TOX/2019/12

COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

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"

Background

1. EFSA published an Opinion on phthalates for public consultation on 21 February 2019 (Annex A). Key points are briefly summarised below.

2. The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP Panel) was asked by the European Commission to update its 2005 risk assessments of DBP, BBP, DEHP, DINP and DIDP which are authorised for use in plastic FCM, by using the same database as ECHA for its 2017 assessment of certain phthalates.

3. In following this mandate the CEP Panel's assessment is mainly centred on phthalate-induced reproductive toxicity which were the basis for ECHA's assessment of certain phthalates~~and DIDP~~, together with the 2013 ECHA assessment of DINP and DIDP and their 2018 opinion on harmonised classification of DINP.

4. The Panel acknowledged the limitations of this approach, and considered that all the potential toxicological endpoints (not just reproductive toxicity) should be examined with the same degree of rigour. However, due to the limited time for the completion of the opinion and the amount of new evidence available since the 2005 opinion, the Panel considered it unfeasible to perform a comprehensive review of all the new data on these phthalates.

Therefore, the CEP Panel decided to:

(i) undertake the review of the toxicological data used by ECHA on DBP, BBP and DEHP mainly dealing with reproductive toxicity;

(ii) additionally review the toxicological data for reproductive effects of DINP and DIDP (published after EFSA's previous assessment of phthalates in 2005);

(iii) analyse the possibility of setting a group-health based guidance value for these substances;

(iv) refine the assessment of dietary consumer exposure to these substances which are all authorised in plastic FCMs;

(v) carry out a risk characterisation on this basis.

5. The Panel highlighted that other possible effects (as pointed out by the 2017 ECHA RAC assessment) e.g. on the immune and metabolic systems and/or on neurodevelopment, were not evaluated in-depth but were taken into account in the uncertainty analysis and recommendations of the opinion.

6. The CEP Panel re-confirmed the same critical effects and individual TDIs (mg/kg bw per day) derived in 2005 for all the phthalates, i.e. reproductive effects for DBP (0.01), BBP (0.5), DEHP (0.05), and liver effects for DINP and DIDP (0.15 each). Based on a plausible common mode of action (i.e. reduction in fetal testosterone) underlying the reproductive effects of DEHP, DBP and BBP, the Panel considered it appropriate to establish a group-TDI for these phthalates, taking DEHP as index compound as a basis for introducing relative potency factors.

7. The Panel noted that DINP also affected fetal testosterone levels at doses around three-fold higher than liver effects and therefore considered it prudent to include it within the group-TDI. To account for the different potencies towards the hepatic and reproductive endpoints an additional factor of 3.3 was used in the relative potency factor for DINP to ensure that it would not exceed the TDI derived from hepatic effects.

8. DIDP was not included in the group-TDI as its reproductive effects (i.e decreased survival rate in F2) are not considered to be associated with anti-androgenicity. Therefore, DIDP maintained its individual TDI for liver effects of 0.15 mg/kg bw per day. The Panel noted that there was an argument to include DIDP within the group TDI on pragmatic grounds due to the difficulties in clearly distinguishing DINP and DIDP analytically.

9. The group-TDI was calculated by means of relative potency factors with DEHP taken as the index compound as it has the most robust toxicological dataset. The relative potency factors were calculated from the ratio of the TDI for DEHP to the HBGVs of the three other phthalates. The group-TDI was established to be 0.05 mg/kg bw per day, expressed as DEHP equivalents.

10. Dietary exposure estimates (mean and high (P95)) were obtained by combining literature occurrence data with consumption data from the EFSA Comprehensive Database. The highest exposure was found for DINP, ranging from 0.2-4.3 and from 0.4-7.0 µg/kg bw per day for mean and high consumers, respectively. For high level consumers exposure estimates are 3-23% of the TDI. There was not enough information to draw conclusions on how much migration from plastic FCM contributes to this dietary exposure to phthalates.

11. The COT Secretariat is aware that concerns have been expressed that the database on DINP reproductive toxicity has been incompletely reviewed by EFSA and have invited industry experts to present an overview of the entire database to COT.

12. Questions to be asked of the Committee

i). Do the Committee have any thoughts 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 and are they reasonable choices within the constraints?

iv). Do the Committee feel that the evidence on reproductive toxicity has been adequately evaluated and do they consider DINP should be considered to have an anti-androgenic mode of action?

v). Do the Committee consider the group TDI for the selected phthalates and the relative potency factors are appropriate?

vi). Are Members content that there would not be a risk from phthalates for high level consumers if the group TDI were used?

vii). Do Members consider the uncertainty assessment is adequate and do they have any observations on it?

viii). Do the Committee have any other comments on this opinion?

Secretariat
March 2019

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The opinion can be found at
http://www.efsa.europa.eu/sites/default/files/consultation/consultation/Phthalates_in_plastic_FCM_draft_opinion_for_public_consultation.pdf

Secretariat
March 2019