TOX/2021/34

COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

The potential human health risks of bamboo bio-composites in food contact materials

Background

1. In May 2020, a paper entitled “Scoping paper: alternatives to conventional plastics for food & drinks packaging (TOX/2020/24)”[1] was presented to the Committee. The Committee was asked to provide further guidance on the potential toxicological hazards associated with bio-based food contact materials (BBFCMs).

2. In October 2020, a paper entitled “Update on alternatives to conventional plastics for food and drinks packaging TOX/2020/50”[2] was taken to the COT, which provided a table of enquiries received from the FSA Food Contact Material (FCM) Policy Team in addition to relevant market data.

3. The safety assessment and legislation covering bamboo coffee cups was raised, owing to an increasing number of incidents of non-compliant products with respect to formaldehyde/melamine content. Additionally, interactions between bamboo and melamine could result in increased migration levels of formaldehyde. Manufacturers often used conventional plastics alongside BBFCMs. The Committee was informed that biobased materials used for food contact were subject to the same requirements as other materials, under The Materials and Article in Contact with Food (England) Regulations 2012 as amended. For use in the material, whatever its source, the product needs to be safe for the use to which it is put. “Safe” as a concept was not restricted by a specific definition within the legislation.

4. It was noted that composite materials, such as bamboo with a melamine binder, were often labelled simply as being of biological origin which was potentially misleading. However, the plastic component of the material was subject to the existing stringent requirements on chemical migration from food contact plastics. The FSA had a working assumption that the plastics legislation was directly applicable if 50% or more of the article was a polymer resin; whilst that legislation should be referred to for compliance

[1] https://cot.food.gov.uk/sites/default/files/2020-10/Tox%202020%2024%20Alternatives%20to%20conventional%20plastics%20for%20foods%20and%20drinks.pdf
[2] https://cot.food.gov.uk/sites/default/files/2020-10/TOX.2020.50%20BBFCM%20paper%20update.pdf

assurances if under 50%, with non-compliance determined under the general rather than specific provisions.

5. The European Commission had indicated it held a different view, implying that it would consider a product to be a plastic if it contained a percentage composition of less than 50%. Based on the 2019 EFSA opinion, Bamboo was not an authorised plastic additive, this is because it was stated that bamboo was not in the same taxonomic class as other permitted plant material (EFSA, 2019). The FSA was not currently recommending that such products were removed from the market solely on that basis. The same stance was being taken across Europe given that the EU has not put forward its proposals for handling the expected vast number of applications for the authorisation of such materials, with the majority expected to come from those who are already placing articles on the market. Further details about the transitional measures were essential. In the meantime, enforcement action can be taken on misleading labelling, or if migration levels of specific chemicals exceed Specific Migration Limits.

6. Following the issued EFSA Opinion and the European Commission's position on bamboo FCMs not being authorised in the European Union, the COT are asked to examine the toxicological risks of bamboo in composite plastic articles.

Regulatory aspects

7. Bamboo and bamboo filler, are not currently authorised as an addictive within Annex I of EU Regulation 10/2011 on plastic food contact materials. However, coffee mugs, kitchenware and utensils derived from bamboo composites are currently sold on both and marketed as sustainable, recyclable, natural, and eco-friendly on the UK market. Although, they contain variable proportions of plastic, several companies have mislabelled these items as either 'eco-friendly' '100% natural', '100% bamboo' or 'fully compostable' (Commission Regulation (EU) 2011/10).

8. In early 2019, a surge in plastic composite articles containing bamboo lead the European Commission to discuss this matter with member states at the working group on food contact materials. Although, not legally binding the Experts of the Working Group on FCM of the SC-PAFF stated that the following are not listed in Annex I to Regulation (EU) No 10/2011: ground bamboo, bamboo flour, and many similar substances including corn. It was noted that these additives cannot be considered as wood and would therefore require a specific authorisation. Based on the compositional requirements set out in the Regulation, plastic FCM containing unauthorised additives are not compliant. Further, comments were made on the number of RASFF notifications concerning migration of melamine and formaldehyde above the specific migration limits (SMLs). It was concluded that the labelling and advertising of these FCMs can be considered to as misleading to enforcement authorities and not in compliance with the Regulation (European Commission, 2020).

9. In 2019, EFSA published an update of the risk assessment of 'wood flour and fibres, untreated' (FCM No 96) for use in food contact materials, and criteria for future applications of materials from plant origin as additives for plastic food contact materials. In summary, it highlighted concerns regarding the continued authorisation status of FCM no. 96 in food contact plastic, and therefore recommended that any items containing wood and similar materials from plant origin (including bamboo) should be evaluated on a case by case basis (EFSA, 2019).

10. In early 2020, following the publication of the EFSA Opinion, The European Commission indicated that an authorisation would need to be obtained for any products that intends to use these additives within food contact plastic materials and articles. Immediately following the EFSA reassessment of FCM no. 96, the European Commission did not provide clarification on whether business operators could continue to legitimately place these products onto the market whilst seeking an assessment from EFSA and an eventual authorisation from the European Commission. It also did not provide details about the length of any transition period.

11. In June 2020, the European Commission published a revised document on 23rd June 2020, reflecting the EFSA reassessment of FCM no.96. This provided additional clarity concerning the status of bamboo (including ground and bamboo flour) and set out that an authorisation would be required. Some EU Member States are now enacting their individual enforcement powers.

Chemical composition of bamboo

12. Petroleum based thermoplastics are widely used but their usage has resulted in soaring pollutant emissions. Bio-based food contact materials (BBFCMs) which are derived from renewable resources such as animal or plant biomass are considered as attractive alternatives because they are considered as biodegradable or compostable. Over time, there has been an increase in the use of bamboo in food contact articles. These articles are marketed as natural alternatives to plastics however in most cases the bamboo is added to a polymer (plastic) backbone (FERA, 2019).

13. Bamboo is a tree-like grass and is it available abundantly in Southeast Asian countries. Bamboo is one of the fastest growing renewable plants and has a maturity cycle of 3-4 years. It also possesses adequate mechanical properties such as a high tensile strength (Fazita et al, 2016).

14. The major compositions of bamboo which contribute to more than 95% of the bamboo total mass include cellulose (73.83%), hemicellulose (12.49%), pectin (0.37%), aqueous extract (3.16%) and lignin (10.15%). Other minor components of bamboo include resins, tannins, waxes and inorganic salts (Fazita et al, 2016).

15. The manufacturing of bamboo plastic composite starts off with bamboo

fibres being used as a biobased filler or reinforcer. Heat and pressure are applied to mix bamboo fibres and epoxy resin, so it is held in place (Khalil et al, 2012).

Toxicology

16. Zimmermann et al. (2020) investigated if bioplastics and plant-based materials were safer than conventional plastics. Forty-three everyday bio-based as well as their precursors were tested, the samples included 27 bioplastics and 16 plant-based materials (starch, cellulose, bamboo). The bamboo extract was from a re-useable coffee cup. *In vitro* bioassays and non-target high-resolution mass spectrometry were used to characterise these products. All bioassays were conducted with negative controls, solvent controls (DMSO), blanks and a solvent blank. All samples, solvent controls and blanks were diluted 100-fold (baseline toxicity), 200-fold (oxidative stress response) or 480-fold (endocrine activity) with medium, resulting in a maximum final solvent solution of 1%, 0.5% or 0.2% (v/v), respectively. The bioluminescence inhibition of Aliivibrio fischeri is an indicator for baseline toxicity that is more sensitive than other endpoints for unspecific toxicity. For extracts, the dilutions corresponded to 0.18 – 22.5 mg plastic. 50 µL of A. fischeri suspension was added to 100 µL diluted sample. The bamboo product did not have any baseline toxicity in the Mictotox assay.

17. Yeast-based reporter-gene assays were used to investigate the induction of agnostic activity at the human estrogen receptor α and antagonistic activity at the human androgen receptor. Samples were diluted 480-fold in medium resulting in a final sample concentration of 3.5 mg plastic well^{-1}. Endocrine activity was not observed in the tested bamboo product (Zimmermann et al, 2020).

18. Oxidative stress response was examined in the AREc32 assay. Human MCF-7 cells were used to investigate the induction of the Nrf2-ARE regulated oxidative stress response. 12,000 cells well^{-1} were seeded in 96-well plates. After 24 hours, 100 µL medium well^{-1} was replaced by medium containing serial dilutions (1:2 in medium) of the samples (0.06 – 7.5 mg plastic well $^{-1}$). Cell viability and luciferase activity was determined after 24 hours. The bamboo-based sample did not induce an effect. 5429 chemical features were detected by UPLC-QTOF-MS/MS in a bamboo reusable coffee cup (Zimmermann et al, 2020).

<u>Formaldehyde</u>

19. Low levels of formaldehyde occur naturally in the body and in a wide range of foods such as vegetables and fruit (IARC, 2009). Formaldehyde blood levels of 0.1 µM were detected in humans, rats and monkeys exposed to formaldehyde (Cassonova et al, 1988; Heck at al, 1982; Heck at al, 1985). This indicates that formaldehyde has a first-pass effect, as the systemic availability of formaldehyde is low (BfR, 2006). In another human study, the blood and intracellular steady sate concentrations of formaldehyde was estimated to be around 2.6 mg/L (87µM) and 12 mg/L (400 µM), respectively.

A nasal intracellular baseline formaldehyde acetal concentration of 400 µM was measured in nasal tissue (EFSA 2013; EFSA 2014).

20. Formaldehyde exposure mainly effects the respiratory epithelium, gastrointestinal tract and skin. After absorption via various enzyme systems it is rapidly converted to formic acid (Pandey et al, 2000). Formic acid then slowly converts into water and carbon dioxide via an enzymatic reaction that is dependent on folate. The accumulation of formic acid can lead to metabolic acidosis. The surplus formic acid is then excreted via urine as sodium salt (Netherlands Food and Consumer Product Safety Authority, 2021). In humans, the blood and intracellular steady sate concentrations of formaldehyde was estimated to be around 2.6 mg/L (87µM) and 12 mg/L (400 µM), respectively. The nasal intracellular baseline formaldehyde acetal concentration was 400 µM.

21. Formaldehyde is classified as a human carcinogen via inhalation exposure (IARC, 2009). EFSA stated that there is no indication that formaldehyde is carcinogenic via oral exposure. EFSA derived a TDI of 0.15 mg/kg/bw/day based on the critical effect of gastric mucosa damage which can lead to hyperkeratosis and gastric ulcer (EFSA, 2006).

Melamine

22. Melamine can be present in food because of its use in food contact materials, including articles made of melamine-formaldehyde plastics, can coatings, paper and board and adhesives. Melamine is rapidly absorbed from the gastrointestinal tract and excreted mostly in its unchanged form. A high concentration of melamine in the urine can form crystals and this can cause damage to the proximal tubule in the kidney. EFSA derived a TDI of 0.2 mg/kg/bw/day based on the critical effect of stone formation in the kidneys or urinary tract (EFSA, 2010).

23. Recent studies have identified melamine-cyanurate crystals in the kidneys of fish, rates and pigs who solely consume melamine. However, the mechanism remains unknown. The mechanism of melamine-induced renal toxicity was investigated. It was reported that cyanuric acid can be produced in the gut via microbial transformation of melamine which results in the development of melamine-cyanurate crystals in the kidneys leading to acute or chronic kidney failure. It was suspected that melamine is degraded by intestinal microbes through a mechanism of nitrogen consumption by environmental aerobic bacteria (Zheng et al, 2013)

24. In 2008, there were reports of an increased incidence of kidney stones and renal failure in Chinese infants and children. Kidney stones and urinary tract effects were observed in 300,000 infants and children, 6 deaths were also reported. After an investigation, it was found that melamine had been deliberately added to infant formula (Gossner et al, 2009). In 2007, outbreaks of renal outbreaks in pets were observed in pets in South Korea and the

United States, it was found that melamine was deliberately added as a pet food ingredient. (Brown et al, 2007)

Risk assessment

25. In February 2021, the Netherlands Food and Consumer Product Safety Authority (NVWA) conducted a risk assessment on formaldehyde exposure from melamine crockery with bamboo fibre to adults and young children. The Specific Migration Limit (SML) for formaldehyde was 15 mg/kg food. The exposure assessment was based on the consumption of hot beverages from bamboo/melamine cups. The NVWA based their exposure assessment on the assumption that 2 cups of hot beverages would be consumed per day (0.4 kg/day). The body weight of the adult consumer was assumed to be 60kg. For children's crockery, a daily intake of 200g of warm food and 100 g of warm drinks was assumed for a child aged 1-3 years old. The body weight was assumed to be 10.1 kg. There is a health risk if the formaldehyde migration level is 19 mg/kg or higher. The average UK adult consumption of hot drinks (6.4 g/kg bw/day) (Bates et al, 2014 and 2016; Roberts et al, 2018). is similar to what is reported by the NVWA (6.7 g/kg bw/day).

26. The NVWA study showed that 89% of the cups tested complied with the SML for formaldehyde (15 mg/kg food). The highest migration value found for formaldehyde was 247 mg/kg. Background exposure to formaldehyde via food, smoking, the environment and other consumer products was also taken into consideration. The estimated background exposure was 0.025 to 0.7 mg/kg/bw/day. The lowest reported value of 0.025 mg/kg/bw/day was taken into account as background exposure for this risk assessment. For a child that weighed 10.1 kg, the estimated background formaldehyde exposure amounted to 0.25 mg/day; for an adult that weighed 60kg the daily exposure it was 1.5 mg/day. It was concluded that although the SML for formaldehyde and TDI may be exceeded in some cases via background exposure, the NVWA were unable to quantitatively determine this risk. (Netherlands Food and Consumer Product Safety Authority, 2021).

27. The NVWA study found that the formaldehyde TDI value of 0.15 mg/kg was exceeded in the case of babies and children exposed to a daily intake of 0.3 kg of warm food and drink that had been in contact with bamboo tableware. It was concluded that the formaldehyde SML of 15 mg/kg food offered insufficient protection (Netherlands Food and Consumer Product Safety Authority, 2021).

28. A risk assessment on melamine was conducted. The assumption was a daily intake of 0.4 kg of hot beverages from bamboo/melamine cups. The test was based on the health-based guidance value for melamine of 0.2 mg/kg/bw/day and a background exposure of 1.6 µg/kg/bw/day. A body weight of 60 kg was taken into account. Based on the exposure values, there was no exceedance of the SML of 30 mg/kg. This value was not found in the RASFF notifications or the German market study. For tableware for babies

and children the assumption was that a child (from the age of 1 year) will consume 0.3 kg/day of warm food and drinks that may have come in contact with bamboo/melamine children's tableware. A body weight of 10.1 kg was assumed. EFSA established a TDI of 0.2 mg/kg/bw for melamine based on the critical effect of the formation of stones in the kidneys or urinary tract. From a migration of 6.6 mg/kg or higher, the health-based guidance value was exceeded. This value is above the specific migration limit of 2.5 mg/kg (Netherlands Food and Consumer Product Safety Authority, 2021). It was concluded that a potential health risk was more likely to be present in children who were exposed to bamboo tableware in comparison to bamboo cups. The NVWA stated that plastic FCM such as cups and children's tableware in which bamboo fibre or corn has been processed should not be placed on the European market (Netherlands Food and Consumer Product Safety Authority, 2021).

29. In 2020, the German Federal Institute for Risk Assessment (BfR) carried out an assessment on whether the routine use of refillable melamine formaldehyde resin (MFR) tableware such as reusable coffee-to-go cups, children cups or trays with hot liquid foods such as coffee, tea or baby food involves any risks to health. The BfR based its risk assessment on data provided by the German food monitoring authorities and their own research data. The risk assessment was based on the assumption that adults consumed coffee beverages from a reusable coffee-to-go cup five days a week. It was assumed that infants would consume tea, milk-based drinks or baby food from cups, mugs or bowls made from MFR daily.

30. For roughly one in four 'bambooware' articles, the amount of formaldehyde released into 70°C drinks led to an exposure that was up to 30 times higher than the TDI for adults and up to 120 times higher for children. Also, the maximum tolerable concentration in food(simulant) was significantly exceeded by the release of formaldehyde from tableware samples in this group (up to roughly 90 times higher). Formaldehyde release was substantially lower for the rest of the 'bambooware' investigated. Nevertheless, it was still around 30% higher on average compared to release from 'conventional' MFR tableware. If consumers used fillable tableware made from either of these materials very frequently, daily formaldehyde exposure can be almost three times higher than the TDI. The maximum tolerable formaldehyde concentration in food(simulant) is exceeded by the formaldehyde release from 12% of 'conventional' MFR tableware and 27% of 'bambooware' articles (BfR, 2020).

31. With regard to melamine, the average release from 'bambooware' was more than twice as high as average release from 'conventional' MFR tableware. For adults, the measured melamine release did not represent a health risk. However, infants who consumed hot food products from MFR tableware very often and from 'bambooware' daily exposure could be up to three times the TDI. The BfR therefore considered an increased risk to health to be possible, if consumers filled hot liquid foodstuffs into MFR tableware and consumed these foods on a daily basis. In the case of a long-term daily use of 'bambooware' tableware with exceptionally high formaldehyde release, the

BfR considered an increased risk to health to be likely. Repeated tests on the very same piece of tableware have also shown an increase of melamine release from test to test (BfR, 2020).

32. These results suggested that the material is degraded and damaged by contact with hot liquids. In the opinion of the BfR, MFR is therefore generally not suited for repeated usage in contact with hot liquid foodstuffs, as is the case with reusable coffee-to-go mugs or cups, for example. Accordingly, the BfR recommends (as previously, in opinion no. 012/2011) not to consume hot meals or beverages from MFR tableware. This recommendation applies both to tableware made from 'conventional' MFR and especially to 'bambooware'. Once again, the BfR points out that all articles made from MFR are unsuitable for use in microwave ovens. MFR tableware can be used to consume foodstuffs at room temperature safely, however, since the release of melamine and formaldehyde at levels relevant for health occurs at high temperatures only. To ensure that consumer health is adequately protected, the BfR also recommends lowering the specific migration limit (SML) set out in the EU Plastics Regulation (Regulation (EU) No 10/2011) for formaldehyde from 15 to 6.0 mg per kg food (BfR, 2020).

Conclusion

33. The BfR considered an increased risk to health to be possible, if consumers filled hot liquid foodstuffs into MFR tableware and consumed these foods on a daily basis. In the case of a long-term daily use of 'bambooware' tableware with exceptionally high formaldehyde release, the BfR considered an increased risk to health to be likely (BfR).

34. The NVWA concluded that plastic FCM such as cups and children's tableware in which bamboo fibre or corn has been processed should not be placed on the European market due to an increased risk to health (Netherlands Food and Consumer Product Safety Authority, 2021).

35. Currently, there are no UK specific data on the migration levels of melamine and formaldehyde in bamboo bio-composite FCMs. FERA have made plans to determine the risk associated with bamboo-based packaging and other biobased materials.

Questions on which the views of the Committee are sought

i) Would members like UK specific exposure data to be used to conduct a risk assessment?

ii) What thoughts do members have on the BfR and NVWA risk assessments?

iii) Does the committee consider that consumer awareness of the compounds of bamboo composites should be increased?

iv). Do members have any more comments?

Secretariat
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