

**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)**

Comments and Proposals from EuPC and Flexible Packaging Europe



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Key points

- The opinion offers the potential to be applied to all food contact materials.
- EFSA recognises that one major area to revisit is the estimation of consumer's exposure in the risk assessment of food contact materials.
- Compliance issues with the 4 food categories
- Toxicological assessment, especially for oligomers and NIAS
- Legislation: implications and proposals



Extension of Risk Assessment to all FCM

- The EFSA proposed Risk Assessment can be applied regardless the chemical nature of the FCM, i.e. whether plastic or non-plastic
- A great opportunity to address all FCM's with one single regulatory measure which would allow a harmonized approach, in line with the EU Parliament initiative
- A highly positive message to consumers
- Requires proper allocation of resources to minimise timeline



Believes that,... the Commission should prioritise the drawing-up of specific EU measures for paper, board, coatings, inks and adhesives;



Estimation of consumers exposure

- The introduction of more refined food consumption data represents a step forward in the estimation of exposure
- Exposure to migrants shall however be completed by using more refined data on Substance Use and Material Use Factors
- If this won't happen (i.e. adjusting only the food consumption) the system will simply become more over-conservative and will artificially create non-compliance for many packaging materials



Estimation of exposure: proposal

- Use refined/updated dietary intake studies in combination with existing Material Use Factors as available from the Matrix and/or Facet projects
- Run further refinement through more specific studies, which we recommend to undertake and would be happy to participate in.



Compliance issues with the 4 food categories

Comments in the following 2 slides are referred to Table 1 of the EFSA opinion, reported below

Table 1: Food consumption figures based on the categorisation of application(s) of the food contact material(s) 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

(a): This means that the critical population (infants or toddlers) consuming the foods grouped in a category has the highest consumption of one or more of the foods in that category; this does not mean that the critical population consumes all food types falling into that category.

(b): Infants are young children aged up to 12 months.

(c): Toddlers are young children aged from 12 months up to and including 36 months.



Compliance issues with the 4 food categories

- As the current food consumption scenario is split into four food categories, four different SMLs will become applicable to a substance if it is used for all food categories
- Testing and compliance activities will highly increase; considering that the 4 food categories are not associated to the same food simulants, such increase will become very significant



Compliance with the 4 food categories: proposal

- We propose that for food category 4, the reference consumption of 20 g/kg bw/day is sufficiently close to the current scenario of 17 g/kg bw/day so that the existing SML values can remain unchanged
- We propose that the applicable SML for food categories 1-3 would be done by setting up a table of correction factors, e.g. 9 for food category 1; 5 for food category 2 and 3 for food category 3. These correction factors would not be applicable for SML corresponding to “non-detectable”
- We also propose that these correction factors would replace (not come on top of) the current rules for compliance assessment for foods for infants and toddlers (i.e. the calculation with the actual S/V ratio)
- As OML is independent of food consumption and S/V, it should not be subject to a correction factor



Toxicological assessment

- We welcome the use of the concept of read- across (ch. 8.5). We would like non-testing methods accepted for NIAS also to be accepted for IAS, allowing more efficient use of resources and reducing the use of experimental animals
- Nanomaterials: although science is evolving, the way the section is written puts all approaches under question marks and the requirements are too vague, which makes the assessment of the compliance totally unworkable for industry



Compliance issues with NIAS

- NIAS: requiring tests on the finished FCM that depends on knowledge not available at that stage is highly ineffective and introduce unacceptable liability to manufacturers
- We can anticipate that the proposed SML of 50 ppb for oligomers of substances, e.g. 871, 1031, 1052 will hardly work because that restriction cannot be tested at final FCM level. As the information may be known upstream, that restriction would pose additional complexity to the exchange of information practices
- Commission and EFSA should more thoroughly consult industry stakeholders, and come up with restrictions that work.



Legislation: implications and proposals

1. Use of Allocation Factors for addressing exposure from FCM, as well as non-FCMs
2. Use an holistic approach to the legislation on FCM, based on Exposure



1. Use of Allocation Factors: Developing a *Risk Cup* Distribution Model for Risk Management of FCMs

- If multi exposure routes are present, allocation factors for individual exposure routes can be applied to the ADI and/or TDI . The allocation factors must take into consideration all the different sources of exposure
- Starting from ADI- example: FC use 20% allocation factor to FCMs
- Starting from TDI- example: if only FC applications drive the exposure 100 % of the TDI is used for the FCMs. If FC and non-FC applications drive the exposure allocation shall be used, e.g. 80 % of the TDI for the FCMs, 10% to food flavorings and 10% to materials in contact with drinking water



Risk cup principle



When the risk cup starts to overflow (too high exposure) exposure drivers need to be reduced either by eliminating or at least minimizing a use (equal to a route of exposure) or by reducing the allocation factor for such critical exposure

The acceptance of the principal of the use of allocation factors to account for multiple exposure routes leads the way to refining the exposure from FCM by utilising more refined Material Use Factors

2. Use an holistic approach to the legislation on FCM, based on Exposure

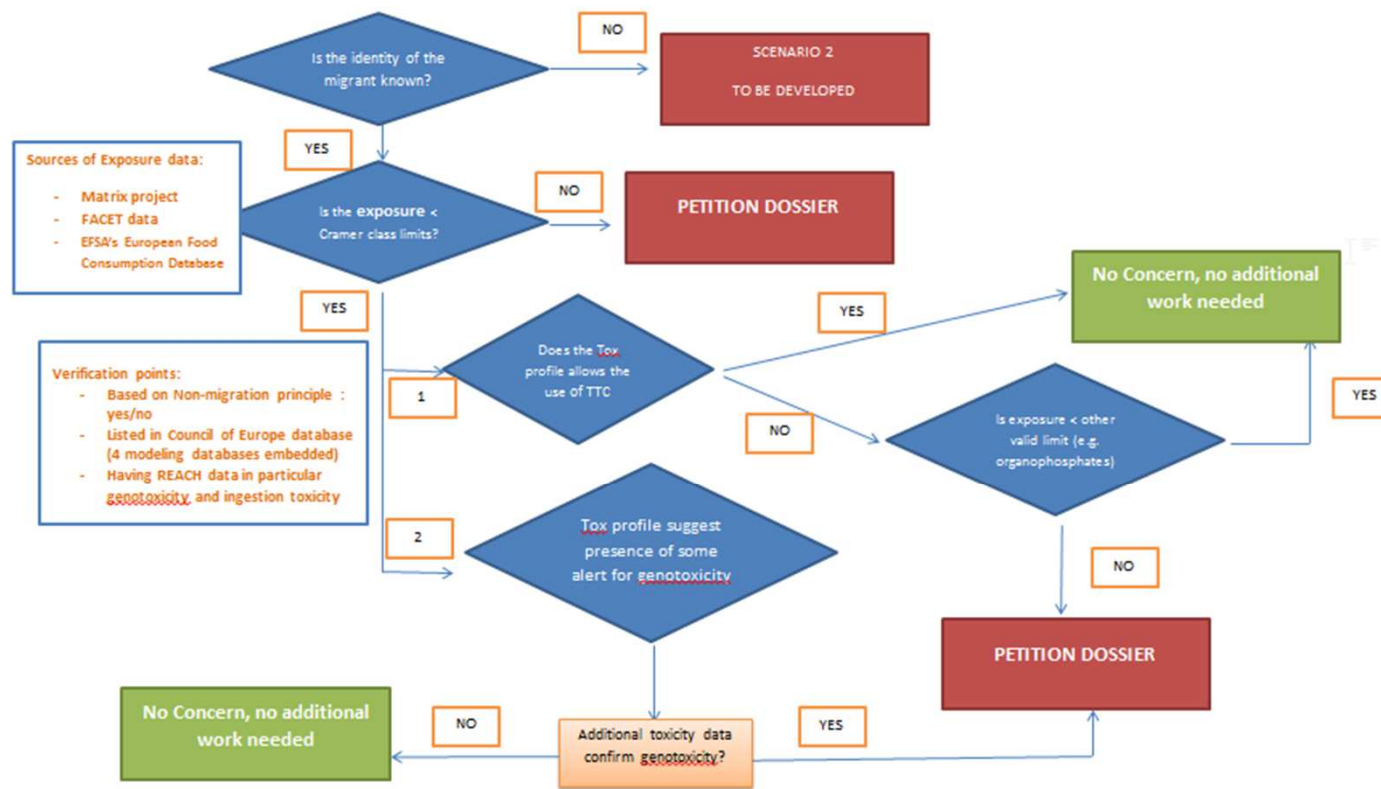
- *The scheme reported in the next slide represents the PCG thinking on a possible approach to address all substances migrating from FCMs – regardless whether plastic or non-plastic*
- *It should be seen as a discussion document rather than a structured final proposal; it may represent a first bulding block for future legislation*



Starting point: **Final food contact material / article and migration behavior**, taking into account basic principles such as: Right choice of raw materials, Right choice of the quality of these raw materials, GMP

Scenario 1 – Known Migrants:

*This is a **discussion document**, not a structured final proposal; it may represent a first building block for future legislation*



Further discussion points

- Minimization of animal testing likewise in REACH and Cosmetics regulation
- Acceptance of use of the Council of Europe substance database
- Use the REACH data
- Use of Letters of Access
- Need of Guidelines to address Exposure evaluation

