	Draft screening report in preparatio n.	Restrictio n probably needed.
27	2,2'-dichloro-4,4'- methylenedianiline (MOCA) EC No: 202-918-9 CAS No: 101-14-4	Carcinogen ic (category 1B)	22 May 2016	22 Novem ber 2017	2022	Draft screening report in preparatio n.	To be assessed.
28	Dichromium tris(chromate) ² EC No: 246-356-2 CAS No: 24613-89-6	Carcinogen ic (category 1B)	22 July 2017	22 January 2019	2021	Call for evidence over. Screening report in finalisation	No need for restriction at present.
29	Strontium chromate ² EC No: 232-142-6 CAS No: 7789-06-2	Carcinogen ic (category 1B)	22 July 2017	22 January 2019	2021	Call for evidence over. Screening report in finalisation	No need for restriction at present.
30	Potassium hydroxyoctaoxodizincatedi chromate ² EC No: 234-329-8 CAS No: 11103-86-9	Carcinogen ic (category 1A)	22 July 2017	22 January 2019	2021	Call for evidence over. Screening report in finalisation	No need for restriction at present.
31	Pentazinc chromate octahydroxide ² EC No: 256-418-0 CAS No: 49663-84-5	Carcinogen ic (category 1A)	22 July 2017	22 January 2019	2021	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 reproducti on (category 1B)	4 January 2019	4 July 2020	2021	Call for evidence over. Screening report in finalisation	To be assessed.

Ent ry No	Substance(s)	Intrinsic property(ies) referred to in Article 57	Latest applicat ion date	Sunset date	Expecte d date of completi on of assessm ent by ECHA	Current progress ⁸	Conclusio n
33	Diisopentylphthalate ¹² EC No: 210-088-4 CAS No: 605-50-5	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020	2022	Draft screening report in preparatio n.	To be assessed.
34	1,2-Benzenedicarboxylic acid, di- C6-8-branched alkyl esters, C7 rich ³ EC No: 276-158-1 CAS No: 71888-89-6	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020	2022	Draft screening report in preparatio n.	To be assessed.
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 January 2019	4 July 2020	2022	Draft screening report in preparatio n.	To be assessed.
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 January 2019	4 July 2020	2022	Draft screening report in preparatio n.	To be assessed.
37	Bis(2-methoxyethyl) phthalate ³ EC No: 204-212-6 CAS No: 117-82-8	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020	2022	Draft screening report in preparatio n.	To be assessed.
38	Dipentylphthalate ³ EC No: 205-017-9 CAS No: 131-18-0	Toxic for reproduction (category 1B)	4 January 2019	4 July 2020	2022	Draft screening report in preparatio n.	To be assessed.
39	N-pentyl-isopentylphthalate ³ EC No: — CAS No: 776297-69-9	Toxic for reproducti on (category 1B)	4 January 2019	4 July 2020	2022	Draft screening report in preparatio n.	To be assessed.
40	Anthracene oil EC No: 292-602-7 CAS No: 90640-80-5	Carcinogenic (category 1B) (***), PBT, vPvB	4 April 2019	4 October 2020	2021	Draft screening report in preparatio n. Call for evidence ending 29 October 2021.	Restriction probably needed.

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 $^{^{12}}$ Phthalates will all be taken as one group. To be considered in the restriction proposal on ortho phthalates (Restrictions roadmap)

Ent ry No	Substance(s)	Intrinsic property(ies) referred to in Article 57	Latest applicat ion date	Sunset date	Expecte d date of completi on of assessm ent by ECHA	Current progress ⁸	Conclusio n
41	Pitch, coal tar, high temp. (CTPHT) EC No: 266-028-2 CAS No: 65996-93-2	Carcinogenic (category 1B), PBT, vPvB	4 April 2019	4 October 2020	Annex XV restriction report in October 2021. Screening report in 2021.	Annex XV restriction report proposed for use in clay targets. RoI in Q2 2021. Submitted on 1 October 2021. Draft screening report on other uses in preparatio n. Call for evidence ending 29 October 2021.	Clay targets: Restriction on the placing on the market and use of substances containing polycyclic aromatic hydrocarbo ns (PAHs) in clay targets for shooting. submitted (covers CTPHT and other substances -group restriction). Other uses: Restriction probably needed.
42	4-(1,1,3,3- Tetramethylbutyl)phenol, ethoxylated (covering well- defined substances and UVCB substances, polymers and homologues) EC No: — CAS No: —	Endocrine disrupting properties (Article 57(f) — environment)	4 July 2019	4 January 2021	2022	Draft screening report in preparatio n.	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- 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 July 2019	4 January 2021	2022	Draft screening report in preparatio n.	To be assessed.
44	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear ³	Toxic for reproduction (Article 57c)	27 August 2021	27 February 2023	2022	Draft screening report in	To be assessed.

Ent ry No	Substance(s)	Intrinsic property(ies) referred to in Article 57	Latest applicat ion date	Sunset date	Expecte d date of completi on of assessm ent by ECHA	Current progress ⁸	Conclusio n
	EC: 271-093-5 CAS: 68515-50-4					preparatio n.	
45	Dihexyl phthalate ³ EC: 201-559-5 CAS: 84-75-3	Toxic for reproduction (Article 57c)	27 August 2021	27 February 2023	2022	Draft screening report in preparatio n.	To be assessed.
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) ³	Toxic for reproduction (Article 57c)	27 August 2021	27 February 2023	2021	Draft screening report in preparatio n.	To be assessed.
47	Trixylyl phosphate EC: 246-677-8 CAS: 25155-23-1	Toxic for reproduction (Article 57c)	27 November 2021	27 May 2023	2022	Screening work has not started.	-
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 November 2021	27 May 2023	2022	Screening work has not started.	
49	Sodium peroxometaborate	Toxic for reproduction (Article 57c)	27 November 2021	27 May 2023	2022	Screening work has not started.	-
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 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	vPvB (Article 57e)	27 February2 022	27 August 2023	-	Screening work has not started.	-

Ent ry No	Substance(s)	Intrinsic property(ies) referred to in Article 57	Latest applicat ion date	Sunset date	Expecte d date of completi on of assessm ent by ECHA	Current progress ⁸	Conclusio n
	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.: -						
51	2-(2H-benzotriazol-2-yl)-4,6- ditertpentylphenol	PBT (Article 57d) vPvB (Article 57e)	27 May 2022	27 Novembe r 2023		Screening work has not started.	
52	2,4-di-tert-butyl-6-(5- chlorobenzotriazol-2-yl)phenol	vPvB (Article 57e)	27 May 2022	27 Novembe r 2023		Screening work has not started.	-
53	2-(2H-benzotriazol-2-yl)-4-(tert- butyl)-6-(sec-butyl)phenol	vPvB (Article 57e)	27 May 2022	27 Novembe r 2023		Screening work has not started.	-
54	2-benzotriazol-2-yl-4,6-di-tert- butylphenol	PBT (Article 57d) vPvB (Article 57e)	27 May 2022	27 Novembe r 2023	-	Screening work has not started.	-