FCM Network meeting, 6-7 November 2019

Update of the risk assessment for '**wood flour and fibres, untreated**' (FCM No 96) and **criteria for future applications** of materials from plant origin as plastic additive

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Background

- ‘wood flour and fibres, untreated’ added to the list of additives for plastic FCM in 1995 (Directive 95/3/EC)
  - Rationale for SCF evaluation: **inertness**
  - But: **no data on evaluation available**
- in recent years: technological developments and innovations, e.g. **plastic materials containing substances from different biomass sources**
  - Compliance problems
  - Marketing of these articles (e.g. ‘natural’, ‘bamboo’ etc)

→**Regulatory framework** is **unclear**

Mandate (13 Dec 2018)

In accordance with Article 12(3) of Regulation (EC) No 1935/2004[2], the European Commission asks EFSA to review whether the authorisation of untreated wood flour and fibres (FCM No 96) is still in accordance with Regulation (EC) No 1935/2004, as provided for in Article 12(3).

The substance is presently authorised based on its inertness as an additive for the manufacture of plastic food contact materials (FCM), and listed in Annex I of Regulation (EU) No 10/2011, with no Specific Migration Limit (SML).

Step 1

EFSA should evaluate whether the authorisation of FCM 96 based on its inertness is still in accordance with Regulation (EC) No 1935/2004, as provided for in Article 12(3).

It may not be possible to conclude that the authorisation of FCM 96 is still in accordance with the Regulation, for instance because insufficient specific data on the relevant parameters is available.

Step 2

In that case, EFSA should define to the extent possible, the information that will be necessary, and is not presently set out in its notes of guidance for FCM, to assess the safety and support the use of wood and the use of similar materials from a plant origin as plastic additives under Article 9 of Regulation (EC) No 1935/2004.

In doing so, EFSA should take account of parameters that EFSA considers relevant such as wood species, sources, plant parts, treatment and processing, final application in plastic, and the final composition of the plastic containing the wood/plants elements. EFSA should elaborate its views based on a literature search and expert judgement.

Interpretation of mandate

- Terminology 'untreated' is not defined in the context of the initial authorisation

  →interpretation for this assessment:

  - **Source material** (i.e. wood) **can be treated**, and has to in order to produce the flour and fibres
  - But **the product/additive does not undergo further treatment**

- terminology 'wood' in the context of this evaluation is understood as the **hard tissue of trees**. Other parts like **bark, fruits and leaves** of the tree are **excluded**

- Assessment of 'wood flour and fibres, untreated' and criteria do **not apply to recycled/re-used wood and similar materials from plant origin**

Evaluation - background

- Tradition of use in many **food contact** applications, e.g. crates, boxes, worktops, kitchen utensils, barrels
- Wood-plastic-composites for **non-food contact** applications as e.g. building materials (fences, floors, furniture etc) → use of additives like coupling/foaming agents, lubricants, etc.
- Some tree species are '**poisonous**' or have 'poisonous' parts, e.g. pines, red cherry, yellow poplar, holly
- EFSA Compendium on botanicals lists numerous tree species

Evaluation - background

- **National provisions** on wood:
  - Dutch regulation on food contact materials
  - French Information Note on wood for food contact
  - Chinese Draft National Standard for Food Contact Materials – bamboo, wood and cork

Evaluation – wood chemical composition

- Complex and varying composition due to differences in species, age, genetic and geographical factors, growth
- Main macromolecular components
  - **Cellulose, lignin and hemicelluloses**
- Extractives
- Mineral components
- Environmental contamination, residues from wood preservation, chlorophenols etc.

→Important for the context of FCM evaluation:

composition and **content** of **migratable substances**

Evaluation – Migration of substances from wood

- **No information** on migration of wood substances from **plastics made with wood flour and fibres**

- **Some information** on migration of substances from wood as FCM, mainly related to the use of wooden **barrels for wine making**

Criteria – general basis

- Variability in composition and possible presence of toxic substances in some woods

→**Evaluation** of wood and similar materials from plant origin **as for any other plastic additives**

→following the criteria set out in the EFSA **Note for Guidance** For the Preparation of an Application for the Safety Assessment of a Substance to be used in Plastic Food Contact Materials (EFSA, 2008)

Proposed specific criteria for safety evaluation of wood and other plant materials

- **species**
- possible variability related to age and growth conditions, geographical **origin**
- Treatment during cultivation/storage
- **manufacturing** from the **source material** into the **additive**
- substances used together with the additive to **produce the plastic material**
- comprehensive analysis of the **low molecular weight constituents**, including contaminants
- **migration of substances resulting from using the additive**, comparing **samples made with and without the additive**
- **toxicological data** covering the migrating **substances detected in this analysis**

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