

IMPORTANT! THIS NOTE REFLECTS DISCUSSIONS OF THE EXPERT WORKING GROUP ON FOOD CONTACT MATERIALS OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED. IT HAS NOT BEEN ADOPTED OR ENDORSED BY THE EUROPEAN COMMISSION. THE VIEWS MAY NOT IN ANY CIRCUMSTANCES BE REGARDED AS STATING AN OFFICIAL POSITION OF THE EUROPEAN COMMISSION. THIS NOTE IS INTENDED ONLY TO REFLECT A SUMMARY OF DISCUSSIONS IN THE CONTEXT OF THE APPLICATION OF REGULATION (EC) NO 1935/2004 AND COMMISSION REGULATION (EU) NO 10/2011. ONLY THE COURT OF JUSTICE OF THE EUROPEAN UNION IS COMPETENT TO AUTHORITATIVELY INTERPRET UNION LAW.

Brussels, 23 June 2020

Summary of discussions of the Expert Working Group on Food Contact Materials ('FCM') on the use and placing on the market of plastic food contact materials and articles containing ground bamboo or other similar constituents

NOTICE: This note updates and replaces the note published in June 2019

Investigations by Member States have shown that in recent years an increasing number of food contact materials and articles are placed on the market that are manufactured from plastic and to which bamboo and/or other 'natural' substances are added¹. One common example is kitchenware or tableware, such as reusable plates, bowls and coffee beakers. These materials and articles are often similar in appearance and function to melamine tableware or kitchenware as they typically also consist of melamine plastic but also contain ground bamboo ('bamboo-melamine') or other similar constituents such as corn, as an additive, often functioning as a filler. They are less shiny however. Other examples include, but are not restricted to, bamboo fibres that are added to a polymer resin binder to form a composite product.

These investigations also established that a number of these bamboo-melamine food contact materials and articles placed on the market are sold on the premise of being sustainable, recyclable and natural. They are labelled and marketed as 'biodegradable', 'eco-friendly', 'organic' or 'natural' or even in some cases '100% bamboo', which does not reflect the true nature of the product. In many cases their trade name and/ or description are used in support of that marketing approach and they are not readily identified as consisting of plastic.

The Working Group notes that Article 3(2) of Regulation (EC) No 1935/2004² requires that '*the labelling, advertising and presentation of a material or article shall not mislead consumers*'. Business operators should therefore ensure that the labelling and advertising of such products are consistent with the product that is placed on the market, taking into account the actual composition of the products. In cases where melamine or other types of plastics are used as the main structural component in materials and articles, which also consist of other components such as bamboo, such promotional statements, especially those implying that the products are composed only of non-plastic material or do not contain any plastic, may be

¹ The types of materials and articles that are the subject of these discussions are noticeably different from those in which the bamboo or other natural products such as wood are used in or close to their natural form. Although adhesives and coatings may still be present on or in these materials and articles, the composition of the product does not involve the use of other filler materials or resin.

² <http://data.europa.eu/eli/reg/2004/1935/oj>

considered misleading by enforcement authorities of the Member States and therefore non-compliant with Regulation (EC) No 1935/2004³.

Over the last few years, there have been a number of notifications under the Rapid Alert System for Food and Feed (RASFF)⁴ concerning bamboo-melamine food contact materials and articles. Migration of melamine and formaldehyde has been found on a number of occasions to be considerably above the Specific Migration Limits (SMLs) of 2,5 mg/kg and 15 mg/kg respectively, laid down in Commission Regulation (EU) No 10/2011⁵, leading to the withdrawal of the product from the market. In addition, it was observed that the migration could go up in subsequent tests⁶.

The migration of melamine and formaldehyde above the respective SMLs indicates non-compliance with the restrictions with the use and presence of melamine and formaldehyde in plastic food contact materials. The Working Group has therefore discussed and highlighted the need for enforcement authorities and business operators to pay special attention to such products, taking into consideration possible mislabelling, insofar as levels of melamine or formaldehyde may also migrate from these products in quantities above the SMLs laid down in the legislation.

For such materials and articles consisting of a polymer but also containing ground bamboo or other similar constituents as an additive, the Working Group considers that Regulation (EU) No. 10/2011 applies⁷. This Regulation requires that only substances included in the Union list of authorised substances, set out in Annex I to that Regulation, may be used in the manufacture of plastic layers in plastic materials and articles, including additives. Neither the Regulation nor the associated guidelines⁸ provide a maximum (or minimum) content of additives that a final material or article could contain under the definition of a plastic.

The use of bamboo or any other additive in the manufacture of plastic food contact materials and articles, for example to fill or reinforce the plastic, requires an authorisation in accordance with Articles 9 – 11 of Regulation (EC) No 1935/2004. Such an authorisation must be given and laid down in Annex I to Commission Regulation (EU) No 10/2011 before these additives can be used in the manufacture of plastic food contact materials and articles and the resulting product placed on the market.

No such authorisation has been given for bamboo. Such an authorisation has been given for FCM no. 96 "wood flour and fibers, untreated". The first version of this note concluded that the extent to which bamboo falls within this authorisation may have been unclear since bamboo is from the Poaceae (grass) family, whereas wood is derived from the trunk or branches of a various other families of the tree or shrub. Therefore, the use of bamboo as an additive may have been considered authorised by some under FCM no. 96.

³ Related to this issue but not the subject of this note are polymeric materials manufactured from bio-sourced starting substances, which are also erroneously not marketed as plastics such as PLA (polylactic acid) and PHA (polyhydroxyalkanoates) but are nevertheless subject to Regulation (EU) No 10/2011. Here the marketing may assume a different definition of plastics based on the notation that plastics are manufactured from fossil sources only.

⁴ https://ec.europa.eu/food/safety/rasff_en

⁵ <http://data.europa.eu/eli/reg/2011/10/oj>

⁶ [BfR Statement on "Bamboo ware"; 25.11.2019](#)

⁷ Regulation (EU) 10/2011 defines a plastic as follows: '*plastic*' means polymer to which additives or other substances may have been added, which is capable of functioning as a main structural component of final materials and articles; – there is no specification of the maximum amount of additives that may be added.

⁸ https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_plastic-guidance_201110_en.pdf

Since the first publication of this note, the European Food Safety Authority published its opinion as regards FCM no. 96 "wood flour and fibers, untreated". This opinion concludes⁹:

“Wood cannot be considered inert per se owing to the many low molecular weight substances it contains, and when migrating into food, the safety of these constituents must be assessed. Presently available information is insufficient to support that the authorisation of ‘wood flour and fibres, untreated’ (FCM No 96) is in accordance with Regulation (EC) No 1935/2004. Given the chemical differences in composition of wood species, the safety of migrants from these materials must be evaluated on a case-by-case basis, considering beyond species also origin, processing, treatment for compatibilisation with the host polymer and assessment of the low molecular weight constituents migrating into food. This applies to other plant materials as well.”

According to the Authority, the safety of wood should therefore be evaluated species by species, rather than at the level of the wood family. This opinion thus does not support the application of the existing authorisation of FCM 96 to additives derived from the grass family. As no other substance is listed which covers the use of bamboo, and no applicable derogation is set out under Article 6, no legal basis exists for the use of bamboo flour as an additive in plastics. Its use is therefore considered to be not in compliance with the compositional requirements set out in chapter II of Regulation (EU) No 10/2011. This would also be true for other non-wood species if no species-specific authorisation is provided for in Annex I to Regulation (EU) No 10/2011. According to Article 4 of that Regulation, plastic food contact materials and articles may only be placed on the market if they comply with the compositional requirements set out in the Regulation. The Working Group noted that for ground sunflower seed hulls (FCM No. 1060) such an authorisation is indeed available.

The Working Group has discussed that additives from a natural origin such as bamboo in a plastic matrix may themselves constitute a low health risk. Health risks may arise however if the quality of those natural additives is poor, if they contain impurities or contaminants, if they contain or contribute to the formation of reaction or decomposition products which constitute a health risk, or if the material swells and thus result in adverse surface alterations. Indeed, recent investigations on bamboo-melamine food contact materials and articles have shown such effects. In such cases, the material may not be fit for purpose and may lead to elevated levels of substances from the plastic, including melamine and formaldehyde, migrating into foods.

The EFSA opinion shows that additives from a natural origin may contain toxic substances. EFSA also considers compatibility with the host polymer to be a relevant parameter for wood, and noted that when an additive is used at high levels, it may influence the migration properties of the host plastic, also in case of other plant materials.

The Working Group agrees that it is the responsibility of business operators to ensure that such food contact materials and articles and the substances used for their production are suitable for the intended and foreseeable use of the materials or articles, as required under Article 8 of Regulation (EU) No 10/2011. For instance, if an article can foreseeably contain foods such as soups that are hot, liquid, and fatty, they should also be compliant when in contact with such foods and for example where necessary, tested accordingly using the correct simulants. In Accordance with Article 16 of that Regulation, documentary evidence shall be presented to the competent authorities upon their request that supports the Declaration of Compliance (DoC). This evidence shall be sufficient to allow the competent authorities to establish that these articles were produced using good manufacturing practices, as required under Regulation (EC) No 2023/2006.

⁹ <https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2019.5902>

Manufacturers or importers of bamboo-melamine food contact materials and articles may not consider these materials as being plastic materials and articles by mistake or by lack of knowledge over the applicable legislation. Consequently, no verification of compliance with Regulation (EU) No 10/2011 is undertaken. This may lead to the placing on the market of materials and articles from which substances, such as of melamine or formaldehyde contained in the plastic, migrate in quantities above the SMLs. Market controls of bamboo containing plastic materials and articles demonstrate this. There are over 50 RASFF notifications concerning high levels of formaldehyde migration from such products, of which over 10% were found to be exceeding the specific migration limit by more than a factor 10.

Finally, the working group has noted that when a melamine resin is used in a bamboo containing plastic, Regulation (EU) No 284/2011 applies to materials and articles manufactured with that plastic, where they also fulfil the other conditions of that Regulation.

Conclusion of the Experts of the Working Group on FCM of the SC-PAFF:

Ground bamboo, bamboo flour, and many similar substances including corn are not listed in Annex I to Regulation (EU) No 10/2011. These additives cannot be considered wood, and would require a specific authorisation such as exists for ground sunflower hulls. When such additives are used in a polymer, the resulting material is a plastic. Therefore, plastic FCM containing such unauthorised additives are not in compliance with the compositional requirements set out in that Regulation when placed on the EU market.

Furthermore, Member States have reported a number of notifications concerning migration of melamine and formaldehyde above the specific migration limits (SMLs). In certain cases, the labelling and advertising of these FCMs may also be considered misleading by enforcement authorities and therefore not in compliance with the Regulation.