



Brussels,  
SANTE/E2/JB/amf (2020)4456913

Dear Dr Url,

**Subject: Part 1 of a 2-part mandate on a re-evaluation of the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances from food contact materials (FCMs)**

Firstly, let me thank you for EFSA's updated risk assessment of five phthalic acid esters (ortho-phthalates), namely DBP, BBP, DEHP, DINP and DIDP, authorised for use as additives in plastic food contact materials (FCMs), published in December 2019<sup>1</sup>. Based on this new opinion, DG SANTE is considering whether any changes to the existing EU legislation are necessary. We will of course keep you informed of the outcome.

The previous mandate sent by the Commission was limited to new scientific information which was assessed by the European Chemicals Agency (ECHA) as regards reprotoxicity. This assessment subsequently resulted in several new restrictions under the REACH Regulation (EC) No 1907/2006. The recently adopted EFSA opinion did not identify any risk to human health from current exposure to these five ortho-phthalates from dietary sources. Nevertheless, it highlighted limitations of the work carried out and has set the Tolerable Daily Intakes (TDIs) on a temporary basis. It is therefore appropriate to address these limitations and establish a greater degree of certainty as regards the possible risks from these phthalates in food, from FCMs.

Additionally, the scope of the previous mandate was restricted to the five ortho-phthalates authorised as additives in annex I to Commission Regulation (EU) No 10/2011, which are used as plasticisers and technical support agents in plastic FCM. However, information collected by the Commission, including a short EU stakeholder survey<sup>2</sup> as well as results of controls carried out by Member States under Commission Recommendation 2019/794<sup>3</sup>, confirms that these five ortho-phthalates are to a large

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<sup>1</sup> EFSA Journal 2019;17(12):5838

<sup>2</sup> [https://ec.europa.eu/food/sites/food/files/safety/docs/cs\\_fcm\\_wg\\_20200224\\_pres-02.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_wg_20200224_pres-02.pdf)

<sup>3</sup> <http://data.europa.eu/eli/reco/2019/794/oj>

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extent being replaced by other plasticisers such as terephthalates, cyclohexanoates and epoxy esters. A list including these substances is provided in annex II to this letter. The information, which we have provided to EFSA, also indicates that other phthalates are used as technical support agents in addition to those specifically authorised for plastic FCM. Of additional importance is the use and occurrence of phthalates and non-phthalate plasticisers in FCM other than plastic, most notably rubber. Whilst it should be stressed that our present findings are not statistically robust enough to draw comprehensive conclusions, it is nevertheless important to take this information into account in the design of the work.

It is understood that ongoing screening and prioritisation work by ECHA on groups of structurally similar substances covers substances that may be relevant as regards their use in FCMs within the scope of this mandate and therefore their possible assessment by EFSA. With reference to the Memorandum of Understanding between ECHA and EFSA<sup>4</sup>, the Commission would therefore like to request that the two agencies work together during the first part of this mandate for identification, prioritisation and preparatory tasks in advance of the second part of the mandate concerning the risk assessment work. This pooling of resources and expertise will promote inter-agency cooperation, maximising efficiency and avoiding duplication of work. This will help ensure that the risk from phthalates, structurally similar substances and their replacements are comprehensively assessed and eventually managed.

Therefore, in collaboration with ECHA, EFSA is requested to:

1. Prioritise and identify those phthalates, structurally similar substances and replacement substances based on the list in annex II to this mandate letter that warrant further data collection and insofar as they may be relevant for eventual inclusion in an assessment of the risks associated with their presence and migration from food contact materials. Existing relevant information, such as that which may be held by ECHA should also be identified.

In preparation for future risk assessments, it is essential to define a priori transparent scientific criteria concerning the quality, selection and appraisal of the studies to be included in the hazard and exposure assessments. This will enable a comprehensive assessment based on robust science and avoid the need to react to ad-hoc requests to respond to individual scientific studies or assessments. Taking account of EFSA's previous experience in developing protocols, the Commission therefore requests EFSA to:

2. Establish a protocol for:
  - a) A dietary exposure assessment of the prioritised substances, with the aim of addressing the relative contribution from FCM to dietary exposure considering data on migration from FCM and eventual comparison of these contributions with the overall exposure of EU consumers;
  - b) A hazard assessment protocol for the prioritised substances, detailing the criteria for inclusion and appraisal of the toxicological evidence publicly available since 2005 and not yet assessed by EFSA.

To complete the first part of this mandate and as regards occurrence, EFSA is also requested to:

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<sup>4</sup> <https://www.efsa.europa.eu/sites/default/files/assets/mouecha.pdf>

3. Establish a call for data on occurrence of the prioritised substances in food to support dietary exposure estimates. Data on migration levels from plastic and rubber FCMs as well as other materials which may be relevant such as printed paper and board should also be collected, where available. This should include articles throughout the whole food chain, including food manufacturing and processing equipment, as well as packaging, kitchenware and tableware. A search and identification of potentially relevant literature on exposure should also be started as part of this task.

The work set out in task 1 of the first part of this mandate is expected to be completed by the end of May 2021. Tasks 2(a) and 2(b) should be completed within 12 months after the list of prioritised substances is established (task 1) i.e. by 31 May 2022. The call for data in task 3 should be launched by April 2022 in alignment with EFSA's annual chemical monitoring data collection cycle.

Once the first part of this mandate is completed during the first half of 2022 and whilst data is being collected, the Commission will send part 2 of the mandate to EFSA concerning the elaboration of the work on the risks to public health related to the presence of the substances in foodstuffs originating from FCMs, identified as a priority in the initial phase of this work. In this second part of the mandate, the Commission will indicate a deadline by which a final opinion should be adopted, taking into account the substances selected for risk assessment.

My services remain at your disposal for further information. On this matter, you can contact Mr Jonathan Briggs, who is responsible for this dossier in Unit E2 in charge of Food processing technologies and novel foods, and Mr Luis Vivas-Alegre, who is the relevant contact point in Unit D1 in charge of Food chain science and stakeholder relations. Their respective phone numbers and e-mail addresses are indicated below.

Yours sincerely,

Claire Bury

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## Annex I

### Terms of Reference

In accordance with Article 29(1)(a) of Regulation (EC) No 178/2002<sup>5</sup>, the European Commission asks EFSA to re-evaluate the risks to public health related to the presence of phthalates, structurally similar substances and replacement substances, as a consequence of migration from food contact materials (FCMs). The following tasks, which constitute the first part of a two-part mandate, should therefore be performed:

1. Prioritise and identify those phthalates, structurally similar substances and replacement substances based on the list in annex II to this mandate letter that warrant further data collection and insofar as they may be relevant for eventual inclusion in an assessment of the risks associated with their presence and migration from food contact materials. Existing relevant information, such as that which may be held by ECHA should also be identified.
2. With a view to ensuring transparency and efficiency during the second part of the mandate, establish a protocol for:
  - a) A dietary exposure assessment of the prioritised substances, with the aim of addressing the relative contribution from FCM to dietary exposure considering data on migration from FCM and eventual comparison of these contributions with the overall exposure of EU consumers;
  - b) A hazard assessment protocol for the prioritised substances, detailing the criteria for inclusion and appraisal of the toxicological evidence publicly available since 2005 and not yet assessed by EFSA.
3. Establish a call for data on occurrence of the prioritised substances in food to support dietary exposure estimates. Data on migration levels from plastic and rubber FCMs as well as other materials which may be relevant such as printed paper and board should also be collected, where available. This should include articles throughout the whole food chain, including food manufacturing and processing equipment, as well as packaging, kitchenware and tableware. A search and identification of potentially relevant literature on exposure should also be started as part of this task.

The work set out in task 1 of the first part of this mandate is expected to be completed by the end of May 2021. Tasks 2(a) and 2(b) should be completed within 12 months after list of prioritised substances is established (task 1) i.e. by 31 May 2022. The call for data in task 3 should be launched by April 2022 in alignment with EFSA's annual chemical monitoring data collection cycle.

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<sup>5</sup> OJ L 13, 1.2.2002, p. 1.

## Annex II

### Substances to be considered as part of the prioritisation exercise\*

Substance abbreviation (full name)	EC Number	CAS Number	FCM Number
DCHP (Dicyclohexyl phthalate)	201-545-9	84-61-7	
DEP (Di-ethyl Phthalate)	201-550-6	84-66-2	
DIBP (Di-isobutyl Phthalate)	201-553-2	84-69-5	
DBP (Di-Butyl Phthalate)	201-557-4	84-74-2	157
BBP (Butyl-Benzyl-phthalate)	201-622-7	85-68-7	159
DEHP (Bis(2-ethylhexyl)phthalate)	204-211-0	117-81-7	283
DAP (Phthalic acid, diallyl ester)	205-016-3	131-17-9	316
DNOP (Di-N-Octyl phthalate)	204-214-7	117-84-0	
Diisopropyl Phthalate	210-086-3	605-45-8	
DINP (Di-isononyl-phthalate)	249-079-5 271-090-9	28553-12-0 68515-48-0	728
DIDP (Di-isodecyl-phthalate)	247-977-1 271-091-4	26761-40-0 68515-49-1	729
DTDP (Diisotridecyl phthalate)	248-368-3	27253-26-5	
DPHP(Bis (2-propylheptyl) phthalate)	258-469-4	53306-54-0	
DIUP (Diisoundecyl phthalate)	306-165-8	96507-86-7	
Ethyl Isobutyl phthalate		94491-96-0	
Di-n-butyl adipate	203-350-4	105-99-7	
Di-n -hexyl azelate/ Dihexyl azelate	203-664-1	109-31-9	
DOTP/ DEHT (Bis (2-ethylhexyl) terephthalate)	229-176-9	6422-86-2	798
TOTM (Trioctyl trimellitate) Synonym: TEHTM	222-020-0	3319-31-1	
PTA (Terephthalic acid)	202-830-0	100-21-0	785
ATBC (Acetyl Tributyl Citrate)	201-067-0	77-90-7	138
DOA or DEHA (Bis (2-ethylhexyl) ester adipate)	203-090-1	103-23-1	207
Dibutyl sebacate	203-672-5	109-43-3	242
TPhP (Triphenyl phosphate)	204-112-2	115-86-6	
EHDP (2-Ethylhexyl Diphenyl phosphate)	214-987-2	1241-94-7	392
ESBO (Epoxidised Soybean oil)	232-391-0	8013-07-8	532
DINA (Di-isononyl adipate)	251-646-7	33703-08-1	
Hydrogenated acetylated castor oil	295-625-0	92113-20-7	
Diisobutyl adipate		141-04-8	
Acetyl triethylhexyl citrate		144-15-0	
Glycerol monoacetate		26446-35-5	
Glycerol diacetate/ diacetin	246-941-2	25395-31-7	
Glycerol triacetate/ triacetin		102-76-1	
Glycerides, castor-oil mono-, hydrogenated, acetates		736150-63-3	783
MB10 (tradename: Jayflex™ MB10; monoester of benzoic acid and isodecyl alcohol)	421-090-1	131298-44-7	
DINCH (1,2-Cyclohexanedicarboxylic acid 1,2-disononyl ester)	431-890-2	166412-78-8	775
Hexanedioic acid polymer with 2,2-dimethyl-1,3-propanediol and 1,2-propanediol, isononyl ester	606-665-9	208945-12-4	
BMMF (9,9-Bis(methoxymethyl)-9H-fluorene)	682-678-3	182121-12-6	779
Hexanedioic acid polymer with 1,3-butanediol and 1,2-propanediol, 2-ethylhexyl ester	n/a	73018-26-5	

Hexanedioic acid polymer with 1,2-propanediol, decyl octyl ester	n/a	136155-46-9	
Hexanedioic acid polymer with 1,2-propanediol, octyl ester	n/a	82904-80-1	
Hexanedioic acid polymer with 1,2-propanediol, acetate	n/a	55799-38-7	
Isosorbide esters			

\*These substances were identified as part of a DG SANTE survey on phthalates and replacement substances, controls by Member States and substances authorised at EU level. The list of substances is non-exhaustive and under development with a view to establishing those substances for prioritisation as per task 1 of this mandate