EU Food Contact Materials requirements and safety assessment

Eric Barthélémy
European Food Safety Authority (EFSA)

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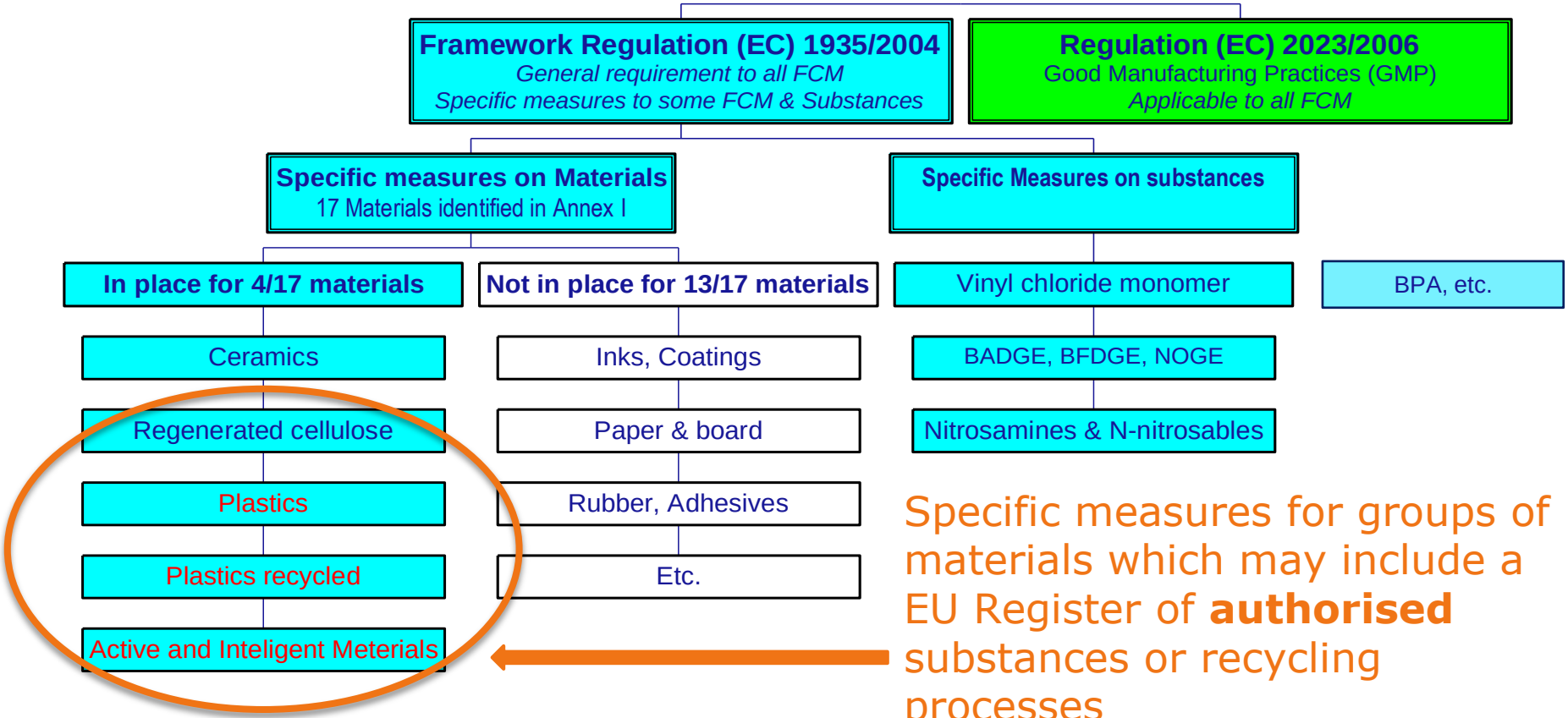
To consult the opinions of EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF), and CEP Panel since July 2018 (= CEF without flavourings)

see www.efsa.europa.eu

Outline

- ✓ **Current requirement and safety assessment**
- ✓ **EFSA CEF Panel opinion on recent development and proposals for revision**

EU legislation on FCM



Specific measures for groups of materials which may include a EU Register of **authorised** substances or recycling processes

General requirements for specific measures

- ✓ When a list of substances or processes is adopted, **anyone seeking an authorisation** for a substance or a process not yet included in that list shall submit an **application**
- ✓ **EFSA** shall give an opinion on the safety assessment of the substance (or process)
- ✓ Lays down the **workflow** and makes reference to **guidance for the safety assessment** of a substance by EFSA

EFSA guidance

- ✓ **Guidances** for submission of an application (dossier) for safety assessment of substance/process prior to its authorisation
  - Recycled plastics (Reg. (EU) 282/2008) => EFSA guidance for plastics recycling (2008) and EFSA criteria for PET recycling (2011)
  - Active & intelligent Materials (Reg. (EU) 450/2009) => EFSA guidance (2009)
  - **Plastics (Reg. (EU) 10/2011) => SCF guidelines (2001) and EFSA Note for Guidance (2017)**

What is evaluated for plastics?

- ✓ In accordance with regulation (EU) 10/2011,
  - the regulated substance and its impurities
  - The expected (and intentional) reaction and transformation products coming from use of the substance. An antioxidant will be oxidised and a monomer will form oligomers. These are predictable and can be analysed for and evaluated.
  - Main reaction and degradation products coming from the use should be considered (evaluated) & included in restrictions of substance. They are not listed.
- ✓ **Not** colorants, solvents, aids to polymerisation

Overview of data to be supplied

- Identity (structure, CAS, MW, (im)purity...)
- Physical & chemical properties (stability, solubility, reactivity...)
- Intended uses (manufacture, contact conditions, t, T, food, S/mass…)
- Migration potential & residual content
- Toxicity data acc. to the level of migration
- Microbiological *properties (biocides)*

More details in EFSA Note for Guidance, in particular in EFSA explanatory guidance

Principle for toxicological data requirement

The **higher the "exposure" into food**, the **greater the amount of data is required**

Applicable for all substances: monomers, additives, reactions products, etc.

Toxicological data required

- **Tiered approach with three tiers**

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

Default exposure Assumptions (SCF, 2001)

- ✓ In 2001, human exposure data were not available
  - A person (60 kg bw) consumes daily and throughout whole life-time, up to 1 kg food packaged in 6 dm^2 FCM always releasing the substance at full SML
  - Exposure ⇔ migration per kg food (simulant)
- ✓ **"One major area to revisit is the estimation of consumer exposure" (EFSA CEF Panel, 2016)** as it does not take into account **infants and toddlers** who have highest consumption per kg bw ; also toxicological tiers should take this into account

Further considerations on infant & children

- ✓ EFSA considered that **consumption of food per kg b.w. by infant & children** is expected to be higher than of adults (AFC Panel, 2003, 2005), and recommended to develop specific migration limit in baby foods for soybean oil, epoxidised from PVC gasket (AFC Panel, 2004)

Determination of Migration of substance

- ✓ Migration evaluated considering:
  - 100% mass transfer from the material
  - Migration modelling (EU JRC)
  - **Data on migration into food simulants**
- ✓ Worst conditions of materials, thickness, max. substance use/content, contact conditions
- ✓ Migration tests performed **under defined testing conditions (Reg. (EU)10/2011)** that correspond to uses requested: t, T and food contact

Contact Condition when using food simulants

- ✓ **List of simulants** depending on foodstuffs (*Reg. EU 10/2011 – Annex III*)
  - A (aqueous): 10% ethanol
  - B (acidic) : 3% acetic acid (m/v)
  - C (alcool): 20% ethanol (v/v)
  - D1 (milk, alcool/spirits): 50% ethanol(v/v)
  - D2 (gras): vegetable oil
  - E (dry): Tenax

Oligomers

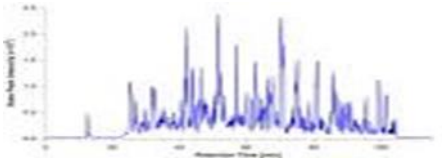
- ✓ Of interest for monomers & polymeric additives
- ✓ Low molecular weight fraction (LMWF) below 1000 Da is relevant fraction by default except for per/poly-fuorosubstances (1500 Da)
- ✓ If monomers bear structural alert for genotoxicity, genotoxicity tests on LMWF could be provided unless genotoxic potential can be ruled out
- ✓ General toxicity on LMWF could be provided according to tiers as for substances

The current practice is aligned with EFSA CEF Panel Opinion (2016)

Non Intentionally Added Substances (NIAS)

- ✓ Evaluation follows the **same approach as regulated substances** with more consideration for addressing the genotoxicity potential
  - TTC (0.0025 µg/kg bw per day) (EFSA, 2012)
  - Computational tools (SAR/QSAR)
  - 'Read-across (as for regulated chemicals)'

- ✓ **Limitations/challenges**
  - Chemical analysis (identification and quantification)
  - To get enough material for testing the potential toxicity
  - Experimental versus TTC levels of detections



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How are the migration limits set?

✓ Two main situations

- There is no toxicological value of reference such as "TDI" available (case of migration < 0.05 mg/kg food simulant)

  => Restriction on migration (SML) based on tier of 0.05 mg/kg food AND/OR max. intended uses, food contact conditions

- A toxicological value of reference can be used; case of migration above 0.05 mg/kg food (0.05-5 and 5-60 mg kg/food)

  i. NOAEL/UF ("TDI") > tier (i.e. 5 or 60 mg/kg food) **=>** Restriction on migration based on tier and/or uses…

  ii. NOAEL/UF < tier **=>** Restriction on migration based on "TDI" and/or uses…

Revision is needed – EFSA CEF Panel, 2016

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Recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials

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

Abstract

This Opinion describes recent developments in the safety assessment of chemicals in food and explores their potential impact on EFSA evaluation of food contact materials (FCM). It is not intended to be a guidance document. The draft opinion was subject to a public consultation and this final Opinion takes into account the scientific comments received. The Opinion will provide the European Commission with the scientific basis for a discussion among risk managers on possible implications for risk management. One major area to revisit is the estimation of consumer exposure. Four food consumption categories could be set. They are approximately 9, 5, 3 and 1.2 times higher than the current SCF default scenario, i.e. 17 g/kg bw per day, and so using them would afford a higher level of protection, particularly for infants and toddlers. Special exposure scenarios might be used if consumption were lower. The amount of toxicity data needed should be related to the expected human exposure. The tiered approach of the SCF is updated. For substances used in FCM, genotoxicity testing is always required, even if their migration leads to a low exposure. Beyond this, three threshold levels of human exposure, namely 1.5, 30 and 80 µg/kg bw per day, are proposed as triggers for the requirement for additional toxicity data. Regarding the identification and evaluation of migrating substances, experience has shown that more focus is needed on the finished materials and articles. Considering the non-intentionally added substances (NIAS), such as impurities of the substance along with reaction and degradation products including oligomers, the same approach as is used for authorised substances could, in principle, be applied for their toxicological assessment, as the same degree of safety should be warranted for all migrating substances. However, non-testing methods could have increased importance for the assessment of genotoxicity of NIAS.

Scope and limitations

The opinion indicates CEF Panel thinking about the science underpinning the safety assessment of

any substance that migrates from any FCM

Key message

The scientific opinion describes how the safety assessment of substances used in food contact materials could be refined and could afford a higher level of protection for infants and toddlers

It also clarifies current practices (NIAS, oligomers) and align with 'new' EFSA positions (e.g. TTC, nano, genotoxicity)

Food consumption data are available

- ✓ With MS, EFSA has developed **EU consumption databases** in order to support risk assessment
  - EFSA Concise EU Food Consumption database (2008): on limited number of broad categories, limited to preliminary assessment
  - EFSA Comprehensive EU Food Consumption database (2011): more detailed database based on 32 dietary surveys, EXPOCHI, providing food consumption data on a EU-wide basis

Revisiting estimation of consumer exposure

Proposed new approach is to estimate **exposure from 4 specific food categories** covering the intended uses (special exposure scenarios could be used if consumption is lower)

4 food consumption scenario

✓ Based on use(s) of the FCM containing the substance under evaluation:

Category	Food categories for which the FCM containing the substance under evaluation are intended to be used	Population driving the consumption[a]	Food consumption to be considered for the estimation of exposure (g/kg bw per day)
1	Water and baby bottle contents such as reconstituted milk formula	Infants[b]	150
2	Milk, milk products and other non-alcoholic drinks (e.g. fruit and vegetable juices)	Toddlers[c]	80
3	Solid foods specifically intended for infant and toddlers	Toddlers	50
4	Foodstuffs not covered by categories 1, 2 and 3	Toddlers	20

260 g/kg bw per day infant below 16 weeks (EFSA SC, 2017)

Other sources

✓ **Other sources need to be considered**

Known or anticipated exposure from:

- other plastics, non-plastic FCMs
- other food sources
- non-dietary sources when exposure is significant

Toxicological data requirement

Whereas the toxicity data requirement stays related to the **tiered approach** recommended by SCF (2001), the **related tier values and toxicological data needed for the safety evaluation could be updated**

Tiered approach to tox data requirements

✓ Based on highest calculated exposure (µg/kg bw/day)

Minimum requirement	– 2 genotoxicity tests *in vitro* – available information including an appropriate literature search More data (1) if existing data indicate potential to affect endocrine or *neural systems*; (2) for substances with a high potential to accumulate in humans; (3) for nano
1.5 (or 30 if substance is classified as Cramer class I**) ≤ Exp ≤ 80**	As above, PLUS: – extended 90-day oral toxicity study in rodents (***** with prenatal treatment period or an extended one generation reproduction study (EOGRTS), if there are existing data indicating endocrine activity suggesting potential effect from prenatal exposure) – an ADME for substances for which a potential for accumulation in man could be anticipated
Exp > 80	As above, PLUS: – study on ADME – studies on reproduction (EOGRTS) & developmental toxicity – studies on long-term toxicity (*****)/carcinogenicity

Additional requirements - endocrine effects

- **For all tiers, additional studies on specific endpoints may be needed**

- ***In vitro* studies on endocrine effects** are useful to identify potential modes of action but do not necessarily reflect *in vivo* situation and should be interpreted carefully...

Read-across

- ✓ Read-across may also be used in the hazard characterisation of **all migrating substances**
  - **A chemical for which toxicological effects have been tested** can be used to predict the same toxicological endpoints for an untested chemical...
  - Case-by-case and if adequate justification and supporting data available
  - Possible additional uncertainty factor
  - Guidances: OECD 2014; ECHA 2013, 2015

Next steps

- ✓ EFSA will prepare the **guidance on data requirements for the evaluation of substances** (with public consultation)
- ✓ But on-hold pending EC decision and ongoing evaluation of the FCM regulation which the end is foreseen early 2020 (https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/evaluation_en)

THANK YOU FOR YOUR ATTENTION

EFSA:

http://www.efsa.europa.eu/

EFSA Journal on Wiley:

https://efsa.onlinelibrary.wiley.com/journal/18314732

EFSA Scientific Network on FCM:
https://www.efsa.europa.eu/it/food-ingredients-and-packaging/networks

Let us contribute together to a safe food…