

Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Date: 30/11/2021

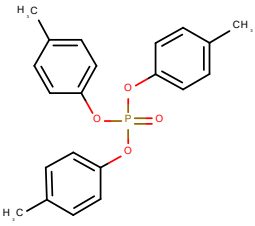
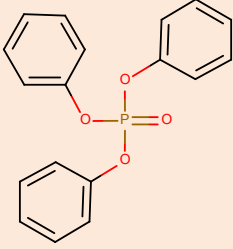
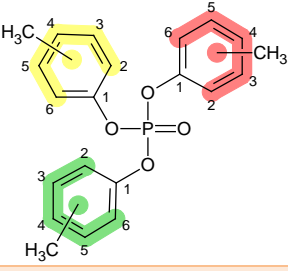
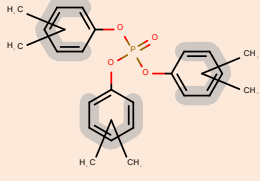
Group Name: Triphenylphosphate derivatives

General structure: -

Revision history

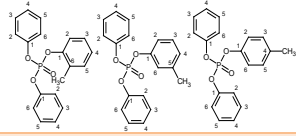
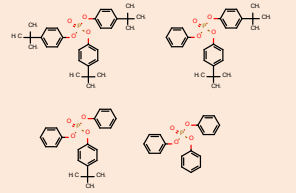
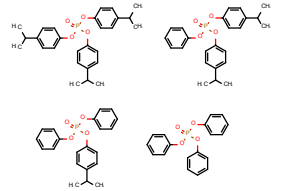
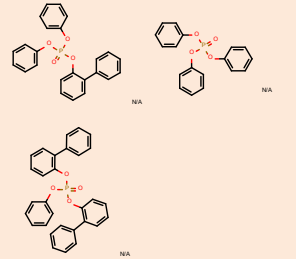
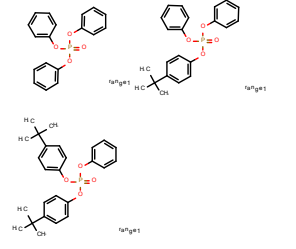
<i>Version</i>	<i>Date</i>	<i>Description</i>
1.0	30/11/2021	

Substances within this group:

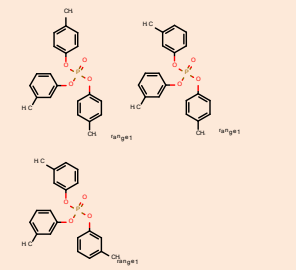
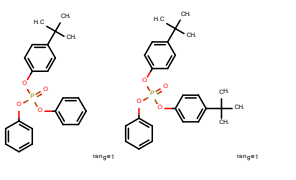
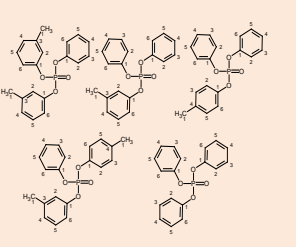
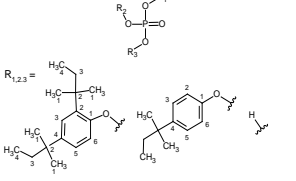
EC/List number	CAS number	Substance name and Substance name acronyms	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
Sub-group 1				
201-105-6	78-32-0	tri-p-tolyl phosphate "TPCP"		C&L notification
204-112-2	115-86-6	triphenyl phosphate "TPP"		Full, >1000
215-548-8	1330-78-5	tris(methylphenyl) phosphate		C&L notification
246-677-8	25155-23-1	trixylyl phosphate "TXP"		Full, not (publicly) available

¹ Note that the total aggregated tonnage band may be available on ECHA's webpage at <https://echa.europa.eu/information-on-chemicals/registered-substances>

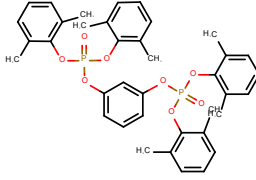
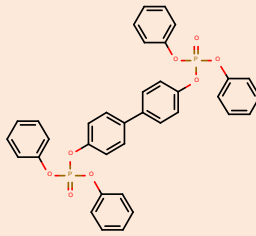
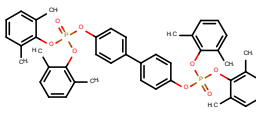
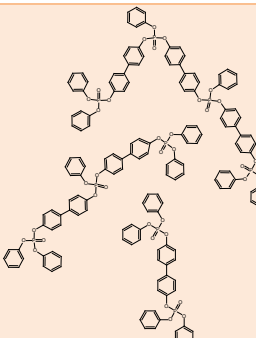
ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name and Substance name acronyms	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
247-693-8	26444-49-5	diphenyl tolyl phosphate		C&L notification
273-065-8	68937-40-6	Phenol, isobutyleneated, phosphate (3:1)	 <i>(representative structures)</i>	C&L notification
273-066-3	68937-41-7	Phenol, isopropylated, phosphate (3:1)	 <i>(representative structures)</i>	Full, >1000
700-393-5		Reaction mass of biphenyl-2-yl diphenyl phosphate and triphenyl phosphate and bis(biphenyl-2-yl) phenyl phosphate		Full, not (publicly) available
700-990-0		Reaction mass of 4-tert-butylphenyl diphenyl phosphate and bis(4-tert-butylphenyl) phenyl phosphate and triphenyl phosphate		Full, >1000

ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name and Substance name acronyms	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
809-930-9	1330-78-5	Reaction mass of 3-methylphenyl bis(4-methylphenyl) phosphate and bis(3-methylphenyl) 4-methylphenyl phosphate and tris(3-methylphenyl) phosphate (tricresyl phosphate, TCP, TMPP)		Full, > 1000
939-505-4		Reaction mass of p-t-butylphenyldiphenyl phosphate and bis(p-t-butylphenyl) phenyl phosphate		Full, 100-1000
945-730-9		Reaction mass of 3-methylphenyl diphenyl phosphate, 4-methylphenyl diphenyl phosphate, bis(3-methylphenyl) phenyl phosphate, 3-methylphenyl 4-methylphenyl phenyl phosphate		Full, >1000
946-992-7		Reaction product of 2,4-bis(2-methylbutan-2-yl)phenol and phosphorous pentoxide	 <p>(R₁, R₂, R₃ cannot all be H)</p>	Full, not (publicly) available
Sub-group 2				

ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name and Substance name acronyms	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
432-770-2	139189-30-3	tetrakis(2,6-dimethylphenyl)-m-phenylene biphosphate		Full, not (publicly) available
700-627-6	17270-01-8	biphenyl-4,4'-diyl tetraphenyl bis(phosphate)		Full, not (publicly) available
807-250-7	147263-99-8	Biphenyl-4,4'-diyl tetrakis(2,6-dimethylphenyl) bis(phosphate)		Full, not (publicly) available
947-151-7		Phosphoric acid, mixed esters with biphenyl-4,4'-diol and phenol		Full, not (publicly) available

This table contains also group members that are only notified under the CLP Regulation. However, the list is currently non-exhaustive. Should further regulatory risk management action on one or more substances in the group be considered, ECHA will make an additional search for related C&L notified substances to be included in the group and develop an assessment of regulatory needs for them.

Contents

Foreword	8
Glossary	9
1 Overview of the group	10
2 Justification for the need for regulatory risk management action at EU level	11
3 Conclusions and actions	16
Annex 1: Overview of classifications	20
Annex 2: Overview of uses based on information available in registration dossiers	22
Annex 3: Overview of completed or ongoing regulatory risk management activities	24

DISCLAIMER

The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA, the Member States or other regulatory agencies may initiate at a later stage. Assessment of regulatory needs and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

Foreword

The purpose of the assessment of regulatory needs of a group of substances is to help authorities conclude on the most appropriate way to address the identified concerns for a group of substances or a single substance, i.e. the combination of the regulatory risk management instruments to be used and any intermediate steps, such as data generation, needed to initiate and introduce these regulatory measures.

An assessment of regulatory needs can conclude that regulatory risk management at EU level is required for a (group of) substance(s) (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. While the assessment is done for a group of substances, the (no) need for regulatory action can be identified for the whole group, a subgroup or for single substance(s).

The assessment of regulatory needs is an important step under ECHA's Integrated Regulatory Strategy. However, it is not part of the formal processes defined in the legislation but aims to support them.

The assessment of regulatory needs can be applied to any group of substances or single substance, i.e., any type of hazards or uses and regardless of the previous regulatory history or lack of such. It can be done based on different level of information. A Member State or ECHA can carry out this case-by-case analysis. The starting point is available information in the REACH registrations and any other REACH and CLP information. However, more extensive set of information can be available, e.g. assessment done under REACH/CLP or other EU legislation, or can be generated in some cases (e.g. further hazard information under dossier evaluation). Uncertainties associated to the level of information used should be reflected in the documentation. It will be revisited when necessary. For example, after further information is generated and the hazard has been clarified or when new insights on uses are available. It can be revisited by the same or another authority.

The responsibility for the content of this assessment rests with the authority that developed it. It is possible that other authorities do not have the same view and may develop further assessment of regulatory needs. The assessment of regulatory needs does not yet initiate any regulatory process but any authority can consequently do so and should indicate this by appropriate means, such as the Registry of Intentions.

For more information on Assessment of regulatory needs please consult ECHA website².

² <https://echa.europa.eu/understanding-assessment-regulatory-needs>

Glossary

ARN	Assessment of Regulatory Needs
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern

1 Overview of the group

ECHA has grouped together structurally similar substances based on the presence of the triphenylphosphate derivatives moiety. Based on information reported in the REACH registration dossiers and other sources³ most of the substances in the group are used as additive flame retardants.

All 17 substances in the group can be regarded as triphenylphosphate derivatives, although 3 of these substances contain biphenyl-bridged phosphate triester constituents. The group contains mono-constituent (5), multi-constituent (7), and UVCB (5) substances.

The substances have been divided into two sub-groups considering structural similarities, chemical properties and use profile:

- Sub-group 1: The 13 substances in sub-group 1 contain only one phosphate group. Most substances in this sub-group were covered by the earlier manual screening done by the Netherlands. They are used as additives in technical fluids (metal working fluids, heat transfer fluids and hydraulic fluids) and lubricants, and in polymeric materials that end up in articles.
- Sub-group 2: The four substances in sub-group 2 contain more than one phosphate-group. None of the substances in this sub-group were covered by the earlier manual screening done by the Netherlands. They are mostly used as additives in polymeric materials that end up in articles.

Based on information reported in the REACH registration dossiers, the reported technical functions for the substances that are used in technical fluids (metal working fluids, heat transfer fluids and hydraulic fluids) are corrosion inhibitor, softener and as flame retardant. The sectors highlighted are vehicles and machinery.

In the polymeric materials the main reported technical functions are flame retardant and plasticiser. The materials mentioned by the registrants are plastics, thermoplastics, rubber and rigid and flexible foams. The sectors highlighted are building and construction work, furniture and electronic and electronic devices.

The uses are widespread with potential exposure to professional workers and consumers of mixtures and articles (e.g. in articles made of rubber, plastics, paper, textiles and leather) from which these substances could also be released to the environment. There is potential for exposure to these substances from the wide range of applications and markets.

³ E.g. Information from the PLASI initiative (<https://echa.europa.eu/plastic-additives-initiative>); US EPA list of substances identified as flame retardants (<https://comptox.epa.gov/dashboard/chemical-lists/FLAMERETARD>); Phosphorous flame retardants (2017), Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley & Sons; Environmental and health screening profiles of phosphorous flame retardants (DK EPA 2016), <https://www2.mst.dk/Udgiv/publications/2016/01/978-87-93435-23-0.pdf>; and The Nordic Expert Group for Criteria Documentation of Health Risks from Chemicals, 143. Phosphate triesters with flame retardant properties, nr 2010, 44(6), https://gupea.ub.gu.se/bitstream/handle/2077/23825/gupea_2077_23825_1.pdf;jsessionid=9304BCD35B4ADB829B7D3EEC94F365CD?sequence=1

EC 246-677-8 has a harmonised classification (Repr. 1B H360F) and it is on the Candidate list⁴ due to its hazard for toxic for reproduction and subsequently included on the Authorisation list⁵ with the Sunset date of 27 May 2023.

Note on the scope of ECHA's assessment of regulatory needs

Regarding hazards, the focus of ECHA's assessment is on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g. substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the table in section 3. This does not mean that the substances do not have other known or potential hazards. In some specific cases, where ECHA identifies a need for regulatory risk management action at EU level for other hazards (e.g. neurotoxicity, STOT RE), such additional hazards may be addressed in the assessment. An overview of classification is presented in Annex 1.

On the exposure side, ECHA is mainly using the information on uses reported in the registration dossiers (IUCLID) as a proxy for assessing the potential for exposure to humans and releases to the environment. The potential for release / exposure is generally considered high for "widespread" uses, i.e. professional and consumer uses and uses in articles. For these uses, normally happening at many places, the expected level of control is *à priori* considered limited. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

2 Justification for the need for regulatory risk management action at EU level

Based on currently available information, there is a need for (further) EU regulatory risk management – restriction for reproductive toxicity and/or endocrine disrupting (ED – both human health and environment) hazards for all uses due to the potential for release and exposure of all sub-group 1 members.

Based on ECHA's assessment of currently available hazard information, potential hazards were identified for human health. The available information indicates that the main potential human health hazards for the substances in sub-group 1 are reproductive toxicity and endocrine disruption for human health and the environment:

- TXP (EC 246-677-8) has a harmonised classification as Repr. cat. 1B and it is included on Annex XIV. This potential hazard can also be extrapolated to

⁴ <https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807dd3a3>

⁵ <https://echa.europa.eu/authorisation-list/-/dislist/details/0b0236e180912982>

the rest of the substances in sub-group 1 although there are some data gaps for some substances that need to be addressed. ECHA has not received any applications for authorisation for this substance by the latest application date (27 November 2021). Investigation according to article 69(2) will be carried out to find out if there are uses of the substance in articles and whether the uses cause risk.

- TPP (EC 204-112-2) is under SEv by UK and France⁶ for endocrine disrupting properties for human health and environment and data is being generated (Fish Sexual Development Test). In addition, the US NTP is performing an extended one-generation reproductive toxicity study.
- If TPP is confirmed as an endocrine disruptor, substances containing TPP at relevant concentrations in its composition will also be endocrine disruptors. This impacts most of the registered substances in sub-group 1.
- In addition, ED potential for human health and the environment does not apply only for TPP and substances containing TPP since there is evidence of ED properties for other alkyl-substituted constituents present in the composition of the substances.
- EC 273-066-3 is under SEv for potential endocrine disruptor and suspected PBT/vPvB. Following a testing proposal an extended one-generation reproductive toxicity study is being performed.

It is proposed to generate data via CCH for ECs 809-930-9 and 945-730-9 to clarify reprotoxicity and ED properties. If data being generated under CCH does not demonstrate that the substances are ED, further data may be generated under SEV. The data being-generated may allow to read-across reprotoxicity and ED hazard within the sub-group. In addition, it is proposed to initiate substance evaluation for environment ED substances ECs 809-930-9 and 939-505-4.

As regards neurotoxicity, several organophosphorus flame retardants are known to cause organophosphorus-induced delayed neuropathy (OPIDN) after single (acute) and repeated exposure. OPIDN was observed not only in animal studies, but also in humans. Metabolism to highly neurotoxic derivatives such as saligenin cyclic o-cresyl phosphate is possible from o-methyl/cresyl isomers (The Nordic Expert Group 2010)⁷, therefore all sub-group members containing TOCP (tri-o-cresylphosphate, EC 201-103-5) as constituent or impurity may be neurotoxic. Regulatory actions regarding reprotoxicity/ED would already address the risks related to neurotoxicity. However, if reprotoxicity and ED hazards are not confirmed, we envision the need to generate specific data to address this concern via SEv.

In general, substances in this sub-group are unlikely to meet the PBT/vPvB criteria based on the data available. Several substances are readily biodegradable (EC/List

⁶ <https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807eb287>

⁷ (The Nordic Expert Group 2010) The Nordic Expert Group for Criteria Documentation of Health Risks from Chemicals, 143. Phosphate triesters with flame retardant properties; nr 2010; 44(6); isbn 978-91-85971-23-7; https://gupea.ub.gu.se/bitstream/2077/23825/1/gupea_2077_23825_1.pdf

204-112-2, 215-548-8, 809-930-9⁸, 945-730-9, 700-990-0, 939-505-4). However, EC 246-677-8 and 273-066-3 are under SEv for suspected PBT/vPvB properties.

The first steps of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via harmonised classification (CLH) as toxic to reproduction cat. 1B (excluding EC 246-677-8 having already this classification) and the confirmation of ED hazard via SVHC identification and inclusion on the Candidate List as ED for human health and the environment. Clarifying ED potential may lead to non-threshold considerations in risk management.⁹

CLH as Repr. cat. 1B i) will require company level risk management measures (RMM) under the OSH legislation for workers, to be in place, ii) is needed or highly recommended for further regulatory processes under REACH and iii) is a prerequisite to restrict the presence of the substances in consumer mixtures, by means of the restriction entry 30.

For substances used in clothing, other textiles and footwear articles only, CLH is also a prerequisite to restrict the presence of the substances in clothing, other textiles, and footwear articles, by means of the restriction entry 72 of REACH Annex XVII (this would require addition of the relevant substances to Appendix 12 by the Commission through Article 68(2)).

CLH will also support regulatory action under other regulations. For instance, in this specific case:

- harmonised classification as CMR cat. 1 will trigger regulatory action under the Cosmetic products regulation (EC) No 1223/2009 for uses as fragrance, since CMR cat. 1 are restricted by this regulation (relevant for EC 204-112-2).

SVHC identification is highly recommended for further regulatory processes under REACH (Restriction). In addition, SVHC identification brings immediate obligations for suppliers of the substances such as (i) supplying a safety data sheet and communicating on the safe use of the substances, (ii) responding to consumer requests within 45 days and (iii) notifying ECHA if the article they produce contains the substance above regulatory threshold.

The professional uses (e.g. technical fluids, coatings, paints, lubricants, greases, adhesives and sealants, polymeric materials) are expected to be widespread (at many sites and by many users). When the substances are in polymeric materials (10 to 20% w/w) the main reported sectors are building and construction work, furniture upholstery and electronic and electronic devices. When the substances are used in technical fluids the main reported sectors are vehicles and machinery. Professional use is often widespread with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. In addition, professional users may be self-employed and therefore not covered by occupational safety and health (OSH) legislation.

Consumers may be co-exposed to the substances used by professionals e.g. house painters.

⁸ For List 809-930-9 a SEv was closed with a conclusion that the PBT concern was refuted.

⁹ If reproductive toxicity and ED are not confirmed, to be considered if further data generation through SEV should be considered to follow-up the potential hazard on neurotoxicity for substances containing ortho-methyl phenoxy moieties.

Therefore, a **restriction of the substance as such or in mixtures (concentration limit in mixtures) used by professionals** is suggested after CLH.

Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses.

In addition, the use of the most harmful substances by professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability¹⁰ which aims to extend to professional users under REACH the level of protection granted to consumers.

Moreover, **restricting substances in articles** used by professionals or consumers (reported for all substances, except for EC 946-992-7) is proposed as potential for exposure from articles is likely (substances used as additives (10 to 35% w/w)¹¹ in polymeric materials that end up in articles).

It is suggested to cover possibly also **industrial uses as part of the restriction**. The need for authorisation might be considered for industrial uses excluded from the scope of the restriction as it may not be proportionate to restrict all uses. Insofar substances will also be identified as ED ENV, the release to the environment should be considered.

Based on currently available information, it is not possible to assess the need for regulatory risk management as information on hazard is not sufficient to conclude on reproductive toxicity, ED, and/or STOT RE (neurotoxicity) hazards of the all sub-group 2 members.

The composition reported for substances List No. 700-627-6 and 947-151-7 includes the presence of EC 204-112-2 (TPP) as an impurity in relevant concentrations. Therefore, if TPP (sub-group 1) is confirmed to be Repr. cat. 1B or an endocrine disruptor, and if the impurities are above the generic concentration limit (GCLs) the registrants will need to self-classify these substances accordingly. Further, the group restriction mentioned above for substances in sub-group 1 will also apply to substances in sub-group 2 containing TPP as impurity. However, it can be questioned whether there will be any regulatory impact on these substances because i) TPP content from these substances in mixtures and articles will be 'diluted' to a concentration well below 0.1 %, and ii) impurities could perhaps be technically removed in the manufacturing process.

Further, the neurotoxicity hazard is an (inconclusive) for EC/List No. 807-250-7 and 432-770-2, which contain 2,6-xyleneol (EC 209-400-1) in their structure. The suspicion is based on the ortho-methylated phenols in the structure which seems to be an indicator for neurotoxicity in triphenylphosphates from the data available for substances in sub-group 1. ECHA proposes generating repeated dose toxicity/neurotoxicity data via CCH for substance EC 432-770-2.

¹⁰ European Commission, *Chemical Strategy for Sustainability Towards a Toxic-Free Environment*, available at <https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf>

¹¹ <https://echa.europa.eu/mapping-exercise-plastic-additives-initiative>

ASSESSMENT OF REGULATORY NEEDS

In general, substances in this sub-group are unlikely to meet the PBT criteria based on the data available, but CCH is needed to clarify the persistence and fate for EC/List No. 700-627-6, 947-151-7 and 432-770-2.

The substances in sub-group 2 are used as additives in polymeric materials where the function of the substance is mainly flame retardant. There are no professional or consumer uses but there is potential for exposure to consumers exposed to articles in which these substances are present and could be released. However, it is proposed to wait the outcome of the data generation for substances in sub-group 1 and 2 and update the assessment of regulatory needs for sub-group 2 substances as appropriate. If reprotoxicity and ED hazards are not confirmed, ECHA foresees the need to generate specific data to address potential neurotoxicity hazard via SEV (ECs 807-250-7 and 432-770-2).

3 Conclusions and actions

The conclusions and actions proposed in the table below are based on the REACH and CLP information available at the time of the assessment by ECHA. The main source of information is the registration dossiers. Relevant public assessments may also be considered. When new information (e.g. on hazards through evaluation processes, or on uses) will become available, the document will be updated and conclusions and actions revisited.

As indicated in the Restrictions Roadmap¹² ECHA will prepare an overall strategy on flame retardants by 2022, which will support the Commission when it decides to request ECHA to prepare (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 overall strategy on flame retardants may bring new perspectives and may result in a need to revise some of the conclusions in this ARN.

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Sub-group 1: 201-105-6 204-112-2 215-548-8 246-677-8 247-693-8 273-065-8	Known or potential hazard for reproductive toxicity and for ED Inconclusive for neurotoxicity hazard	Known or potential hazard for ED Inconclusive for PBT/vPvB properties for EC 246-677-8 and 273-066-3	Many professional and consumer uses with exposure and release potential and potential for exposure from article service life (additives in functional fluids and lubricants and in polymeric materials in articles).	Need for EU RRM: Restriction <u>Justification:</u> The harmonised classification as Repr. cat. 1B would trigger the restriction entry 30 and by that ensure that the substances are not included in consumer	First step: CCH (ECs 809-930-9 and 945-730-9) and SEV (ECs 809-930-9 and 939-505-4) Next steps (if hazard confirmed): CLH (except EC 246-677-8), SVHC and restriction

¹² <https://ec.europa.eu/docsroom/documents/49734>

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
273-066-3				mixtures above the limits specified in that entry. Releases to the environment from consumer and widespread professional uses cannot be avoided. The reported professional uses are widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. Widespread professional uses are typically non-contained and non-automated leading to releases to the environment. Restriction of professional uses is	
700-393-5					
700-990-0					
809-930-9					
939-505-4					
945-730-9					
946-992-7					

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				<p>preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses.</p> <p>Specific restriction for use in articles is proposed as potential exposure from articles is likely. Industrial uses to be considered as part of the restriction.</p>	
<p>Sub-group 2: 432-770-2 700-627-6 807-250-7 947-151-7</p>	<p>Inconclusive hazard for reproductive toxicity, ED and neurotoxicity</p>	<p>No hazard or unlikely hazard</p>	<p>Potential exposure from article service life (additives in polymeric materials in articles).</p>	<p>Currently not possible to assess the regulatory needs</p> <p><u>Justification:</u> It is proposed to wait the outcome of the data generation for substances in sub-group 1 and 2.</p>	<p>First step: CCH (ECs 432-770-2, 700-627-6, 947-151-7)</p> <p>Next steps (if hazard confirmed): Substance evaluation (ECs 807-250-7 and 432-770-2) if</p>

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
					reprotoxicity or ED not confirmed

Annex 1: Overview of classifications

Data extracted on 18 January 2021.

EC/List No	Substance name	Harmonised classification	Classification in registrations
201-105-6	tri-p-tolyl phosphate	Not included in Annex VI	-
204-112-2	triphenyl phosphate	Not included in Annex VI	Aquatic Acute 1 H400 Aquatic Chronic 2 H411
215-548-8	tris(methylphenyl) phosphate	Not included in Annex VI	-
246-677-8	trixylyl phosphate	Repr. 1B H360F	Repr. 1B H360 STOT Rep. Exp. 2 H373 Aquatic Acute 1 H400, M-factor: 10.0000000000 Aquatic Chronic 1 H410
247-693-8	diphenyl tolyl phosphate	Not included in Annex VI	-
273-065-8	Phenol, isobutylated, phosphate (3:1)	Not included in Annex VI	-
273-066-3	Phenol, isopropylated, phosphate (3:1)	Not included in Annex VI	Repr. 2 H361 STOT Rep. Exp. 2 H373 Aquatic Chronic 1 H410, M-factor: 10.0000000000 Aquatic Chronic 4 H413
432-770-2	432-770-2	Skin Sens. 1 H317 ¹³	Skin Sens. 1B H317
700-393-5	Reaction mass of biphenyl-2-yl diphenyl phosphate and triphenyl phosphate and bis(biphenyl-2-yl) phenyl phosphate	Not included in Annex VI	Eye Damage 1 H318
700-627-6	700-627-6	Not included in Annex VI	-
700-990-0	Reaction mass of 4-tert-butylphenyl diphenyl phosphate and bis(4-tert-butylphenyl) phenyl phosphate	Not included in Annex VI	Aquatic Acute 1 H400 Aquatic Chronic 1 H410

¹³ Removed by RAC in 2019 (<https://echa.europa.eu/documents/10162/29ec3835-d8fe-b378-0b4c-44ed1656f861>)

ASSESSMENT OF REGULATORY NEEDS

	and triphenyl phosphate		
807-250-7	Biphenyl-4,4'-diyl tetrakis(2,6-dimethylphenyl) bis(phosphate)	Not included in Annex VI	-
809-930-9	Reaction mass of 3-methylphenyl bis(4-methylphenyl) phosphate and bis(3-methylphenyl) 4-methylphenyl phosphate and tris(3-methylphenyl) phosphate	Not included in Annex VI	Repr. 2 H361 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
939-505-4	939-505-4	Not included in Annex VI	-
945-730-9	Reaction mass of 3-methylphenyl diphenyl phosphate, 4-methylphenyl diphenyl phosphate, bis(3-methylphenyl) phenyl phosphate, 3-methylphenyl 4-methylphenyl phenyl phosphate	Not included in Annex VI	Aquatic Acute 1 H400
946-992-7	Reaction product of 2,4-bis(2-methylbutan-2-yl)phenol and phosphorous pentoxide	Not included in Annex VI	Flam. Liquid 3 H226 Skin Corr. 1C H314 Eye Damage 1 H318 Skin Sens. 1B H317 Aquatic Chronic 2 H411
947-151-7	Phosphoric acid, mixed esters with biphenyl-4,4'-diol and phenol	Not included in Annex VI	-

(*) the number in brackets indicates the number of notifications received. Each notification can represent a group of notifiers, therefore the number may differ from the C&L inventory which displays number of notifiers.

Annex 2: Overview of uses based on information available in registration dossiers

Data extracted on 15 February 2021.

Main types of applications structured by product or article types	204-112-2	246-677-8	273-066-3	700-393-5	700-990-0	809-930-9	939-505-4	945-730-9	946-992-7	432-770-2	700-627-6	807-250-7	947-151-7
Washing and cleaning products	F												
Cosmetics, personal care products	F, C												
Polishes and wax blends	C												
Lubricants, greases, release products		F, I, P, A	F, I, P, C, A		F, I, P, A	F, I, P, A	F, I, P	F, I, P, C	F, I, P, C				
Metal working fluids		F, I, P	F, I, P		F, I, P, A	F, I, P, A	F, I, P	F, I, P	F, I, P				
Heat transfer fluids		P	F, I, P		P	F, I, P, C		F, I					
Hydraulic fluids		F, I, P	F, I, P, C		F, I, P, A	F, I, P, C	F, P, A	F, P, C	F, I, P				
Fuels									F, I, P, C				
Polymer preparations and compounds	F, I, P, C, A	I	F, I, P, C, A	F, I, A	F, I, P, C, A	F, I, P, C, A	F, I, P, A	F, I, P, C, A		F, A	F, I, A	F, A	F, I, A
Adhesives, sealants	F, P, C, A		F, I, P, C, A			F, I, P, C, A		F, I, P, C					
Finger paint								F, I, P, C					
Fillers, putties, plasters, modelling clay								F, I, P, C					
Coatings and paints, thinners, paint	F, C		F, I, P, C, A		F, I, P	F, I, P, C, A	F, I, P, A	F, I, P, C					

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	204-112-2	246-677-8	273-066-3	700-393-5	700-990-0	809-930-9	939-505-4	945-730-9	946-992-7	432-770-2	700-627-6	807-250-7	947-151-7
removes													
Paper and board treatment products	A												
Textile dyes, and impregnating products	I						A						F, I, A
Leather treatment products	A							F, I, A					
Laboratory chemicals	P		F, I			F, I		F, I	F				
Intermediate							F						
Photo-chemicals			F, I, P, C, A			F, I, P, C, A		F, I, P, C					

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; P, C and A are highlighted in red to indicate widespread use with potential for exposure/release

Annex 3: Overview of completed or ongoing regulatory risk management activities

Data extracted on 5 February 2021.

EC/List number	RMOA	Authorisation		Restriction*		CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)		
204-112-2	Yes						
246-677-8		Yes	Yes			Yes	

*Some of the broad restriction entries in the Annex XVII of REACH are not represented in the overview, e.g. when the scope of the restriction is defined by its classification or the substance identification is broad (e.g. entries 3, 28-30 and 40).

There are no relevant completed or ongoing regulatory risk management activities for the other substances.