

Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)

Minutes of the 4th meeting of the Working Group on Phthalates

Held on 4 June 2018, Parma (Italy)

(Agreed on 25 June 2018)

Participants

- **Working Group Members:**

Laurence Castle (chair), Jean-Pierre Cravedi, Inger-Lise Steffensen, Maria de Fátima Tavares Poças and Ine Waalkens-Berendsen

Cristina Fortes, Detlef Wölfle and Raymond Pieters have participated via teleconference

- **Hearing Experts¹:**

Not Applicable

- **European Commission and/or Member States representatives:**

Not Applicable

- **EFSA:**

FIP Unit: Julia Cara Carmona, Anna F. Castoldi, Katharina Volk

DATA Unit: Davide Arcella, Claudia Maria Cascio

- **Others:**

Not Applicable

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Takis Daskaleros (DG SANTE) and from the hearing experts Maarten Roggeman (ECHA) and Mark Blainey (ECHA).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 3rd Working Group meeting held on 18-19 April 2018, Parma.

The minutes of the 3rd Working Group meeting were agreed by written procedure on 8 May 2018.⁴

² <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

⁴ https://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/minutes_phthalateswg.pdf

5. Scientific topic(s) for discussion

5.1. Update of the risk assessment for di-butylphthalate (DBP, FCM No 157), butyl-benzyl-phthalate (BBP, FCM No 159) and Bis(2-ethylhexyl)phthalate (DEHP, FCM No 283) (EFSA-Q-2017-00588⁵/-00589⁶/-00590⁷)

The Working Group (WG) discussed outstanding issues on occurrence data of phthalates with support of EFSA's DATA Unit. Different approaches for assessment of dietary exposure to phthalates were discussed.

In addition, the WG discussed the feedback received from the experts concerning the screening of literature and appraisal of studies. General considerations on the scope, content and structure of the opinion were raised.

6. Any Other Business

EFSA informed the WG about the receipt of an updated mandate. In addition to the initial request from the European Commission, i.e. updating EFSA's 2005 opinions on the safety assessment of di-butylphthalate (DBP, FCM No 157), butyl-benzyl-phthalate (BBP, FCM No 159), Bis(2-ethylhexyl)phthalate (DEHP, FCM No 283), which have been authorised for use as plasticisers and technical support agents in plastic Food Contact Materials (FCM), the updated mandate tasks EFSA also with the safety assessment of two other phthalates that are authorised for use in plastic FCM (namely DINP and DIDP). For this purpose, EFSA should consider exposure and toxicity data on these respective substances, focusing on reproductive effects as these were the basis on which ECHA established a Derived No Effect Level (DNEL) for DEHP, DBP and BBP.

EFSA also informed the WG about an on-going public consultation (PC) hosted by ECHA on behalf of the European Commission. This PC is related to a planned amendment of Annex XIV of the REACH Regulation, owing to the additional identification of four phthalates (DBP, BBP, DEHP, DIBP) as substances of very high concern (SVHCs) with endocrine disrupting effects on human health or the environment.

7. Next meeting(s)

17 September 2018

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00588>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00589>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00590>

Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)

Minutes of the 3rd meeting of the Working Group on Phthalates

Held on 18-19 April 2018, Parma

(Agreed on 8 May 2018, by written procedure)

Participants

- **Working Group Members:**

Laurence Castle (chair), Jean-Pierre Cravedi, Cristina Fortes, Inger-Lise Steffensen, Ine Waalkens-Berendsen and Detlef Wölfle

Maria de Fátima Tavares Poças has participated via teleconference

- **Hearing Experts¹:**

European Chemical Agency (ECHA): Marteen Roggeman²

- **European Commission and/or Member States representatives:**

Not Applicable

- **EFSA:**

FIP Unit: Julia Cara Carmona, Anna F. Castoldi, Cristina Croera³, Alexis Lioupis, Ellen Van Haver⁴ and Katharina Volk

DATA Unit: Claudia Maria Cascio⁵

- **Others:**

Not Applicable

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

² Participated on 18 April only

³ Participated on 18 April only

⁴ Participated on 18 April only

⁵ Participated on 18 April only

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Raymond Pieters (member) and Takis Daskaleros (DG SANTE).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁶ and the Decision of the Executive Director on Declarations of Interest⁷, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 2nd Working Group meeting held on 8-9 March 2018, Parma.

The minutes of the 2nd Working Group meeting were agreed by written procedure on 28 March 2018.⁸

5. Scientific topic(s) for discussion

5.1. Update of the risk assessment for di-butylphthalate (DBP, FCM No 157), butyl-benzyl-phthalate (BBP, FCM No 159) and Bis(2-ethylhexyl)phthalate (DEHP, FCM No 283) (EFSA-Q-2017-00588⁹/-00589¹⁰/-00590¹¹)

Preliminary data on occurrence of phthalates extracted from the EFSA Occurrence Database were presented to the Working Group (WG) by EFSA's DATA Unit. Different approaches for assessment of dietary exposure to phthalates were discussed.

⁶ <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

⁷ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

⁸ https://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/minutes_phthalateswg.pdf

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00588>

¹⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00589>

¹¹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00590>

In addition, the WG discussed the feedback received from the experts concerning the screening of literature and appraisal of studies. General considerations on the scope, content and structure of the opinion were raised.

6. Any Other Business

Not Applicable

7. Next meeting

4 June 2018

Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)

Minutes of the 2nd meeting of the Working Group on Phthalates

Held on 8-9 March 2018, Parma (Italy)

(Agreed on 28 March 2018, by written procedure)

Participants

- **Working Group Members:**

Laurence Castle (chair), Jean-Pierre Cravedi, Inger-Lise Steffensen, Maria de Fátima Tavares Poças, Ine Waalkens-Berendsen¹ and Detlef Wölflé

Cristina Fortes and Raymond Pieters² have participated via teleconference

- **Hearing Experts³:**

European Chemical Agency (ECHA): Marteen Roggeman⁴

- **European Commission and/or Member States representatives:**

Not Applicable

- **EFSA:**

FIP Unit: Julia Cara Carmona, Anna F. Castoldi and Katharina Volk

DATA Unit: Claudia Maria Cascio⁵

¹ Participated on 9 March by teleconference

² Participated on 8 March only (by teleconference)

³ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

⁴ Participated on 8 March only (by teleconference)

⁵ Participated on 8 March only

- **Others:**

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Takis Daskaleros (DG SANTE).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁶ and the Decision of the Executive Director on Declarations of Interest⁷, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 1st Working Group meeting held on 7-8 February 2018, Parma.

The minutes of the 1st Working Group meeting were agreed by written procedure on 27 February 2018.⁸

5. Scientific topic(s) for discussion

5.1. Update of the risk assessment for di-butylphthalate (DBP, FCM No 157), butyl-benzyl-phthalate (BBP, FCM No 159) and Bis(2-ethylhexyl)phthalate (DEHP, FCM No 283) (EFSA-Q-2017-00588⁹/-00589¹⁰/-00590¹¹)

Preliminary data on occurrence of phthalates extracted from the EFSA Food Consumption Database were presented to the Working Group (WG)

⁶ <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

⁷ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

⁸ http://www.efsa.europa.eu/sites/default/files/wqs/food-ingredients-and-packaging/minutes_phthalateswg.pdf

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00588>

¹⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00589>

¹¹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00590>

by EFSA's DATA Unit. Different approaches for assessment of dietary exposure to phthalates were discussed.

In addition, the WG discussed the feedback received from the experts concerning the screening of the literature and appraisal of studies. General considerations on the scope and content of the opinion were raised.

6. Any Other Business

Not applicable

7. Next meeting

18-19 April 2018

Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)

Minutes of the 1st meeting of the Working Group on Phthalates

Held on 7-8 February 2018, Parma (Italy)

(Agreed on 27 February 2018, by written procedure)

Participants

- **Working Group Members:**

Laurence Castle (chair), Jean-Pierre Cravedi, Inger-Lise Steffensen, Maria de Fátima Tavares Poças, Ine Waalkens-Berendsen and Detlef Wölfle

- **Hearing Experts¹:**

European Chemical Agency (ECHA): Mark Blainey² and Maarten Roggeman³

- **European Commission and/or Member States representatives:**

Takis Daskaleros (DG SANTE)

- **EFSA:**

FIP Unit: Eric Barthélémy, Julia Cara Carmona, Anna F. Castoldi, Cristina Croera, Alexandros Lioupis, Ellen van Haver and Katharina Volk

- **Others:**

Not Applicable

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

² Participated on 7 February 2018 only (by teleconference)

³ Participated on 8 February 2018 only (by teleconference)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Raymond Pieters (member). The participants introduced themselves and their scientific background.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of the Working Group Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the previous Working Group meeting.

Not Applicable.

5. Scientific topic(s) for discussion

5.1 Update of the risk assessment for di-butylphthalate (DBP, FCM No 157), butyl-benzyl-phthalate (BBP, FCM No 159) and Bis(2-ethylhexyl)phthalate (DEHP, FCM No 283) (EFSA-Q-2017-00588⁶/-00589⁷/-00590⁸)

EFSA presented the mandate received from the European Commission to update its 2005 opinions on the safety assessment of di-butylphthalate (DBP, FCM No 157), butyl-benzyl-phthalate (BBP, FCM No 159), Bis(2-ethylhexyl)phthalate (DEHP, FCM No 283), which have been authorised for use as plasticisers and technical support agents in plastic Food Contact Materials (FCM).

This mandate follows the publication in March 2017 of an opinion on DBP, BBP, DEHP and DIBP by the ECHA's Risk Assessment Committee (RAC) in

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00588>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00589>

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00590>

the context of a restriction dossier under Annex XV of the REACH Regulation⁹.

During the introductory presentation, the EFSA opinions from 2005 and the ECHA RAC opinion from 2017 were summarised and compared, with commonalities, differences and challenges being identified.

The members of the working group (WG) discussed the draft table of contents of the draft opinion on DBP, BBP and DEHP, as well as the work plan. Tasks were distributed among the members.

It was noted that the three phthalates mentioned in the mandate (especially DEHP) are being replaced by other phthalates such as DINP. Consideration of this aspect could be important for the combined exposure assessment, as it would better reflect the current exposure pattern of the general population.

6. AOB

Not applicable.

7. Next meeting

8-9 March 2018

⁹ Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 396 30.12.2006, p.1