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TOX/2021/61

Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment

Phthalates

EFSA draft opinion and exposure protocol open for public consultation

1. On 5th November 2021, EFSA published a "draft opinion on identification and prioritisation for risk assessments of phthalates, structurally similar substances potentially used as plasticisers in materials and articles intended to come into contact with food" (Annex A) and a "draft protocol for the exposure assessment as part of the safety assessment of phthalates, structurally similar substances potentially used as plasticisers in materials and articles intended to come into contact with food" (Annex B) for public consultation.

2. The new assessment follows on from EFSA's previous update on the risk assessment of five phthalic acid esters (ortho-ohthalates), namely 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 (FCMs) in December 2019. While the COT raised a number of concerns about and uncertainties in the EFSA assessment, overall the Committee considered it reasonable to group DINP with DEHP, DBP, BBP in a low tier cumulative risk assessment. The Committee further considered the group tolerable daily intake (TDI) and the relative potency factors to be appropriate for DEHP, DBP and BBP (Annex C).

3. The COT last discussed phthalates within the scope of the review of the risk of toxicity of chemicals in the diets of infants and young children aged 1-5 years in 2018 (Annex D).

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Key points from the 2021 EFSA assessment

4. The previous mandate set by the European Commission (EC) in 2019 was limited to new scientific information on reprotoxicity, as assessed by the European Chemicals Agency (ECHA) and restricted to the five ortho-phthalates. The subsequent risk assessment did not identify any risk to human health from current dietary exposure to these five phthalates, however it highlighted limitations in the work carried out. Hence, the TDIs were set on a temporary basis. In addition, information collected by the Commission, a stakeholder survey and results of controls carried out by Member States confirmed that these phthalates are being replaced by other plasticisers and other phthalates are used as technical support agents.

5. The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP Panel) was asked by the European Commission in 2021 to re-evaluate the risk to public health related to the presence of phthalates, structurally similar substances and replacement substances, as a consequence of migration from FCMs. The mandate comprised of a two-step approach.

1) to identify and prioritise substances; the aim was not to establish a continuous process of identifying and prioritising additional substances as they may become available over time but to describe the situation at the moment of endorsement/adoption of the scientific opinion.

2) establish a protocol for a dietary exposure assessment of the prioritised substances; the aim was to address the relative contribution from FCMs to the dietary exposure, consider data on migration from FCMs and the eventual comparison of both to the overall dietary and non-dietary exposure of EU consumers.

Identify and prioritise substances

6. In total, EFSA identified 543; substances originated either from Annex II of the mandate, or were identified from the inventory of plasticisers established by ECHA in cooperation with industry (PLASI) or from substances listed in Annex I of Regulation (EU) No 10/2011 (plastics FCM) or Annex II of Directive 2007/42/EC (RCF) and for which a link with plasticiser use was established based on information available to ECHA. Substances not registered under REACH or registered for uses as intermediates in the manufacturing of other substances were not considered, unless included in Annex II of the mandate.

7. To ensure scientific and regulatory relevance, substances without an authorisation at EU or national level were excluded. Substances with EU or national authorisation were treated separately in the prioritisation step to allow for targeted risk management action.

8. Substances were screened for possible severe hazard properties (i.e. carcinogenic, mutagenic, reprotox (CMR) or peristant, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB), endocrine disrupting (ED)) and included in a separate group (‘exclusion group’). Risk assessment of these substances would only be conducted if they were used in FCMs following the implementation of risk management measures. In addition, several substances were excluded from the next steps due to ongoing data generation with relevance to risk assessment in the context of FCM.

9. Prioritisation was based on the date of the assessment, giving high priority to substances assessed before 2001, medium priority to substances assessed between 2001 and 2011 and low priority to substances assessed after 2011. Substances for which it was not possible to retrieve specific assessments/assessment dates (e.g substances included in the RCF Directive only), were considered to have been assessed prior to 2001.

10. Of the 75 EU authorised substances, 58, 14 and 3 were considered of high, medium and low priority, respectively. Of the 49 nationally authorised substances 43, 3 and 3 were considered high, medium and low priority, respectively. EFSA acknowledged that the distribution of substance was dominated by substances of high priority. However, this could be expected given the long historical use of plasticisers.

11. Rather than refine the prioritization and ranking of substances at this stage, the CEF Panel decided to wait for the outcome of the follow-up calls for data in support of the exposure assessment. The additional data is expected to provide information on the migration from and occurrence of these substances in FCMs, as well as occurrence in food. The higher the possible exposure to the consumer to a substance from FCMs use, the higher that specific substance would be ranked regarding its priority for risk assessment.

12. EFSA acknowledged that there are a number of uncertainties in their assessment, such as the completeness of the listing of potential plasticisers, including differences between EU and non-EU FCMs, and the placing of the substances into the 3-tier prioritisation. While mitigation measures were taken, the main uncertainty remains the focus on the named substance and hence the lack of consideration of impurities and reaction products.

Exposure assessment

13. The exposure assessment was developed to explain the strategy applied for cleaning and selecting data, appraising the relevant evidence, and analysing and integrating that evidence to be used in the risk assessment of substances prioritised under part one of the mandate.

14. The CEF Panel considered three main assessment questions

1) What is the overall chronic and/or acute exposure in different population groups and age classes in the EU.

2) How much of the chronic and/or acute dietary exposure originates from FCMs; this includes food that comes into contact with FCMs along the food chain.

3) How does dietary exposure due to FCMs compare with overall dietary and non-dietary exposure of EU consumers.

15. The CEF Panel further outlined the evidence and methods needed to answer its assessment questions.

1) Occurrence data in food (including drinking water) will be collected through continued call of data and evaluated following standard EFSA operating procedures. In addition, a systematic literature search will be conducted (including research activities and published surveys) and the available information will be assessed on a case-by-case basis. It may not be necessary to use the literature data, should enough information be collected via the call for data. The estimation of human dietary exposure will follow the standard (EFSA) integration of occurrence and consumption data. If the toxicological evidence indicated that two or more plasticisers should be grouped into a common assessment group, the data set will be examined for the occurrence of each substance individually (in each food) and then co-occurrence of the group members will be calculated for each sample/type, taking into account potency adjustment factors, if appropriate.

2) An ad hoc call for data is currently under development to identify FCMs in which the prioritised substances occur, the concentration ranges in and frequency of use. In addition, information will be gathered on the different applications of FCMs, as well as possible exposure through migration during storage and preparation. Information will also be gathered on the occurrence/concentration on the migration of these substances from FCM into food. Prediction of migration from plastic FCMs into foods and food simulants can be achieved using scientifically recognised and validated migration

modelling. Read-across may be applied in instances where the objective is to replace a plasticiser with alternatives and where reliable use levels and migration data are available for the plasticiser to be substituted.

3) The overall exposure will be determined either by deterministic or probabilistic approach, depending on the quality of the data. The estimated overall exposure obtained by aggregation of non-dietary exposure from substance use in consumer products and dietary exposure from FCMs and other sources will be compared to estimates of exposure obtained through human biomonitoring HBM data. Should the HBM estimated exposure significantly exceed the exposure estimated by aggregation, important sources of exposure may have been missed or underestimated. The reverse case will provide an indication that the assumptions made may have been overly conservative and should be refined. Occupational exposure would be outside the scope of the assessment/mandate.

16. EFSA acknowledged that there are a number of uncertainties in their exposure assessment, surrounding the sampling strategy and data retrieval, the substance use in and migration from FCMs, the relevant food consumption and methods to combine the estimated exposures.

Questions on which the views of the Committee are sought

I. Do the Committee have any comments on the mandate and the approach taken by EFSA?
II. Do the Committee consider that the approach is scientifically valid a) generally and b) within the constraints of the mandate?
III. Does the Committee feel that the rationales and decisions are sufficiently described?
IV. Do Members consider the uncertainty assessment adequate and do they have any additional observations/uncertainties?
V. Do the Committee have any other comments on the opinion?

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Secretariat

December 2021

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List of Abbreviations and Technical terms

BBP	butyl-benzyl-phthalate
DBP	di-butylphthalate
DEHP	bis(2- ethylhexyl)phthalate
DIDP	di-isodecylphthalate
DINP	di-isononylphthalate
CMR	carcinogenic, mutagenic, reprotox
ED	endocrine disrupting
FCMs	food contact materials
HBM	human biomonitoring
PBT	bioaccumulative and toxic
TDI	Tolerable daily intake
vPvB	very persistent and very bioaccumulative
CEP Panel	The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids
ECD	European Commission
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EU	European Union
PLASI	Inventory of plasticisers established by ECHA in cooperation with industry
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals

Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment

Phthalates

EFSA draft opinion open for public consultation

Please find the Link to the 2021 EFSA “Draft opinion on identification and prioritisation for risk assessments of phthalates, structurally similar substances potentially used as plasticisers in materials and articles intended to come into contact with food”

Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment

Phthalates

EFSA draft exposure protocol open for public consultation

Please find the Link to the 2021 EFSA “Draft protocol for the exposure assessment as part of the safety assessment of phthalates, structurally similar substances potentially used as plasticisers in materials and articles intended to come into contact with food”

Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment

Phthalates

COT discussion of 2019 EFSA opinion

Please find the Link to the 2019 COT "Discussion paper on the public consultation on the EFSA Opinion "Draft 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"

Please find this Link to the meeting minutes of the COT meeting held on 19th March 2019; the discussion of the EFSA phthalates opinion can be found under ITEM 8.

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TOX/2021/61 Annex D

Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment

Phthalates

COT discussion of phthalates in the infant diet

Please find this Link to the 2018 COT "Review of potential risks from contaminants in the diet of infants aged 0 to 12 months and children aged 1 to 5 years"; The discussion paper on phthalates can be found in Annex 4.

Please find this Link to the meeting minutes of the COT meeting held on 3rd July 2018; the discussion of the EFSA phthalates opinion can be found under ITEM 8.