Annex to:

EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP), Lambré C, Barat Baviera JM, Bolognesi C, Chesson A, Cocconcelli PS, Crebelli R, Gott DM, Grob K, Lampi E, Mengelers M, Mortensen A, Rivière F, 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 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. doi: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

No.	Name/Organisation and Country	Section Title	Comments (incl. attachments)	Response
1	Anonymous, Spain	Abstract	Please find information in Appendix A - list of substances identified as potential plasticisers on the plastisicers used in inks for printing FCM.	Further details were provided in comment 41 and the corresponding EFSA reply is provided there.
2	Anonymous	Abstract	hgfdrse	Comment and attached document are not relevant.
3	French Agency for Food, Environmental and Occupational Health & Safety (ANSES), France	Abstract	It could be useful to clearly defined what a plasticiser is	This is a useful suggestion. It does not seem appropriate for an abstract and there is no legal definition of a plasticiser substance in food contact materials (FCMs), but some clarifying text has been added to the Section 1.2 on *Interpretation of the Terms of Reference*.

4	Cefic – European Plasticisers, Belgium	Abstract	Title of report L8 refers to "plasticisers" – it would appear that many of the substances are not in fact plasticisers. Also L17/L19/L23/L40 "plasticisers" is used.	Within the scope of this Opinion are substances used as plasticisers or that plausibly could be used as (replacement) plasticisers. Please see also the response to comment 3.
			L16 states "re-evaluate" – for some substances in the original list in the DG Sante mandate this would be a first evaluation.	It is noted that the terminology used came as part of the mandate (incl. Annex with preliminary list of substances) received from the European Commission (EC). As some substances on the original list provided by the EC appear to not be authorised in plastic FCM, it would indeed not be a re-evaluation. However, the methodology developed for identifying and prioritising substances was limited to the authorised substances only (either at EU or at national level). Therefore, the substances eventually included in scope have all been assessed previously in the context of FCMs (either by EFSA, SCF or at national level), and therefore it is appropriate to use the terminology 're-evaluation'.
			L26-30 states that five substances classified as CMR or ED or PBT/vPvB were placed into an exclusion group. Such an approach is inconsistent with the 1) the general risk assessment approach which EFSA has taken for many years with respect to food contact materials 2) the most recent	According to its founding regulation (EC 178/2002, chapter III) the mission and tasks of EFSA is to provide scientific advice, and scientific and technical support for the Community [Union] legislation and policies in all fields which have a direct or indirect impact on food and feed safety.

			temporary opinion of 2019 of EFSA which concluded that the use of four of the five substances in food contact poses no public health risk and 3) most recent discussions during the EFSA Scientific Committee in June 2021 (where observers were allowed to participate), and where clear statements in continued support of risk assessment were made by members of the EFSA Scientific Committee including taking into account the European Commission CSS. It would therefore seem inappropriate to create an "exclusion group" in the context of a plasticisers assessment when other non-plasticiser substances may also be impacted and without further assessment and discussion with EFSA including the EFSA Scientific Committee. This approach also appears to be contradictory to the purpose of the new mandate which includes doing further assessment of DEHP, DBP and BBP and move the temporary opinion to a more final opinion for these substances.	This advice and support are given principally via the production of opinions and technical reports. These documents are mostly in the form of risk assessments of substances as per the legal requirements for regulated substances or following a request by the EC in line with the relevant legislation. EFSA's output is then made publicly available. Thus, the two missions, risk management and risk assessment are clearly separated, under the responsibility of the EC and EFSA, respectively. In the case of regulated substances such as Food Contact Materials, risk assessments are carried out according to a methodology elaborated by EFSA, which sets out the general approach for risk assessment of substances to be used in FCMs (EFSA CEF Panel, 2008). The EU's Chemicals Strategy for Sustainability (CSS; EC, 2020) commits to the use of a generic risk approach (GRA) for certain hazard classes of substances in FCM, namely CMRs, EDs and PBTs/ vPvBs. This approach is already established in other chemicals legislation and depends primarily on the hazardous properties of a substance. Whilst the implementation of the GRA is still subject to consultation as part of the revision of the FCM legislation, the approach taken by the EFSA Scientific Committee, in consultation with the EC, is consistent with the commitment already given in the CSS (EC, 2020). However, this does not prejudice future risk assessment work on any of the

			L30-36 – it is noted that the prioritization at this stage is very basic re: data of FCM evaluation but that the outcome of the follow-up calls for data in support of exposure assessment will be used for a final ranking. Should degree and nature of hazard/potential concern based on data not be used also for a final ranking?	substances included in the exclusion group, should the need arise, for example in cases where such substances may continue to be used in accordance with the essential use concept, once this concept is also implemented. Indeed, it is foreseen to use data provided during the calls for data on occurrence in food and FCMs for the final ranking as such information can give a first indication of possible exposure (e.g. if no information are received, this could indicate that the substance is not used anymore). Regarding the use of hazard data for the prioritisation, it is considered that such an approach would require a careful review of the data (in case readily available); this would be part of the risk assessment and is therefore not in scope of the prioritisation exercise.
5	Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT), Great Britain	Background from the mandate letter	1.1 (lines 146-148) The COT were unclear whether the reference to a hazard assessment protocol in the terms of references was a proposed third document or included within the identification and prioritisation of chemicals. If the latter, little information had been added since the main EFSA discussion of phthalates in 2019.	In section 2 (interpretation of ToR) it had been mentioned that the scientific opinion only relates to identification and prioritisation of substances. The protocol for hazard assessment (https://open.efsa.europa.eu/questions/EFSA-Q-2021-00593) will be published as a separate document, which is currently under development. Footnote 5 of the scientific opinion has been expanded to clarify which additional outputs will be published as separate documents.

6	CHEM Trust, Germany	1 Introduction	CHEM Trust supports efforts to address the risks from phthalates in FCM use. A recent ´review of reviews´ summarized epidemiological studies that explore human health outcomes associated with exposure to phthalates. This publication emphasizes the important implications for policy to identify and control health related impacts from phthalate plasticisers. The findings are also of particular concern given the potential for mixture effects from combined exposures. Reference: Eales, J. et al. (2021). "Human health impacts of exposure to phthalate plasticizers: An overview of reviews." Environment International. DOI: 10.1016/j.envint.2021.106903 CHEM Trust also agrees with the need to focus on groups of structurally similar substances and welcomes the collaboration between EFSA and ECHA to strive and make assessments more effective.	Thank you for these supportive comments and for providing the recent reference which may be considered in the next steps.
7	CHEM Trust, Germany	1.2 Interpretation of the Terms of Reference	Line 203 This interpretation seems to suggest that only CMRs Cat 1 would fall under the generic approach to risk management. The sentence needs to be expanded to also mention CMRs cat 2. It also misses out to mention substances identified as SVHCs under REACH to include EDCs and persistent and bioaccumulative chemicals. (The latter are later correctly included in lines 299-302 as part of the exclusion group	The implementation of the GRA approach for CMRs, EDs and PBTs/ vPvBs referred to in the CSS (EC, 2020) is still subject to consultation as part of the revision of the FCM legislation. The approach taken by the CEP Panel to include CMR Cat 1 is intentional and pragmatic insofar as these classes and categories of substances have already been formally identified in accordance with EU legislation (Regulation (EC) 1272/2008) as being known or presumed to possess these hazardous properties relevant for humans. Furthermore, the text in the opinion was modified, to make it clear that PBT/vPvB and ED substances are included.

				The implementation of the GRA approach will be considered and consulted on by the EC as part of its revision of the FCM legislation (https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12497-Revision-of-EU-rules-on-food-contact-materials_en), including Cat 2 substances as well as substances that may be ED or PBT/ vPvB, taking into account relevant initiatives including the revision of Regulation (EC) 1272/2008, which aims to address classification of EDs and PBTs/ vPvBs. The outcome of the revision of the FCM legislation and approaches therein will be taken into account in the subsequent steps of addressing the mandate, once these approaches are agreed.
8	Cefic – European Plasticisers, Belgium	1.2 Interpretation of the Terms of Reference	Again plasticisers are referred to but many of the substances in Annex II are not plasticisers e.g. L104 refers to plasticisers. Please see Annex II for the list of substances which are and are not plasticisers as understood by European Plasticisers. L197-205 refers to the "generic approach to risk management" for the most harmful chemicals. This we understand in fact as "hazard based substitution" and would be contrary to the long standing commitment of EFSA to risk assessment as well as to the OSOA principle, which EFSA is committed to put into practice using phthalates as a pilot example. Adoption of the "generic approach to risk management" i.e. hazard	See response to comment 42. See response to comment 4.

			based substitution would appear to be contrary to the views of the EFSA scientific committee on risk assessment as expressed at their meeting in June 2021 i.e. including specific exposure assessment with establishment of TDIs and comparison of estimated exposure to the TDI. It would seem premature to adopt such an approach re: generic risk management via an assessment on plasticisers before more extensive discussion within EFSA. L203-205-it is positive to note that the report clearly refers to the CLP in defining CMR adverse effects with formal classification i.e. clear and unambiguous identification of adverse effects.	Thank you for the supportive comment.
9	FCA, Food Contact Additives Sector Group of Cefic (European Chemical Industry Council), Belgium	1.2 Interpretation of the Terms of Reference	Food Contact Additives (FCA), a Sector Group of the European Chemical Industry Council (Cefic), welcomes the opportunity to provide input to EFSA's public consultation on the above-mentioned EFSA draft opinion. As the present exercise aims at piloting the "One-Substance, One-Assessment" approach under the Chemicals Strategy for Sustainability, our contribution focuses on specific overarching principles outlined in the draft opinion. For more comprehensive input, FCA highlights the submission of European Plasticisers (a Cefic Sector Group). FCA welcomes the overall approach being envisaged in the present pilot project, by which an FCM-specific risk	Thank you for the supportive comment.

			assessment is aimed at being carried out. (Lines in the EFSA draft opinion: 160-212)	
10	Marike Kolossa-Gehring, HBM4EU coordinator (Submission on Personal Capacity), Germany	2 Data and Methodologies	Please see the uploaded file "HBM4EU_EFSA-PC-0097-chapter2" From the attachment: **Feedback from HBM4EU** With regard to human biomonitoring we would like to refer to the European Human Biomonitoring Initiative HBM4EU (2017 – 2021) which aims at coordinating and advancing human biomonitoring in Europe in order to assess human exposure to chemicals in Europe in a harmonised way, to better understand the associated health impacts and to improve chemical risk assessment. The initiative focuses on human internal exposure from a variety of exposure sources. In prioritising and providing HBM data, there may be overlap between the initiative and the regulatory requirements. The strategy for the prioritisation of substances within three	These are statements which do not seem to need a response.

			HBM4EU rounds was developed according to Ougier et al. (2021). Within the framework of HBM4EU, as well plasticisers, i.e. phthalates and substitutes, including those that may be contained in FCMs, have been investigated. *2 Data and Methodologies* *2.1 Identification of substances, pp 8-11; Annex A* *(also 3.1.3 Exclusion group, p 19)* From the point of view of HBM4EU, the EFSA **identification and categorisation strategy** seems comprehensible and commensurate with regulatory resources, e.g. by excluding reprotoxic phthalates currently approved for FCM but to be substituted, i.e. substances such as dibutylphthalate (DnBP), benzylbutylphthalate (BBzP), di(2-ethylhexyl)phthalate (DEHP) ("CMR-group").	Thank you for the supportive comment.

			2.2 Prioritisation of substances, pp11-14 (2.2.1 Methodology, 2.2.2 Date of assessment); Annex A *(also 3.1.4 EU/national substances for prioritisation, p19)* From the substances approved for FCM at EU level and which are included in the EFSA **prioritisation strategy**, the two phthalates di-isononylphthalate (DINP), di-isodecylphthalate (DIDP) and the two phthalate substitutes 1,2-cyclohexane dicarboxylic acid diisononyl ester (DINCH) and bis (2-ethylhexyl) terephthalate (DEHTP) were also addressed in HBM4EU. We would like to draw attention to the fact that the as well for FCM approved **phthalates DINP and DIDP** are in the current EFSA strategy classified with low priority ("low-RA") due to a current EFSA risk assessment (EFSA 2019)[1], although EFSA explicitly stated that the risk assessment was not yet complete. There might be other endpoints more sensitive than liver toxicity selected for the	It is hard to justify why these 2 substances (DINP and DIDP) should be given a higher priority at this stage compared to other substances for which the tox data base may be incomplete and there may be other endpoints more sensitive. Additionally, the EC may decide on different priorities in case of new toxicity/exposure/epidemiological data emerging. Also, the possibility of a further refinement of the ranking of substances within and between the priority groups is provided for (section 3.3, 2nd paragraph) depending on the outcome of the calls for data in support of the exposure assessment. This would apply not only to DINP and DIDP, but also to DINCH and DEHTP.

[1] Update of the risk assessment of di-butylphthalate (DBP),butyl-benzyl-phthalate (BBP), bis(2-ethylhexyl)phthalate(DEHP), di-isononylphthalate (DINP) and di-isodecylphthala te (DIDP) for use in food contact materials. Scientific Opinion. Food Safety Authority. EFSA Journal 2019;17(12):5838. https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5838

			assessment as well as a contribution to additive effects. Thus, we would recommend a higher prioritization level for DINP and DIDP. The **phthalate substitutes DINCH and DEHTP** are assigned with priority "medium-RA" in the EFSA strategy. As a compilation of CMR-group and substitute plasticizer HBM exposure data from the population representative German Environmental Survey (GerES) and the Environmental Specimen Bank demonstrates the co-exposure and the constant overall levels of plasticisers in the body (Lemke et al. 2021), in general a higher priority of phthalate substitutes for risk assessment should be considered. **References** Ougier E, Ganzleben C, Lecoq P, Bessems J, David M, Schoeters G, Lange R, Meslin M, Uhl M, Kolossa-Gehring M, Rouselle C, Lobo Vicente J. Chemical priorisation strategy in the European Human Biomonitoring Initiative (HBM4EU) – Developments and results. International Journal of Hygiene and Environmental Health. 2021;236.	

			https://doi.org/10.1016/j.ijheh.2021.113778 Lemke A, Murawski A, Lange R, Weber T, Apel P, Dębiak M, Koch H M., Kolossa-Gehring M. Substitutes mimic the exposure behaviour of REACH regulated phthalates – A review of the German HBM system on the example of plasticizers. International Journal of Hygiene and Environmental Health. 2021; 236. https://doi.org/10.1016/j.ijheh.2021.113780	
11	French Agency for Food, Environmental and Occupational Health & Safety (ANSES), France	2.1 Identification of substances	1) The prioritisation focus only on previously evaluated/authorised substances. Could Efsa panel explain why non-evaluated / non-authorised plasticisers were not considered? 2) As some phthalates are currently classified as Repr. 1B, there are progressively substituted by other phthalates or plasticiser that may not be currently registered under Reach. However their tonnages may highly increase in the	1) The identification of potentially relevant substances and their subsequent prioritisation indeed focus on substances already authorised (and consequently evaluated) for use in FCMs. For other substances that are not yet authorised but are used/of interest for industry, a respective application for safety assessment shall be submitted to the responsible institution(s) (i.e. EFSA for EU-harmonised FCMs, e.g. plastic; and national institutions depending on the provisions made at MS level). 2) Following the rationale provided under bullet point 1, in order for a substance to be used for FCMs, it first needs an authorisation. The prioritisation exercise represents a snapshot of potentially relevant (as authorised and mostly registered) substances at a given timepoint, therefore without

			next few years. Thus, exclusion of non registered plasticisers under Reach regulation may not allow to identify these new substances.	anticipation of future developments. However, the focus on registered substances can be rationalised with the commercial viability of these substances at this point in time. In the case of non-registered substances, no information on substance properties and uses would be available, and therefore no meaningful evaluation could be conducted. Based on this rationale (i.e. no registration = no commercial viability), some substances have not been considered for the pool of substances, although they are authorised for use in FCMs: By way of example, dihexyl azelate (CAS 109-31-9) is authorised but not registered.
			3) The ESCO list is not used to identify the plasticisers. Could Efsa panel explain why this list was not considered?	3) i) The ESCO list is for non-plastic Food Contact Materials. Seven non-plastic material categories were covered and so substances used in plastics are not included. Any plasticiser used exclusively in plastics and not in one or more of the seven non-plastic FCM categories, would not be captured in the ESCO list. ii) The ESCO list was based on an inventory of the evaluations carried out in Member States, Switzerland and Norway. This inventory was finalised in 2011 with the report of the ECSO activity. iii) The ECSO list does not assign a technical function to the ca. 2800 entries in the list and so a plasticiser function is not pin-pointed. For these three reasons it was decided to consult with Members States for this specific task on

				plasticisers and in this way the approach of ESCO was mirrored and refreshed.
12	Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT), Great Britain	2.1 Identification of substances	The COT noted that the current work was undertaken in collaboration with ECHA as part of EFSA's chemical sustainability strategy and that both organisations have moved some of the low-molecular weight phthalates into an exclusion category. This appeared in line with the ongoing work of one chemical one assessment and the intention to remove these compounds from the food chain, unless beneficial to FCMs.	Thank you for this supportive statement.
13	FCA, Food Contact Additives Sector Group of Cefic (European Chemical Industry Council), Belgium	2.1 Identification of substances	The draft opinion states: "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". It should be underlined that for the envisaged grouping approach there is a risk of identifying substances as plasticisers for FCMs that are not actually used as plasticisers in food contact applications. FCA stresses that overall, any grouping attempt of substances must consider risk and hazard profiles, in addition to structural similarity. Structural similarity on its own cannot be conclusive;	The possibility that some substances identified may not be used as plasticisers in food contact applications has been anticipated in the document with the resulting emphasis on the calls for occurrence data to help inform the final ranking and the choice of substance(s) by the EC to be put forward for risk assessment. The second part of this comment and the reference provided, deals with grouping of substances as a tool in chemical hazard assessment. The aim of the grouping approach applied in the context of this first phase of the mandate (i.e. identification and prioritisation) was only to identify potential plasticisers. The outcome of this grouping was not intended to be used directly for hazard assessment of prioritised substances, and it does not prejudge

			structurally similar chemicals may have different toxicological, ecotoxicological, physico-chemical and toxico-kinetic properties. In addition, substances with a similar family name or similar chemical backbone may not necessarily present the same potential concern of relevance for a FCM risk assessment. For further details we would like to refer to Cefic position paper on grouping of substances (https://cefic.org/app/uploads/2021/06/Cefic-views-on-grouping-of-substances.pdf) Lines in the EFSA draft opinion: 215-323	any possibility for read-across. The text in section 2.1.1 has been amended to make this clearer. Indeed, any grouping for the purpose of hazard/risk assessment must consider also toxicological, ecotoxicological, physico-chemical and toxico-kinetic properties of the substances and this will be considered, where appropriate, during the risk assessment phase.
14	Food Packaging Forum, Switzerland	2.1.1 Building the pool of substances	Several chemicals were excluded from the prioritization due to them "not expected to function as a plasticizer based on their chemical nature" (2.1.1, line 253) Excluding chemicals from a prioritization must be well documented and clearly argued. This is not the case here: no list of which chemicals were excluded is provided, nor are the detailed criteria for their exclusion described. It is therefore recommended that the functionality of a plasticiser is described in detail, and the related chemical properties are listed in detail, or a reference is provided where this expert information can be obtained. In addition, the excluded substances shall be listed. Including all of this information will best serve EFSA's ambition of transparency.	New text has been added to the section on 'Interpretation of the ToR' to help better define what is considered to be within the scope of the Opinion vis-à-vis 'Plasticisers'. The full list of excluded substances is not available due to confidentiality considerations on some information supplied by interested business operators to ECHA as part of the registration process. Specific examples of excluded substances have been provided in Section 2.1.1.

15	Cefic – European Plasticisers, Belgium	2.1.1 Building the pool of substances	L217. Not all substances in Annex II are plasticisers. L218 Not all of the substances in the mandate Appendix A, Table A1 are plasticisers. See comments on Annex II. L228-239- Plasticisers from a chemical structure perspective are organic esters (i.e. a combination of an acid and an alcohol). Organic esters are also naturally abundant in nature. L242 773 substances were identified as plasticisers using the approach outlined while the final pool of substances was reduced to 543 and the prioritization list counts 124 substances. The pool of substances under consideration is still large considering that about 50 substances are commercial REACH registered plasticisers. Further prioritization will take place after collection of exposure and hazard data and the 124 substances are all granted with a FCM authorisation at EU or national level, according to the report. This suggests there are substances used only in food contact which may or may not be plasticisers, as well as substances which may be authorized but which are no longer used.	A similar comment was made elsewhere. Please see the responses to comments 3 and 4. It needs to be noted that the refinement of the ranking will be based on the calls for data on uses and occurrence, and hazard data will not be collected at that stage (see also reply to comment 4). As specifically regards substances that are authorised, but no longer used, please see the response to comment 11, where this issue of commercial viability is dealt with (incl. an example of a substance falling into this category).

16	Food Packaging Forum, Switzerland	2.1.2 Categorisation of substances	Unclear recommendation for the exclusion group of chemicals with severe hazard properties According to the CSS, the prioritization of chemicals for further assessment and phasing out should be based on their hazard properties, as is also outlined in the toxic-free hierarchy for chemicals management (CSS, p.4). The purpose for this approach is to minimize substances of concern in products (CSS, p.6). The CSS states explicitly that, due to its implementation, "consumer products do not contain chemicals that cause cancers" and other detrimental health effects (CSS, p.10). Therefore, for achieving this purpose, a "generic approach to risk management" is required, as the regulation on a case-by-case has not delivered. This failure of chemical risk assessment on a case-by-case basis is especially apparent for the five phthalates addressed in this Scientific Opinion, four of which are being found in humans (including vulnerable population groups) at levels well below regulatory "safe" exposure thresholds (Maffini et al. 2021), but these low-level phthalate exposures are robustly linked to adverse health outcomes in humans, such as cardiovascular disease, neurological disorders, asthma and breast/uterine cancers (Eales et al. 2021; Trasande et al. 2021). As consequence, the use of these four phthalates should be discontinued in food contact materials (FCMs), and their	The practical implementation of the CSS concepts (EC, 2020), including the generic approach to risk management, is with the EC's remit, as is the decision on granting or revoking the authorisation of a substances for a certain use. Therefore, EFSA as risk assessment body cannot decide on the ban of substances and consequently, such an approach is not discussed in the opinion.

			presence as non-intentionally added substances in FCMs should be further investigated and minimized accordingly. However, a clear recommendation to this effect is absent from the Scientific Opinion. While the phthalates in question have indeed been grouped as "exclusion group", the logical consequence of a ban is not explicitly mentioned. Indeed, such an approach focused on exposure, not hazard, is not aligned with the CSS.	
17	CHEM Trust, Germany	2.1.2 Categorisation of substances	Line 307-309 The following statement could be misunderstood and may be reformulated: "The substances included in this group are suggested to be brought forward for risk 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." As the CSS states on page 10: `The Commission will extend the generic approach to risk management to ensure that consumer products do not contain chemicals that cause cancers, gene mutations, affect the reproductive or the	On page 10 of the CSS (EC, 2020), is indicated the following: "*Extending the generic approach will ensure that consumers, vulnerable groups and the natural environment are more consistently protected, while still allowing for the use of these most harmful chemicals where proven essential for society. The criteria for essential uses of these chemicals will have to be properly defined to ensure coherent application across EU legislation, and will in particular take into consideration the needs for achieving the green and digital transition*.". Additionally, the CSS states (in the box, page 10) that: "*the Commission will define criteria for*

			endocrine system, or are persistent and bioaccumulative.´ This means the use of substances with these properties will be excluded also from food contact materials.	*essential uses to ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health. These criteria will guide the application of essential uses in all relevant EU legislation for both generic and specific risk assessments*". The text of the opinion was updated to make it clearer.
18	French Agency for Food, Environmental and Occupational Health & Safety (ANSES), France	2.1.2 Categorisation of substances	1) lines 288-289 : we understand that in the remit of the CEP Panel, substances for which no authorisation was identified were set aside and not brought forward to the next steps. However, could EFSA consider to put this list of substances in the remit of the CONTAM Panel for further consideration?	As explained in reply to comment 11, the methodology developed for identification and prioritisation takes into account those substances, which are already authorised for use in FCMs at the moment of the prioritisation exercise. Substances that are neither authorised nor subject to a derogation cannot be legally used in the context of FCMs, and in the context of the prioritisation exercise, it was not foreseen to investigate on other uses. Without such information it would seem premature to consider all non-authorised substances as contaminants. Evaluation of substances present as adventitious contamination in the context of the CONTAM Panel can be further investigated in discussion with risk managers where such a need may arise [e.g. where their presence is linked to environmental contamination rather than migration from FCM].
19	Committee on Toxicity of Chemicals in Food, Consumer Products and the	2.1.2 Categorisation of substances	The COT highlighted the difficulties of grouping phthalates for hazard assessment purposes, given that reproductive toxicity was not the main toxicological outcome for all substances (i.e. DIMP and DIPP). Oher compounds with different toxicities have	This opinion is not intended to assess the toxicity of phthalates, but to identify – more generally – plasticisers used in FCMs and to prioritise them for further risk assessment. The protocol for hazard assessment (https://open.efsa.europa.eu/questions/EFSA-Q-2021-00593) is currently under development and

	Environment (COT), Great Britain		yet to be assessed, including some higher molecular weight phthalates.	will be published as a separate document (see also response to comment 5) The purpose and the character of the grouping approach used was also explained in response to comment 13.
20	Cefic – European Plasticisers, Belgium	2.1.2 Categorisation of substances	L292-309 Hazard is indeed being used for prioritization with CMRs/EDs/PBT/vPvB being identified and placed in an exclusion group and with reference to "generic approach to risk management" i.e. hazard based substitution. Please see prior comments on EFSA long-standing practice on risk assessment and the stated views of members of the EFSA Scientific Committee(June 2021). L309-Re: consumers being exposed due to the use of the substance(s) in FCMs, we note DEHP and other LMW phthalates are being used still widely outside the EU in both FCMs and non-FCM applications. Imported packaged foods may possibly be packaged with material made using DEHP and other LMW phthalates including LMW SVHC (CMR/ED) phthalates which are used at very low levels as chain transfer agents, which can be considered as process aids (and not necessarily as substances permitted for use in FCMs) with minimal amounts being present in final plastics packaging.	See answer to comment 4. This is a statement that does not seem to need a direct response. As a reminder, in parallel with this Opinion and in response to the terms of reference, a Protocol for assessing exposure of consumers to the prioritised substances has been developed (EFSA-Q-2021-00592; EFSA et al., 2022) and was the subject of a public consultation exercise. With regards to other uses at levels lower than classical plasticisers, it should be noted that there will be a call for data on use and use levels in FCMs.

21	Food Packaging Forum, Switzerland	2.2 Prioritisation of substances	Chemicals were prioritised based on the date of their risk assessment, not on their hazard properties. The Scientific Opinion states that "The first prioritization criterion is the date of assessment of the substance" (2.2.1, line 331). In line with the CSS, a first prioritization criterion should be based on chemical hazard properties alone, and not on any other aspect. The chosen approach does not agree with what is laid out in the CSS. Indeed, compiling hazard properties for some hundred chemicals is a feasible task for an expert, and achievable in a reasonable time frame. These hazard data should then be used as starting point for identifying the most hazardous chemicals which can then be prioritized further, for example by selecting those for which a risk assessment was done before 2001. Systematic methodologies for a hazard-based prioritisation approach should be applied and are already published in the scientific literature (Groh et al. 2021 https://doi.org/10.1016/j.envint.2020.106225). Importantly, this effort would also highlight for which chemicals no relevant hazard data are available, which would lead to another group of substances requiring further investigation.	It should be noted that by the introduction of an 'exclusion group', the developed identification and prioritisation methodology already covers some hazard-focused aspects of the CSS (EC, 2020). The exclusion group gathers substances that are CMR Cat 1, PBT/vPvB or ED, which – following the generic approach to risk management – shall not be contained anymore in consumer products (incl. FCMs). A risk assessment of such substances would be required only if, following the implementation of risk management measures in accordance with the CSS (such as on the basis of a claim for essential use), the substances could still be considered for use in FCMs (see also replies to comments 7 and 17 as well as section 2.1.2 of the scientific opinion). After having set aside the substances with severe hazards, the first prioritisation criterion was then based on the date of risk assessment, with 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. Regarding the consideration of hazard properties, it needs to be noted that this cannot only be done through a simple compilation of the data. As mentioned in reply to comment 4, it would require a careful review of the data (in case readily available); this would be part of the risk assessment and is therefore not in scope of the prioritisation exercise. New text has been added to section 2.2.1 to make this clearer.

				As outlined in the scientific opinion, a refinement of the final ranking of substances will be elaborated by taking into account data on actual presence/use of substances in food/FCMs (provided during calls for data), as first indication of exposure.
22	French Agency for Food, Environmental and Occupational Health & Safety (ANSES), France	2.2 Prioritisation of substances	1) FCM hazard identification is based on a tiered approach. The higher the migration into food, the greater the amount of toxicological data is required. Could Efsa panel explain why migration or at least the range of plasticisers usage level in FCM formulation were not used for the prioritisation process? Could Efsa consider to conduct the final ranking to identify substances for risk assessment with inclusion of criteria based on the toxicity and exposure to the substance, not only on the use of the substances and the date of previous assessment?	1) regarding the use of migration data or usage information for the purpose of prioritisation, it needs to be noted that such information is not readily available, especially considering the wide range of materials covered in the prioritisation exercise (i.e. not only plastics, but also rubber, adhesives, etc.). In order to gather such information, which will indeed be essential for the final risk assessment(s), a targeted ad-hoc call for data will be launched, allowing data providers to submit data on occurrence in and migration from FCMs. Through a separate call for data, information on occurrence in food will be gathered. As outlined in the opinion, it is foreseen to use data provided during these calls for data for a final ranking of the substances as such information can give a first indication of possible exposure (e.g. if no information are received, this could indicate that the substance is not used anymore). Regarding the inclusion of criteria based on the toxicity, the commenter is kindly referred to

			2) Could Efsa consider to introduce an additional criteria for prioritisation to take into account the availability of toxicity data to conduct a risk assessment ? Data with relevant toxicity data for a risk assessment would be included for the next steps. Substances for which these data are lacking would be parked and a call for toxicity data would be open.	comments 4 and 21 (where similar issues were brought up) and the respective answers. 2) As mentioned in reply to comment 21, a simple compilation of available hazard data would not be sufficient. Such an approach would require a careful review of the data (in case readily available); this would be part of the risk assessment and is therefore not in scope of the prioritisation exercise. A protocol for hazard assessment (https://open.efsa.europa.eu/questions/EFSA-Q-2021-00593) is currently under development as a separate document, and it will outline criteria for retrieving and evaluating toxicity data.
23	Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT), Great Britain	2.2 Prioritisation of substances	(lines 331-344) The COT noted that EFSA based its current prioritisation list on the previous assessment date of phthalates, which appears logical. However, as some of these compounds are currently undergoing further assessment by ECHA, The COT noted that additional data with a focus on genotoxicity and reproductive effects may be forthcoming to assist with prioritisation.	Hazard data were not taken into account during the prioritisation phase (see comments 4, 21, 22), but will be considered in the second, risk assessment phase of this EC request. In the methodology developed for this process of prioritisation, the possibility that new data will be generated under REACH is taken into account. In this case, the substance is parked until the data become available.

24	FCA, Food Contact Additives Sector Group of Cefic (European Chemical Industry Council), Belgium	2.2 Prioritisation of substances	In the draft opinion five substances classified as CMR, ED or PBT/vPvB were placed into an "exclusion group". This is conflicting with EFSA's general risk assessment approach, the latest opinion from EFSA (2019) , and the overall purpose of the new mandate which requests further assessment of DEHP, DBP and BBP for final opinion for these substances. As such, the creation of an "exclusion group" in the context of a plasticisers assessment when other non-plasticiser substances may also be impacted and without further assessment is inconsistent. (Lines in the EFSA draft opinion: 325-377) The draft opinion prioritised the selected substances based on the date of the most recent risk assessment. FCA welcomes this approach as a first screening; however, further considerations must be assessed. Additional scientific criteria such as QSAR screening may help to refine this first screening to further determine which substances would need to be allocated into the different priority groups for further risk assessment. (Lines in the EFSA draft opinion: 325-451)	See answer to comment 4. A separate Hazard Assessment Protocol for the prioritised substances is under development as the second task of the mandate (EFSA-Q-2021-00593) and as described in the Terms of Reference. The use of (Q)SAR tools needs careful consideration and expert evaluation and if applicable they will be described in the Hazard assessment protocol.
25	CHEM Trust, Germany	2.2.1 Methodology	We propose that the prioritisation should also include tonnage levels and indications of toxicity so substances used at the highest tonnage levels and with the expected highest toxicity should be prioritised.	It is considered that indications on tonnage could inform only rough and possibly misleading exposure estimates, covering not only FCM uses but all different uses of the respective substance. Some new text covering this point has been added in Section 2.2.1.

				As described in the scientific opinion, two calls for data are foreseen through which information on occurrence in food, and occurrence in/migration from FCMs will be gathered. It is anticipated that such data are more reliable (in the context of diet/FCMs) than information on tonnage level of substances, and will come into play at a later stage for the refinement of the ranking of the substances. For the proposal of considering also information on toxicity in the prioritisation, please see answers provided to similar comments, e.g. 4, 21, 22.
			Line 353 ff: There will be a considerable delay due to the foreseen ´parking of substances´. This approach can only work if REACH compliance and data provision will be accelerated. Otherwise it means that those companies providing less data will have an advantage (´no data, no problem´).	Ensuring timely provision of information required under REACH is outside the scope of this project. In case of a delay in the provision of the required information, this will not prevent from conducting a risk assessment based on the available information, if considered necessary by the EC. Note that to address the lack of compliance of registration dossiers under REACH, ECHA and the EC have developed a joint action plan.[1] Furthermore, in the context of the implementation of the CSS (EC, 2020), the EC is exploring various options in the framework of the REACH revision to ensure compliance and that sufficient information for identifying hazard properties and potential risks of substances is made available in a timely manner.[2] [1] REACH Evaluation joint Action Plan: https://echa.europa.eu/documents/10162/2187783

				6/final_echa_com_reach_evaluation_action_plan_en/0003c9fc-652e-5f0b-90f9-dff9d5371d17 [2] https://ec.europa.eu/environment/system/files/2021-11/Background%20document%20Enforcement%20and%20compliance.pdf
26	French Agency for Food, Environmental and Occupational Health & Safety (ANSES), France	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	1) Only reference to data generation process under Reach regulation is made in this section. However, please also consider ongoing CLP process for these substances (declared in the ROI but without RAC opinion) [confidential information: for example, initiative is currently ongoing between ECHA and some Member States to submit a CLH proposal for groups of phthalates] 2) It is not very clear who is target to "confirm the hazard properties after data generation". Indeed, when data are generated under Reach regulation (in particular CCH and TPE), ECHA assesses these data and can propose possible outcomes. However, ECHA has no mandate to submit CLH proposal which is based on volunteering of Member States. And if we understand well, the substances will remain parked without this confirmation while data can be available. Please consider how to ensure that substance will be effectively classified (if needed) on receipt of relevant data.	1) Ongoing CLP processes are referred in section 2.2.3 of the opinion as "confirmation of hazard properties under CLP". 2) When referring to confirmation of hazard properties under CLP, we refer to classification of a substance through harmonised classification and labelling (CLH) process under CLP. Indeed, currently only Member States (and under certain circumstances industry) can submit CLH dossiers. However, in the context of the revision of the CLP Regulation, the EC is examining the possibility to introduce a mandate for ECHA to prepare proposals for harmonised classification and labelling under CLP. Note that in case of a delay in confirming the hazard properties under CLP, this will not prevent from starting a risk assessment for a substance based on the available information, if considered necessary by

		classification and labelling)		the EC.
27	French Agency for Food, Environmental and Occupational Health & Safety (ANSES), France	3.1 Pool of substances	1) France provided a list of 19 substances and not 17 as indicated in the document. The 2 substances provided by France and missing from the document are DIDP and DINP. 2) Could the Panel explain the methodology used to replace the Phenyl esters of sulfonic acids (C12–C20) provided by France with C14-17 alkanes, sec-mono- and 492 disulfonic acids, phenyl esters from the PLASI inventory?	1) France provided a list of ten substances which are "listed by EFSA and assessed by France", a list of five "substances listed by EFSA and authorized in France in Rubber", a list of four "substances not listed by EFSA and authorised in France in Rubber" and a list of four "substances listed by EFSA that would no longer be used by the rubber industry". Excluding the substances from the last list, the total number of substances is indeed 19, however; one should note that two substances appeared both in the first and the second list: DiNP (CAS 28553-12-0) and DIDP (CAS 26761-40-0). Consequently, these substances were considered in the prioritisation exercise. Additionally, in the Excel file filled by each MS, 17 substances brought by France appear. 2) We understand that the substance of interest refers to FCM 884. It has been related to the CAS 91082-17-6 for "Sulfonic acids, C10-21-alkane, Ph esters". The substance displays some complexity arising from the variable carbon chain length and the level of sulfonation. Taking into accounts these

				characteristics and the conventions followed under REACH for the identification of this type of UVCB substances (for further information, please consult the ECHA Substance Identification Guidance), it was possible to relate this entry to the substance manufactured/imported in EU and registered under REACH with the name "C14-17 alkanes, sec-mono- and disulfonic acids, phenyl esters". This name depicts the predominant constituents which the substance consists of.
28	Cefic – European Plasticisers, Belgium	3.1.3 Exclusion group	European Plasticisers appreciate the detailed description of how the substance list was generated and how substances were included and eliminated, including all the substances with authorized as FCM at national level. L604-616 - Please see previous comments on the 'exclusion' group. It would seem premature to propose this approach given the long standing EFSA commitment to risk assessment. It is also noted that DIBP is authorized at national level (Germany, Italy, Netherlands) and could have specific impacts in those countries.	Thank you for the supportive comment. Please see answer to comment 4.
29	Cefic – European Plasticisers, Belgium	3.1.4 EU/national substances for prioritisation	L621 - 75 substances are considered for the prioritization stream of EU authorized substances. L634 Table 2 – of these 75 substances it is noted that 49 are high priority and proposed for risk assessment, 11 are medium priority and proposed for risk assessment and 2 are low priority and proposed for risk assessment i.e. 62 substances proposed for risk assessment.	These are statements that do not seem to require a response.

			The other substances being parked due to data generation ongoing. L624 - It is noted that 49 substances were considered for the prioritization stream of nationally authorized substances.	
30	CHEM Trust, Germany	3.2 Prioritisation	More priority should be placed on substances already found widely in the general population including in children, see e.g.: 1)Metabolites of the substitute plasticiser Di-(2-ethylhexyl) terephthalate (DEHTP) in urine of children and adolescents investigated in the German Environmental Survey GerES V, 2014–2017 G. Schwedler et al, International Journal of Hygiene and Environmental Health, Volume 230, September 2020, 113589, https://www.sciencedirect.com/science/article/pii/S1438463920305356 2)Hexamoll® DINCH and DPHP metabolites in urine of children and adolescents in Germany. Human biomonitoring results of the German Environmental Survey GerES V, 2014–2017 Schwedler G. et al, International Journal of Hygiene and Environmental Health Volume 229, August 2020, 113397 https://www.sciencedirect.com/science/article/pii/S1438463919306066 3)Phthalate metabolites in urine of children and adolescents in Germany. Human	Please see the response to comment 10.

			biomonitoring results of the German Environmental Survey GerES V, 2014–2017 Schwedler G. et al, International Journal of Hygiene and Environmental Health, Volume 225, April 2020, 113444 https://www.sciencedirect.com/science/article/pii/S1438463919308478 4) Substitutes mimic the exposure behaviour of REACH regulated phthalates – A review of the German HBM system on the example of plasticizers Lembke, N., et al International Journal of Hygiene and Environmental Health 236 (2021) 113780, https://www.sciencedirect.com/science/article/pii/S1438463919308478	
31	French Agency for Food, Environmental and Occupational Health & Safety (ANSES), France	3.2 Prioritisation	1) The final pool of substances consists of 543 substances. Nevertheless 75 substances were considered in the EU stream and 49 in the national stream. Could the panel confirm that the authorised/unauthorised status of the substances as well as the CMR classification were the only exclusion criteria that were used to obtained this number of 75 and 49 substances?	Indeed, the status of authorisation of a substance at EU/national level was taken into account. Additionally, for the exclusion group, classification as CMR Cat 1, ED, PBT/vPvB were considered. The 75 substances include also group entries, which cover two or more substances that are amongst the 543 (see Table 2 in the opinion). After the public consultation, the figures for substances included in the EU and national stream have been updated taking into account additional feedback received from the Netherlands, but the essence of this reply is unchanged.
32	Cefic – European Plasticisers, Belgium	3.2.2 National stream	L 642 Table 3 – of the 49 substances it is noted that 38 are high priority and proposed for risk assessment, 3 are medium priority and proposed for risk	This is a statement that does not seem to require a response.

			assessment and 1 is low priority and proposed for risk assessment i.e. 42 substances are proposed for risk assessment.	
33	CHEM Trust, Germany	3.3 Discussion	Line 655 – 672: The proposed further ranking will depend on the evidence provided during the calls for data and it remains to be seen how successful the call for data is, in particular if the incentive for companies to provide data is missing. We propose to also do a further refinement based on hazard data: Very interesting work to consider can be found in the recent publication Overview of intentionally used food contact chemicals and their hazards by Groh, K et al. (2021), Environment International, doi: 10.1016/j.envint.2020.106225	It can indeed not be anticipated what will be provided through the calls for data. However, in order to give additional emphasis on the importance of information provided during the calls for data, this aspect had already previously been mentioned in the conclusions (section 5): stakeholders 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. See answer provided under comment 21.
34	Cefic – European Plasticisers, Belgium	3.3 Discussion	L647 - We agree this is a very comprehensive process – but many substances are not plasticisers according to the understanding of European Plasticisers- see comments on Annex II of the Prioritisation report. L654 - It is noted that a significant majority of the substances are high priority-it should though also be noted that some of the	See answer provided under comment 42. It should be noted that substances included in the exclusion group are set aside before the

			major plasticisers used in FCMs are in the medium and low priority group i.e. they have been reviewed more recently re: DOTP, DINCH, DINP, DIDP. 4 of the 5 substances in the exclusion group also fall into the low priority group since they have also been reviewed recently.	prioritisation based on assessment dates is conducted (see Figure 2 in the opinion).
35	Cefic – European Plasticisers, Belgium	4 Uncertainty analysis	No major comments on this section. EFSA has certainly done a very thorough job in trying to identify all relevant substances. This may then though have led to identification of some substances as plasticisers when they do not fulfil the definition of a plasticiser. Line 755 – Reference is made to uncertainties concerning impurities – in this regard it is relevant to note that REACH registration requires detailed substance composition information to be provided with analytical data (GC traces etc).	See answer provided under comment 42. As described in section 4 (Uncertainty analysis – limitation of not considering impurities and reaction products) during the prioritisation focus has been laid on the substance itself, therefore the uncertainties around impurities cannot be reduced at this stage. However, impurities and reaction/degradation products will be considered in the actual substance-specific risk assessment process.
36	APPLiA - Home Appliance Europe, Belgium	5 Conclusions	Please refer to the attached document for APPLiA general comments on the consultation. From the attachment: **APPLiA reaction and further comment on the EFSA consultations on Phthalates on its draft opinion and draft protocol**	

			APPLiA, representing EU manufacturers of home appliances, including large domestic appliances, small domestic appliances and heating, ventilation, and air-conditioning (HVAC) equipment, would like to provide the EFSA, with the views of the sector and further comment on the consultations launched regarding Phthalates used as plasticisers in materials and articles intended to come in contact with food on the 5 November 2021. Through this paper, APPLiA members-companies would like to react to the approach used in these consultations served as pilot, namely the "One-Substance, One-Assessment" approach, as embedded in the Chemicals Strategy for Sustainability. Indeed, as already requested to the Commission, clarifications are needed on whether the approach covers "one substance, one hazard assessment with multiple related risks-assessments and management measures", or something else? This latter question is highly relevant for the authorities, including EFSA, to clarify as we would recommend for this approach to render a homogeneous and transversal manner to Risk-assessment/Risk-management (RA/RM) chemicals in the EU, through synergy between ECHA, EFSA and relevant Member States authorities. Until there would not be such clarifications, we would question the	As part of the Chemicals Strategy for Sustainability, the Commission has committed to looking at how to strengthen the legal framework and review how to use the EU's agencies and scientific bodies better to move towards 'one substance – one assessment' (OSOA) and more integrated and holistic assessment of chemicals. While the 'one substance – one assessment' is not (yet) an established approach, this collaboration between ECHA and EFSA on plasticisers used in food contact materials is one of the projects aiming at enhancing collaboration and coordination between the agencies and collecting learnings which can concretely support future implementation of OSOA. See answer provided to comment 13.

			feasibility of using such an approach in assessing substances such as Phthalates. From the home appliances sector's point of view, grouping substances based on their same (eco)toxicological properties and further profiles could be an acceptable approach under some conditions, relevant while conducting this type of consultation such as for Phthalates that are broadly used in diverse types of application. In that case, "grouping" should not be based only on the structure of chemicals. A group of substances, in addition to their common structure, functional group(s) constituents or chemical classes, should share a least a combination of two of the following similarities: -Common molecular structures of significant similarity -Common (eco-toxicological effects, hazard classification or toxicokinetics -Common mode or mechanism of action -Common adverse outcome pathway -Common environmental fate/behaviour Moreover, we would further recommend defining a group of substances in line with the following "SME" principle: **Specific** - grouping must be considered on a product group-specific basis; **Measurable** - any legislative requirement setting limit values on the presence of a group of substances must also be	

			measurable as a group, i.e. analytical test methods should exist to measure a specific group of substances in question in an accurate and reliable manner. **Enforceable** - any legislative requirement setting limit values on the presence of a group of substances must be verifiable and enforceable through Market Surveillance authorities ensuring harmonisation across Member States. Finally, we would recommend keeping on further strengthening the current approach to RA/RM for food contact materials as currently being carried out in the FCM Framework Regulation, and this being further used for the identification and prioritisation for risk assessment of phthalates. APPLiA and its members would like to thank the EFSA for its consideration of the above comment.	
37	CHEM Trust, Germany	5 Conclusions	This project is supposed to serve as a pilot for the implementation of the CSS (line 191). But the CSS aims at ensuring a higher level of protection and the proposed current approach is falling short in meeting this goal: This prioritisation exercise, taken together with the very detailed exposure assessment, will take many years and will be very resource intensive for various actors. Still many data gaps will remain, leading to the need to make many assumptions and thus the assessments will include many uncertainties. Given that there is no moratorium on the substances	New text has been added in section 1.2 in order to better clarify the context of this project in relation to the implementation of the CSS (EC, 2020). Whilst the EC will assess how to best introduce a mixture assessment factor specifically as part of the REACH legislation, it has also committed to introduce or reinforce provisions to take account of the combination effects in other relevant legislation, including FCMs. To that end, EFSA will work closely with the EC and stakeholders for achieving this part of the revision of the FCM legislation. It should be noted that that the current opinion has the purpose of prioritising substances and therefore does not yet include their risk assessment.

			used for the time these assessments are taking place, in CHEM Trust`s view a quicker move to exposure reduction should be taken. One useful tool would be the application of a mixture assessment factor: we would recommend including a generic mixture risk assessment factor of 100 as a way to consider the risks from other exposure sources. In addition, it could account for the exposure to similar substances from other uses/regulations leading to with the same adverse outcome. This will ensure a protective approach while at the same time being easy and quick, and further save a lot of resources.	
38	French Agency for Food, Environmental and Occupational Health & Safety (ANSES), France	5 Conclusions	1) Could Efsa consider for the final ranking to take into account the availability of the toxicity data to conduct a risk assessment?	See answers to comments 4, 21 and 22.
39	Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT), Great Britain	5 Conclusions	The COT considered the overall process proposed for identifying and prioritising phthalates was sensible, however did note, that until a complete list and toxicological profile for these substances are available, further comment on the (hazard) assessment would prove difficult. Overall, the COT agreed that the approach taken was logical and pragmatic.	Thank you for the supportive comment.

<table>
<tr>
<td>40</td>
<td>Cefic – European Plasticisers, Belgium</td>
<td>5 Conclusions</td>
<td>L777-781 - As already noted in prior sections it would seem premature to designate an exclusion group based on hazard alone given EFSAs long standing practice of risk assessment, as well as recent statements at the EFSA Scientific Committee Meeting in June 2021. The intent of the new mandate was partially to provide a more final opinion on some of the substances placed in the exclusion group (DEHP, DBP, BBP, DIBP) – so this is not consistent with the original mandate. Similarly, DIBP also has a specific national authorization and DCHP, which is permitted in regenerated cellulose film, is now in the exclusion group in the current work. It would seem a broader discussion on this approach is needed rather than adopting this approach as part of a review of plasticisers – such an approach has much broader implications including for other non-plasticiser substances used in FCM.</td>
<td>Regarding the first point of the comment on the exclusion group, see answer to comment 4.
Regarding the second part of this comment on the approach used, it should be noted that the mandate is intended to be a follow-up to the opinion on risk assessment of 5 ortho-phthalates for use in food contact materials (CEP Panel, 2019)). With this new mandate, the EC requested 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). Therefore, there is indeed a difference (i.e. broadening) in the scope of the work compared to the previous opinion; this was agreed in order to cover also other plasticiser substances of potential relevance for FCMs, which all underwent the same process for the prioritisation exercise.
The CSS (EC, 2020) provides information on future developments in the area of chemicals use and assessment, and these recent policy developments have been taken into account in the development of the prioritisation approach.</td>
</tr>
<tr>
<td>41</td>
<td>Anonymous, Spain</td>
<td>Annex A - List of substances identified as potential plasticisers and prioritised</td>
<td>Tributyl O-acetylcitrate (CAS 77-90-7) is the primary plasticiser used in solvent-based flexographic inks. Triacetin may also be used but occasionally in very specific situations

From the attachment:
<table>
<tr><th>CAS NUMBER</th><th>substance</th><th></th><th>Typical Quantity in formula</th></tr>
</table>
</td>
<td>Information on application and formulation cannot be taken into account in the phase of prioritisation. However, such information is of relevance for the exposure assessment and should therefore be submitted via the dedicated call for data.</td>
</tr>
</table>

		according to the approach described in this Scientific Opinion	<table><tr><td>77-90-7</td><td>Tributyl O-acetylcitrate</td><td>Flexographic printing inks</td><td>< 5%</td></tr><tr><td>102-76-1</td><td>Triacetin</td><td>Flexographic printing inks</td><td>< 5%</td></tr></table>	
42	Cefic – European Plasticisers, Belgium	Annex A - List of substances identified as potential plasticisers and prioritised according to the approach described in this Scientific Opinion	The statement of "structurally similar substance" is not justified in many cases. We assume this means structurally similar to "phthalates" meaning ortho-phthalates– while such a statement can apply to tere-phthalates, iso-phthalates and possibly trimellitates i.e. structure with an aromatic ring and 2 or more ester groups, it is not appropriate to state this for adipates, azelates, succinates, sebacates, myristates, ricinoleates, glutarates, cyclohexanoates, citrates etc etc. Of the first 48 substances (nationally authorized) in the spreadsheet, 37 are produced in quantities <1000 tonnes per year, 7 are produced in quantities of 1 – 10 ktonnes/year, 3 are produced in quantities of 10-100 ktonnes/year and 1 substance 100kt-1 Million tonnes per year. Exposure potential is directionally obviously greater the larger the quantity produced. It would though appear many of the substances on the list are produced in very small quantities often by SME producers.	Much of the content of this comment seems to come about due to a possible misunderstanding of the plasticiser substances that are in the scope of this Opinion. They are phthalates, structurally similar substances (i.e. similar to phthalates), and replacement substances (structure not defined, but must be plausible candidates as actual or potential technological replacements) potentially used as plasticisers in FCMs. This has been further clarified by additional text at section 1.2 (and also in the reply to e.g. comment 3). With respect to the suggestion to use tonnage information, please refer to the response given to comment 25. With regards to the extent of use, or not, of the different substances, please take note of the other responses (e.g. to comments 4, 13, 21, 22, 33) dealing with the follow-up calls for data in support of the exposure assessment will be used for a final ranking. This comment 42 emphasises the importance of stakeholders submitting data to enable an informed conclusion on the risk assessment and to support the continued use of a plasticiser substance.

			8 of the first 51 substances are not plasticisers which if repeated for the many other substances (could be even greater percentage which are not plasticisers) is a significant percentage. As an example, Isopropyl myristate is NOT a plasticiser used to any significant degree in food contact plastics – it is rather a softening agent for skin used cosmetics and personal care products. Myristic acid is a C14 fatty acid and is one of the most abundant fatty acids in milk fat. It appears to have a minor use in a catalyst used to make polypropylene. Such a small use and the nature of the material would suggest a low priority for further evaluation. It is noted that there are other myristate derivatives and also other fatty acid derivatives such as Hexadecyl palmitate identified–these are not "structurally similar to phthalates". Line by line comments in the attached Excel file (click on "Review" - "Show comments"). The first attachment provided by the commenter can be found in the online version of this output ('Supporting information' Section → file 'Annex B_Attachment to comment 42_PCSF-216204_Annex A_draft opinion_prioritisation_phthalates_public consultation_2020-00725_comments').	Responses to comments made in the attachment: - Row 23 (EC number 203-090-1): information regarding status of data generation has been updated, and substance is parked. - Row 123 (EC number 222-020-0): the link to the EFSA assessment from 2019 has been added. It needs to be noted that the substance is not yet included in Annex I of Regulation (EU) No

				10/2011, and therefore the substances remains among the nationally authorised substances. - Row 200 (EC number 249-079-5): The substance in row 200 is known as DINP2. DINP1 is reported as a separate entry in the pool (EC number 271-090-9, row 260). These substances are closely related but are considered rightfully reported separately as they have different chemical identifiers. The information in these 2 entries is not inconsistent. DINP, like the other plasticisers, underwent the prioritisation exercise and was placed in the low priority group due to its recent assessment date. - Row 216 (EC number 258-469-4): the substance had already been parked, therefore no changes are needed with respect to this entry. - Row 539 (CAS Number 208945-13-5): no need for amendments of this entry were identified as the substance is considered not authorised and therefore excluded from prioritisation. - Row 541 (CAS Number 82904-80-1): the substance had already been associated to FCM No 73, therefore no changes are needed with respect to this entry. - Row 542 (CAS Number 55799-38-7): the substance had already been associated to FCM No 73, therefore no changes are needed with respect to this entry. - Row 545 (CAS Number 150923-12-9): the substance had already been associated to FCM No

				73, therefore no changes are needed with respect to this entry.
			From the attachment n. 2: Attachment to EFSA Annex A -List of substances identified as potential plasticisers Substance cells 55 -down–Dioctyl phthalate –this may well be a misunderstanding – Dioctyl phthalate or Di-n-octyl phthalate is not a commercial substance in the EU (not REACH registered). However DOP/Dioctyl phthalate is a common name for DEHP (Di-2-ethylhexl phthalate) which has of course been a major phthalate in the EU (now phased out and substituted to a major degree –included in the "exclusion group" in this report). Many substances are relatively small volume (<1000 tonnes per year). Many are not structurally related to phthalates re: adipates, azelates, sebacates, benzoates etc are not structurally related to phthalates. Some are not REACH registered. For all of the prioritized substances we would recommend that it is checked whether they are REACH registered or not and in what quantities. There seem to be many substances which are not	Dioctyl phthalate originated from Annex II, and the respective CAS number does not refer to DEHP, but directly to di-n-octyl phthalate. All substances from Annex II were considered for the pool of substances, even if not REACH registered (as explained in section 2.1.1 of the opinion). The other statements made in attachment n.2 are very similar to comments made previously. - Regarding the issue of structural similarity, please see the reply provided further up in this comment, as well as reply given to comment 3. - Regarding the issue of use of the substances as plasticisers, see replies to e.g. comments 13, 22, 25. - Regarding the issue of tonnage, please see e.g. comment 25.

			commercial, which are not plasticisers and which are only produced in small quantities. This will mean directionally (depending upon precise use) that exposure is limited, and certainly availability of exposure information will be very limited (since if not commercial then no need for such information). We certainly agree that if not authorized for food contact then the substance should not be prioritized. Looking the EU approved spreadsheet there appear to be very many fatty acid derivatives-with the fatty acids coming from natural sources. Phthalates (ortho, tere, iso can have fatty alcohol side chains (from natural and synthetic origins) and in this respect have some structural similarity to fatty acids – but it is then a big leap to state that a linear fatty acid derivative without any aromatic component is then structurally similar to phthalates, which are characterized by the aromatic ring with two ester groups (phthalic structure). Further review shows natural acids also re: resin and rosin acids, glycerides etc. These fatty acids are not plasticisers for flexible vinyl food contact materials in the way that orthophthalates, terephthalates, cyclohexanoates, adipates etc are. Scanning through the spreadsheet shows an endless list of glyceride materials –it would seem there would be some possibilities for grouping many of the materials by their common names/(real)	

			structural similarity –the listing seems rather random at the moment (understandably given the huge nature of the work carried out).	
43	Cefic – European Plasticisers, Belgium	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	Please see 2 documents attached. From the attachment n. 1: **Cefic European Plasticisers – comments on use of plasticisers in food contact applications in response to the DG Sante survey on use of phthalates and other plasticisers in food contact applications –October 23, 2019** Cefic European Plasticisers represents the major European plasticiser manufacturers and as such has information on the use of the products in food contact materials and the relevant EU and national regulations on such food contact applications. However, European Plasticisers members do not manufacture food contact materials and hence do not have the full details on the precise applications and quantities of plasticisers used. Implicit in the statements below is the understanding that all producers, distributors and downstream users in the value chain should comply with the relevant national and EU regulations pertaining to food contact applications. **SVHC Phthalates– DEHP, DBP and BBP** The understanding of European Plasticisers is that DEHP, DBP and BBP has been largely	Thank you for the information provided in this attachment. It was noted that this information does not relate directly to the prioritisation, but rather to use and applications of certain substances in FCMs. As mentioned in replies to earlier comments (e.g. comment 33), it is important to receive information from stakeholders during the two calls for data foreseen to gather data in support of the exposure assessment: - Call for data on occurrence in food (through EFSA's annual data collection on chemical monitoring data) - Call for data on occurrence in FCMs and migration from FCMs. Therefore, the commenter is kindly invited to participate actively in those calls for data.

			deselected from use in food contact applications within the European Union. Outside the European Union DEHP is though still a major plasticiser in China, India, South-East Asia, and Latin America and can be used in the following applications in these countries/regions subject to compliance with specific national regulatory requirements: •Flexible vinyl gloves •Flexible vinyl metal to glass closures •Flexible vinyl conveyor belts •Flexible vinyl hoses and tubing •Flexible vinyl waterproofing membranes with potential for contact with potable water •Flexible vinyl table accessories in the home, restaurants, cafeterias in public buildings re: table cloths, place mats, menu covers In general the amount of DEHP which can be used in such applications is less than 30wt% of the flexible vinyl formulation, although in some instances such as gloves the weight percentage can be higher. DBP and BBP may also be used to a lesser degree in the above applications outside the EU. DBP is also a product used as a chain transfer agent for polyolefin manufacture outside the EU, although residues in final polyolefin packaging will be very low. The implications of the above are that imported food contact materials, imported	

			food (from processing and packaging) may contain the SVHC phthalates, DEHP, DBP and BBP. DIBP is used outside the EU in printing inks (which may be used on food contact packaging and labels for packaging) as well as adhesives which may then be used in food packaging with the implications for imported food. European Plasticisers also understands there may be some use of DCHP in cellophane applications for food contact both in the EU and outside the EU. **Non-SVHC phthalates DINP and DIDP** The non-SVHC phthalates DINP and DIDP have in the past replaced DEHP, DBP and BBP to a major degree in food contact applications within the EU and to some degree outside the EU and are still used in the following applications within the EU: •Flexible vinyl gloves •Flexible vinyl conveyor belts •Flexible vinyl waterproofing membranes with potential for contact with potable water •Flexible vinyl table accessories in the home, restaurants, cafeterias in public buildings re: table cloths, place mats, menu covers In general, the amount of DINP and DIDP which can be used in such applications is less than 30wt% of the flexible vinyl formulation, although in some instances	

			such as gloves the weight percentage can be higher. Within the EU the use of DINP and DIDP in flexible vinyl metal to glass closures has been replaced by use of Epoxidized Soya Bean Oil (and sodium bicarbonate as a blowing agent replacing azodicarbonamide). The use of DINP and DIDP in flexible vinyl hoses and tubing have been replaced by DOTP and DINCH to a significant degree. Outside the EU DINP and DIDP are still used in all the above applications with then the associated potential for presence in imported food contact materials and at low levels in imported food which has been subject to processing or packaging with materials made with DINP and DIDP. **Other plasticisers** Within the EU DINCH and DOTP have replaced DINP and DIDP to some degree in the relevant applications (as already indicated). DINCH and DOTP are therefore used within the EU in all the above applications, namely: •Flexible vinyl gloves •Flexible vinyl metal to glass closures •Flexible vinyl conveyor belts •Flexible vinyl hoses and tubing •Flexible vinyl waterproofing membranes with potential for contact with potable water •Flexible vinyl table accessories in the home, restaurants, cafeterias in public	

			buildings re: table cloths, place mats, menu covers In general, the amount of DINCH and DOTP which can be used in such applications is less than 30wt% of the flexible vinyl formulation, although in some instances such as gloves the weight percentage can be higher. Similarly, outside the EU, DINCH and DOTP are seeing increasing use in the above applications with the potential for presence at low levels in imported food which has been subject to processing or presence in packaging with materials made with DINCH and DOTP.ATBC (Acetyl tri-n-butyl citrate) is also used in the above applications within and outside the EU. Polymeric plasticisers are also used in food contact applications and in particular for their low migration properties for fatty foods for example. Examples of the polymeric plasticisers include: •Hexanedioic acid, polymer with 1,2-propanediol, acetate CAS# 55799-38-7 •Hexanedioic acid, polymer with 1,2-propanediol, octyl ester CAS# 82904-80-1 •Hexanedioic acid, polymer with 2,2-dimethyl-1,3-propanediol and 1,2-propanediol, isononyl ester CAS# 208945-13-5 / CAS# 208945-12-4 / CAS # 150923-12- Other plasticisers used in food contact materials include:	All of these substances have been considered in the list of substances proposed in the opinion.

			•Dibutyl sebacate •Di-ethylhexyl adipate •Epoxidized Soya Bean Oil •Hydrogentated acetylated castor oil •Isosorbide esters European Plasticisers also notes from recent minutes from the EFSA CEP that there is an application for use of TEHTM (TOTM) in food contact applications and that this has in fact been granted. The second attachment provided by the commenter can be found in the online version of this output ('Supporting information' Section → file 'Annex B_Attachment to comment 43_PCSF-216203_EFSA mandate for plasticisers_Information to support prioritization_Oct_25_2021-DRAFT).	Thank you for the information provided in this attachment. As regards the information on uses, please refer to what is replied in response to the first attachment linked to this comment. After the public consultation and prior to the finalisation of the opinion, care was taken to update information on the status of data generation and/or hazard classification.
44	Food Packaging Forum Foundation, Switzerland			No comment was provided.

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