



# EFSA's activities

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10 July 2018, FCM Network

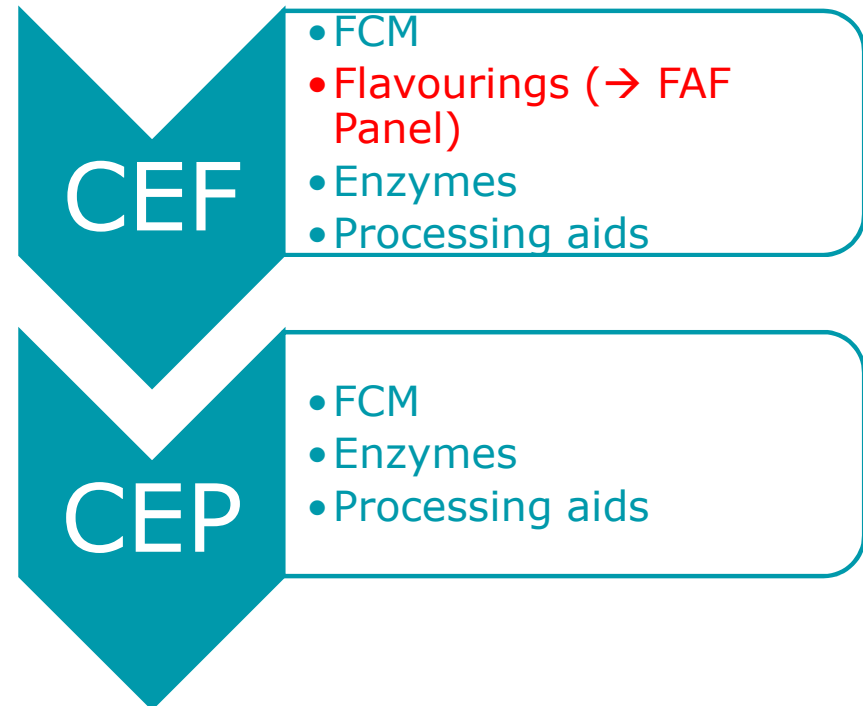
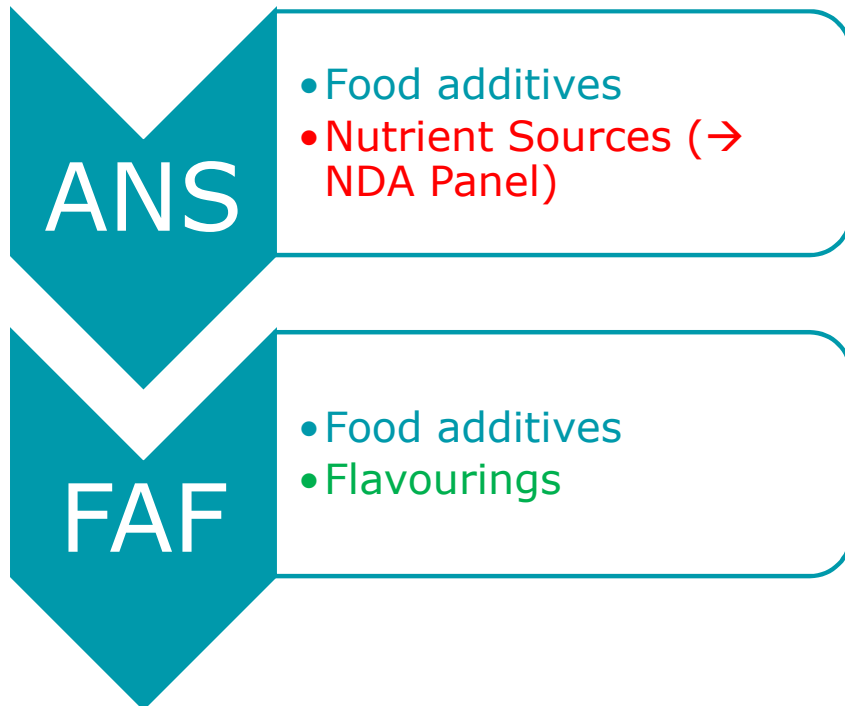
# outline

- Panel renewal
- Tasking grant - GP/EFSA/FIP/2018/01
- Re-evaluation of phthalates
- Re-evaluation of BPA

# Panel renewal

# Panel renewal

- 3-5 July: On-boarding event + 1st Panel session
- 3-years-mandate
- FIP Unit Panels:

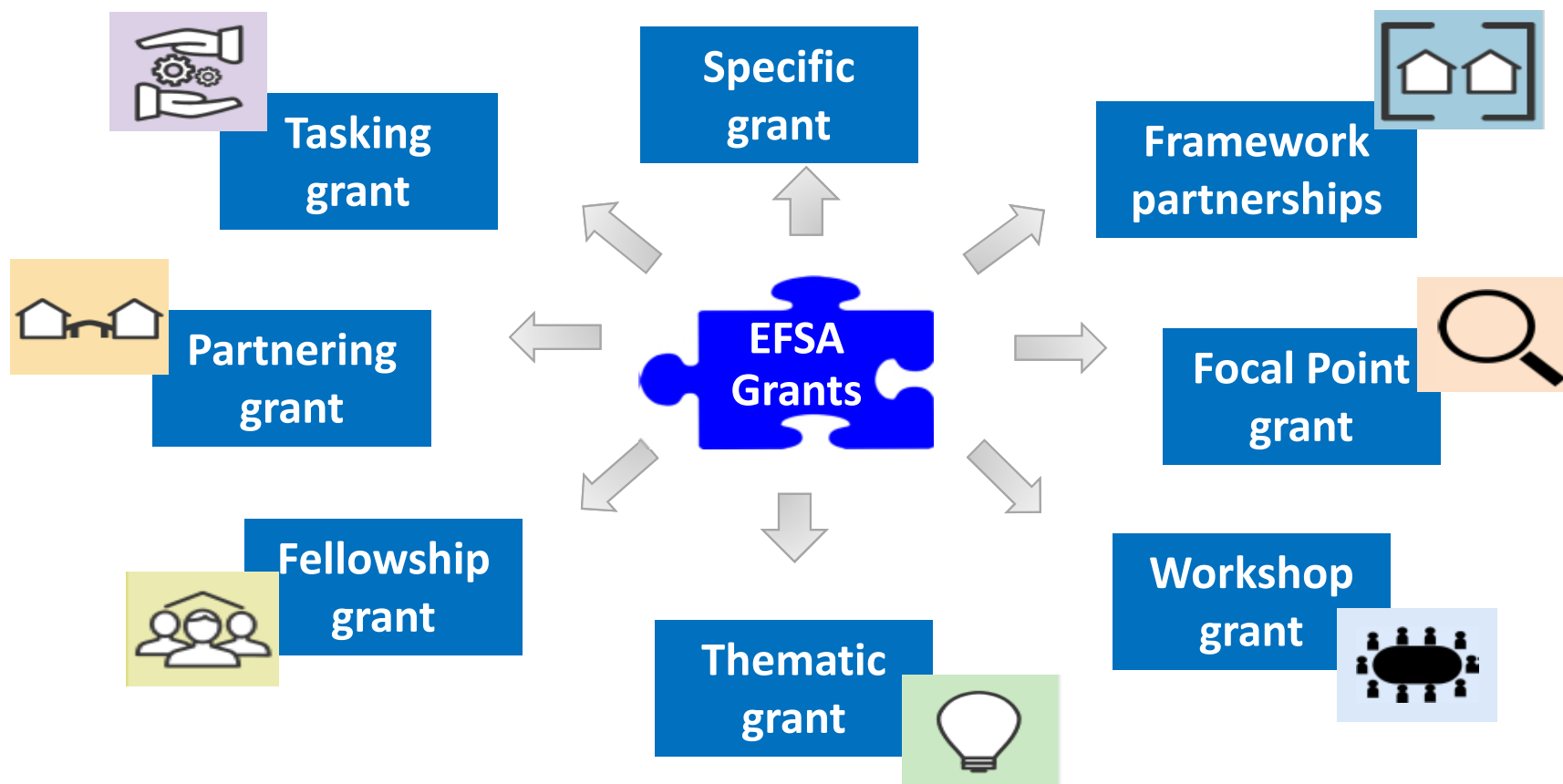


# Establishment of Working Groups on...

- Food contact materials
- Recycling plastics
- Phthalates
- BPA

**Tasking grant**




# EFSA grants - background



Organisations on the Art.36 List only

<http://www.efsa.europa.eu/sites/default/files/assets/art36listg.pdf>

# Tasking grant

<p>Specific grants</p>		<p>Provide EFSA with access to specific expertise in competent Member States organisations.</p> <p><b>Example</b>   <i>Genotoxicity studies to refine risk assessment.</i></p>	<p>Implementing distinct projects</p>
<p>Tasking grants</p>		<p>Allow direct scientific and technical support from Member States organisations.</p> <p><b>Example</b>   <i>Support in assessing large volumes of pesticide dossiers.</i></p>	<p>Receiving direct support</p>
<p>Framework Partnership Agreements (FPA)</p>		<p>Establish long-term partnerships with organisations for recurring scientific and technical support or novel project.</p> <p><b>Example</b>   <i>Risk characterisation of ciguatoxin poisoning by 14 organisations from 6 Member States and EFSA.</i></p>	<p>Creating long-term partnerships</p>



# Tasking grant - GP/EFSA/FIP/2018/01

## “Entrusting support tasks in the area of Food Ingredients and Packaging”

<https://www.efsa.europa.eu/en/art36grants/article36/180502>

- Restricted to Article 36 competent organisations
- Scientific advice and assistance in:
  - Development of a new Guidance on the data required for the risk assessment of **flavourings**
  - Safety evaluation of **food enzymes**
  - Implementation of the evidence-based risk assessment for the re-evaluation of
    - approved **sweeteners**,
    - Bisphenol A (**BPA**) and
    - substances authorised for use in Food Contact Materials (**FCM**).

# Timeline

**2 May**

- Launch of the call

**17 August**

- Deadline for applicants to raise clarification questions to EFSA

**24 August**

- Deadline for EFSA to reply to any clarification questions

**3 September**

- Deadline to submit your proposal

# **Re-evaluation of Phthalates**

# Mandate

Received from the  
European Commission in July 2017

Request:

**„Update of the risk assessments for  
3 phthalates authorised for use in plastic Food  
Contact Materials (FCM)“**

# Mandate - background

## 2005: publication of **EFSA's** opinions

Authorised for  
 use as  
*plasticisers* and  
*technical support*  
*agents*  
 in **plastic FCM**

- DBP  
•Di-butylphthalate
- BBP  
•Butyl-benzyl-phthalate
- DEHP  
•Bis(2-ethylhexyl)phthalate

## 2017: Publication of **ECHA RAC's** opinion

- DBP
- BBP
- DEHP
- DIBP  
•Not authorised  
for use in FCM

**NEW assessment**  
**by ECHA**  
 including also data from  
 after 2005



**Committee for Risk Assessment (RAC)**  
**Committee for Socio-economic Analysis (SEAC)**

Opinion  
 on an Annex XV dossier proposing restrictions on  
**FOUR PHTHALATES (DEHP, BBP, DBP, DIBP)**

# Mandate – Terms of References

- Update EFSA's 2005 opinions on the safety assessment of DBP, BBP, DEHP
  - **using all the information available to the ECHA RAC**, in the context of the dossier under Annex XV of the REACH Regulation proposing restrictions on these three phthalates
- Considering also recent **exposure** and toxicity (focus on **reproductive effects**) data on 2 other phthalates authorised for use in plastic FCM: DINP and DIDP
- Assessing the
  - **contribution of plastic FCM to the individual TDI** for each of these phthalates and
  - potential health risks resulting from the **combined exposure** of consumers **to these phthalates** from food contact materials.
- Deadline: December 2018

# Derivation of TDI/DNEL

- based on N(L)OAEs for **anti-androgenic effects** seen in developmental studies, e.g.
  - testicular toxicity and developmental toxicity (DEHP)
  - loss of germ cell development and mammary gland changes (DBP)
  - reduced anogenital distance (AGD) in F1 and F2 males at birth (BBP)

	EFSA (2005)			ECHA (2017)		
	DEHP	DBP	BBP	DEHP	DBP	BBP
Study reference for PoD	Wolfe and Layton (2003)	Lee et al., 2004	Tyl et al., 2001, 2004	Wolfe and Layton (2003)	Lee et al., 2004	Tyl et al., 2001, 2004
N(L)OAE (mg/kg bw/day)	NOAEL 5	LOAEL 2	NOAEL 50	NOAEL 4.8	LOAEL 2	NOAEL 50
Assessment/Uncertainty Factors	100	200*	100	100	300	100
TDI (mg/kg bw/day)	0.05	0.01	0.5			
DNEL (Derived No Effect Level) internal dose (mg/kg b.w /day)				0.034	0.0067	0.50

→ Agreement on the pivotal studies

\*Factor of 2 for absence of NOAEL

# Other effects investigated - ECHA RA 2017

- Other effects investigated include:
  - effects on the **immune** system;
  - effects on **metabolism**;
  - Effects related to **neurological** development.
- Only a limited search of the literature was conducted

## → Conclusion:

- **need for more robust data** to support these effects in quantitative risk assessment
- But: **time constraints** → therefore no systematic review of the literature; **focus on reproductive effects**



# Exposure assessment

- Biggest change compared to EFSA's 2005 opinions

	EFSA (2005)	ECHA (2017)	
<b>Approach to exposure assessment</b>	Analytical determination of phthalate concentration taking into account main <b>dietary sources</b>	Urinary biomonitoring data	Exposure modelling <b>(different sources:</b> food, indoor environment and contact with articles)
	Exposure to <b>single</b> phthalates	<b>Single exposure</b> to the four phthalates and <b>combined risk</b> considering all sources of exposure	

- Challenges:
  - How to derive the contribution from plastic FCM to the overall exposure?
  - Combined exposure → common mode of action? → group TDI?

# **Re-evaluation of BPA**

# Mandate on BPA re-evaluation



EUROPEAN COMMISSION  
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Director -General

INCOMING N° 4931  
12 OTT. 2016  
EFSA

Brussels,  
SANTE/E2/JB/aa (2016)6194724

Dear Dr Url,

**Subject:** Re-evaluation of the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs and protocol for the risk assessment strategy

## Annex

### Terms of Reference

In accordance with Article 29(1)(a) of Regulation (EC) No 178/2002<sup>2</sup>, the European Commission asks EFSA to:

Finished

- establish a protocol detailing the criteria for new study inclusion and for toxicological evidence appraisal for the re-evaluation of BPA, to ensure an efficient and transparent re-assessment of BPA;

Current

- re-evaluate the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs. In particular, the re-evaluation should take into consideration new data available from the results of the US NTP/ FDA study due in 2017 as well as all other new available information not previously evaluated by EFSA and which fulfil the criteria laid down in an established protocol. This re-evaluation should seek to clarify the remaining uncertainties concerning the toxicological endpoints of BPA, especially those concerning the mammary gland, reproductive, metabolic, neurobehavioural and immune systems and to establish a full tolerable daily intake (TDI) on the basis of the new information available.

# Recent activities

## BPA hazard assessment protocol

- detailing *a priori* the **approach and methodology** for performing BPA hazard identification and characterisation.
- Published 21 December 2017
- <http://www.efsa.europa.eu/en/supporting/pub/en-1354>

## Literature screening and data extraction

- Outsourced to a contractor

## Call for data

- to gather human and animal hazard studies/data (published, unpublished or newly generated) relevant to BPA hazards
- **open until 31 August 2018**

## Start of the re-evaluation

- Establishment of a new Working Group on BPA
- 1st meeting in September/October 2018

# Call for data: please contribute!!

<https://www.efsa.europa.eu/en/consultations/call/180309-0>

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Procurement

## Call for data relevant to the hazard assessment of Bisphenol A (BPA)

Deadline: 31 August 2018

[Document](#)  (233.15 KB)

EFSA-Q-number: EFSA-Q-2018-00221

- **Published: 09/03/2018**
- **Deadline for registering interest: 30/06/2018**
- **Deadline for submission of data: 31/08/2018**

### Background

Bisphenol A (BPA) is an authorised chemical substance to be used in the manufacture of food contact materials such as polycarbonate bottles and internal lining of cans. Its use has been restricted for some articles for infants (infant feeding bottles).

In its latest BPA risk assessment published in 2015, the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) reduced and set the

### Subject area

 [Food ingredients and packaging](#) >

### See also

> [Bisphenol A](#)



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