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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)

Abstract

The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) 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 working with the European Chemicals Agency (ECHA) was requested in the mandate, for all tasks leading up to the risk assessment work. The CEP Panel established a stepwise approach to address this task. Potential 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. Substances classified as carcinogenic, mutagenic, toxic to reproduction (CMR) Cat. 1 (under CLP) or endocrine disruptors (ED), persistent, bioaccumulative and toxic (PBT), very persistent/very bioaccumulative (vPvB) (under REACH) were placed into an 'exclusion group' and there were five such substances. 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 75 listed substances split 58, 14 and 3 into the high-, medium- and low-priority groups, respectively. For the nationally authorised stream, the split of the 49 substances was 43, 3 and 3, respectively. The outcome of follow-up calls for data in support of exposure assessment will be used for a final ranking. This draft Opinion has been endorsed by the CEP Panel for public consultation.

Keywords

Food contact materials, prioritisation, safety assessment, phthalates, plasticisers.

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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.

[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

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 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 (EC) 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 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 (i.e. plasticising effects) in different materials. The relevant materials pointed out in the terms of reference may be regulated by EU specific measures (as is the case for plastic and 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 EU authorisation requirements remains the responsibility of the Member States.

Due to the wide spectrum of uses of phthalates (or plasticisers more generally), 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 EC'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] Serving as a pilot for the implementation of the recent CSS, new ways of working and approaches to address the scientific issues had to be built using the agencies' respective combined expertise, e.g. for identification of relevant substances with a potential plasticiser function in addition to those highlighted by the EC (Annex II of the mandate, see Appendix A, Table A1 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 EC's inception impact assessment on the revision of EU rules on FCMs (European Commission, 2020b). In this context, it is understood that such substances, which are referred to as carcinogenic, mutagenic or toxic for reproduction (CMR), are formally classified in CMR categories 1A or 1B under the CLP Regulation[6].

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 endorsement/adoption of the scientific opinion, both as regards the identified substances *per se* as well as the information underlying the prioritisation exercise.

[5] The other tasks will be dealt with separately and respective outputs will be published accordingly. Upon finalisation of all the preparatory tasks, the EC will issue specific mandates for the follow-up risk assessment 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.

2 Data and Methodologies

2.1 Identification of substances

2.1.1 Building the pool of substances

The pool of substances potentially used as plasticisers was created from two main sources of information (see Figure 1): Annex II of the mandate[7] (see Appendix A, Table A1 in this scientific opinion) and an inventory of plasticisers established by ECHA in cooperation with industry (the PLASI initiative[8]), 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.[9] 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. 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 judgment 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[10] (plastic FCMs) or Annex II of Directive 2007/42/EC[11] (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 (such as inorganics, organic acids, organic alcohols, organic amines, monomers) in this third source. For instance, it was noted that softeners authorised for RCF (such as alcohols, polyols and related substances) would fall 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 Annex II of the RCF Directive and for which a link with plasticiser use was established based on information available to ECHA.

[7] Two substances from Annex II of the mandate, terephthalic acid and BMMB, were disregarded given that they were not considered to be plasticisers.
[8] Plastic additives initiative. Further information on the scope of the PLASI inventory is available at: https://echa.europa.eu/mapping-exercise-plastic-additives-initiative
[9] Further information on ECHA's grouping approach is available at: https://echa.europa.eu/working-with-groups
[10] 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.
[11] 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.

Substances that have not been registered under REACH (i.e. are outside the scope of the registration[12] or are not manufactured or placed on the market in the European Union as such or in mixture at 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. 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[13] or meaningful name is not available for dissemination on the ECHA website have been withdrawn from the pool. The final pool of substances consists of 543[14] substances (see Annex A). An indication as to whether a substance in the pool is covered by an entry in Annex I of the Plastics Regulation or in Annex II of the RCF Directive 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).

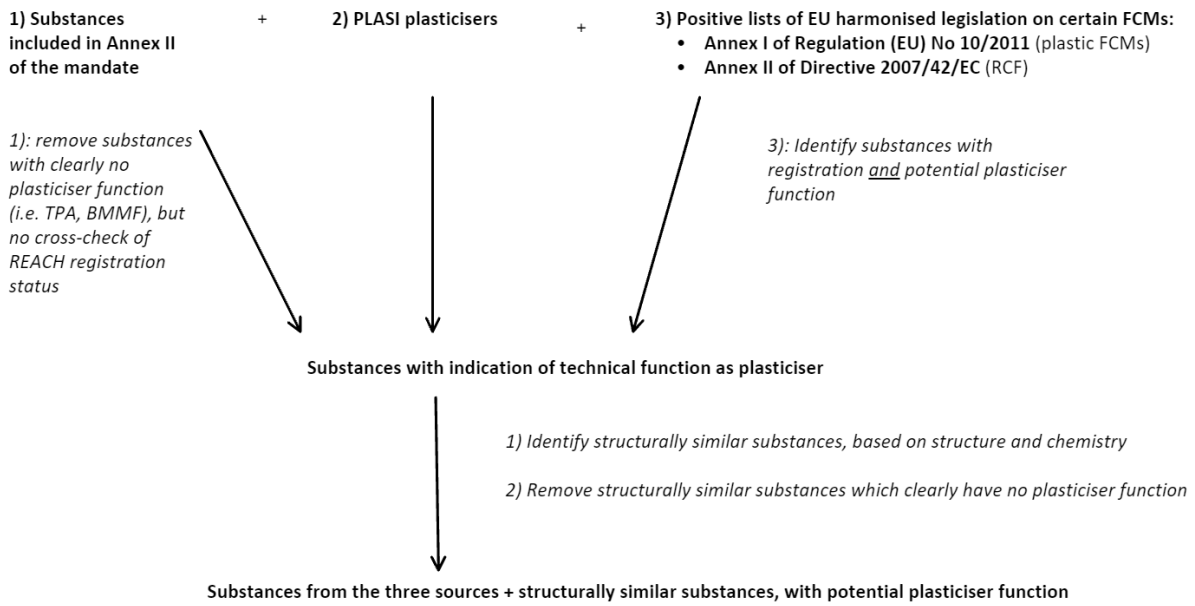

Figure 1. Building the pool of substances

[12] 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).

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

[14] 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.

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).

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.[15] 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[16] 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. Substances considered to have severe hazard properties for the purpose of this work 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)[17] and/or
- identified as having persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) or endocrine disrupting (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.[18]

Those classified were included in a separate group of substances with the above-listed hazard properties (hereafter referred to as the 'exclusion group'). This approach reflects the indications provided in the CSS regarding a 'generic approach to risk management' via which it is anticipated to act with priority on the most hazardous substances present in consumer products. The substances included in this group are suggested to be brought forward for risk

[15] Three Member States provided their responses to the consultation after 30 April 2021, and it was decided to also take these replies into account.
[16] 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.
[17] Further information on classification and inclusion of substances in Annex VI of CLP Regulation: https://echa.europa.eu/regulations/clp/legislation
[18] Further information on identification of substances of very high concern under REACH: https://echa.europa.eu/substances-of-very-high-concern-identification-explained

assessment only if, following the implementation of risk management measures in accordance with the CSS, consumers may be exposed due to the use of the substance(s) in FCMs.

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' was considered to allow for targeted risk management follow-up actions. Where the feedback from a Member State was such that: i) the respective national legislation makes a general statement on 'endorsing' the substances authorised by a harmonised measure; or ii) 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, that substance was only brought forward via the 'EU-authorised' stream. Substances brought forward via Member State consultation, and not found to be authorised in harmonised legislation, are proposed to follow the stream of nationally authorised substances.

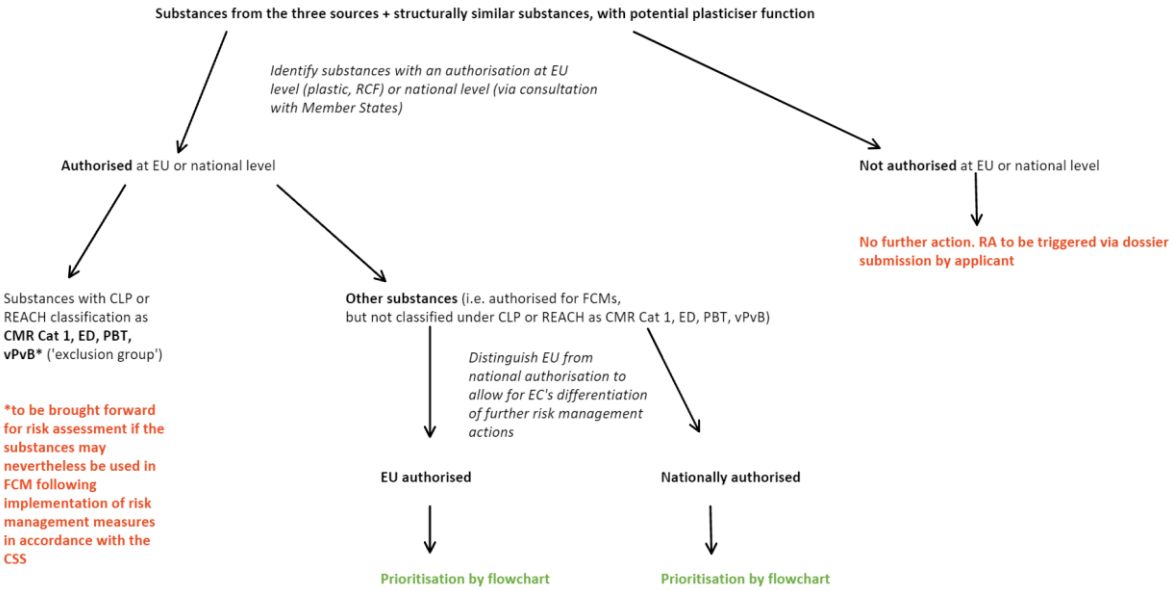

Figure 2. Categorisation of substances

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.

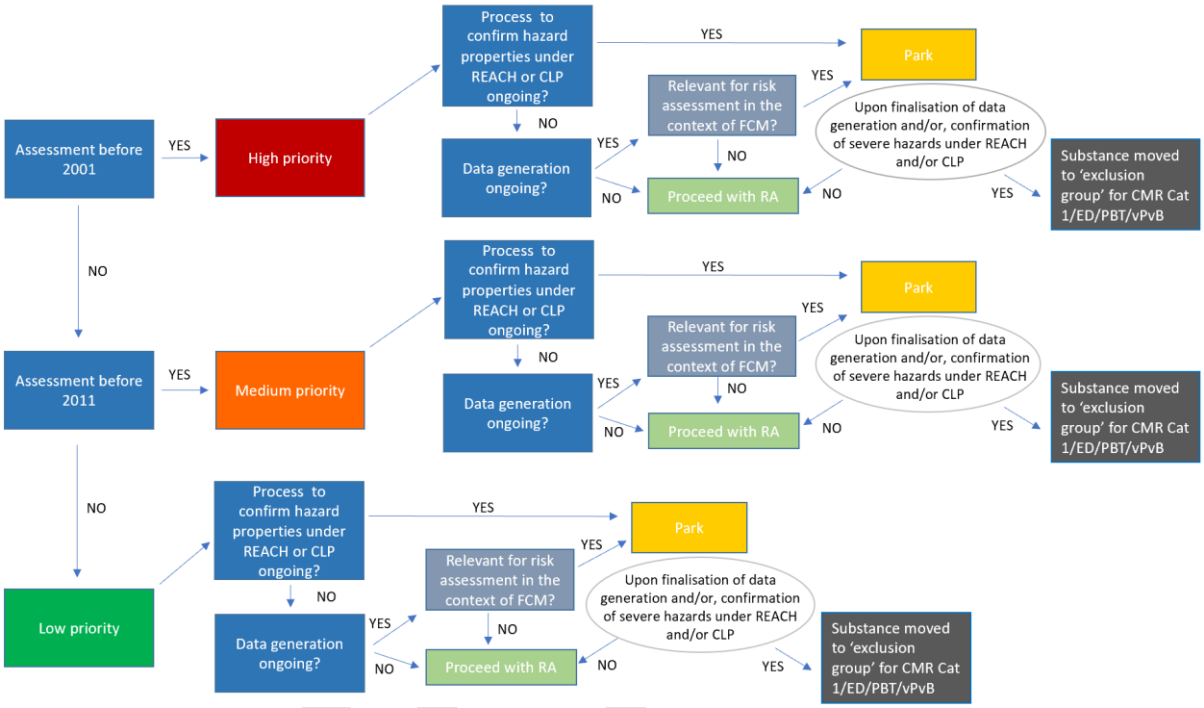

Figure 3. Decision tree for prioritisation

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 sub-group 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 EC 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 the substances may nevertheless be used in FCM following the implementation of risk management measures in accordance with the CSS (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.

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 by 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, as amended by Regulation (EU) No 2020/1245 of 2 September 2020), 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[19]
- EFSA's OpenFoodTox[20] (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

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

numbers) and provides, among other information, toxicological studies (systemic, developmental, reproductive, etc.) including 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 be 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.

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[21] 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.[22] Substances for which the data show

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

that they have PBT/vPvB or ED properties, can be identified as substances of very high concern (SVHCs) under REACH.[23]

The list of substances authorised at national or EU 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 pool of substances created according to the approach described in Section 2.1.1 consisted of 542 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, 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.

- **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

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

[24] CAS No 131-11-3; CAS No 84-74-2; CAS No 84-69-5; CAS No 85-68-7; CAS No 117-81-7; CAS No 28553-12-0; CAS No 26761-40-0; CAS No 84-61-7; CAS No 117-84-0; CAS No 84-66-2; CAS No 103-23-1; CAS No 109-43-3; CAS No 8013-07-8; CAS No 91082-17-6; CAS No 8042-47-5; Polyesters of adipic acid and of a mixture of 1,3-butanediol and 1,6-hexanediol (Mean MW > 1000); Polyesters of adipic acid and of a mixture of 1,3- and 1,4-butanediol for which hydroxyl groups are acetylated (Mean MW > 1000).

were not listed as such by EFSA and are authorised in France in rubber (French Order of the 5th of August 2020):

i. Phenyl esters of sulfonic acids (C12–C20);
ii. White mineral oils, paraffinic, derived from petroleum-based hydrocarbon feedstocks. CAS number 8042-47-5, FCM 95;
iii. Polyesters of adipic acid and of a mixture of 1,3-butanediol and 1,6-hexanediol (Mean MW > 1000);
iv. Polyesters of adipic acid and of a mixture of 1,3- and 1,4-butanediol for which hydroxyl groups are acetylated (Mean MW > 1000).

Substance i. 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(C 10-C 21)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 ii. was assigned to the EU stream as this was not previously included in the list of substances, but found to be represented by FCM 95. Although its chemical nature (saturated hydrocarbons) differs from the plasticisers in Annex II of the mandate and the PLASI plasticiser inventory, this substance is reported to be commonly used in the processing and softening of rubbers.

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

Substance iv. 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.

- 27 substances had been identified as potentially relevant in the initial list 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

[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 No 77-90-7, CAS No 84-74-2, CAS No 103-23-1, CAS No 110-30-5, CAS No 120-61-6, CAS No 1338-39-2, CAS No 1338-41-6, CAS No 6422-86-2, CAS No 8001-78-3, CAS No 8013-07-8, CAS No 8050-26-8, CAS No 8050-31-5, CAS No 9005-64-5, CAS No 9005-67-8, CAS No 31566-31-1, CAS No 85116-93-4, CAS No 84-61-7, CAS No 85408-76-0.
[27] CAS No 90218-76-1, CAS No 3319-31-1, CAS No 84-69-5, CAS No 110-27-0, CAS No 131-11-3, CAS No 627-93-0, CAS No 1119-40-0, CAS No 8047-99-2, CAS No 103-24-2.

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 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 initial list of substances and found to be covered by EU-harmonised legislation, the Panel decided to consider them under the EU-authorised stream.

The other 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 initial list 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

[28] CAS No 77-90-7, CAS No 8013-07-8, CAS No 166412-78-8, CAS No 736150-63-3, CAS No 103-23-1, CAS No 141-04-8, CAS No 105-99-7, CAS No 109-43-3, CAS No 84-61-7, CAS No 84-74-2, CAS No 85-68-7, CAS No 117-81-7, CAS No 26761-40-0, CAS No 28553-12-0, CAS No 1241-94-7, CAS No 25395-31-7, glycerol acetate, dihexyl azelate.
[29] CAS 144-15-0, CAS 84-66-2, CAS 84-69-5, CAS 117-84-0.

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 EU 'Plastics' Regulation 10/2011, are considered to be authorised in Spain not only for plastics but also for polymeric materials and articles more generally, including such as 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 specifically indicated in the list provided by Spain as having a national authorisation:

Three substances[30] in the draft pool of substances provided by EFSA 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 initial list 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') to the list, as a nationally authorised substance, although the substance seemed to already be on the list. Upon checking, it transpired that there is a contradiction for the substance EC# 246-941-2 since the EC name refers to glycerol 1,3-diacetate but another EC entry (EC# 203-323-7) exists for this specific isomer. The CAS No. 25395-31-7 that is associated with EC# 246-941-2, refers to glycerol diacetate with the isomers unspecified, and so both isomers (the 1,2- and the 1,3-diacetates) are included. Thus, the EC name for substance EC# 246-941-2 was considered inappropriate and the name diacetin is 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 out of the list of pre-identified substances shared with the Member States, 206 substances are authorised at their national level.

- 99 substances had already been identified as relevant in the initial list of substances and found to be covered by EU-harmonised legislation. Therefore, the Panel decided to consider them under the EU-authorised stream.
- 107 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 indicated by other Member States and they followed the agreed categorisation into the respective priority groups;
    - the remaining 36 substances entered the nationally authorised stream.

Overall, the feedback received during the Member State consultation resulted in the consideration of the three additional substances that already have an EU authorisation (FCM

[30] CAS No 8016-11-3, CAS No 84-66-2, CAS No 131-11-3.
[31] CAS No 102-76-1, CAS No 84-61-7.

884, FCM 95, FCM 73), while 50 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[32] as CMR Cat. 1 for reproductive toxicity and identified as EDs and 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 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, Netherlands). The other four substances had been identified in the initial list 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 initial list of substances, the feedback received during the Member State consultation and categorisation of four substances (DCHP, DBP, BBP, DEHP) into the exclusion group, 75 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, 49 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 75 substances of the EU-authorised stream, the prioritisation gave the distribution shown in Table 2. Seventeen 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.[33]

Table 2 Prioritisation of EU-authorised substances

Priority group		Number of substances
High	Proposed for risk assessment	45

[32] The classification status was last checked on 24 September 2021.
[33] The status of data generation and processes of confirmation of severe hazard properties was last checked on 24 September 2021.

		(39 individual substances; 6 group entries covering in total 49 substances → 32 substances with 2 FCM Nos)
	Parked	13
Medium	Proposed for risk assessment	11 (8 individual substances; 3 group entries covering in total 102 individual substances)
	Parked	3
Low	Proposed for risk assessment	2 (2 group entries covering in total 4 substances)
	Parked	1

3.2.2 National stream

Applying the approach described under Section 2.2.1 to the 49 substances of the nationally authorised stream, the prioritisation gave the distribution shown in Table 3. Six 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. [34]

Table 3 Prioritisation of nationally authorised substances

Priority group		**Number of substances**
High	Proposed for risk assessment	38 (1 – ES/NL, 1 – DE/NL, 2 –IT/NL/, 1 – IT/ES, 1 – FR, 1 – DE, 31 – NL)
	Parked	5 (NL)
Medium	Proposed for risk assessment	3 (2 – DE, 1 – ES/DE)
	Parked	0
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

[34] The status of data generation and processes of confirmation of severe hazard properties was last checked on 24 September 2021.

the EU stream, the 75 listed substances split 58, 14 and 3 into the high-, medium- and low-priority groups, respectively. For the nationally authorised stream, the split of the 49 substances was 43, 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/ranking of substances within 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 (in terms of priority for risk assessment) that substance will be ranked. 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 of a substance 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, and 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/authorisation 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 FCM

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)[35] 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[36]. 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 if usage or occurrence data are available for any substance not currently captured (low impact).

- Focus on the EU

For FCMs 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 the FCMs are used in food production and processing in non-EU countries and the foods then exported to the EU (low impact).

- Limitation of not considering 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). The choice of 2011 is conventional and was chosen to divide the time period by decades, although it does coincide with the date of the plastics Regulation. It is not supported by any other specific publications (guidelines or regulations) on non-plastics 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

[35] 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.

[36] 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.

reported/adopted an existing list from older documents without assessing the substance or the group of substances. Consequently, the actual date of last 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 ED properties for environment. This may unnecessarily delay the evaluation of such substances if the ED property is not confirmed. In addition, for 4 substances dossier or substance evaluation under REACH is ongoing (including the earlier mentioned substance with ongoing data generation for ED properties for environment), 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 3-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 very 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 initial list of 542 substances, only substances authorised for FCM at EU or national levels 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 the substances may nevertheless be used in FCM following the implementation of risk management measures in accordance with the CSS (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 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.

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

For the EU stream, the 75 listed substances split 58, 14 and 3 into the high-, medium- and low-priority groups, respectively. For the nationally authorised stream, the split of the 49 substances was 43, 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 and 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/authorisation of the substances.

When developing the follow-up mandates for risk assessment, the Panel recommends the EC 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.

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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 EC

Table A1.

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)	249-079-5 271-090-9	28553-12-0 68515-48-0	728
DIDP (Di-isodecyl-phthalate)	247-977-1 271-091-4	26761-40-0 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
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.

Abbreviations and acronyms

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

GMT	Group Management Team
OSOA	one substance, one assessment
PBT	persistent, bioaccumulative and toxic
RA	Risk assessment
RCF	regenerated cellulose film
REACH	Registration, evaluation, authorisation and restriction of chemicals
SCF	Scientific Committee on Food
SVHC	substance of very high concern
vPvB	very persistent, very bioaccumulative

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

See the attached excel file.