



Roles and activities of the Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF PANEL)

**Vittorio SILANO – Chairman of the
CEF Panel**



THE CEF PANEL (2014 –2017) AND THE FIP UNIT

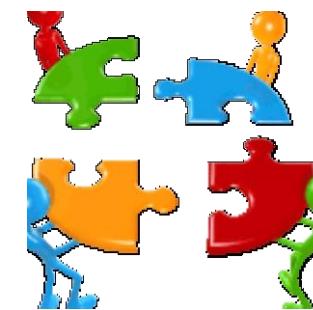
CEF Panel - 18 members with expertise in:
chemistry toxicology or exposure assessment

The FIP Unit:

- Co-ordinates the work programme
- Provides scientific support in drafting opinions, statements and reports
- Organises meetings and travels of the members.

The CEF Panel and the FIP Unit deal with the safety of regulated products including:

- Flavourings
- Smoke flavourings
- Food contact materials
- Enzymes
- Processing aids



More information about the CEF experts <http://www.efsa.europa.eu/en/fip/cefpanelmembers.htm>



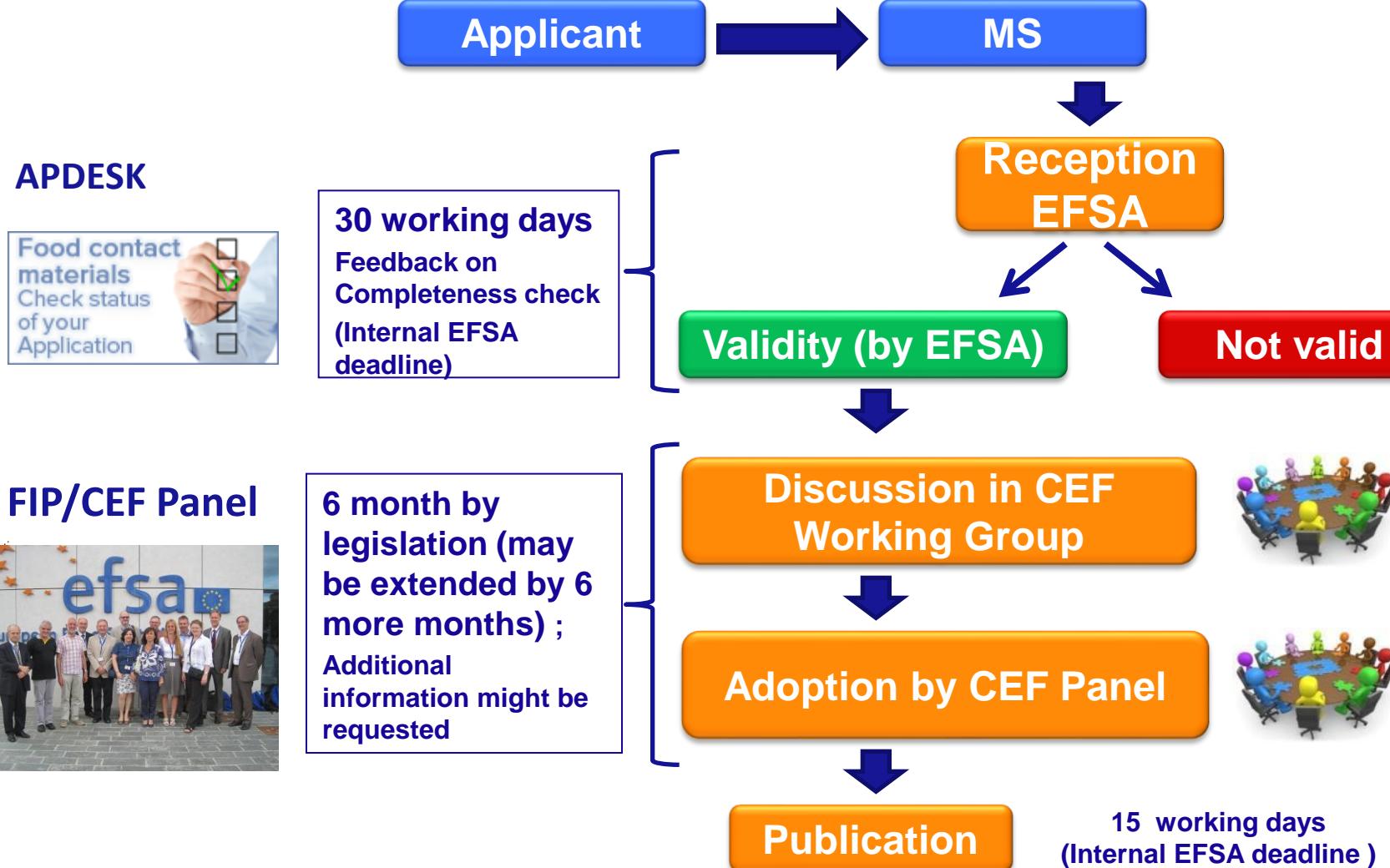
WORKLOAD IN 2015

Flavourings	17
Food Contact Materials	26 Substances
Recycling Processes	11
Guidance on FCM	1
Enzymes	1
Processing Aids	1

Statement on the Refinement of the
Exposure for Food Enzymes for Public
Consultation



TYPICAL WORKFLOW: e.g. FCM APPLICATIONS





WORK AREA : FLAVOURINGS - EVALUATION

New Application

Regulation EC 1331/2008

Regulation EC 1334/2008

EFSA Genotoxicity Guideline

EFSA Flavouring Guideline

Exposure

APET

Evaluation of substance in (EU) No 872/2012

Regulation EC 1565/2000

EFSA Genotoxicity Guideline

Exposure

MSDI/mTAMDI

WORK AREA : FLAVOURINGS - EVALUATION IN A SNAPSHOT

EFSA-FLAVIS Database: 2673 substances

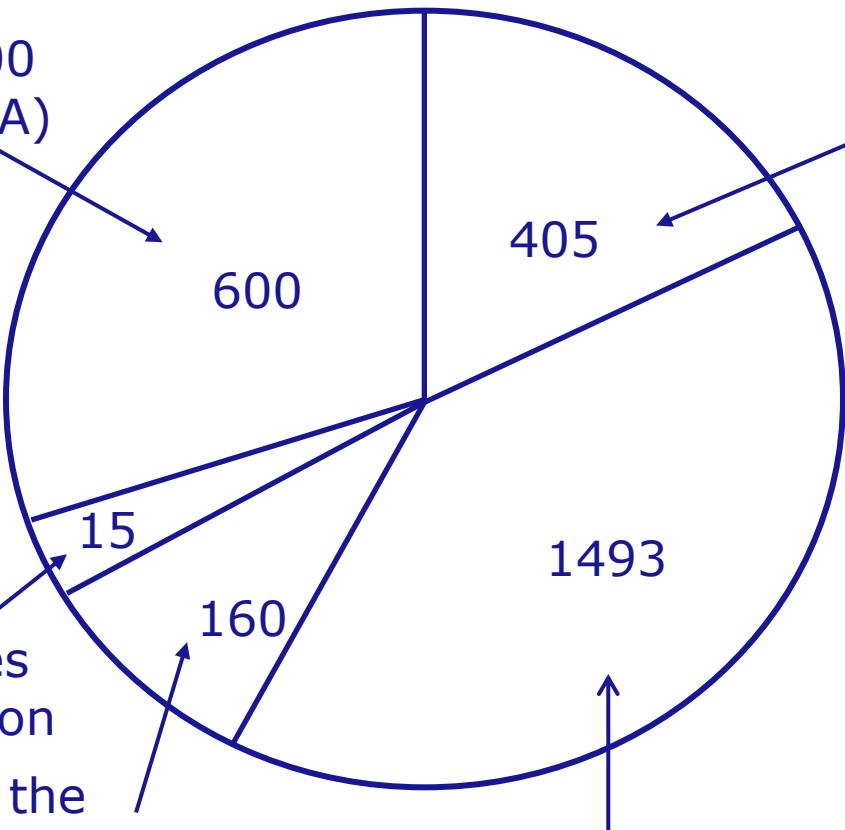
assessed
before 2000
(SCF, JECFA)

additional data
have been requested

new substances
under evaluation

deleted by the
Union List for
different reasons

assessed by EFSA
no safety concern



2069

WORK AREA : FLAVOURINGS - RISK ASSESSMENT

Is the flavouring substance of genotoxic potential?

yes

safety concern

no

**Examination for structural/metabolic similarity to
flavouring substances in an existing FGE**

*Experimental data and/or
relevant literature data
available to demonstrate
sufficient similarity*

**Group -based evaluation
via Procedure**

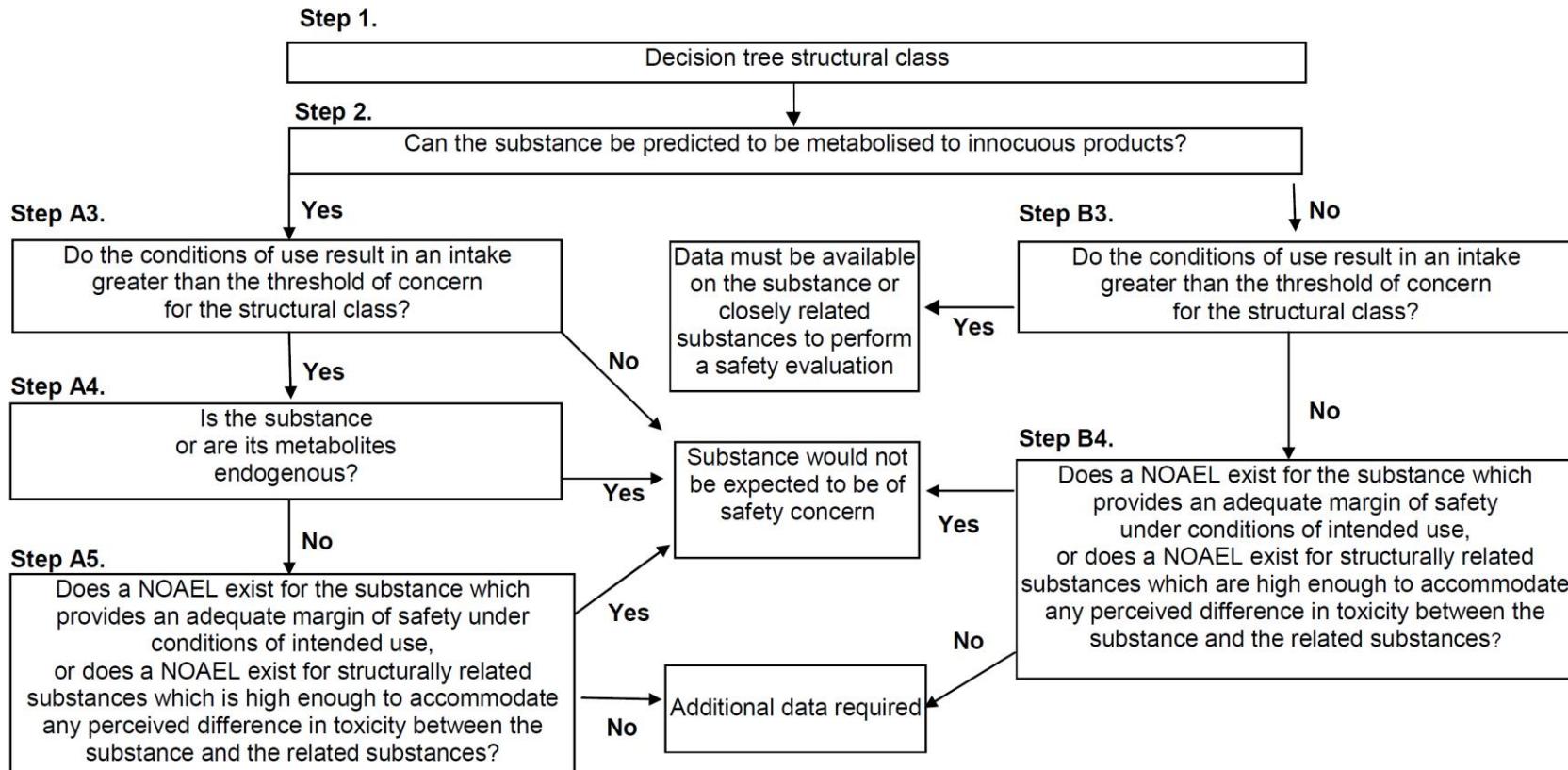
*34 structurally-related
chemical groups*

insufficient similarity

**Individual evaluation of
the flavouring substance**

WORK AREA : FLAVOURINGS - THE PROCEDURE

Procedure for safety evaluation of chemically defined flavouring substances



Note: BMDL may be used instead of NOAEL.



WORK AREA : SMOKE FLAVOURINGS

- According to Regulation (EC) No 2065/2003, the use of a liquid smoke flavouring (defined as a primary product in the legislation) shall only be authorized if it does not present a risk to human health, based on EFSA's safety evaluation.
16 dossiers were submitted in 2005 based on the guidelines adopted in 2004.
- Until 2012 EFSA evaluated **11 smoke flavourings** with the outcome that only three primary smoke flavouring products were found **not to raise safety concerns at the proposed use levels and under the intended conditions of use**.



WORK AREA : FCM

- **In the context of EU specific measures**
 - ❖ Plastics (1982,... 2002, 2011)
 - ❖ Recycled plastics (2008)
 - ❖ Active & intelligent Materials (2009)
- **Based on guidelines** for submission of an application (dossier) for safety assessment of substance/process prior to its authorisation
 - ❖ For plastics => SCF guidelines (1990, 2001), EFSA Explanatory guidance (2008)



PRINCIPLE FOR TOX DATA REQUIREMENT

- The higher the “migration” into food, the greater the amount of data is required

Migration (mg/kg food)	<0.05	0.05-5	5-60
Genotoxicity tests <i>in vitro</i>	+	+	+
90-day oral study in rodents		+	+
Accumulation information		+	+
ADME study			+
Reproduction study			+
Developmental study			+
Long term/carcinogenicity study			+



REVISION OF GUIDELINES IS NEEDED (EFSA, 2011)

- To **ensure** that specific and sensitive populations such as **infants and toddlers** are sufficiently covered
- To take into account new knowledge (**consumption data**) and to align with new EFSA positions
- To **harmonise** with other areas under CEF Panel
- To have a **more robust** scientific basis for the safety assessment



A MULTI-STEPS PROCEDURE

1. **EFSA** opinion outlining scientific rational for revising the guidance document - published together with the technical report on the public consultation on 28 January 2016
2. Next step is for **EC** to discuss with MS the implications for risk managements and advise EFSA on the level of protection for consumers
3. **EFSA** opinion presenting the data requirement for submitting a dossier for safety assessment of a substance to be used in FCM



SCOPE AND LIMITATIONS

Although only for substances (i) used in plastics and (ii) subject to EU authorisation, **the draft opinion indicates our thinking about the science underpinning the safety assessment of any substance that migrates from any FCM**



PUBLIC CONSULTATION

- **209 comments and data were submitted by 11 countries, 21 organisations**
- The CEF Panel **considered stakeholder feedback** whilst finalising their opinion:
 - ❖ additional food consumption category
 - ❖ clarified how to combine food consumption with migration of chemicals into food
 - ❖ clarified the need to take account of other sources of exposure to these substances
 - ❖ additional tier in toxicological data requirement

RECYCLED PLASTICS MATERIALS

- **Post-consumer** bottles are recycled through a recycling process that decontaminates and produces NEW bottles or sheets (e.g. PET water bottles)
- **Within closed and controlled loop** recycling (no consumer contamination, e.g. crates for fruits & vegetables)





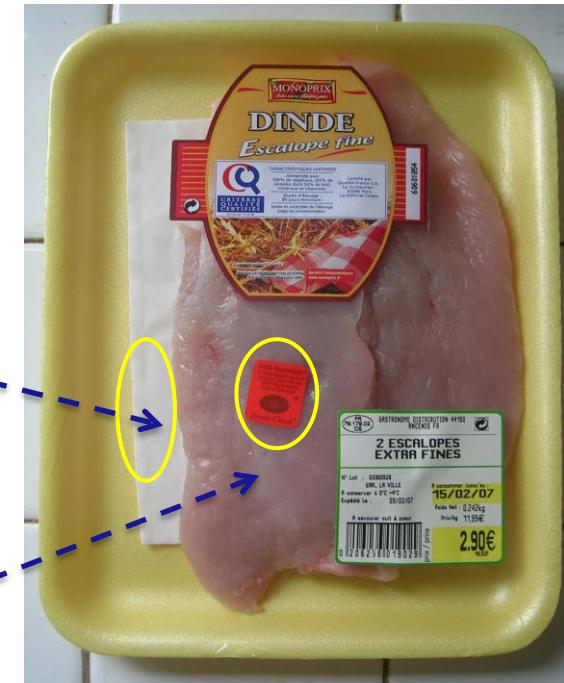
RECYCLED PLASTICS MATERIALS

- ❑ **Specific regulation (EU) 282/2008** on recycled plastic materials and articles intended to come into contact with foods
- ❑ EFSA **guidelines** on submission of a dossier for safety evaluation of a recycling process to produce recycled plastics (2008)
- ❑ EFSA **criteria** for safety evaluation of a mechanical recycling process to produce recycled **PET** (2011)
- ❑ **134 applications** submitted and valid, **57 opinions on 106 valid applications**

ACTIVE & INTELLIGENT MATERIALS

□ Active materials

Function to extend shelf-life or maintain/improve conditions of packaged food (e.g. **liquid, absorber pads, O₂ scavenger, CO₂ scavenger & O₂ emitter...**)



□ Intelligent materials

Function to monitor conditions of packaged food or surrounding environment (e.g. time-temperature indicator)



ACTIVE & INTELLIGENT MATERIALS

- **Specific regulation (EU) 450/2009** for active and intelligent materials (AIM) should include a Community Register of **authorised** substances
- **EFSA guidance for evaluation** of substances to be included in a EU list of authorised substances (2009)
- **43 applications** submitted by January 2016, **28 opinions** on **33 valid applications**



WORK AREA : FOOD CONTACT MATERIALS

Number of dossiers on Food Contact Materials assessed in past years and in 2015

YEAR 2004-2014

322 (FCM substances)

YEAR 2015

26 (FCM substances)

YEAR 2008-2014

123 (Rec processes)

YEAR 2015

11 (Rec processes)



URGENT REQUEST FOR SAFETY EVALUATION

- **Phthalate** plasticisers, **semicarbazide** (SEM) and **epoxidised soybean oil** (ESBO). Of particular concern because of their presence in packaging materials used for food consumed by infants and young children
- **Isopropylthioxanthone** (ITX), **benzo-phenone** and **4-methylbenzophenone**, used in printing inks which were detected analytically in certain foods following migration from the packaging and the safety of which had not previously been evaluated

WORK AREA : BYSPHENOL A

BPA

- Dec 2014: Adoption of the opinion on the health risks for consumers from BPA exposure. Previously, BPA has been evaluated by EFSA in 2006, 2008 and 2010.
- Huge amount of work: 3 years, 26 WG experts, more than 1000 pages long opinion, 73 WG meetings, 2 stakeholder events, 2 public consultations, 500 comments
- Novel approaches applied for this risk assessment:
 - (1) Structured weight of evidence in tabular format
 - (2) Oral human equivalent dose approach
 - (3) Assessment of dietary and non-dietary (dermal, inhalation) exposure
 - (4) Quantitative analysis of uncertainties to identify the extra-factor to apply for the TDI derivation
 - (5) Included in the "Top Ten abstracts in risk assessment Award" at the Annual meeting of the US Society of Toxicology (SOT March 2015)





WORK AREA : FOOD ENZYMES

2008.12.16

Reg. (EC) 1331/2008: **common authorisation procedure**

Reg. (EC) 1332/2008: **food enzyme**

Reg. (EC) 1333/2008: food additives

Reg. (EC) 1334/2008: flavourings

2011.3.10

Reg. (EU) 234/2011: **implementing Reg. (EC) 1331/2008 on content and procedure**

2012.6.27

Reg. (EU) 562/2012 : **specific data requirement**

deadline for receiving applications

2015.3.11

2009.7.23

EFSA GD on submission of food enzyme dossier

2011.7.8 - **Explanatory note (v1)**

2013.1.17 – 1st EFSA Info session

2014.4.7 - Explanatory note (v2)

2014.5.14 – 1st Sci Op

2014.5.27 – 2nd EFSA Info session

2014.7.25 – three more Sci Op

2014.11.14 – Explanatory note (v3)

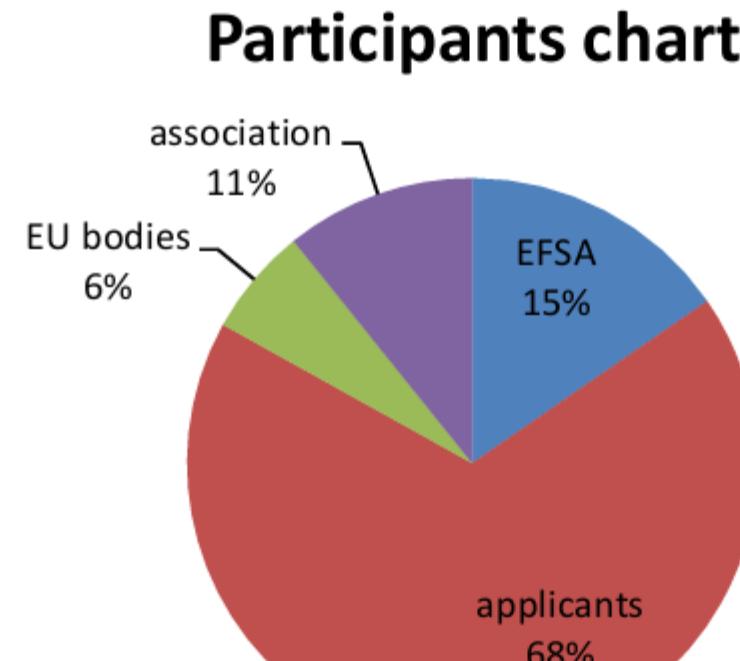
2015.2.18 – the 5th Sci Op

2016.2.3 – 3rd EFSA Info session



WORK AREA : FOOD ENZYMES

The CEF Panel draft statement on the refinement of exposure of food enzymes presented and its use illustrated by the examples during Info session in Brussels on 3 February 2016





MAIN TOPICS DISCUSSED DURING INFO SESSION

- ❑ Budget method: basis of consumption data, validity within today's diet and data availability
- ❑ Why a tiered approach was proposed by the EFSA CEF Panel?
- ❑ Importance and challenge in matching indicative uses of the enzymes with final foods list
- ❑ Possibilities to link the enzyme concentration data and consumption data: type of data provided in the dossier, type of data needed for risk assessment



FUTURE DEVELOPMENTS ON FOOD ENZYMES

- Public consultation on the draft statement elaborated by the CEF Panel
- Revision of draft statement based on the comments received during the Info session and public consultation
- Adoption of the final statement by the CEF Panel
- Agreement on a work program based on priorities between EFSA and the EC

PUBLIC CONSULTATION ON DRAFT STATEMENT

- Open from 16 February 2016 until 31 March 2016
- Details can be found:



<http://www.efsa.europa.eu/en/consultations/call/160216>

Draft Statement on Exposure Assessment of Food Enzymes

Deadline: 31 March 2016

Subject area

Food ingredients and Packaging

Consultations

- Closed consultations

Calls for data

Observers

Colloquia

Careers

Procurement

Grants

Document (533.15 KB)

Privacy statement (89.73 KB)

EFSA's Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) has launched a public consultation on its draft Statement on exposure assessment of food enzymes. This document proposes a strategy to refine the exposure estimation by following a tiered approach as a self-tasking mandate of the CEF Panel.

This strategy was presented to stakeholders during an **Info Session on food enzymes on 3 February 2016**. In line with EFSA's policy on openness and transparency and in order for EFSA to receive comments from a wider scientific community and stakeholders, EFSA has launched this public consultation.

This document is intended to be an annex to the **CEF guidance on food enzymes**. After receiving feedback from interested parties, the document will be revised accordingly and published together with a report summarising the outcome of the public consultation.

How to participate

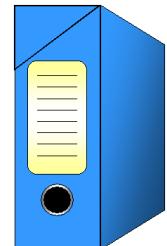
All stakeholders and interested parties are invited to submit written comments by **31/03/2016**. Please use the electronic template provided (<http://registerofquestions.efsa.europa.eu/roqFrontend/consultation/doc/61>) to submit comments and refer to the line and page numbers. Kindly note that after 2 hours of non-activity your working session will expire and comments submitted after that time will not be recorded and transmitted. Therefore, if the page is left inactive for more than 2 hours, please re-open it from the link before restarting to comment. If you would like to submit additional data to support your comments or file send an email to: [\[FIP.PublicConsult.61@efsa.europa.eu\]](mailto:[FIP.PublicConsult.61@efsa.europa.eu]). Please note that comments will not be considered

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22/02/2016



WORK AREA : PROCESSING AIDS

- Processing aids are not covered by specific legislation (except for extraction solvents: Directive 2009/32/EC)¹⁾
- Mandates fall under Article 29 of Regulation (EC) No 178/2002
- Only a limited number of applications received by EFSA
- One new mandate in 2015
(Increase in MRL for dimethyl ether)



SCIENTIFIC OPINION

Scientific Opinion on the evaluation of the safety and efficacy of lactic acid for the removal of microbial surface contamination of beef carcasses, cuts and trimmings¹

EFSA Panel on Biological Hazards (BIOHAZ)^{2,4}

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)^{3,4}

SCIENTIFIC OPINION

Safety in use of dimethyl ether as an extraction solvent¹

Scientific Opinion of the Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing aids (CEF)

¹⁾ <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32009L0032>



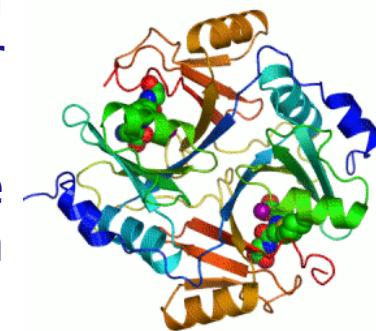
COOPERATION WITH MEMBER STATES

- FIP Network
- Sharing information on regulated products:
 - ❖ according to Article 6 of Regulation (EC) No 1331/2008 the Enzymes additional information is made available to the Member States (through the FIP collaborative workspace)
 - ❖ according to Article 9 of Regulation (EC) No 1935/2004 the FCM applications and supplementary information supplied by the applicants is made available to the Member States (through the FIP collaborative workspace)



FUTURE WORK OF THE CEF PANEL

- ❑ Updating and applying the guidance on data submission on the evaluation of substances for food contact material;
- ❑ Updating the approach for the exposure estimation of food enzymes and evaluation of a very large number of already presented dossier;
- ❑ Completing the on going safety evaluation of existing flavouring;
- ❑ Re-evaluation of the safety of BPA – Development of a protocol detailing the strategy for the hazard assessment.





Thank you very much for your attention