Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Date: July 2021

Group Name: Isophthalates, Terephthalates and Trimellitates

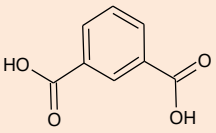
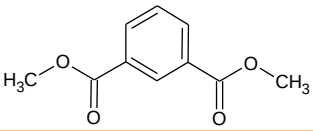
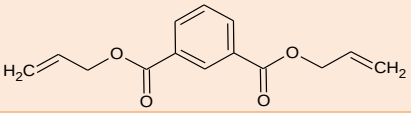
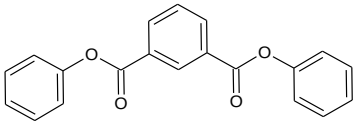
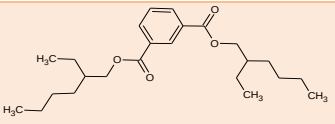
General structure: -

Revision history

Version	*Date*	*Description*
1.0	July 2021	

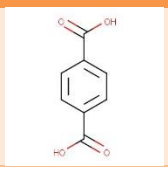
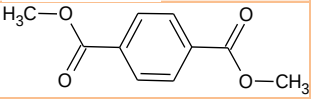
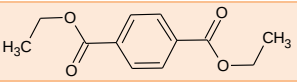
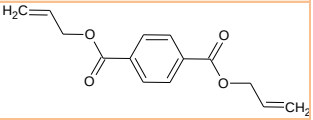
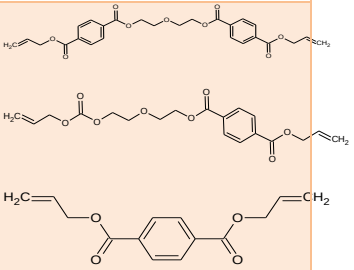
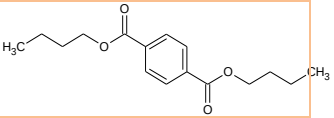
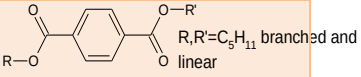
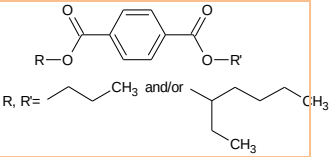
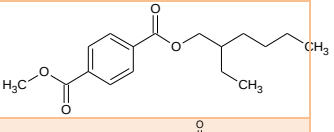
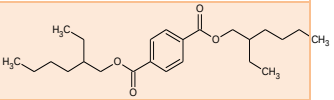
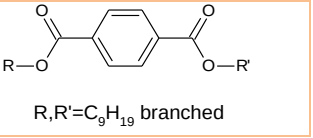
Substances within this group:

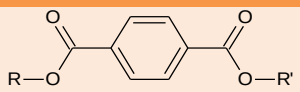
Table 1 Substances within the isophthalate group:

EC/List number	CAS number	Substance name	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]	Chemical structures
204-506-4	121-91-5	isophthalic acid	Full: > 1000	
215-951-9	1459-93-4	dimethyl isophthalate	Full: 100-1000	
214-122-9	1087-21-4	diallyl isophthalate	Full: 100-1000	
212-014-6	744-45-6	Diphenyl isophthalate	Not registered	
205-308-0	137-89-3	Bis(2-ethylhexyl) isophthalate	Not registered	
445-050-8	-	Not (publicly) available	NONS	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

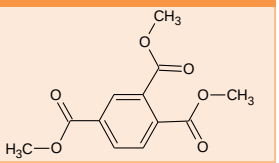
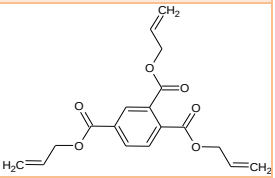
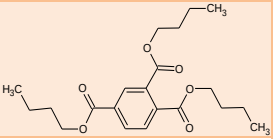
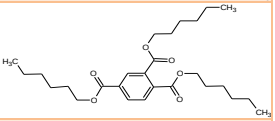
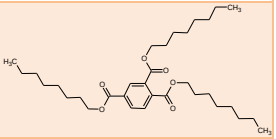
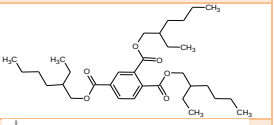
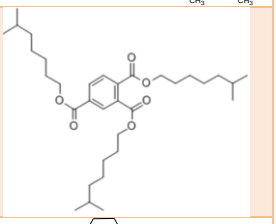
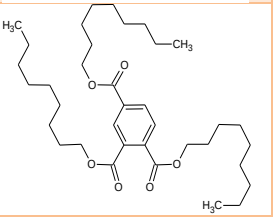
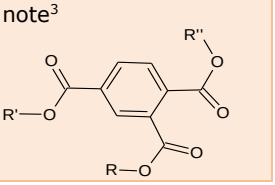
Table 2 Substances within the terephthalate group:

EC/List number	CAS number	Substance name	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]	Chemical structures
202-830-0	100-21-0	terephthalic acid (TPA)	Full: > 1000	
204-411-8	120-61-6	dimethyl terephthalate (DMT)	Full: > 1000	
211-249-1	636-09-9	diethyl terephthalate	Not registered	
213-835-2	1026-92-2	diallyl terephthalate	Not registered	
947-863-8	-	Reaction mass of 1-prop-2-en-1-yl 4-[2-(2-{4-[(prop-2-en-1-yloxy)carbonyl]benzoyloxy}ethoxy)ethyl] benzene-1,4-dicarboxylate and 1-prop-2-en-1-yl 4-[2-(2-{[(prop-2-en-1-yloxy)carbonyl]oxy}ethoxy)ethyl] benzene-1,4-dicarboxylate and diallyl terephthalate	Intermediate (OSII or TII)	
217-803-9	1962-75-0	dibutyl terephthalate	Full: > 1000	
940-272-6	2097734-13-7	Bis[C5-(linear and branched)-alkyl] benzene-1,4-dicarboxylate	Full: > 1000	
946-149-3	1571954-81-8	Reaction mass of bis(2-ethylhexyl) terephthalate, butyl 2-ethylhexyl terephthalate, and dibutyl terephthalate	Full: > 1000	
Not (publicly) available	-	terephtalic acid compound with diamines	Full: > 1000	Not (publicly) available
264-249-9	63468-13-3	2-ethylhexyl methyl terephthalate	Not registered	
229-176-9	6422-86-2	Bis(2-ethylhexyl) terephthalate (DEHT)	Full: > 1000	
700-453-0	59802-05-0	1,4-Benzenedicarboxylic acid, 1,4-diisononyl ester	Intermediate (OSII or TII)	

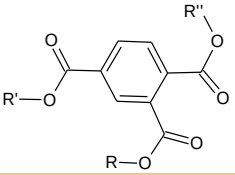
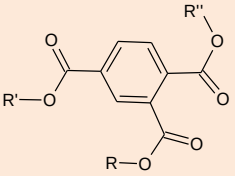
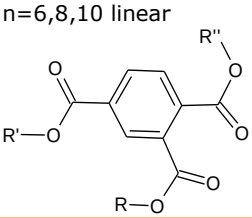
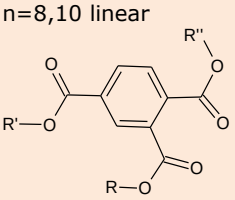
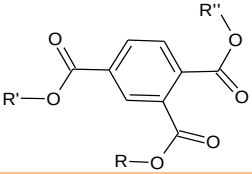
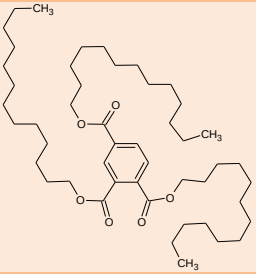
EC/List number	CAS number	Substance name	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]	Chemical structures
416-740-6	-	Ester reaction products of 1,4-Benzenedicarboxylic acid with C11-14 iso-alcohols, C13-rich[2]	Full: 100-1000	 R, R'=C_nH_{2n+1} n=11-14 branched

[2] Name provided in the IUPAC name field of the registration dossier

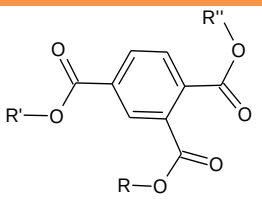
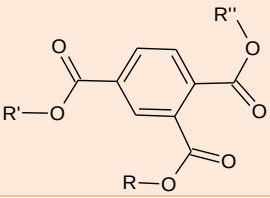
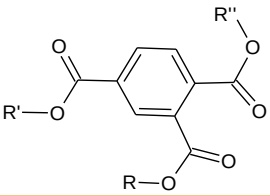
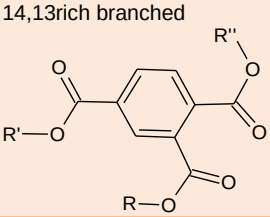
Table 3 Substances within the trimellitate group:

EC/List number	CAS number	Substance name	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]	Chemical structures
219-547-3	2459-10-1	Trimethyl benzene-1,2,4-tricarboxylate	Full: 10-100	
220-264-2	2694-54-4	Triallyl benzene-1,2,4-tricarboxylate	Not registered	
217-038-0	1726-23-4	Tributyl benzene-1,2,4-tricarboxylate	Not registered	
216-208-1	1528-49-0	Trihexyl benzene-1,2,4-tricarboxylate	Full: 1-10	
201-877-4	89-04-3	Trioctyl benzene-1,2,4-tricarboxylate (TM8)	Full: > 1000	
222-020-0	3319-31-1	Tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate (TOTM)	Full: > 1000	
248-365-7	27251-75-8	Triisooctyl benzene-1,2,4-tricarboxylate	Not registered	
252-552-9	35415-27-1	Trinonyl benzene-1,2,4-tricarboxylate	Not registered	
941-303-6	1689576-55-3	5-Isobenzofurancarboxylic acid, 1,3-dihydro-1,3-dioxo-, reaction products with 1-nonanol	Full: 100-1000	R,R',R''=C_9H_{19} branched and linear note[3] 

[3] Structure based on the reported composition

EC/List number	CAS number	Substance name	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]	Chemical structures
258-847-9	53894-23-8	Triisononyl benzene-1,2,4-tricarboxylate (TINTM)	Full: 100-1000	R,R',R''=C_nH_{2n+1} n=8-10,9 rich branched note[4] 
253-138-0	36631-30-8	Triisodecyl benzene-1,2,4-tricarboxylate	Full: 100-1000	R,R',R''=$C_{10}H_{21}$ branched 
268-593-0	68130-50-7	1,2,4-Benzenetricarboxylic acid, mixed decyl and hexyl and octyl esters	Not registered	R,R',R''=C_nH_{2n+1} n=6,8,10 linear 
268-007-3	67989-23-5	1,2,4-Benzenetricarboxylic acid, decyl octyl ester	Not registered	R,R',R''=C_nH_{2n+1} n=8,10 linear 
290-754-9	90218-76-1	1,2,4-Benzenetricarboxylic acid, mixed decyl and octyl triesters	Full: > 1000	R,R',R''=C_nH_{2n+1} n=8,10 linear 
302-446-4	94109-09-8	Tri(tridecyl) benzene-1,2,4-tricarboxylate	Full: 100-1000	
304-780-6	94279-36-4	1,2,4-Benzenetricarboxylic acid, tri-C9-11-alkyl esters	Full: 100-1000	R,R',R''=C_nH_{2n+1} n=9-11 linear

[4] Structure based on the reported composition

EC/List number	CAS number	Substance name	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]	Chemical structures
				
700-342-7	1163775-81-2	1,2,4-Benzenetricarboxylic acid, mixed lauryl and octyl triesters	Full: 100-1000	R,R',R"=C_8H_{17} and $C_{12}H_{25}$ linear 
615-086-0	70225-05-7	1,2,4-Benzenetricarboxylic acid, mixed branched tridecyl and isodecyl esters	Full: 10-100	R,R',R"=$C_{13}H_{27}$ and $C_{10}H_{21}$ branched 
276-594-2	72361-35-4	Triisotridecyl benzene-1,2,4-tricarboxylate	Full: 100-1000	R,R',R"=C_nH_{2n+1} n=11-14,13rich branched 

The tables above contain also group members that are not registered (yet) but have a C&L notification under the CLP Regulation. However, the list is currently non-exhaustive. Once further regulatory risk management action on one or more registered substances is being 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.

In addition, there are two non-registered isophthalates and three non-registered and one registered terephthalates for which all substance identifiers are confidential.

Contents

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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 website[5].

[5] https://echa.europa.eu/understanding-assessment-regulatory-needs

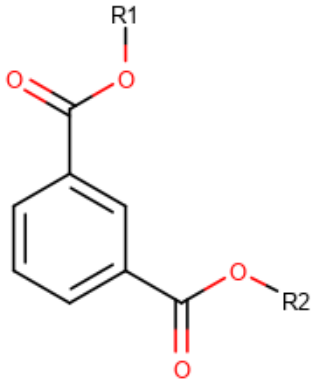
Glossary

CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
FCM	Food Contact Material
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

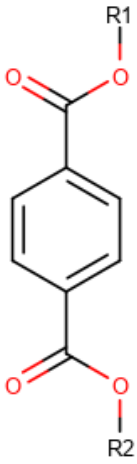
1 Overview of the group

ECHA has grouped structurally similar phthalate and phthalate-like esters, acids and salts in 4 groups, based on the number and position of the alkyl/aryl substituents: (i) *ortho*-phthalates, (ii) isophthalates, (iii) terephthalates and (iv) trimellitates. Assessment of regulatory needs for substances belonging to the isophthalates, terephthalates and trimellitates group has been performed and documented in this report. Another report documents the assessment of regulatory needs for *ortho*-phthalates.

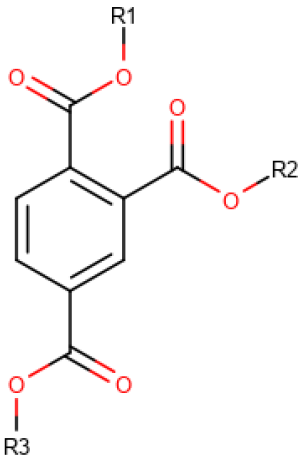
This report covers 43 phthalate or phthalate-like substances, belonging to the three subgroups mentioned above. 28 substances are registered under REACH, including 2 NONS and 1 inactive registration. 14 substances are not registered and one substance has an invalid registration.



Isophthalates



Terephthalates



Trimellitates

Although these groups are structurally similar to each other, i.e. consisting of a phenyl ring bound to two/three carboxyl functionalities, they are addressed separately throughout this report. Similarity to *ortho*-phthalates in terms of hazard and use is addressed at specific points in the below sections.

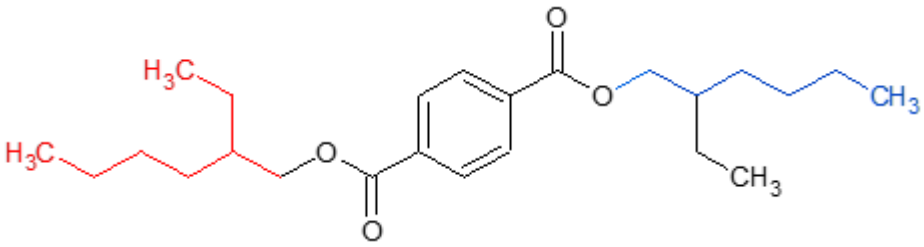
The isophthalate group consists of isophthalic acid and 7 phthalate esters substances with alkyl chains in the meta positions and carbon chains ranging from C1 to C9 (including linear and branched). One substance has substituents consisting of polyol carbonate allyl moieties. Only three substances in this group have active registrations.

There are 16 substances in the terephthalate group, including terephthalic acid, one diamine salt and 14 phthalate ester substances with alkyl chains in the para positions and carbon chains ranging from C1 to C14. 8 of these substances are registered under REACH.

In the trimellitate group there are 19 substances with alkyl chains in *ortho* and *para* positions and carbon chains ranging from C1 to C12, 13 of which are registered.

The term "backbone", when used in this report, is meant to describe the longest hydrocarbyl chain on the alkyl substituent and not the total carbon range of the

alkyl substituent. This is exemplified below for bis(2-ethylhexyl) terephthalate (DEHT) which has two ethylhexyl (C8, red) alkyl substituents with a C6 (blue) backbone due to the branching in the ethylhexyl substituents.



None of the substances in these groups have a harmonised classification under CLP or a regulatory action under REACH.

Based on information reported in the REACH registration dossiers, the substances are mainly used as plasticiser and softener but have other functions as well, e.g. as monomer, lubricating agent, dispersing agent, binding agent, viscosity adjustor, flotation agent, dust suppressant. They are used in many applications such as polymers, plastic articles, paints, inks, adhesives, lubricants, metal working fluids, hydraulic fluids, laboratory use. Some of the substances are used in cosmetics, medical devices or food contact materials (FCMs).

Based on registration information, many of them are therefore used widespread in high tonnages with potential for exposure to both human and the environment. The substances are registered for uses in industrial settings, by professional workers and consumers as well as for uses in articles.

The main (potential) human health hazard for these substances were reproductive toxicity and ED properties due to structural similarity with *ortho*-phthalates (see assessment on regulatory needs done on *ortho*-phthalates). Although somewhat less varied, these substances also show a very similar use pattern to the *ortho*-phthalates and could replace (and in some cases already have replaced) *ortho*-phthalates.

The hazard data density for the three groups under assessment in this report is relatively poor. However, the limited available data indicate that these substances are in general potentially less hazardous or less potent than the *ortho*-phthalates. However, potential hazards were concluded for a number of substances, which remain to be confirmed by further data generation (see section 2).

None of the substances in these groups have a harmonised classification under CLP or other regulatory action under REACH (e.g. none is restricted or on the Authorisation List). This again differs significantly from the *ortho*-phthalate group.

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 combined with authorisation for potential mutagenicity, toxicity to reproduction, endocrine disrupting properties and potential PBT/vPvB, and potential for release/ exposure of some of the substances in the group *(covering the following EC numbers: 214-122-9, 217-803-9, 940-272-6, 946-149-3, 416-740-6, 216-208-1, 201-877-4, 222-020-0, 941-303-6, 258-847-9, 253-138-0, 290-754-9, 302-446-4, 304-780-6, 700-342-7, 615-086-0, 276-594-2)* or due to potential for substitution *(covering the following EC numbers: 219-547-3, 217-038-0, 248-365-7, 252-552-9, 268-593-0, 268-007-3).*

Based on the available data, toxicity to reproduction and endocrine disrupting properties for human health (ED HH) are suspected for 15 substances, 3 of them are suspected to be ED HH due to effect on thyroid. One substance shows potential hazard for mutagenicity and skin sensitisation. Some substances in this group show also potential for aquatic toxicity (4 substances) and/or endocrine disrupting properties for the environment (ED ENV) (15 substances) and/or potential PBT/vPvB properties (12 substances).

These substances are almost all used as plasticisers and have wide-dispersive uses (i.e. including professional or consumer uses). One substance (EC 416-740-6) has no plasticiser use but is used as lubricant and metal working fluid by professional workers and consumers. Two substances (EC 302-446-4 and EC 615-086-0) are registered for use in cosmetics and personal care products (consumer use assumed). The majority of the substances are used in tonnages > 100 t/y in the EU, and some of those even in much higher tonnages (> 1000 t/y).

According to registration information, almost all substances are used in articles. Based on the use description, it can be assumed that also the two substances without a reported articles service life (EC 217-803-9 and EC 216-208-1) end up in articles. Although not always further described, typical articles mentioned are plastic articles, fabrics and textiles, rubber products, cables, car interiors. The use in medical devices is registered for four substances and use in cosmetics for six substances. Two substances are registered for use as co-formulants in plant protection and in biocidal products. Four substances (EC 222-020-0, EC 216-208-1, EC 201-877-4 and EC 290-754-9) may be used in food contact materials, according to information from EFSA (FCM)[6].

Given the similarity in structure to *ortho*-phthalates (structural isomers) and the fact that these substances can (and in some cases have already) replace(d) the *ortho*-phthalates in some of their uses, the needs for regulatory action for these substances was assessed also with the aim to ensure sufficient coherence with the measures foreseen for the *ortho*-phthalates (see assessment of regulatory needs on *Ortho*-phthalates) to avoid regrettable substitution.

With the above in mind, in case the above hazard properties are confirmed following data generation, the most appropriate regulatory risk management tools to address the concern linked to the substances is a combination of restriction and authorisation.

For the substances ending up in articles, a restriction is foreseen necessary to address risks from article use (as risks from imported articles cannot be managed through authorisation). Although this could be done *via* the Art. 69(2) restriction procedure after the sunset date (if the substances were included in the Authorisation List), it is proposed to initiate the restriction on use in articles directly after or in parallel to the CLH process to avoid several years of delay.

Furthermore, it is proposed to identify the substances as SVHC and include them in the Candidate list. This is of importance in particular for recognition of the likely ED and PBT/vPvB properties (if confirmed). Candidate Listing does not just induce legal obligations for companies to inform and communicate about the safe use of their substances but has also been identified as an important trigger for companies to start potential substitution activities.[7]

Pursuing the authorisation route (i.e. recommendation and inclusion in Annex XIV) would ensure that these substances would not be used to replace structurally similar substances such as *ortho*-phthalates of which quite a number are already in the Authorisation List.

Furthermore, we propose similar actions on substances that have the potential to substitute the ones described above even though they are currently either not registered or only for use with limited exposure (EC 219-547-3). The reasoning is described below.

Trimethyl benzene-1,2,4-tricarboxylate (EC 219-547-3) has potential mutagenicity hazards as well as reproductive toxicity and ED HH properties. On the other hand,

[6] "Draft opinion on identification and prioritisation for risk assessment of phthalates, structurally similar substances potentially used as plasticisers in materials and articles intended to come into contact with food" under public consultation 5 Nov-16 Dec 2021 (Link: https://connect.efsa.europa.eu/RM/s/publicconsultation2/a0l1v00000E7o6u/pc0097)

[7] See for example: ECHA (July 2020): Impact of REACH restriction and authorisation on substitution in the EU (https://echa.europa.eu/documents/10162/24152346/impact_rest_auth_on_substitution_en.pdf/7c95222f-5f84-57f7-4cba-65b8463c79d4)

aquatic toxicity and PBT/vPvB are assumed unlikely but no conclusion can be currently made for ED ENV.

The substance is used at industrial sites as monomer with an EU tonnage < 100 t/y. The substance is listed in Annex I of EU 10/2011 (Union List of substances permitted for use in FCM) with the following specification: "Only to be used as a co-monomer up to 0,35 % w/w to produce modified polyesters intended to be used in contact with aqueous and dry foodstuffs containing no free fat at the surface" (FCM# 971). Based on the above, the release potential is expected to be low.

The use is described as monomer and use as intermediate which is not within the scope of authorisation. However, the substance can also be used as plasticiser, co-monomer and crosslinker. Although articles service life is not registered, it might be that the substance ends up in articles.

Considering the above, it is assumed that the substance could replace other similar substances in this category.

There is a number of substances (7) which are currently not registered (or which have inactive or invalid registrations) but for which the same hazard profile is expected. To avoid regrettable substitution, these substances are also proposed for further EU RRM. After generation of data on the registered substances, the next steps will be decided on. These substances could be considered in a possible restriction for use in articles. In case, the registration status was to change, data generation and actions will be re-considered.

Based on currently available information, it is not possible to assess the need for regulatory risk management as information is not sufficient to conclude on potential hazards of substances covered by the following EC numbers: 215-951-9, 204-411-8 and terephtalic acid compound with diamines.

No or very limited information is available on hazard or use for these substances. Of the three substances, one (terephtalic acid compound with diamines,) can be considered a structural outlier of the group. It is proposed to await the outcome of the assessment of regulatory needs on "primary aliphatic diamines and their salts" before initiating CCH (and any potential further actions).

The two other substances subject to full registration (EC 215-951-9 and 204-411-8) are considered unlikely to have human health hazards but no conclusion can be currently drawn with regard to ED ENV hazards. It is proposed to await the outcome of data generation on reproductive toxicity in mammalian species before deciding on any further steps. These two substances are included in the Union list of substances authorised for use in the manufacture of plastic materials to be intended to come into contact with food (Annex I of EU 10/2011): dimethyl terephthalate (DMT) (EC 204-411-8, FCM# 288) and dimethyl isophthalate (EC 215-951-9, FCM#420). The use in FCM is not specifically mentioned in registrations.

Based on currently available information, there is no need for (further) EU regulatory risk management for the following substances: EC numbers: 204-506-4, 202-830-0, 229-176-9, 700-453-0, 212-014-6, 205-308-0, 445-050-8, 211- 249-1, 264-249-9, 213-835-2, 947-863-8, 220-264-2 and three substances for which the identifiers are confidential.

No or very limited information is available on hazard or use for 11 of these substances. The majority are not registered (9 substances), or only registered in such a way that further data generation is currently not possible (i.e. 1 NONs, 1 intermediate). Therefore, it is proposed that for the time being there is no need for EU regulatory risk management. If the registration status changes for the non-

registered substances and the substances subject to NONS registration, data generation and actions will be re-considered when the assessment will be revisited.

For the other substances, no human health or environmental hazards are expected, based on the currently available information for 204-506-4, 202-830-0, 229-176-9, 700-453-0. However, further data generation is proposed for 204-506-4 and 202-830-0 to confirm. For 229-176-9 and 700-453-0 the data is inconclusive for potential ED for environment.

The substances are used wide-dispersively in various applications, e.g. polymers, PVC articles, adhesives, sealants, coatings and paints. Some other uses are registered as well, e.g. hydraulic functional fluid, fuel additive, lubricants. Three substances are used within the EU in tonnages > 100.000 t/y.

Three of the substances are included in the Union list of authorised substances and may be used in the manufacture of plastic materials to be intended to come into contact with food (Annex I of EU 10/2011). Those have an FCM substance number and are the following: bis(2-ethylhexyl) terephthalate (DEHTP, EC 229-176-9, FCM#798), terephthalic acid (EC 202-830-0, FCM#785) and isophthalic acid (EC 204-506-4, FCM#291). It should be noted that the use as FCM is not registered for the two terephthalate substances whereas the use in food packaging is explicitly mentioned in registrations of the isophthalate.

There are also RMOAs by France from 2016/2017 on two of the substances (EC 202-830-0 and 229-176-9). These RMOAs were triggered by the consideration that terephthalic acid (EC 202-830-0) might be used as potential replacement for BPA, and DEHT (EC 229-176-9) for the *ortho*-phthalates (DEHP, BBP, DBP, DIBP), for - among others – use in food containers. France concluded for both substances that there is currently no need for further action as, based on the available information, France considered them not to have reproductive toxicity or ED hazard (although some uncertainties were noted for EC 229-176-9).

Due to the unlikely hazard of these substances it is concluded that there is currently no need for further EU regulatory risk management.

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.

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Substances needing Restriction/Authorisation					
Isophthalates 214-122-9 (diallyl)	Known or potential hazard for mutagenicity, carcinogenicity and skin sensitisation Inconclusive hazard for reproductive toxicity and ED	Known or potential hazard for aquatic toxicity Inconclusive hazard for ED	Use in polymers, synthetic rubber, coating and paints and articles where potential exposure to human health and the environment cannot be excluded (F, I, A)	**Need for EU RRM: Restriction (articles) combined with authorisation** <u>Justification:</u> For the substances ending up in articles, a restriction is foreseen necessary to address risks from article use. It is proposed to initiate the restriction on use in articles directly after or in parallel to the CLH process to avoid several years of delay. In addition, it is proposed to include the substances on the	**First step:** CCH **Next steps (if hazard confirmed):** CLH Restriction (potentially in parallel with CLH) SVHC identification Authorisation
Terephthalates 217-803-9 940-272-6 946-149-3	Known or potential hazard for ED	Known or potential hazard for aquatic toxicity and ED	Use in polymers, PVC, rubber, coatings and paints, adhesives and sealants and articles where potential exposure to human health and the environment cannot be		

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			excluded ((F, I, P, C, A)	Candidate list to pursue the authorisation route (i.e. recommendation and inclusion in Annex XIV) which would ensure that these substances would not be used to replace structurally similar substances such as *ortho*-phthalates of which quite a number are already in the Authorisation List.	
Terephthalates 416-740-6	No hazard or unlikely hazard for ED	Known or potential hazard for PBT/vPvB Inconclusive hazard for ED	Use as lubricant, wax, functional and metal working fluid where potential exposure to human health and the environment cannot be excluded (F, I, P, C)	**Need for EU RRM: Restriction (articles) combined with authorisation** <u>Justification:</u> Even though the uses in articles is not reported it is assumed that this substance could replace other similar substances and therefore similar actions are proposed	**First step:** Await results from data generation on ortho-phthalates **Next steps (if hazard confirmed):** PBT/ED assessment SVHC identification Restriction Authorisation

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Trimellitates 216-208-1 201-877-4 222-020-0 941-303-6 258-847-9 253-138-0 290-754-9 302-446-4 304-780-6 700-342-7 615-086-0 276-594-2	Known or potential hazard for mutagenicity reproductive toxicity and related ED properties	Inconclusive hazard for aquatic toxicity Known or potential hazard for PBT/vPvB (except 216-208-1) and ED	Use in polymers, rubber, inks, toners, adhesives, sealants, textiles, coatings, cables, lubricants, polishes, working fluids and articles where potential exposure to human health and the environment cannot be excluded . (F, I, P, C, A). Some use in cosmetic and medical devices. 222-020-0 potentially used as FCM**Error! Bookmark not defined.** but no indication of that in registrations.	**Need for EU RRM: Restriction (articles) combined with authorisation** <u>Justification:</u> For the substances ending up in articles, a restriction is foreseen necessary to address risks from article use. It is proposed to initiate the restriction on use in articles directly after or in parallel to the CLH process to avoid several years of delay. In addition, it is proposed to include the substances on the Candidate list to pursue the authorisation route (i.e. recommendation and inclusion in Annex XIV) which would ensure that these substances would not be used to replace structurally similar	**First step:** CCH **Next steps (if hazard confirmed):** Substance evaluation for 222-020-0 CLH Restriction (potentially in parallel with CLH SVHC identification Authorisation

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				substances such as *ortho*-phthalates of which quite a number are already in the Authorisation List.	
Trimellitates 219-547-3 (C1)	Known or potential hazard for mutagenicity, reproductive toxicity and ED	Known or potential hazard for ED	Use as monomer, intermediate with low potential for exposure (F, I) However the substance can be used as plasticiser, comonomer and cross linker and might therefore end up in articles (eve though not reported) FCM in EU 10/2011 (#971) up to 0.35%	**Need for EU RRM: Restriction (articles) combined with authorisation** Justification: Even though the uses in articles is not reported it is assumed that this substance could replace other similar substances and therefore similar actions are proposed	**First step:** CCH **Next steps (if hazard confirmed):** CLH Restriction (potentially in parallel with CLH SVHC identification Authorisation
2 Terephthalates – not registered for which identifiers are confidential	Known or potential hazard for ED	Known or potential hazard for aquatic toxicity Inconclusive hazard for ED	No use information.	**Need for EU RRM: Restriction (articles)** Justification: These substances have similar structure and hazard profile and	**First step:** Await CCH for registered substances **Next steps (if hazard confirmed):** CLH

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Trimellitates – not registered/invalid reg/inactive reg 217-038-0 (invalid reg.) 248-365-7 252-552-9 (inactive reg.) 268-593-0 268-007-3	Known or potential hazard For reproductive and related ED properties	Inconclusive hazard for aquatic toxicity for all except EC 217-038-0 with known aquatic toxicity Known or potential hazard for PBT/vPvB for all except EC 217-038-0 Known or potential hazard for ED	No use information.	therefore to avoid regrettable substitution it is proposed to consider them in the possible restriction on uses in articles.	Restriction (potentially in parallel with CLH)
Substances for which it is not possible currently to assess regulatory needs					
Isophthalates 215-951-9 (C1)	No hazard or unlikely hazard	Inconclusive hazard for ED	Use in thermoplastics, monomer (F, I) FCM in EU 10/2011 (#420)	**Currently not possible to assess the regulatory needs** <u>Justification:</u> The information on hazard is not sufficient to conclude on the potential ED properties	CCH
Terephthalates 204-411-8 (C1)	No hazard or unlikely hazard	Inconclusive hazard for ED	Use in polymers, esters, plastic products. (F, I, P, A)	**Currently not possible to assess the regulatory needs**	CCH

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			FCM in EU 10/2011 (#288)	Justification: The information on hazard is not sufficient to conclude on the potential ED properties	
Terephthalates Terephtalic acid compound with diamines	Inconclusive hazard	Inconclusive hazard for aquatic toxicity and ED	Use in polymers. (F, I)	**Currently not possible to assess the regulatory needs** Justification: The information on hazards is not sufficient to conclude on the potential ED and aquatic toxicity properties.	CCH (await outcome of the assessment on the group primary aliphatic diamines and their salts)
Substances for which there is currently no need for EU regulatory risk management					
Isophthalates 204-506-4 (isophthalic acid)	No hazard or unlikely hazard	No hazard or unlikely hazard	Use in polymers, resins, lubricants, food packaging, polishes and waxes, functional fluids and articles where potential exposure to human health and the environment cannot be excluded (F, I, P, C, A) Use in food packaging	**Currently no need for EU RRM** Justification No or unlikely hazard to be confirmed via CCH	**CCH**

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			mentioned in registrations FCM in EU 10/2011 (#291)		
Terephthalates 202-830-0 (terephthalic acid)	No hazard or unlikely hazard	No hazard or unlikely hazard	Polymers, PET, plastic products and articles where potential exposure to human health and the environment cannot be excluded. Acc. to RMOA (by FR), potential replacement for BPA or other phthalates (e.g. also for food beverage containers), but use in FCM not mentioned in registrations. FCM in EU 10/2011 for EC 202-830-0 (#785)	**Currently no need for EU RRM** Justification No or unlikely hazard to be confirmed via CCH	**CCH**
229-176-9 (DEHT) 700-453-0	No hazard or unlikely hazard	ED ENV inconclusive	Polymers, PET, plastic products and articles where potential exposure to human health and the environment cannot be excluded.	**Currently no need for EU RRM** Justification No or unlikely hazard	**No action**

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
			Acc. to RMOA (by FR), potential replacement for BPA or other phthalates (e.g. also for food beverage containers), but use in FCM not mentioned in registrations. FCM in EU 10/2011 for EC 229-176-9 (#798)		
Isophthalates – not registered 212-014-6 205-308-0	Inconclusive hazard	Inconclusive hazard for aquatic toxicity, PBT/vPvB and ED	No use information.	**Currently no need for EU RRM** <u>Justification:</u> No or very limited information is available on hazard or use for substances. The majority are not registered or only registered in such a way that further data generation is currently not possible. If the registration status changes for the non-registered substances and the substance subject to NONS registration, data generation and actions	No action
Terephthalates – not registered/TII without data 211- 249-1 264-249-9 213-835-2 947-863-8 (TII)	Inconclusive hazard: 213-835-2 and 947-863-8 No hazard or unlikely hazard: 211-249-1, 264-249-9	Inconclusive hazard for aquatic toxicity for EC 264-249-9, 213-835-2 and EC 947-863-8 No hazard or unlikely hazard for aquatic toxicity for EC 211-249-1 Inconclusive hazard for ED			

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Trimellitates – not registered 220-264-2	Inconclusive hazard	Inconclusive hazard for aquatic toxicity Inconclusive hazard for PBT/vPvB Known or potential hazard for ED		will be re-considered when the assessment will be revisited	

Annex 1: Overview of classifications

Data extracted in November 2020

EC/List Number	CAS Number	Substance Name	classification in registrations	classification in C&L notifications
201-877-4	89-04-3	trioctyl benzene-1,2,4-tricarboxylate	-	-
202-830-0	100-21-0	terephthalic acid	-	Eye Irrit. 2A H319[1 out of 67] STOT Single Exp. 3 H335, affected organs: [1 out of 67] Repr. 2 H361[1 out of 67] Acute Tox. 4 H302[2 out of 67] STOT Single Exp. 3 H335, affected organs: organs[1 out of 67] Skin Irrit. 2 H315[12 out of 67] Eye Irrit. 2 H319[10 out of 67] STOT Single Exp. 3 H335, affected organs: Respiratory tract[3 out of 67] STOT Single Exp. 3 H335, affected organs: lungs[1 out of 67]
204-411-8	120-61-6	dimethyl terephthalate	-	STOT Single Exp. 3 H335, affected organs: organs[2 out of 43] Aquatic Chronic 3 H412[2 out of 43] Skin Sens. 1 H317[4 out of 43] Eye Irrit. 2 H319[5 out of 43]
204-506-4	121-91-5	isophthalic acid	-	Eye Irrit. 2 H319[10 out of 83] Skin Irrit. 2 H315[3 out of 83] STOT Single Exp. 3 H335, affected organs: [2 out of 83]
205-308-0	137-89-3	bis(2-ethylhexyl) isophthalate	-	Repr. 1B H360, specific effect:May damage fertility. Suspected of damaging the unborn child.[1 out of 3] Aquatic Acute 1 H400[1 out of 3]
211-249-1	636-09-9	diethyl terephthalate	-	Skin Irrit. 2 H315[1 out of 1] STOT Single Exp. 3 H335[1 out of 1] Eye Irrit. 2 H319[1 out of 1]
212-014-6	744-45-6	diphenyl isophthalate	-	Eye Irrit. 2 H319[2 out of 4] Skin Irrit. 2 H315[2 out of 4]
213-835-2	1026-92-2	diallyl terephthalate	-	Acute Tox. 4 H302[1 out of 1] Eye Irrit. 2 H319[1 out of 1] Skin Irrit. 2 H315[1 out of 1]
214-122-9	1087-21-4	diallyl isophthalate	Acute Tox. 4 H302 Acute Tox. 4 H332 Skin Sens. 1B H317 Aquatic Acute 1 H400	Eye Irrit. 2 H319[1 out of 2] Skin Irrit. 2 H315[1 out of 2]
215-951-9	1459-93-4	dimethyl isophthalate	Eye Irrit. 2 H319	Skin Irrit. 2 H315[1 out of 9]

EC/List Number	CAS Number	Substance Name	classification in registrations	classification in C&L notifications
216-208-1	1528-49-0	trihexyl benzene-1,2,4-tricarboxylate	Aquatic Chronic 4 H413	-
217-038-0	1726-23-4	tributyl benzene-1,2,4-tricarboxylate	-	-
217-803-9	1962-75-0	dibutyl terephthalate	-	Eye Irrit. 2A H319[2 out of 4] Aquatic Chronic 3 H412[2 out of 4] Skin Irrit. 2 H315[2 out of 4]
219-547-3	2459-10-1	trimethyl benzene-1,2,4-tricarboxylate	Aquatic Chronic 2 H411	-
220-264-2	2694-54-4	triallyl benzene-1,2,4-tricarboxylate	-	-
222-020-0	3319-31-1	tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate	-	Eye Irrit. 2 H319[1 out of 36] Skin Irrit. 2 H315[1 out of 36] Aquatic Chronic 4 H413[5 out of 36] STOT Single Exp. 3 H335, affected organs: respiratory system[1 out of 36] Repr. 2 H361[2 out of 36]
229-176-9	6422-86-2	bis(2-ethylhexyl) terephthalate	-	-
248-365-7	27251-75-8	triisooctyl benzene-1,2,4-tricarboxylate	-	-
252-552-9	35415-27-1	trinonyl benzene-1,2,4-tricarboxylate	-	-
253-138-0	36631-30-8	triisodecyl benzene-1,2,4-tricarboxylate	-	STOT Single Exp. 3 H335, affected organs: lungs[1 out of 13] Eye Irrit. 2 H319[1 out of 13] Skin Irrit. 2 H315[1 out of 13] Aquatic Chronic 4 H413[1 out of 13]
258-847-9	53894-23-8	triisononyl benzene-1,2,4-tricarboxylate	-	Aquatic Chronic 4 H413[1 out of 3]
264-249-9	63468-13-3	2-ethylhexyl methyl terephthalate	-	STOT Single Exp. 3 H335, affected organs: Respiratory tract[2 out of 3] Eye Irrit. 2A H319[2 out of 3] Acute Tox. 4 H302[1 out of 3] Skin Irrit. 2 H315[2 out of 3]
268-007-3	67989-23-5	1,2,4-Benzenetricarboxylic acid, decyl octyl ester	-	-
268-593-0	68130-50-7	1,2,4-Benzenetricarboxylic acid, mixed decyl and hexyl and octyl esters	-	-

EC/List Number	CAS Number	Substance Name	classification in registrations	classification in C&L notifications
276-594-2	72361-35-4	triisotridecyl benzene-1,2,4-tricarboxylate	-	Aquatic Chronic 4 H413[1 out of 7]
290-754-9	90218-76-1	1,2,4-Benzenetricarboxylic acid, mixed decyl and octyl triesters	-	-
302-446-4	94109-09-8	tri(tridecyl) benzene-1,2,4-tricarboxylate	-	Aquatic Acute 1 H400[1 out of 5]
304-780-6	94279-36-4	1,2,4-Benzenetricarboxylic acid, tri-C9-11-alkyl esters	-	-
416-740-6	-	416-740-6	-	-
615-086-0	70225-05-7	615-086-0	-	-
700-342-7	1163775-81-2	tris(dodecyl and/or octyl) benzene-1,2,4-tricarboxylate	-	-
700-453-0	59802-05-0	700-453-0	-	-
940-272-6	-	di-[C5(linear and branched)-alkyl] terephthalate	-	-
941-303-6	1689576-55-3	Esterification products of 1,3-dioxo-2-benzofuran-5-carboxylic acid with nonan-1-ol	-	-
946-149-3	1571954-81-8	di(butyl and/or 2-ethylhexyl) 1,4-benzenedicarboxylic acid	-	-
947-863-8	-	Reaction mass of 1-prop-2-en-1-yl 4-[2-(2-{4-[(prop-2-en-1-yloxy)carbonyl] benzoyloxy}ethoxy)ethyl] benzene-1,4-dicarboxylate and 1-prop-2-en-1-yl 4-[2-(2-{[(prop-2-en-1-yloxy)carbonyl] oxy}ethoxy)ethyl] benzene-1,4-dicarboxylate and diallyl terephthalate	Skin Irrit. 2 H315 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)] Aquatic Acute 2 H401 [intermediate (active)]	-

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

Data extracted in November 2020

Main types of applications structured by product or article types	Use in polymers, PVC, rubber, plastic articles, in plastisol and dry-blends	Use in thermoplastics	Paints, coatings, inks, toners	dhesives and sealants	Lubricant, waxes, greases	Polishes and waxes	Metal working fluids	Curing agent	Washing and cleaning products	Hydraulic fluids, functional fluids	Use in cosmetics	Intermediate	Solvent	Laboratory use	Construction materials/ Sealants	Fuel additive/ additised fuels	Textile dyes, impregnating products	Other uses/ remarks
Isophthalates																		
EC 204-506-4	F, I, P, C, A		F, I, P, C, A	F, I, P	F, I, P	F, I				F, I, P		F, I		F, I, P		F, I, P, C	F	
EC 215-951-9		F, I										F, I						
EC 214-122-9	F		F, I, A											F, I				
Terephthalates																		

Main types of applications structured by product or article types	Use in polymers, PVC, rubber, plastic articles, in plastisol and dry-blends	Use in thermoplastics	Paints, coatings, inks, toners	Adhesives and sealants	Lubricant, waxes, greases	Polishes and waxes	Metal working fluids	Curing agent	Washing and cleaning products	Hydraulic fluids, functional fluids	Use in cosmetics	Intermediate	Solvent	Laboratory use	Construction materials/ Sealants	Fuel additive/ additised fuels	Textile dyes, impregnating products	Other uses/ remarks
EC 202-830-0	F, I, P, C, A									F, I, P				F, I, P		F, I, P, C		
EC 204-411-8	F, I, A											I		F, I, P			I	
EC 947-863-8												F, I						
EC 217-803-9			F, I, P	F, I, P										P				
EC 940-272-6	F, I, A																	
EC 946-149-3	F, I, P, (C), A		F, I, P, C	F, I														
EC 229-176-9	F, I, P, C, A		F, I, P, C	I										P	(I), P, C, A			
List 700-453-0												F, I						

Main types of applications structured by product or article types	Use in polymers, PVC, rubber, plastic articles, in plastisol and dry-blends	Use in thermoplastics	Paints, coatings, inks, toners	Adhesives and sealants	Lubricant, waxes, greases	Polishes and waxes	Metal working fluids	Curing agent	Washing and cleaning products	Hydraulic fluids, functional fluids	Use in cosmetics	Intermediate	Solvent	Laboratory use	Construction materials/ Sealants	Fuel additive/ additised fuels	Textile dyes, impregnating products	Other uses/ remarks
EC 416-740-6					F, I, P, C		F, I, P			F, I, P, C								
Trimellitates																		
EC 219-547-3	F, I																	
EC 216-208-1	F, (A?)		F															
EC 201-877-4	F, I, C, A				F, I, P, C, A													Use in Medical devices
EC 222-020-0	F, I, P, C, A		F, I, P, C	F, I, P, C	F, I, P, C, A	F, I, P, C, A	F, I, P	I	F, I, P, C	F, I, P	F, C	I	F, I, P, C	F, I, P	F, I, P, C, A	F, I, P, C	I, A	Use as explosives, mining, gas field drilling, blowing agent, biocide,

Main types of applications structured by product or article types	Use in polymers, PVC, rubber, plastic articles, in plastisol and dry-blends	Use in thermoplastics	Paints, coatings, inks, toners	Adhesives and sealants	Lubricant, waxes, greases	Polishes and waxes	Metal working fluids	Curing agent	Washing and cleaning products	Hydraulic fluids, functional fluids	Use in cosmetics	Intermediate	Solvent	Laboratory use	Construction materials/ Sealants	Fuel additive/ additised fuels	Textile dyes, impregnating products	Other uses/ remarks
																		medical devices
EC 941-303-6	F, I, P, C, A		F, I, P	F, I, P, C, A	F, I, P, C, A													
EC 258-847-9	F, I, P, C, A																	
EC 253-138-0	F, I, P, C, A		F, I, P, C	F, I, P, C, A	F, I, P, C	I, P, C	I, P			I, P, C	F, C				F, I, P, C, A	F, I, P, C		Medical devices
EC 290-754-9	F, I, C, A		F, I, P	F, I, P, C, A	F, I, P, C, A	I	I			I						F, P		Medical devices
EC 302-446-4											F, (C)							

Main types of applications structured by product or article types	Use in polymers, PVC, rubber, plastic articles, in plastisol and dry-blends	Use in thermoplastics	Paints, coatings, inks, toners	Adhesives and sealants	Lubricant, waxes, greases	Polishes and waxes	Metal working fluids	Curing agent	Washing and cleaning products	Hydraulic fluids, functional fluids	Use in cosmetics	Intermediate	Solvent	Laboratory use	Construction materials/ Sealants	Fuel additive/ additised fuels	Textile dyes, impregnating products	Other uses/ remarks
EC 304-780-6	F, I, P, C, (A?)		F, I, P, C	F, I, P, C	F, I, P, C	C		I	(F), (I), C	I, P, C	F, C	I	F, I, P, C	F, I, P	F, I, P, C, A	I, P, C	I, A	Biocidal product, plant protection products, medical devices
List 700-342-7	F, I, P, C, A		F, I, P	F, I, P, C, A	F, I, P, C, A													
EC 615-086-0											F, C			F, I, P				
EC 276-594-2	F, I, P, C (A)		F, I, P, C, A	F, I, P, C	F, I, P, C	I, P, C	F, I, P	I	F, I, P, C	I, P, C	F, I, P, C	I	F, I, P, C	F, I, P	F, I, P, C, A	I, P, C	I, A	

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 17 April 2020

Isophthalates

There are no relevant completed or ongoing regulatory risk management activities for any of the isophthalates.

Terephthalates

EC/List number	RMOA	Authorisation		Restriction	CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
202-830-0	YES (FR 2017 – no need for further action; incl. ED)					ED EG
229-176-9	YES (FR 2016; no action)					

Trimellitates

EC/List number	RMOA	Authorisation		Restriction	CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
222-020-0						PBT/ED EG