SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 22 March 2022

doi: 10.2903/j.efsa.2022.7231

# Identification and prioritisation for risk assessment of phthalates, structurally similar substances and replacement substances potentially used as plasticisers in materials and articles intended to come into contact with food

EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP), Claude Lambré, José Manuel Barat Baviera, Claudia Bolognesi, Andrew Chesson, Pier Sandro Cocconcelli, Riccardo Crebelli, David Michael Gott, Konrad Grob, Evgenia Lampi, Marcel Mengelers, Alicja Mortensen, Gilles Rivière, Inger-Lise Steffensen, Christina Tlustos, Henk Van Loveren, Laurence Vernis, Holger Zorn, Birgit Ahrens*, Evelin Fabjan*, Ronan Nicolas*, Letizia Polci*, Katleen Baert, Katharina Volk and Laurence Castle

## Abstract

The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids was requested by the European Commission to re-evaluate the risks to public health related to the presence of plasticisers such as phthalates, structurally similar substances and replacement substances, as a consequence of migration from food contact materials (FCMs). As the first part of the two-part mandate, EFSA was tasked with identifying and prioritising those plasticisers used in FCMs that may warrant further data collection and eventual risk assessment. Close collaboration with the European Chemicals Agency (ECHA) was requested in the mandate. Substances potentially used as plasticisers were identified using Annex II of the mandate, ECHA's PLASI inventory, the Plastics Regulation and the Regenerated Cellulose Film Directive, the ECHA database, the ECHA grouping approach, and consultation with the Member States. Only substances authorised for FCMs at EU or at national level were prioritised. Five substances classified either as carcinogenic, mutagenic, toxic to reproduction Cat. 1 (under CLP) or as endocrine disruptors, persistent, bioaccumulative and toxic, very persistent/very bioaccumulative (under REACH) were placed into an 'exclusion group'. Prioritisation was based on the date of the most recent risk assessment in the context of FCM, with substances assessed before 2001 being placed in the high-priority group, substances assessed between 2001 and 2011 in the medium-priority group and substances assessed after 2011 in the low-priority group. For the EU stream, the 76 substances were split into 59 high-, 14 medium- and 3 low-priority substances. For the nationally authorised stream, the split of the 72 substances is 66, 3 and 3, respectively. The outcome of follow-up calls for data in support of the exposure assessment will be used for a final ranking.



**Keywords:** food contact materials, prioritisation, risk assessment, phthalates, plasticisers

**Requestor:** European Commission

**Question number:** EFSA-Q-2020-00725

**Correspondence:** FIP@efsa.europa.eu

* European Chemicals Agency (ECHA).

**Panel members:** José Manuel Barat Baviera, Claudia Bolognesi, Andrew Chesson, Pier Sandro Cocconcelli, Riccardo Crebelli, David Michael Gott, Konrad Grob, Claude Lambré, Evgenia Lampi, Marcel Mengelers, Alicja Mortensen, Gilles Rivière, Vittorio Silano (until 21 December 2020†), Inger-Lise Steffensen, Christina Tlustos, Henk Van Loveren, Laurence Vernis and Holger Zorn.

**Declarations of interest:** The declarations of interest of all scientific experts active in EFSA's work are available at https://ess.efsa.europa.eu/doi/doiweb/doisearch.

**Acknowledgments:** The Panel wishes to thank the following for the support provided to this scientific output: Matilde Benedettini and Stavroula Sampani. The Panel wishes to acknowledge all European competent institutions, Member State bodies and other organisations that provided data for this scientific output.

**Suggested citation:** EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids), Lambré C, Barat Baviera JM, Bolognesi C, Chesson A, Cocconcelli PS, Crebelli R, Gott DM, Grob K, Lampi E, Mengelers M, Mortensen A, Rivière G, Steffensen I-L, Tlustos C, Van Loveren H, Vernis L, Zorn H, Ahrens B, Fabjan E, Nicolas R, Polci L, Baert K, Volk K and Castle L, 2022. Scientific Opinion on the identification and prioritisation for risk assessment of phthalates, structurally similar substances and replacement substances potentially used as plasticisers in materials and articles intended to come into contact with food. EFSA Journal 2022;20(5):7231, 26 pp. https://doi.org/10.2903/j.efsa.2022.7231

**ISSN:** 1831-4732



The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.

† Deceased.

# Table of contents

# 1. Introduction

## 1.1. Background and Terms of Reference as provided by the requestor

### Background from the mandate letter

EFSA has recently updated the risk assessment of five phthalic acid esters (ortho-phthalates), namely DBP, BBP, DEHP, DINP and DIDP, authorised for use as additives in plastic food contact materials (FCMs), published in December 2019.[1] Based on this new opinion, DG SANTE is considering whether any changes to the existing EU legislation are necessary.

The previous mandate sent by the Commission was limited to new scientific information which was assessed by the European Chemicals Agency (ECHA) as regards reprotoxicity. This assessment subsequently resulted in several new restrictions under the REACH Regulation (EC) No 1907/2006. The recently adopted EFSA opinion did not identify any risk to human health from current exposure to these five ortho-phthalates from dietary sources. Nevertheless, it highlighted limitations of the work carried out and has set the Tolerable Daily Intakes (TDIs) on a temporary basis. It is therefore appropriate to address these limitations and establish a greater degree of certainty as regards the possible risks from these phthalates in food, from FCMs.

Additionally, the scope of the previous mandate was restricted to the five ortho-phthalates authorised as additives in annex I to Commission Regulation (EU) No 10/2011, which are used as plasticisers and technical support agents in plastic FCM. However, information collected by the Commission, including a short EU stakeholder survey[2] as well as results of controls carried out by Member States under Commission Recommendation 2019/794[3], confirms that these five ortho-phthalates are to a large extent being replaced by other plasticisers such as terephthalates, cyclohexanoates and epoxy esters. A list including these substances is provided in annex II to this letter. The information, which we have provided to EFSA, also indicates that other phthalates are used as technical support agents in addition to those specifically authorised for plastic FCM. Of additional importance is the use and occurrence of phthalates and non-phthalate plasticisers in FCM other than plastic, most notably rubber. Whilst it should be stressed that our present findings are not statistically robust enough to draw comprehensive conclusions, it is nevertheless important to take this information into account in the design of the work.

It is understood that ongoing screening and prioritisation work by ECHA on groups of structurally similar substances covers substances that may be relevant as regards their use in FCMs within the scope of this mandate and therefore their possible assessment by EFSA. With reference to the Memorandum of Understanding between ECHA and EFSA[4], the Commission would therefore like to request that the two agencies work together during the first part of this mandate for identification, prioritisation and preparatory tasks in advance of the second part of the mandate concerning the risk assessment work. This pooling of resources and expertise will promote inter-agency cooperation, maximising efficiency and avoiding duplication of work. This will help ensure that the risk from phthalates, structurally similar substances and their replacements are comprehensively assessed and eventually managed.

### Terms of Reference

In accordance with Article 29(1)(a) of Regulation (EC) No 178/2002, the European Commission asks EFSA to re-evaluate the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances, as a consequence of migration from food contact materials (FCMs). The following tasks, which constitute the first part of a two-part mandate, should therefore be performed:

1) Prioritise and identify those phthalates, structurally similar substances and replacement substances based on the list in annex II to this mandate letter that warrant further data collection and insofar as they may be relevant for eventual inclusion in an assessment of the

[1] EFSA Journal 2019;17(12):5838.
[2] https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_wg_20200224_pres-02.pdf
[3] Commission Recommendation (EU) 2019/794 of 15 May 2019 on a coordinated control plan with a view to establishing the prevalence of certain substances migrating from materials and articles intended to come into contact with food (notified under document C(2019) 3519). OJ L 129, 17.5.2019, p. 37–42.
[4] https://www.efsa.europa.eu/sites/default/files/assets/mouecha.pdf

risks associated with their presence and migration from food contact materials. Existing relevant information, such as that which may be held by ECHA should also be identified.

2) With a view to ensuring transparency and efficiency during the second part of the mandate, establish a protocol for:

   a) A dietary exposure assessment of the prioritised substances, with the aim of addressing the relative contribution from FCM to dietary exposure considering data on migration from FCM and eventual comparison of these contributions with the overall exposure of EU consumers;
   b) A hazard assessment protocol for the prioritised substances, detailing the criteria for inclusion and appraisal of the toxicological evidence publicly available since 2005 and not yet assessed by EFSA.

3) Establish a call for data on occurrence of the prioritised substances in food to support dietary exposure estimates. Data on migration levels from plastic and rubber FCMs as well as other materials which may be relevant such as printed paper and board should also be collected, where available. This should include articles throughout the whole food chain, including food manufacturing and processing equipment, as well as packaging, kitchenware and tableware. A search and identification of potentially relevant literature on exposure should also be started as part of this task.

## 1.2. Interpretation of the Terms of Reference

As a follow-up to the opinion on the 'update of the risk assessment of di-butylphthalate (DBP), butyl-benzyl-phthalate (BBP), bis(2-ethylhexyl)phthalate (DEHP), di-isononylphthalate (DINP) and di-isodecylphthalate (DIDP) for use in food contact materials' (EFSA CEP Panel, 2019), the European Commission requested EFSA to conduct – in a 2-step-approach – further work on the risk assessment of phthalates. By extending the scope of the terms of reference beyond the five *ortho*-phthalates authorised for plastic FCMs previously evaluated, structurally similar substances and replacement substances as well as use in FCMs other than plastic are also expected to be covered. This will provide a holistic approach in addressing a variety of substances used for similar technical purposes (plasticising effects) in different materials.

Annex II of the mandate (see Appendix A, Table A.1 in this scientific opinion), includes plasticisers such as terephthalates, cyclohexanoates and epoxy esters that are being used as replacements of the five *ortho*-phthalates DBP, BBP, DEHP, DINP and DIDP. The mandate letter also recognises that phthalate plasticisers (and by inference possibly their replacements) can have additional functions, such as use as technical support agents. This prioritisation exercise deals with substances that, first and foremost, find actual or potential use as plasticiser additives. There is no legal definition of a plasticiser substance in FCMs. By 'phthalates, structurally similar substances and replacement substances', the Panel considered that the plasticisers in scope of this Opinion are additives that are used (or may plausibly be used) individually or in combination in high amounts, typically at percentage levels, to change and tailor the physical properties of the relevant polymeric materials for their use in non-food and food-contact applications.

It is noted that many plasticisers are not only single substances, but also so-called defined or non-defined mixtures (EFSA CEF Panel, 2008). Defined mixtures correspond to multi-constituent substances and non-defined mixtures to UVCB substances (Unknown or Variable Composition, complex reaction products or of Biological materials) in ECHA terminology. In ECHA terminology, a mixture refers to a blend of substances, integrated in measured proportions, and which is not the result of a chemical reaction. Reference in this opinion to (i) mixtures; (ii) multi-constituent substances; and (iii) UVCB substances, is according to the ECHA definitions. Further details on differentiation between well-defined substances and UVCB substances under REACH can be found in Section 4 of the Guidance for identification and naming of substances under REACH and CLP (ECHA, 2017).

The relevant FCMs pointed out in the terms of reference may be regulated by EU specific measures (as is the case for plastics and for the coatings on a regenerated cellulose film (RCF)) or – in the absence of such EU specific measures – via national legislation. The inclusion of materials for which no EU specific measures exist in the terms of reference implies the inclusion of substances that may be subject to specific national risk management measures. The identification and prioritisation of such substances here are without prejudice to any national measures, and specific risk management

measures, including authorisation of these substances in materials that are not subject to specific EU measures, remain the responsibility of the Member States.

Due to the wide spectrum of uses of phthalates and other substances that provide plasticising properties, this group of substances is covered by several regulatory frameworks within the remit of EFSA and ECHA. As requested in the terms of reference, the work on this mandate was carried out in a collaboration between the two agencies: ECHA staff were involved in the EFSA CEP Panel's Working Group dealing with this mandate; in addition, data and information available to ECHA were also considered when defining and developing the work. This is considered to be in line with the aim of simplifying and consolidating the legal framework for hazard and risk assessment and the management of chemicals, as outlined in the European Commission's Chemicals Strategy for Sustainability (CSS) (European Commission, 2020a), e.g. by promoting a 'one substance, one assessment' (OSOA) approach.

The terms of reference outlined several tasks to be addressed by EFSA in preparation for the eventual risk assessment(s). The scope of this scientific opinion relates to task 1, i.e. identification and prioritisation of substances.[5] The tasks to be carried out under the mandate should facilitate the cooperation between EFSA and ECHA as well as the understanding of how to improve coherence in future of both the risk assessment and the risk management of FCM substances. In this sense, the work also serves as a 'pilot' project for facilitating the implementation of the CSS. Therefore, new ways of working and approaches to address the scientific issues had to be built using the agencies' respective combined expertise and considering their respective legal framework. Accordingly, for the development of this opinion, experts from the two agencies worked together to identify relevant substances with a potential plasticiser function in addition to those highlighted by the European Commission (Annex II of the mandate, see Appendix A, Table A.1 in this scientific opinion). In addition, another aspect of the CSS was considered when developing the approaches for identification and prioritisation of substances: the extension of the 'generic approach to risk management' for the most harmful chemicals. This approach is intended to 'ensure that consumer products do not contain chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative' (European Commission, 2020a) and is also expected to be implemented in the regulatory context of FCMs, as outlined in the European Commission's inception impact assessment on the revision of EU rules on FCMs (European Commission, 2020b). In the context of this opinion, it is understood that: (1) substances referred to in the CSS as causing cancers, gene mutations and affecting reproductive system, are those with harmonised classification in CMR categories 1A or 1B under the CLP Regulation[6]; (2) substances referred to in the CSS as persistent and bioaccumulative are those identified as substances of very high concern (SVHCs) under REACH due to their persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) properties, and (3) substances referred to in the CSS as affecting the endocrine system are those identified as substances of very high concern (SVHC) under REACH due to their endocrine-disrupting (ED) properties.[7]

The approaches for identification and prioritisation outlined in this scientific opinion have been developed to specifically address this mandate. It is not foreseen to establish a continuous process of identifying and prioritising additional substances with potential use as plasticisers/softeners as they may become available over time. The presented results therefore describe the situation at the moment of adoption of the scientific opinion, both as regards the identified substances per se as well as the information underlying the prioritisation exercise.

## 2. Data and methodologies

The draft scientific opinion underwent a public consultation from 5 November to 16 December 2021. The comments received and how they were taken into account when finalising the scientific opinion are published as Annex B of this opinion.

[5] The other tasks (i.e. protocols for exposure assessment (EFSA-Q-2021-00592) and hazard assessment (EFSA-Q-2021-00593)) will be dealt with separately and respective outputs will be published. Upon finalisation of all the preparatory tasks, the European Commission will issue specific mandates for the follow-up risk assessment(s) of substances prioritised as per task 1.

[6] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–1355.

[7] https://echa.europa.eu/substances-of-very-high-concern-identification-explained

## 2.1. Identification of substances

### 2.1.1. Building the pool of substances

The pool of substances potentially used as plasticisers in general was created from two main sources of information (see Figure 1): Annex II of the mandate[8] (see Appendix A, Table A.1 in this scientific opinion) and an inventory of plasticisers established by ECHA in cooperation with industry (the PLASI initiative[9]), representing a total of 88 entries. Additional substances displaying structural similarities to the entries in these two sources of information were retrieved from the data collected by ECHA using its grouping approach.[10] This approach primarily relies on chemical structure searches from the substance identity information provided to ECHA under different regulatory processes, mainly the REACH registration process. The aim of the grouping approach is only to identify potential plasticisers in general; it is not intended to be used directly for hazard assessment of prioritised substances and it does not prejudge any possibility for read-across. A typical group generation approach brings together substances displaying a common set of chemical functionalities. The exact specifications of the chemical commonalities within a group are tailored by expert judgement on a case-by-case basis to ensure the chemical coherence of the group of substances.

Since certain plasticiser types might possibly not be captured by the above-mentioned sources of information, a third source has also been considered. It refers to substances that are listed in Annex I of Regulation (EU) No 10/2011[11] (plastic FCMs) or Annex II of Directive 2007/42/EC[12] (RCF) and for which a link with plasticiser use was established based on information available to ECHA. Given that their effective use as plasticisers may not reach a similar level of certainty as for the entries in Annex II of the mandate and the PLASI plasticiser inventory, care was taken not to include manifestly different substance types in this third source. Illustrative examples of substances for which the structure was not considered relevant and that have therefore been excluded consist of inorganics (e.g. calcium carbonate), organic acids (e.g. hexanoic acid), organic alcohols (e.g. propan-2-ol), organic amines (e.g. ethylenediamine) and monomers (e.g. ε-caprolactam). Of particular note, softeners authorised for RCF (such as alcohols, polyols and related substances) fell into this group of manifestly different substance types, and therefore RCF softeners were not included in the pool of substances. Substances with structural similarities to the entries in this third source (i.e. Regulation (EU) No 10/2011 and Directive 2007/42/EC) were then retrieved following the same approach as for the two other sources.

In total, 773 substances were identified from the application of the approach. 403 substances originate from the use of Annex II of the mandate and 215 additional substances solely from the use of the PLASI plasticisers inventory. The remaining 155 substances come from the processing of substances that are authorised in plastic FCMs or in RCF and for which a link with plasticiser use was established based on information available to ECHA.

Substances that have not been registered under REACH (i.e. are outside the scope of the registration[13] or are not manufactured or placed on the market in the EU as such or in mixture at or above 1 tonne per year) or those registered for uses as intermediates in the manufacturing of other substances were not taken into account, unless they appear in Annex II of the mandate.

A number of substances were removed from the initial list. Substances that are not expected to function as a plasticiser based on their chemical nature were removed ('structural outliers'). Their presence in the list relates to the grouping approach followed by ECHA, where the structural similarity criteria may occasionally bring together substances with a different set of functionalities (e.g. organic acids and esters). Finally, substances for which a public[14] or meaningful name is not available for

[8] Two substances from Annex II of the mandate, terephthalic acid and BMMF, were disregarded given that they were not considered to be plasticisers.

[9] Plastic additives initiative. Further information on the scope of the PLASI inventory is available at: https://echa.europa.eu/mapping-exercise-plastic-additives-initiative

[10] Further information on ECHA's grouping approach is available at: https://echa.europa.eu/working-with-groups

[11] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. OJ L 12, 15.1.2011, p. 1–89.

[12] Commission Directive 2007/42/EC of 29 June 2007 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs. OJ L 172, 30.6.2007, p. 71–82.

[13] For example, certain polymeric substances or substances already incorporated in articles imported into the EU from 3rd countries are not subject to registration (for further information see: https://echa.europa.eu/support/registration/your-registration-obligations/does-my-substance-need-to-be-registered).

[14] ECHA does not disseminate the name of a substance in cases where confidentiality claims made by registrants are accepted.

dissemination on the ECHA website had to be withdrawn from the pool. The final pool of substances consists of 543[15] substances (see Annex A). An indication as to whether a substance in the pool is covered by an entry in Annex I of Regulation (EU) No 10/2011 (plastic FCMs) or in Annex II of Directive 2007/42/EC (RCF) has been specified. For any group entry in these two annexes, the matching to individual substances in the pool has been established based on an assessment of whether the substance in the final pool can be qualitatively described by the name of that group entry. In the context of this scientific opinion, the terminology 'group entry' refers to a generic entry in Regulation (EU) No 10/2011, which describes a possibly broad family of substances, e.g. acetylated mono- and diglycerides of fatty acids (FCM 8).

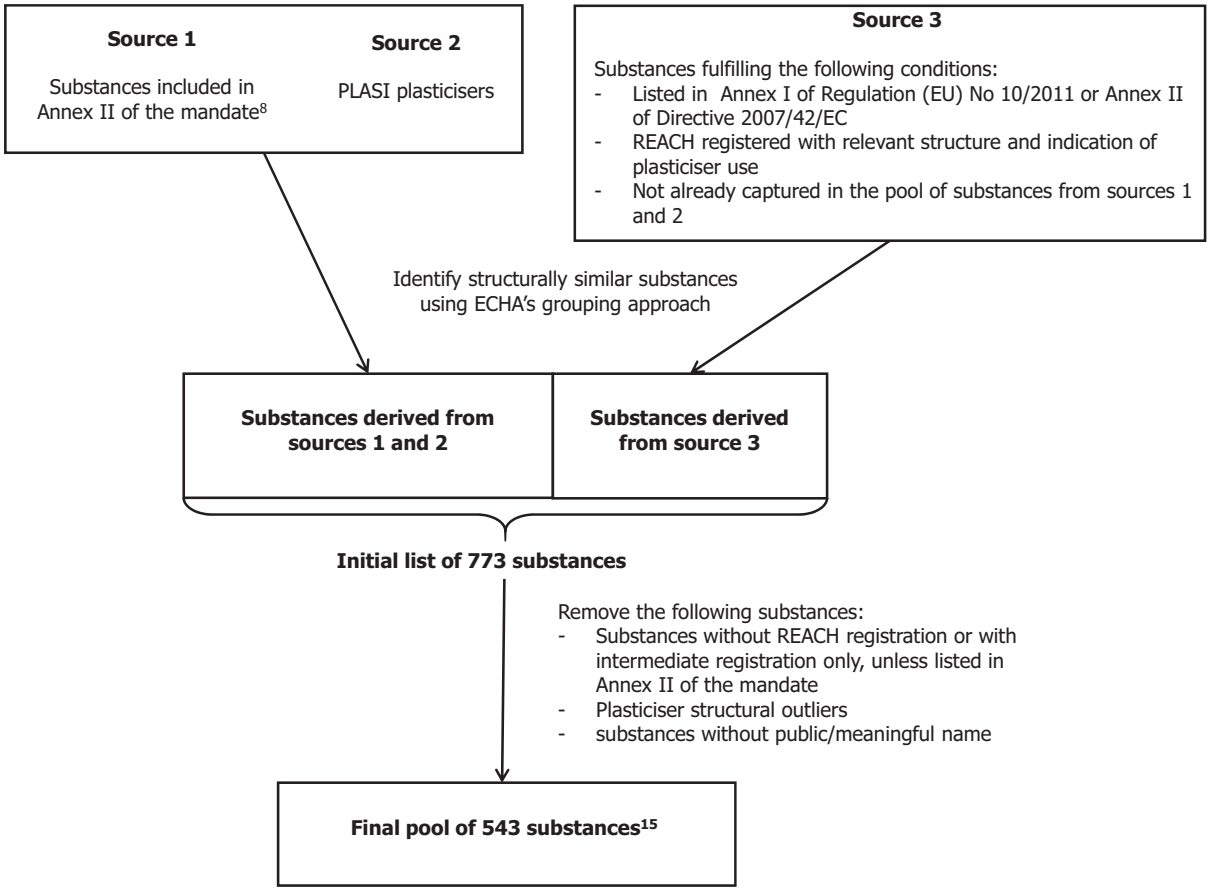


**Figure 1:** Building the pool of substances

### 2.1.2. Categorisation of substances

The pool of substances, compiled as described in Section 2.1.1, was further categorised in order to ensure scientific and regulatory relevance of the substances proposed for eventual prioritisation (see Figure 2).

[15] One of the 543 substances was withdrawn from the final pool as an outlier based on its chemical structure. The withdrawal of the substance from the pool took place after the consultation with Member State authorities.

In a first step, substances with an authorisation either at EU level (for the harmonised FCMs: plastic, RCF) or at national level were identified. National authorisation status was established via a consultation with Member State authorities, which ran from 30 March to 30 April 2021.[16] The list of pre-identified substances (see Annex A) was shared with the Member States, with the request to provide the following information, where applicable:

- authorisation of substance for use in FCM in the Member State
- technical function as a plasticiser/softener
- date of assessment
- reference to regulatory context/material
- assessment publicly available
- link to the assessment.

In case additional substances were added to the list of pre-identified substances, the Member States were requested to provide the EC/List number, CAS number and substance name.

Substances for which no authorisation was identified were set aside and not brought forward to the next steps, based on the rationale that a risk assessment would have to be triggered by an applicant via the usual procedure as laid down in Regulation (EC) No 1935/2004[17] or the respective national rules for evaluation and authorisation of FCM substances.

In a second step, substances authorised at EU or national level were screened for possible severe hazard properties. For the purpose of this work, such substances are those which are:

- classified as carcinogenic, mutagenic or reprotoxic Category 1A or 1B (hereafter referred to as CMR Cat. 1) and listed in Annex VI of the Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation)[18] and/or
- identified as having PBT or vPvB or ED properties according to Article 57 (d, e, f) of the REACH Regulation and included in the Candidate List of substances of very high concern for authorisation.[19]

Those classified were included in a separate group, hereafter referred to as the 'exclusion group'. This approach reflects the European Commission's commitment in the CSS regarding a 'generic approach to risk management' to act with priority on the most hazardous substances present in consumer products and for which further risk assessment work may not be necessary. The substances included in this group will be brought forward for risk assessment only if they could still be considered for use in FCMs (following the implementation of risk management measures in accordance with the CSS, including the concept of the essential use of substances).

In the next step, a distinction of the remaining substances was made between EU and nationally authorised substances, before being brought forward to the final step, i.e. the prioritisation. Dividing EU and nationally authorised substances into two distinct 'streams' allowed targeted risk management follow-up actions. Some Member States indicated that their respective national legislation makes a general statement on 'endorsing' the substances authorised by a harmonised measure, or that a substance authorised at national level in a specific, non-harmonised material was found to be already covered in the EU-harmonised legislation for plastics and RCF. In these cases, such a substance was only brought forward via the EU-authorised stream. Substances brought forward via the Member State consultation, and not found to be authorised in harmonised legislation, are proposed to follow the stream of nationally authorised substances.

[16] Three Member States provided their responses to the consultation after 30 April 2021, and it was decided to also take these replies into account.

[17] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13.11.2004, p. 4–17.

[18] Further information on classification and inclusion of substances in Annex VI of CLP Regulation: https://echa.europa.eu/regulations/clp/legislation

[19] Further information on identification of substances of very high concern under REACH: https://echa.europa.eu/substances-of-very-high-concern-identification-explained

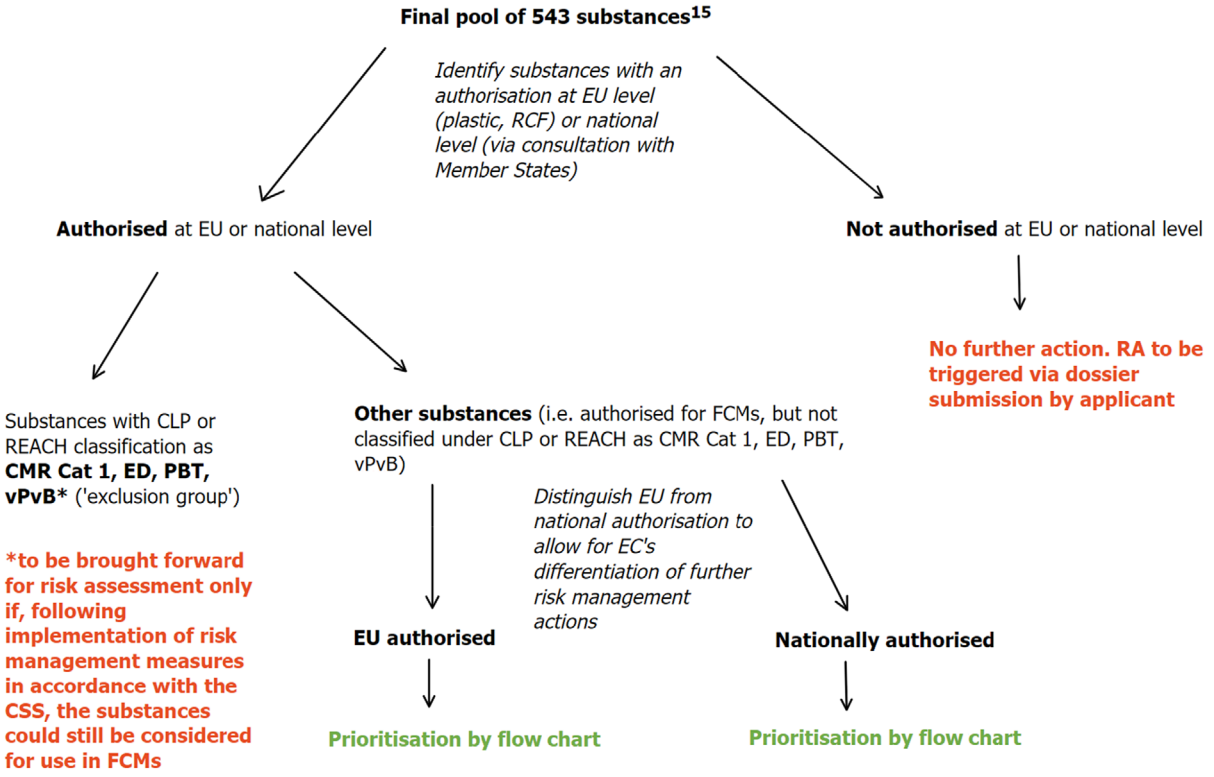


**Figure 2:** Categorisation of substances

## 2.2. Prioritisation of substances

### 2.2.1. Methodology

The criteria employed for prioritisation for risk assessment of the identified substances (see Section 2.1.2) are presented in a decision tree (see Figure 3). This decision tree was applied both for the substances falling into the EU-authorised stream as well as those in the nationally authorised stream.

The first prioritisation criterion is the date of assessment of the substance (relating to an evaluation in the context of the substance's use in FCMs; see Section 2.2.2). Based on the rationale that the older the assessment of a substance, the higher the probability that new data with possible impact on the risk assessment may have become available or new evaluation principles, relevant to risk assessment, may have been developed, the following three prioritisation groups were created:

- high priority: for substances assessed before 2001
- medium priority: for substances assessed from 2001 to 2011
- low priority: for substances assessed after 2011.

The cut-off date of 2001 was chosen as it represents the year of publication of the 'Guidelines of the Scientific Committee on Food (SCF) for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation' (European Commission, 2001). The second cut-off date (2011) was chosen based on a conventional approach of dividing the assessments after 2001 by decades.

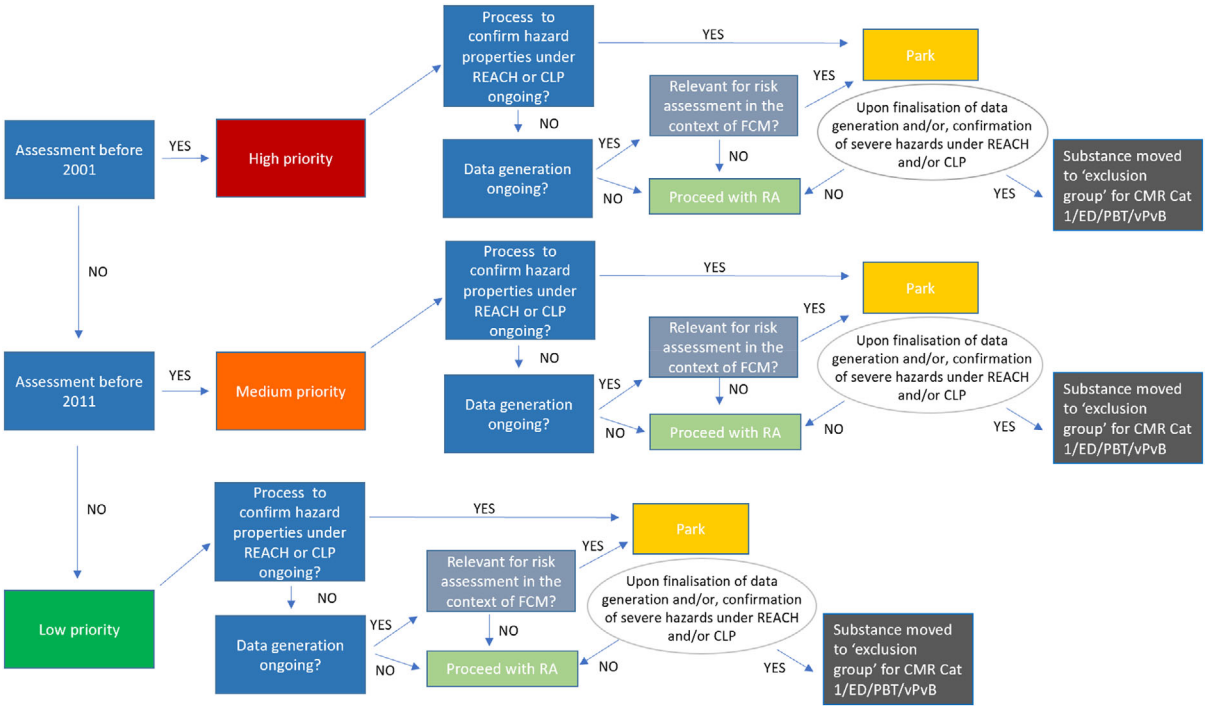


**Figure 3:** Decision tree for prioritisation (RA: risk assessment)

The second prioritisation criterion relates to the confirmation of hazard properties and the status of data generation possibly ongoing for the substances in the context of their assessment under REACH and CLP (see Section 2.2.3).

– Data generation under REACH or confirmation of hazard properties under REACH or CLP processes ongoing:

  Substances for which data generation processes are ongoing in the context of REACH, were reviewed to identify the relevance of the requested data for risk assessment in the context of FCM. Data relevant to risk assessment in that context are considered to be (i) the genotoxicity studies and (ii) the studies via the oral route. If relevant, the substances were temporarily 'parked' in a separate subgroup of the tier and will only be re-evaluated upon finalisation of data generation. Additionally, substances were parked in case they were undergoing processes to confirm the hazard properties under REACH or CLP. This 'parking' is in order to avoid possible duplication of risk assessment efforts and to ensure alignment with the OSOA approach developed by the European Commission in the context of the CSS (European Commission, 2020a). Ongoing studies with other routes of exposure (i.e. via inhalation or dermal application) would not be considered a reason to 'park' a substance. However, the generated data may be considered during the risk assessment.
  Upon finalisation of data generation and/or confirmation of severe hazard properties:

  - Substances classified as CMR Cat. 1 (CLP) or ED, PBT, vPvB (REACH) will be moved into the 'exclusion group' and risk assessment will be conducted only if, following the implementation of risk management measures in accordance with the CSS, the substances could still be considered for use in FCMs (European Commission, 2020a) (see Section 2.1.2).
  - Substances not identified as CMR Cat. 1 (CLP) or ED, PBT, vPvB (REACH) will be proposed for risk assessment.

– No relevant ongoing data generation processes or processes to confirm the hazard properties under REACH or CLP (see Section 2.2.3):

  - Substances will be proposed for risk assessment.

The use of these hazard properties for the purpose of the exclusion group was the only use of hazard information made in this prioritisation exercise. A more extensive use of hazard properties as

possible prioritisation criteria would require a review of the available literature, which is outside the remit of this mandate.

Furthermore, the possibility was considered that information on tonnage (of uses) might be used as input for this prioritisation of substances. However, the Panel considered that indications on tonnage could only provide rough and possibly misleading exposure estimates, covering not only FCM uses, but all different uses of the respective substance. Information from the calls for data on uses and exposure will be considered at a later stage for the refinement of the ranking of the substances.

### 2.2.2. Date of assessment

The prioritisation of the EU stream substances by assessment date was conducted using the publication date of the scientific opinion/report expressed by the SCF or EFSA. If a substance has been evaluated more than once, the date of the most recent assessment was used.

Substances for which an FCM number has been allocated (according to the Union list of FCM substances in Table 1, Annex I of Regulation (EU) No 10/2011) were checked against the following sources of information, based on the packaging material reference number (Ref. No) and/or the FCM number or the CAS number:

- Synoptic Document (European Commission, 2005)
- reports and opinions from the SCF[20]
- EFSA's OpenFoodTox[21] (Dorne et al., 2021).

The Synoptic document includes chemical names, identification numbers, SCF classification numbers of substances for which risk assessment had been conducted by the SCF (until May 2003) or by the EFSA Panel on food additives, flavourings, processing aids and materials in contact with food (AFC; which replaced the SCF, until 27 April 2005). It was used as an information tool to identify risk assessment summary information of the EU authorised substances (e.g. references to primary evaluation reports). The search in the Synoptic Document has been conducted based on Ref. No.

The primary source of information for the identification of the assessment dates for substances evaluated by the SCF was the SCF reports/opinions. In such cases, the date of publication of the SCF report/opinion (1974–2003) has been considered as the assessment date. The search in the SCF reports/opinions has been conducted based on Ref. No.

The OpenFoodTox Database (Dorne et al., 2021) was used to determine whether any of the EU-authorised substances on the list of substances have been evaluated more recently by EFSA. The OpenFoodTox Database is a chemical hazards database that includes data obtained from documents (opinions, statements, conclusions) published by the EFSA Scientific Panels. It links the chemical entities with their chemical identification (e.g. formula, CAS and EC numbers) and provides, among other information, toxicological studies (systemic, developmental, reproductive, etc.). It includes related reference points (e.g. no observed adverse effect level, benchmark dose level, lowest observed adverse effect level) and health-based guidance values (e.g. acceptable daily intake, tolerable daily intake), the study category (human/animal health, ecotoxicological data) and its conclusions on mutagenicity, genotoxicity and carcinogenicity. At the moment of the search for assessment dates in the context of this scientific opinion, the database version published on 27 March 2020 was used (containing information on evaluations published up to November 2019). While the search in the Synoptic Document and the SCF reports/opinions was conducted based on Ref. No, the search in the OpenFoodTox Database was conducted by CAS number and substance name. However, in the case of group entries, once a relevant EFSA opinion (from the AFC, CEF or CEP Panel) on FCM was identified, the Ref. No and/or the FCM number was identified in the EFSA opinion and used as the reference for the respective entry from the list of substances.

For nationally authorised substances, the date as provided by the Member State was used (in some cases the date provided may have been the date of authorisation).

For substances included only in the RCF Directive, it was not possible to retrieve specific assessments and, therefore, they were considered to have been assessed before 2001.

Similarly, substances authorised at EU level or nationally for which the date of assessment could not be retrieved or was not provided, were considered to have been assessed before 2001.

[20] https://ec.europa.eu/food/sci-com/scf_en
[21] https://www.efsa.europa.eu/en/microstrategy/openfoodtox

#### 2.2.3. Data generation under REACH and confirmation of hazard properties under REACH (identification of substances of very high concern based on ED, PBT or vPvB properties) and CLP (harmonised classification and labelling)

When referring to the data generation processes, reference is made to the evaluation processes[22] under REACH which comprise the dossier evaluation (including compliance check and testing proposal examination) and the substance evaluation. These processes enable ECHA to request further information from registrants of substances under REACH to fulfil the standard information requirements (specified in Annexes VI–X of the REACH Regulation) or to clarify a potential risk that a substance may pose to human health or the environment. The information which can be required includes inter alia (eco)toxicological studies needed for hazard and risk assessments of substances, including information relevant for the classification of substances as CMR Cat. 1 or identification of substances as having ED or PBT/vPvB properties.

Where the data are sufficient to confirm that a substance has severe hazard properties, such hazards may be confirmed under certain REACH or CLP processes. Substances for which the hazard data show carcinogenic, mutagenic or reprotoxic properties are subject to harmonised classification and labelling under the CLP Regulation.[23] Substances for which the data show PBT/vPvB or ED properties can be identified as SVHCs under REACH.[7]

The list of substances authorised at EU or national level was checked for any ongoing above-mentioned data generation or ongoing processes for harmonised classification and labelling under CLP or identification as SVHCs under REACH.

# 3. Assessment

## 3.1. Pool of substances

### 3.1.1. Compiling the pool of substances

The final pool of substances created according to the approach described in Section 2.1.1 consisted of 543[15] entries and was provided to the Member States as part of the consultation for the identification of nationally authorised plasticisers in materials other than plastics and regenerated cellulose films.

### 3.1.2. Member State consultation

As a result of the consultation with national authorities, replies from 17 Member States were received.

- Eight Member States (Cyprus, Denmark, Estonia, Finland, Malta, Luxembourg, Poland, Slovakia) indicated that they did not have any specific national evaluation, authorisation, or requirement on substances falling within the context of this work.
- Four Member States (Belgium, Bulgaria, Croatia, Latvia) indicated that substances authorised at EU level (e.g. for plastics) are generally also considered to be authorised at national level (with or without reference to a specific national measure on non-harmonised materials).
- Five Member States (France, Germany, Italy, the Netherlands, Spain) provided feedback on individual substances by: (i) relating substances already included in the set of pre-identified substances to positive lists established at national level; or (ii) proposing the consideration of additional substances stemming from authorisations at national level and possibly relevant for this work. The detailed feedback is reported below for each Member State, along with the decisions on whether and how to consider the feedback.

[22] https://echa.europa.eu/regulations/reach/evaluation/evaluation-procedure
[23] https://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling

- **France**

France provided a list of 17 substances.[24] Thirteen of these substances were present in the list of substances that EFSA provided to the Member States. The four remaining substances were not listed as such by EFSA and are authorised in France in rubber (French Order of the 5th of August 2020):

a) Phenyl esters of sulfonic acids (C12–C20);
b) White mineral oils, paraffinic, derived from petroleum-based hydrocarbon feedstocks. CAS No 8042-47-5, FCM 95;
c) Polyesters of adipic acid and of a mixture of 1,3-butanediol and 1,6-hexanediol (mean MW > 1,000);
d) Polyesters of adipic acid and of a mixture of 1,3- and 1,4-butanediol for which hydroxyl groups are acetylated (mean MW > 1,000).

Substance (a). was not considered as such in the prioritisation exercise. It is related to a similar substance coming from the PLASI plasticiser inventory (C14–17 alkanes, sec-mono- and disulfonic acids, phenyl esters) and also fits under the FCM 884 entry (alkyl(C10–C21)sulphonic acid, esters with phenol). This PLASI substance was already listed by EFSA and is registered under REACH. FCM 884 was included in the EU stream.

Substance (b). was not initially included in the list of substances, but it was found to be represented by FCM 95 and so in principle it should be assigned to the EU stream. However, since its chemical nature (hydrocarbon) differs from the plasticisers in Annex II of the mandate and the PLASI plasticiser inventory, it does not fall into the scope of the work. Whereas this type of substance is reported to be used, e.g. in the processing and softening of rubbers, it was not included in the EU stream.

Substance (c). was assigned to the national stream as this was not previously included in the list of substances.

Substance (d). was assigned to the EU stream for prioritisation, as this polymer is related to others listed in Annex II of the mandate that are covered by FCM 73.[25]

- **Germany**

A list of 31 substances considered to be relevant in the context of this work was provided by Germany:

– Four substances had not been previously identified in the list of substances:

a) Esters of montanic acids with ethanediol and/or 1,3-butanediol mixed with montanic acids, as well as calcium salts of montanic acids;
b) Esters of montanic acids with ethanediol or with 1,3-butanediol;
c) Esters of montanic acids with ethanediol and/or 1,3-butanediol and/or glycerol;
d) Esters of montanic acids with ethanediol and/or 1,3-butanediol and/or glycerol, mixed with montanic acids, as well as calcium salts of montanic acids.

– Twenty-seven substances had been identified as potentially relevant in the final pool of substances: 18 substances[26] were found to be covered already by EU-harmonised legislation on plastic and/or RCF; nine substances[27] were identified as falling into the groups of substances originating from Annex II of the mandate, PLASI or structural similarity.

It was highlighted that in the positive lists of the planned German printing inks ordinance, the technical function is not stated, nor is there a specific substance category for 'plasticisers/softeners' in the BfR recommendations for FCM.

For the four new substances proposed to be added to the list of substances, the Panel decided to not consider them for prioritisation in the nationally authorised stream: two (a and d) included esters, free acids and their Ca salts and were considered as not suitable for use as plasticisers. The other two

[24] CAS Nos 131-11-3; 84-74-2; 84-69-5; 85-68-7; 117-81-7; 28553-12-0; 26761-40-0; 84-61-7; 117-84-0; 84-66-2; 103-23-1; 109-43-3; 8013-07-8; 91082-17-6; 8042-47-5; Polyesters of adipic acid and of a mixture of 1,3-butanediol and 1,6-hexanediol (Mean MW > 1,000); Polyesters of adipic acid and of a mixture of 1,3- and 1,4-butanediol for which hydroxyl groups are acetylated (Mean MW > 1,000).

[25] Polyesters of 1,2-propanediol and/or 1,3- and/or 1,4- butanediol and/or polypropyleneglycol with adipic acid, which may be end-capped with acetic acid or fatty acids C12–C18 or *n*-octanol and/or *n*-decanol.

[26] CAS Nos 77-90-7, 84-74-2, 103-23-1, 110-30-5, 120-61-6, 1338-39-2, 1338-41-6, 6422-86-2, 8001-78-3, 8013-07-8, 8050-26-8, 8050-31-5, 9005-64-5, 9005-67-8, 31566-31-1, 85116-93-4, 84-61-7, 85408-76-0.

[27] CAS Nos 90218-76-1, 3319-31-1, 84-69-5, 110-27-0, 131-11-3, 627-93-0, 1119-40-0, 8047-99-2, 103-24-2.

substances (b and c) were included in BfR recommendations as used for coatings on the outside of hollow glassware (BfR recommendation XLVIII) and surface treatment to fillers (BfR recommendation LII), and so were considered as not suitable for use as plasticisers.

As regards the 18 substances already identified as relevant in the final pool of substances and found to be covered by EU harmonised legislation, the Panel decided to consider them under the EU authorised stream.

The remaining nine substances previously identified as falling into the groups of substances originating from Annex II of the mandate, PLASI or structural similarity, were brought forward under the nationally authorised stream.

- **Italy**

Twenty-two substances were reported by Italy as authorised for use in plastic, rubber and regenerated cellulose (decreto ministeriale of 21 March 1973): 18 substances[28] are covered under EU legislation for plastics and RCF and four substances[29] appear in Annex II of the mandate.

As regards the 18 substances already identified as relevant in the final pool of substances and found to be covered by EU-harmonised legislation, the Panel decided to consider them under the EU-authorised stream.

The other four substances, previously identified as falling into the groups of substances originating from Annex II of the mandate, were brought forward under the nationally authorised stream.

- **Spain**

Spain reported that Royal Decree 1413/1993 implemented the RCF Directive and included all the plasticisers and the softeners listed in that Directive. The Panel noted that the chemical nature of softeners authorised for RCF differs from that of the plasticisers in Annex II of the mandate and in the PLASI plasticiser inventory. These differences arise from performance requirements, such as the compatibility of the additives with the matrix to be plasticised. Any expansion of the scope of the work to RCF softeners would result in the introduction of distinct substance types, such as alcohols, polyols and related substances, to the pool from which the prioritisation takes place. RCF softeners were therefore not considered.

Spain reported that according to Royal Decree 847/2011 those substances that are listed in the Regulation (EU) No 10/2011 (plastics) are considered to be authorised in Spain not only for plastics, but also for polymeric materials and articles more generally, including rubber, adhesives, varnishes and coatings. Royal Decree 847/2011 also gives the conditions of use for these substances in the polymeric materials.

In addition, seven substances were indicated in the list provided by Spain as having a national authorisation:

– Three substances[30] in the final pool of substances were indicated by Spain as having national authorisation for polymeric materials (including plastics), but which are not authorised at EU level. These three substances will enter the nationally authorised stream.

– Two substances[31] had already been identified as relevant in the final pool of substances and found to be covered by EU-harmonised legislation. Therefore, the Panel decided to consider them under the EU-authorised stream.

Spain added the substance glycerol diacetate ('diacetin', identified by EC No 246-941-2 and CAS No 25395-31-7) to the list as a nationally authorised substance, although the substance seemed to already be in the pool of substances by means of entry 'glycerol 1,3-di(acetate)' with EC No 246-941-2, PM ref No 30610 and FCM No 9. Upon checking, it transpired that there is a contradiction for the substance EC No 246-941-2, since the EC name is glycerol 1,3-diacetate. Another EC entry (EC No 203-323-7) exists for this specific isomer. The CAS No 25395-31-7 that is associated with EC No 246-941-2 refers to glycerol diacetate with unspecified isomers. So both isomers (the 1,2- and the 1,3-diacetates) are included. Thus, the EC name (glycerol 1,3-di(acetate)) initially reported for substance EC No 246-941-2 was considered inappropriate and the name diacetin (1,2,3-propanetriol, diacetate) is

[28] CAS Nos 77-90-7, 8013-07-8, 166412-78-8, 736150-63-3, 103-23-1, 141-04-8, 105-99-7, 109-43-3, 84-61-7, 84-74-2, 85-68-7, 117-81-7, 26761-40-0, 28553-12-0, 1241-94-7, 25395-31-7, glycerol acetate, dihexyl azelate.
[29] CAS Nos 144-15-0, 84-66-2, 84-69-5, 117-84-0.
[30] CAS Nos 8016-11-3, 84-66-2, 131-11-3.
[31] CAS Nos 102-76-1, 84-61-7.

to be associated to the substance. The outcome is that the entry put forward by Spain is included in the EU-authorised stream.

- **The Netherlands**

The Netherlands indicated that from the final pool of substances shared with the Member States, 206 substances are authorised at their national level.

- Ninety-nine substances were found to be covered by EU-harmonised legislation. Therefore, the Panel decided to consider them under the EU-authorised stream.
- One hundred and seven substances were identified as falling into the groups of substances originating from Annex II of the mandate, PLASI or structural similarity. They underwent further scrutiny, considering the information on technical functionality as provided by the Netherlands. Of these 107 substances, the Panel focused on the 43 substances which were indicated to function as a plasticiser.
  - Seven substances were also reported by other Member States and they followed the agreed categorisation into the respective priority groups;
  - the remaining 36 substances entered the nationally authorised stream.

As a follow-up to this initial feedback provided by the Netherlands and after the closure of the public consultation, additional substances authorised at national level were brought to the Panel's attention. In order to provide an overview that is as complete as possible, it was decided to take this additional feedback into consideration.

Excluded substances:

- Fourteen substances[32] were excluded since based on their chemical nature (carboxylic acid, alcohols, amines, ether alcohols, inorganics, salts, volatiles) they did not fall into the scope of the work as defined in Section 2.1.1.
- Nine hydrocarbon substances[33] were excluded based on their chemical nature that did not fall into the scope of the work.
- Three substances[34] were excluded as they were considered processing aids rather than plasticiser additives.
- Two substances[35] related to (esters of) montanic acids were similar to substances that had also been brought forward by Germany. Applying the same rationale as described above, it was decided to exclude these substances, as well as two other substances[36] of similar chemical nature.

Included substances:

- EU stream
  - The substance with CAS No 25101-03-5 was considered to be covered by group entry FCM 73 which was already present in the EU stream of substances, and therefore the individual substance was added to the list of substances and attributed to FCM 73.
  - Substances with CAS Nos 106-18-3 and 142-77-8 were considered to be covered by group entry FCM 879 which was already present in the EU stream of substances, and therefore the individual substances were added to the list of substances and attributed to FCM 879.
  - The substance with CAS No 126-13-6 was considered to be covered by entry FCM 308. As this entry had initially not been considered yet, it was added to the list of substances for EU stream.
  - Substances with CAS Nos 8001-26-1, 8001-79-4, 8002-13-9 and 8001-22-7 were considered to be covered by several group entries which were already present in the EU stream of substances; one additional group entry with relevance for these substances was

[32] CAS Nos 8050-09-7, 8013-17-0, 50-70-4, 56-81-5, 57-55-6, 107-21-1, 141-43-5, 25322-68-3, 7631-99-4/6484-52-2, 1592-23-0, 2190-04-7, 637-12-7/1002-89-7/822-16-2, 112-27-6, 108-21-4.
[33] CAS Nos 8002-74-2, 8009-03-8, 8012-95-1, 63231-60-7, 9003-29-6, 9003-53-6, 9002-88-4, 9003-07-0, 542-92-7/77-73-6/25568-84-7.
[34] CAS Nos 68152-90-9, 9003-35-4, 63393-89-5.
[35] (montane wax, consisiting of:) montanic acids C26–C32, esters with ethanediol or 1,3-butanediol, (montane wax, consisting of:) montanic acids C26–C32 or its calcium salts.
[36] CAS Nos 8006-44-8, 8015-86-9.

identified and added to the list of substances (FCM 36). Therefore, the individual substances were added to the list of substances and attributed to the relevant group entries.

- National stream
  - Twenty-three substances or group entries[37] were considered to be within the scope. As they are not authorised at EU level, they were added to the national stream.

Overall, the feedback received during the Member State consultation resulted in the consideration of four additional substances that already have an EU authorisation (FCM 884, FCM 73, FCM 308, FCM 36), while 73 substances were found relevant to be considered due to their authorisation at national level.

### 3.1.3. Exclusion group

Among substances authorised at EU or national level, five substances (all *ortho*-phthalates) are classified[38] as CMR Cat. 1 for reproductive toxicity and identified as EDs. Therefore, they are excluded from the prioritisation exercise:

- dicyclohexyl phthalate (DCHP; CAS No 84-61-7)
- dibutyl phthalate (DBP; CAS No 84-74-2)
- benzyl butyl phthalate (BBP; CAS No 85-68-7)
- bis(2-ethylhexyl) phthalate (DEHP; CAS No 117-81-7)
- diisobutyl phthalate (DIBP; CAS No 84-69-5).

Only DIBP was brought forward as being authorised at national level via the Member State consultation (Germany, Italy, the Netherlands). The other four substances had been identified in the final pool of substances as being authorised via EU-harmonised legislation for RCF (DCHP) and plastic (DBP, BBP, DEHP).

### 3.1.4. EU/national substances for prioritisation

Taking into account the final pool of substances, the feedback received during the Member State consultation and categorisation of four substances (DCHP, DBP, BBP, DEHP) into the exclusion group, 76 substances were considered for the prioritisation stream of EU-authorised substances.

Taking into account the feedback received during the Member State consultation and the categorisation of one substance (DIBP) into the exclusion group, 72 substances were considered for the prioritisation stream of nationally authorised substances.

## 3.2. Prioritisation

### 3.2.1. EU stream

Applying the approach described under Section 2.2.1 to the 76 substances of the EU-authorised stream, the prioritisation gave the distribution shown in Table 2. Twelve substances were parked due to ongoing data generation with relevance for risk assessment in the context of FCM; none were found to be in the process of confirmation of severe hazard properties.[39]

[37] mono-, di- and tristearyl citrate (reference to the following CAS Nos has been made: 7775-50-0, 750511-99-0 and 1337-33-3); CAS Nos 105-97-5; 106-10-5; 110-29-2; 2451-84-5; 25176-75-4; 27214-90-0; 822-23-1; 85-70-1; 83968-18-7; 68389-55-9; polyesters with an average Mw > 1,000, as reaction of: adipic acid, azelaic acid, succinic acid, decane dicarbonic acid, phthtalic acid and sebacic acid with 1,3-butanediol, 2,2-dimethyl-1,3-propanediol, ethanediol, glycerol, 1,6-hexanediol and 1,2-propanediol, where the reaction may optionally be terminated by means of fatty acids as described above, or alcohols as described above; CAS No 1321-57-9; bis(alkoxyalkyl(C3–C18))phthalates (e.g. CAS Nos 117-82-8; 117-83-9; 605-54-9); tris (alkoxyalkyl(C3–C8))phosphates (e.g. CAS Nos 78-51-3; 6163-73-1; 63918-88-7); trialkyl(C4–C16)phosphates (up to 0.5%; e.g. CAS Nos 126-73-8; 2528-38-3; 2528-39-4; 1806-54-8); tetra-alkyl(C1–C8)pyromellitates = (tetra-alkyl(C1–C8)-1,2,4,5-tetracarboxybenzene)); adipic acid, esters of alcohols, monovalent, aliphatic, saturated, C6–C12; azelaic acid, esters of alcohols, monovalent, aliphatic, saturated, C6–C12; trialkyl(C1–C8)trimellitates (up to 0.5%); fatty acids non-branching, sat. & unsat., even numbered C8–C22, non-saponifiable ingredients content ≤ 2% (and/or amides thereof), esterified with pentaerythritol; dialkyl(C1–C8)esters of aliphatic dicarbonic acids, C4–C10; citric acid esters of alcohols, aliphatic, saturated, primary (in Ch10)/monovalent (in Ch2), C6–C12.

[38] The classification status was last checked on 28 January 2022.

[39] The status of data generation and processes of confirmation of severe hazard properties was last checked on 28 January 2022.

**Table 2:** Prioritisation of EU-authorised substances

| Priority group | | Number of substances |
|---|---|---|
| **High** | Proposed for risk assessment | 54 (36 individual substances; 7 group entries covering in total 54 substances → 36 substances with more than one FCM No) |
| | Parked | 5 |
| **Medium** | Proposed for risk assessment | 10<br>(7 individual substances; 3 group entries covering in total 104 individual substances) |
| | Parked | 4 |
| **Low** | Proposed for risk assessment | 0 |
| | Parked | 3<br>(2 group entries covering in total 4 substances) |

### 3.2.2. National stream

Applying the approach described under Section 2.2.1 to the 72 substances of the nationally authorised stream, the prioritisation gave the distribution shown in Table 3. Fourteen substances were parked due to ongoing data generation with relevance for risk assessment in the context of FCM; none were found to be in the process of confirmation of severe hazard properties.[39]

**Table 3:** Prioritisation of nationally authorised substances

| Priority group | | Number of substances |
|---|---|---|
| **High** | Proposed for risk assessment | 55 (1 – ES/NL, 1 – DE/NL, 1 –IT/NL, 1 – FR, 1 – DE, 50 – NL) |
| | Parked | 11 (9 – NL, 1 – IT/ES, 1 – IT/NL) |
| **Medium** | Proposed for risk assessment | 2 (DE) |
| | Parked | 1 (ES/DE) |
| **Low** | Proposed for risk assessment | 1 (DE/NL) |
| | Parked | 2 (1 – DE/NL, 1 – DE) |

DE: Germany; ES: Spain; FR: France; IT: Italy; NL: Netherlands.

## 3.3. Discussion

Using this approach, the list of substances obtained that are actually used as plasticisers or are potentially used as new or replacement plasticisers, is as comprehensive as possible. For the EU stream, the 76 listed substances were split 59, 14 and 3 into the high-, medium- and low-priority groups, respectively. For the nationally authorised stream, the split of the 72 substances was 66, 3 and 3, respectively. Examining the prioritisation results for the substances in the EU stream, the Panel noted the top-heavy distribution of substances, i.e. a large proportion of substances allocated to the high-priority group and a substantially lower proportion of substances in the medium- and low-priority groups. It was noted that this distribution could be reasonably expected, given the historical use of plasticisers.

In order to facilitate an appropriate and relevant follow-up (i.e. the second part of the mandate concerning the risk assessment work), it was considered that a further refinement of the ranking of substances within and possibly between their priority groups will be necessary. To that end, information collected via the follow-up calls for data in support of the exposure assessment will be used. Through these calls for data, it is expected to gather information/data on the prioritised substances as regards migration from and occurrence in FCM, as well as occurrence in food.

The more the provided evidence points in a direction of possible exposure of consumers to a substance due to its use in FCM, the higher that substance will be ranked in terms of priority for risk assessment. For example, the availability of only occurrence data of a substance in food (which could be due to various contamination pathways) will be considered, but will be given less weight than occurrence data in an FCM or migration data from an FCM into food or food simulants. The final ranking of substances will therefore depend on the outcome of these calls for data. Therefore, stakeholders (e.g. industry, Member States and other interested parties) are strongly encouraged to submit available data to EFSA in order to enable an informed conclusion on the risk assessment to

support the continued use of the substances. As the calls for data will only be closed after publication of this scientific opinion, this further ranking based on the afore-described evidence will only be conducted *a posteriori*.

# 4. Uncertainty analysis

The evaluation of the uncertainties in the identification and prioritisation of substances has been performed based on the guidance on uncertainties of the EFSA Scientific Committee (EFSA Scientific Committee, 2018) and the guidance on communication of uncertainty in scientific assessments (EFSA, 2019). The CEP Panel identified the following sources of uncertainty and evaluated the impact in a qualitative manner:

– Risk of not capturing all possible plasticisers used in FCMs

Different approaches were used with the aim of ensuring that all possible plasticisers used in FCMs were listed, including Annex II of the mandate, the PLASI inventory, positive lists of the Plastics Regulation and RCF Directive, the ECHA database, a grouping approach and consultation with Member States (although only 17 of the 27 Member States responded).

Different substance identification and naming conventions may have been used under different chemical regulatory schemes and the matching between the substances registered under REACH and the substances regulated as FCM is not always straightforward. The matching may be further complicated where the regulated substances are not individually defined but are, instead, addressed together with other substances as a group entry under one generic chemical name. It is possible, therefore, that in some cases, the equivalence between a REACH and an FCM substance was not established and therefore the substance was not included in the pool of substances. However, the grouping approach followed, which brings together substances displaying structural similarities, contributes to identifying the REACH substance(s) potentially fitting under an entry in the FCM lists. The EU Chemicals Legislation Finder (EUCLEF)[40] was used to further facilitate the matching between the REACH and FCM substances.

For some polymeric substances that may potentially be used as plasticisers there is no requirement for registration under REACH.[41] Consequently, these may be missing from the list of substances, unless they appear in Annex II of the mandate or have been mentioned by Member States.

One cannot be certain that the list is exhaustive, but the approach likely ensures that the most used plasticisers are listed. Additionally, from the follow-up calls for data in support of the exposure assessment it will become apparent whether usage or occurrence data are available for any substance not currently captured (low impact).

– Focus on the EU

It is possible that substances other than those considered here are used in non-EU countries to make FCMs that are exported to the EU (as such or as packaged foods) or used in food production and processing in non-EU countries and the foods then exported to the EU (low impact).

– Impurities and reaction products

Current risk assessment of substances intended for FCMs includes an evaluation of their impurities and reaction products, whereas this prioritisation exercise is for the named substances only. On the other hand, focus on impurities and reaction products has increased over recent years and so this limitation is reduced by the ranking of substances according to the date (age) of their last evaluation, giving the 'oldest' substances the highest priority (high impact).

– Robustness of cut-off dates

The year 2001 was chosen, since it is the date of publication of the 'Guidelines of the Scientific Committee on Food (SCF) for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation' (European Commission, 2001). It is conventional and was chosen to divide the time period by decades, although it does coincide with the

[40] The EU Chemicals Legislation Finder (EUCLEF, available at https://echa.europa.eu/legislation-finder) gives an overview of the European Union's legislation on chemicals. Searches using chemical identifiers such as EC, CAS numbers and chemical names can be conducted to check legal obligations.

[41] See for instance the entry with CAS No 73018-26-5 in Annex II of the mandate, provided that it meets the polymer definition as specified in Article 3(5) of the REACH Regulation.

date of the Regulation (EU) No 10/2011 on plastic FCMs. It is not supported by any other specific publications (guidelines or regulations) on non-plastic FCMs or any step-changes in the approaches used to assess FCMs.

Some of the input from the Member States identified the publication date of a regulation, a decree or an opinion, as the 'date of last assessment'. However, some texts simply reported/adopted an existing list from older documents without assessing the substance or the group of substances. Consequently, the actual date of the last safety assessment of some substances may be older than indicated and, therefore, the substance may be incorrectly prioritised (moderate impact).

- Data requirements compared with actual need for data for parked substances

Among all parked substances, one substance was parked due to ongoing data generation under REACH to clarify suspected PBT properties. This may unnecessarily delay the evaluation of such substances if the PBT property is not confirmed. In addition, there are seven substances from the EU authorised list and eight substances from the MS authorised list for which dossier or substance evaluation is ongoing, which may or may not lead to a request for data that are of relevance for risk assessment in the context of FCM (low impact).

- Lack of consideration on exposure/use

During this prioritisation process, no information on exposure (direct or indirect information by the means of usage, tonnage or migration) of the population to the substance was taken into consideration. This information on exposure will be considered in the next steps following the calls for data in support of the exposure assessment (see Section 3.3) to be launched after the publication of this scientific opinion (high impact, but expected to be reduced to low impact by the *a posteriori* ranking).

Overall, there are uncertainties in the completeness of the listing of potential plasticisers and in the placing of substances into the three-tier prioritisation. As described, mitigation actions have been taken to reduce these uncertainties as far as possible and they will be further reduced or even removed in subsequent parts of the mandate including the calls for data in support of the exposure assessment. The main uncertainty that remains is the question of impurities and reaction products that may accompany the use of the named plasticiser. That uncertainty cannot be reduced at this stage, since it will require information that is not available until the actual substance-specific risk assessment process is underway.

# 5. Conclusions

As the first part of a multi-step approach, this opinion has identified phthalates, structurally similar substances and replacement substances that are potentially used as plasticisers in materials and articles intended to come into contact with food in the EU. The focus has been on potential plasticisers used in all FCMs (plastics, rubber, inks, etc.) with the exception of the so-called softeners used in regenerated cellulose. These are listed in the RCF Directive, but their inclusion here would have resulted in the introduction of substance types, such as polar alcohols, polyols and related substances, that are different in terms of chemical structure to the classic plasticisers.

Different sources of information were considered to help ensure that all relevant plasticiser substances were captured and listed, including Annex II of the mandate, the PLASI inventory, positive lists of the Plastics Regulation and the RCF Directive, the ECHA database, a grouping approach and consultation with the Member State authorities. From this final pool of substances, only substances authorised for FCMs at EU or national level were further considered in the exercise.

Substances classified as CMR Cat. 1 (CLP) or ED, PBT, vPvB (REACH) were placed into an 'exclusion group' and risk assessment will be conducted only if, following the implementation of risk management measures in accordance with the CSS, the substances could still be considered for use in FCMs (European Commission, 2020a). There are five such substances (DCHP, DBP, BBP, DEHP, DIBP).

Prioritisation was based on the date of the most recent risk assessment in the context of FCMs, with substances assessed before 2001 being placed in the high-priority group, substances assessed between 2001 and 2011 in the medium-priority group and substances assessed after 2011 in the low-priority group.

Where there was ongoing data generation with relevance for risk assessment in the context of FCMs and/or ongoing process to confirm suspect severe hazard properties under REACH or CLP, the substance was parked. Twelve and fourteen substances of the EU and national stream, respectively,

were parked due to ongoing data generation with relevance for risk assessment in the context of FCMs; none were found to be in the process of confirmation of suspect hazard properties.

For the EU stream, the 76 listed substances were split 59, 14 and 3 into the high-, medium- and low-priority groups, respectively. For the nationally authorised stream, the split of the 72 substances was 66, 3 and 3, respectively. It is acknowledged that this distribution of substances is top-heavy, with a large proportion of substances allocated to the high-priority groups. This distribution could be reasonably expected, given the long historical use of plasticisers. It was decided not to attempt to refine the prioritisation at this stage. The outcome of the follow-up calls for data in support of the exposure assessment will be used for a final ranking. Therefore, stakeholders (e.g. industry, Member States and other interested parties) are strongly encouraged to submit available data to EFSA in order to enable an informed conclusion on the risk assessment to support the continued use of the substances.

When developing the follow-up mandates for risk assessment, the Panel recommends the European Commission to also take into account ECHA's ongoing data generation processes and initiation of new data generation processes and/or processes to confirm severe hazard properties for the prioritised substances.

## References

Dorne JLCM, Richardson J, Livaniou A, Carnesecchi E, Ceriani L, Baldin R, Kovarich S, Pavan M, Saouter E, Biganzoli F, Pasinato L, Zare Jeddi M, Robinson TP, Kass GEN, Liem AKD, Toropov AA, Toropova AP, Yang C, Tarkhov A, Georgiadis N, Di Nicola MR, Mostrag A, Verhagen H, Roncaglioni A, Benfenati E and Bassan A, 2021. EFSA's OpenFoodTox: an open source toxicological database on chemicals in food and feed and its future developments. Environment International, 146. https://doi.org/10.1016/j.envint.2020.106293

ECHA (European Chemicals Agency), 2017. Guidance for identification and naming of substances under REACH and CLP. ECHA-16-B-37.1-EN. https://doi.org/10.2823/538683

EFSA (European Food Safety Authority), 2019. Guidance on Communication of Uncertainty in Scientific Assessments. EFSA Journal 2019;17(1):5520, 73 pp. https://doi.org/10.2903/j.efsa.2019.5520

EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2008. Note for Guidance for the preparation of an application for the safety assessment of a substance to be used in plastic Food Contact Materials. EFSA Journal 2008;6(7):21r, 41 pp. https://doi.org/10.2903/j.efsa.2008.21r

EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids), Silano V, Barat Baviera JM, Bolognesi C, Chesson A, Cocconcelli PS, Crebelli R, Gott DM, Grob K, Lampi E, Mortensen A, Rivière G, Steffensen I-L, Tlustos C, Van Loveren H, Vernis L, Zorn H, Cravedi J-P, Fortes C, Tavares Poças MF, Waalkens-Berendsen I, Wölfle D, Arcella D, Cascio C, Castoldi AF, Volk K and Castle L, 2019. Scientific Opinion on the update of the risk assessment of di-butylphthalate (DBP), butyl-benzyl-phthalate (BBP), bis(2-ethylhexyl) phthalate (DEHP), di-isononylphthalate (DINP) and di-isodecylphthalate (DIDP) for use in food contact materials. EFSA Journal 2019;17(12):5838, 85 pp. https://doi.org/10.2903/j.efsa.2019.5838

EFSA Scientific Committee, 2018. Guidance on Uncertainty Analysis in Scientific Assessments. EFSA Journal 2018;16(1):5123, 39 pp. https://doi.org/10.2903/j.efsa.2018.5123

European Commission, 2001. Guidelines of the Scientific Committee on Food (SCF) for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation. Available online: https://ec.europa.eu/food/system/files/2020-12/sci-com_scf_out82_en.pdf

European Commission, 2005. 'Synoptic Document'. Provisional list of monomers and additives notified to European Commission as substances which may be used in the manufacture of plastics and coatings intended to come into contact with foodstuffs. (updated to June 2005). SANCO D3/AS D(2005).

European Commission, 2020a. Chemicals Strategy for Sustainability Towards a Toxic-Free Environment. Available online: https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

European Commission, 2020b. Inception Impact Assessment on the initiative 'Revision of EU rules on food contact materials (FCMs); Ref. Ares(2020)7731375 - 18/12/2020. Available online: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12497-Revision-of-EU-rules-on-food-contact-materials_en

## Abbreviations

| | |
|---|---|
| AFC | Food additives, flavourings, processing aids and materials in contact with food [EFSA Panel] |
| BBP | benzyl butyl phthalate |
| BfR | Bundesinstitut für Risikobewertung |
| CAS | Chemical Abstracts Service |
| CEF | Food Contact Materials, Enzymes, Flavourings and Processing Aids [EFSA Panel] |
| CEP | Food Contact Materials, Enzymes and Processing Aids [EFSA Panel] |
| CLP | classification, labelling and packaging |
| CMR | carcinogenic, mutagenic, or toxic for reproduction |

| | |
|---|---|
| CSS | Chemicals strategy for sustainability |
| DBP | dibutyl phthalate |
| DCHP | dicyclohexyl phthalate |
| DEHP | bis(2-ethylhexyl) phthalate |
| DIBP | diisobutyl phthalate |
| DIDP | diisodecyl phthalate |
| DINP | diisononyl phthalate |
| ED | endocrine disruptor |
| ECHA | European Chemicals Agency |
| EUCLEF | EU Chemical Legislation Finder |
| FCMs | food contact materials |
| OSOA | one substance, one assessment |
| PBT | persistent, bioaccumulative and toxic |
| RCF | regenerated cellulose film |
| REACH | registration, evaluation, authorisation and restriction of chemicals |
| SCF | Scientific Committee on Food |
| SVHC | substance of very high concern |
| TDI | Tolerability Daily Intake |
| UVCB | Unknown or Variable Composition, complex reaction products or of Biological materials |
| vPvB | very persistent, very bioaccumulative |

# Appendix A – List of substances to be considered as part of the prioritisation exercise* as per Annex II of the terms of reference received from the European Commission

**Table A.1:** Substances to be considered as part of the prioritisation exercise* as per Annex II of the terms of reference received from the European Commission

| Substance abbreviation (full name) | EC number | CAS number | FCM number |
|---|---|---|---|
| DCHP (Dicyclohexyl phthalate) | 201-545-9 | 84-61-7 | |
| DEP (Di-ethyl Phthalate) | 201-550-6 | 84-66-2 | |
| DIBP (Di-isobutyl Phtalate) | 201-553-2 | 84-69-5 | |
| DBP (Di-Butyl Phthalate) | 201-557-4 | 84-74-2 | 157 |
| BBP (Butyl-Benzyl-phthalate) | 201-622-7 | 85-68-7 | 159 |
| DEHP (Bis(2-ethylhexyl)phthalate) | 204-211-0 | 117-81-7 | 283 |
| DAP (Phthalic acid, diallyl ester) | 205-016-3 | 131-17-9 | 316 |
| DNOP (Di-*N*-Octyl phthalate) | 204-214-7 | 117-84-0 | |
| Diisopropyl Phthalate | 210-086-3 | 605-45-8 | |
| DINP (Di-isononyl-phthalate) | 249-079-5<br>271-090-9 | 28553-12-0<br>68515-48-0 | 728 |
| DIDP (Di-isodecyl-phthalate) | 247-977-1<br>271-091-4 | 26761-40-0<br>68515-49-1 | 729 |
| DTDP (Diisotridecyl phthalate) | 248-368-3 | 27253-26-5 | |
| DPHP(Bis (2-propylheptyl) phthalate) | 258-469-4 | 53306-54-0 | |
| DIUP (Diisoundecyl phthalate) | 306-165-8 | 96507-86-7 | |
| Ethyl Isobutyl phthalate | | 94491-96-0 | |
| Di-*n*-butyl adipate | 203-350-4 | 105-99-7 | |
| Di-*n* -hexyl azelate/ Dihexyl azelate | 203-664-1 | 109-31-9 | |
| DOTP/ DEHT (Bis (2-ethylhexyl) terephthalate) | 229-176-9 | 6422-86-2 | 798 |
| TOTM (Trioctyl trimellitate) Synonym: TEHTM | 222-020-0 | 3319-31-1 | |
| PTA (Terephthalic acid) | 202-830-0 | 100-21-0 | 785 |
| ATBC (Acetyl Tributyl Citrate) | 201-067-0 | 77-90-7 | 138 |
| DOA or DEHA (Bis (2-ethylhexyl) ester adipate) | 203-090-1 | 103-23-1 | 207 |
| Dibutyl sebacate | 203-672-5 | 109-43-3 | 242 |
| TPhP (Triphenyl phosphate) | 204-112-2 | 115-86-6 | |
| EHDP (2-Ethylhexyl Diphenyl phosphate) | 214-987-2 | 1241-94-7 | 392 |
| ESBO (Epoxidised Soybean oil) | 232-391-0 | 8013-07-8 | 532 |
| DINA (Di-isononyl adipate) | 251-646-7 | 33703-08-1 | |
| Hydrogenated acetylated castor oil | 295-625-0 | 92113-20-7 | |
| Diisobutyl adipate | | 141-04-8 | |
| Acetyl triethylhexyl citrate | | 144-15-0 | |
| Glycerol monoacetate | | 26446-35-5 | |
| Glycerol diacetate/ diacetin | 246-941-2 | 25395-31-7 | |
| Glycerol triacetate/ triacetin | | 102-76-1 | |
| Glycerides, castor oil mono-, hydrogenated, acetates | | 736150-63-3 | 783 |
| MB10 (tradename: Jayflex™ MB10; monoester of benzoic acid and isodecyl alcohol) | 421-090-1 | 131298-44-7 | |
| DINCH (1,2-Cyclohexanedicarboxylic acid 1,2-disononyl ester) | 431-890-2 | 166412-78-8 | 775 |
| Hexanedioic acid polymer with 2,2-dimethyl-1,3-propanediol and 1,2-propanediol, isononyl ester | 606-665-9 | 208945-12-4** | |
| BMMF (9,9-Bis(methoxymethyl)-9H-fluorene) | 682-678-3 | 182121-12-6 | 779 |

| Substance abbreviation (full name) | EC number | CAS number | FCM number |
|---|---|---|---|
| Hexanedioic acid polymer with 1,3-butanediol and 1,2-propanediol, 2-ethylhexyl ester | n/a | 73018-26-5 | |
| Hexanedioic acid polymer with 1,2-propanediol, decyl octyl ester | n/a | 136155-46-9 | |
| Hexanedioic acid polymer with 1,2-propanediol, octyl ester | n/a | 82904-80-1 | |
| Hexanedioic acid polymer with 1,2-propanediol, acetate | n/a | 55799-38-7 | |
| Isosorbide esters | | | |

*: These substances were identified as part of a DG SANTE survey on phthalates and replacement substances, controls by Member States and substances authorised at EU level. The list of substances is non-exhaustive and under development with a view to establishing those substances for prioritisation as per task 1 of this mandate.
**: EFSA comment: following the receipt of the mandate, it was noted that the CAS number provided for the substance 'Hexanedioic acid polymer with 2,2-dimethyl-1,3-propanediol and 1,2-propanediol, isononyl ester' was incorrect. The correct CAS number, that was consequently also used as an identifier in the list of substances, is 208945-13-5.

## Annex A – List of substances identified as potential plasticisers and prioritised according to the approach described in this Scientific Opinion

Annex A can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2022.7231

# Annex B – Outcome of the public consultation on the draft opinion on identification and prioritisation for risk assessment of phthalates, structurally similar substances and replacement substances potentially used as plasticisers in materials and articles intended to come into contact with food

Annex B can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2022.7231