

‘Food Contact Materials’
within the
European Food Safety Authority
(EFSA)’

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The General mission of EFSA

The Authority shall:

1. Provide independent scientific advice and scientific and technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety.
2. Provide independent information on all matters within these fields
3. Communicate on risks.

EFSA bodies that provide independent scientific advice

1. Scientific Committee

Composition

- Chair persons of the 9 Scientific Expert Panels
- 6 scientists not members of a Panel

2. Nine Scientific Panels

The Nine Scientific Panels of EFSA

1. Food additives, flavourings, processing aids and materials in contact with food (**AFC**)
2. Additives and products or substances used in animal feed (**FEEDAP**)
3. Plant protection products and their residues (**PPR**)
4. Plant health (**PLH**)
5. Genetically modified organisms (**GMO**)
6. Dietetic products, nutrition and allergies (**NDA**)
7. Biological hazards (**BIOHAZ**)
8. Contaminants in the food chain (**CONTAM**)
9. Animal health and welfare (**AHAW**)

*The Panel on food additives,
flavourings, processing aids and
materials in contact with food
(AFC Panel)*

AFC Panel - composition

- 21 independent members
(appointed for the period
2006 – 2009)
- 10 different nationalities

<i>Nationality</i>	<i>Number</i>
Belgium	1
Denmark	2
France	3
Germany	3
Ireland	1
Italy	4
Netherlands	2
Portugal	1
Spain	1
U.K.	3

*The AFC Panel deals
with questions related to:*

- the **safety in use** of food additives, flavourings, processing aids and materials in contact with food;
- the safety of other deliberately added substances to food;
- the **safety of processes** and related questions.

The AFC Working Groups

- WG on Food Additives
- WG on Food Flavourings
- WG on Food Contact Materials

WG - Food Contact Materials

- Composition of WG (18 members):
 - AFC Panel members with interest in FCM (9)
 - External independent experts (8)
 - Representative of Commission (1)
- Expertise present in WG:
 - Chemistry
 - Toxicology
 - Intake and exposure
 - (Food) technology and microbiology
- Meetings: 5-6 times a year for 2½ days

Number of questions to AFC 2003-2007

Food additives	45
Flavourings	41 (comprising 2800 substances on EC Register plus 911 from JECFA)
Smoke flavourings	17
Processing aids	4
<i>Food contact materials</i>	<i>182 (34%)</i>
Food supplements	248
<u>Total</u>	<u>537</u>

Questions to FCM WG (2003 – 2007)

Number of questions	182
Number of substances covered by questions	210
Number of substances covered in published FCM opinions	101
Published opinions/ statements on specific issues/substances	<i>BADGE, ESBO, BPA, SEM, ITX, Phthalates, Organotins</i>
Number of substances still to be evaluated	<i>± 80 substances</i>
General issues still to be covered	<i>- Guidelines on recycling of plastics - Active and Intelligent Packaging</i>

AFC – Procedures for evaluating safety of FCM substances

1. Petition is submitted to EFSA

- Data/information provided by petitioner should be according to :

‘Note For Guidance for submission of a dossier on a substance to be used in Food Contact Materials for evaluation by EFSA’

http://www.efsa.europa.eu/en/science/afc/afc_guidance/722.html

2. AFC secretariat investigates completeness of dossier and sends AAP (Administrative Acceptance Procedure)

AFC – Procedures for evaluating FCM substances, (continued)

3. AFC secretariat submits petition to a rapporteur, i.e.:

- an individual expert, member of FCM WG
- an institution contracted by EFSA

4. Rapporteur submits SDS (Summary Data Sheet) to FCM WG for evaluation

SDS contains:

- Description of non-toxicity data,
- Description of toxicity data,
- Conclusions of rapporteur
- Proposal of 'Draft opinion'

AFC – Procedures for evaluating FCM substances, (continued)

5. FCM-WG evaluates substance.

If data are missing, petitioner is contacted again.

If substance accepted by WG, draft opinion is sent to the AFC Plenary meeting for final discussion

6. AFC adopts opinion; published on EFSA home page

7. Commission takes management action

AFC – Procedures for approving FCM substances (continued)

Requested non-toxicity data

- Identity and purity of substance
- Physical and chemical properties
- Intended application of substance
- Data on migration of substance
- Data on residual content in the FCM

AFC – Procedures for approving FCM substances (continued)

Request for microbiological data (when relevant - biocides):

- Intention of use (effect in production vs. final product)
- Spectrum of microbiological activity
- Possibility for formation of resistance
- Efficacy
- Lack of effect in/on the food (if migration to food in effective concentrations the use is considered food additive and should be regulated as such)

AFC – Procedures for approving FCM substances (continued)

Requested toxicity data:

<u>Migration:</u>	< 0.05 mg/kg	< 5 mg/kg	> 5 mg/kg
- 3 mutagenicity tests	+	+	+
- 90 days study	-	+	+
- (bio)accumulation	-	+	-
- Long term and developmental studies	-	-	+

AFC – Procedures for approving FCM substances (continued)

Evaluation by EFSA (SCF-list 1-5):

- List 0: Acceptable (food or similar to food)
- List 1: Acceptable (ADI allocated for food additive)
- List 2: Acceptable (TDI allocated if full tox. dossier)
- List 3: Acceptable (no TDI, possibly restriction e.g. 0.05 mg/kg or 5 mg/kg)
- List 4: Undesirable, but may be used if not migrating to food
- List 5: Not acceptable

AFC – Procedures for approving FCM substances (continued)

Evaluation by EFSA (SCF-list 6-9):

- List 6: Suspicion of harmful effect (if used none, or very low migration)
- List 7: Not enough data. Petitioner contacted to supply missing according to guidelines
- List 8: Practically no data, full dossier requested
- List 9: Substance not satisfactorily defined

AFC – Procedures for approving FCM substances (continued)

General assumptions:

- 1 kg food in contact with 6x1 dm²
- A person is unlikely to consume more than 1 kg food per day in contact with a given material or article
- Specific Migration Limit (SML) = 60 x TDI mg/kg
(assuming 60 kg person)

Thank you