TOX/2021/54

Committee On Toxicity Of Chemicals In Food, Consumer Products And The Environment (COT)

Discussion paper on the German Federal Institute for Risk Assessment (BfR) and Office for Risk assessment & research (BURO)/ Netherlands Food and Consumer Product Safety Authority (NVWA) opinions on the potential health risks of bamboo food contact materials (FCMs)

Introduction

1. The safety assessment and legislation covering bamboo coffee cups has been raised by several authorities. This has resulted in an increase in the number of incidents of non-compliant products, mainly with respect to their formaldehyde/melamine content. The issue of concern was not the presence of bamboo in bio-based food contact materials (BBFCMs), but rather the migration of constituent plasticisers, notably melamine. Additionally, interactions between bamboo and melamine could result in increased migration levels of formaldehyde.

2. Bamboo and bamboo filler are not currently authorised as additives 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 on sale and are 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).

3. At the July meeting, the COT were asked to consider whether exposure to bamboo bio-composites in food contact materials posed a risk to human health in discussion paper TOX-2021-34 Members were informed that a study assessing the health risks associated with bamboo-based packaging and other biobased materials was in progress. The Committee agreed that it would be appropriate to conduct a risk assessment once the data were available. Members also requested for the exposure data from the German Federal Institute for Risk Assessment (BfR) and the Netherlands Food and Consumer Product Safety Authority (NVWA) reports to be assessed separately and more critically.

Background

Formaldehyde

4. 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 undergoes first-pass metabolism, as the systemic availability of formaldehyde is low (BfR, 2006) (EFSA, 2014). In humans, the blood and intracellular steady state concentrations of formaldehyde were 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 (EFSA 2013).

5. Formaldehyde exposure mainly affects the respiratory epithelium, gastrointestinal tract and skin. After absorption, it is rapidly converted to formic acid, via various enzyme systems (Pandey et al, 2000). Formic acid then is slowly converted 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 the urine as a sodium salt (NVWA, 2021).

6. 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 Tolerable Daily Intake (TDI) of 0.15 mg/kg/bw/day based on the critical effect of damage to the gastric mucosa which can lead to hyperkeratosis and gastric ulcer (EFSA, 2006).

Melamine

7. Melamine can be present in food because of its use in food contact materials such as melamine-formaldehyde plastics, can coatings, paper, 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).

8. Recent studies have identified melamine-cyanurate crystals in the kidneys of fish, rates and pigs who solely consume melamine. However, the underlying mechanism remains unknown. One investigation into a possible mechanism 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).

9. 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 failure were observed in pets in South Korea and the United States, upon investigation, it was found that melamine was deliberately added as a pet food ingredient. (Brown et al, 2007)

Risk assessments by BfR and NVWA/BURO

10. The German Institute for risk assessment (BfR) published a position statement in regard to the melamine-formaldehyde resins such as tableware made with bamboo fibres in 2020. In 2021, the Inspector-General of the Netherlands Food and Consumer Product Authority published an advisory report concerning the health risks of bamboo cups. These publications have been summarised in this paper. The full opinions can also be found in Annex B of the report.

Bfr opinion

11. The BfR evaluated the human health risks resulting from melamine and formaldehyde migration (summarised separately) from fillable articles such as conventional melamine formaldehyde resin (MFR) and ’bamboo-ware’. This assessment was based on consumption data collected between 2014 to 2019 by the German food monitoring authorities and the National Reference Laboratory for substances intended to come into contact with food (See Annex A for full data). Data was available for 366 mugs, cups and bowls (111 ‘Conventional’ MFR and 180 ’bamboo-ware’). Only samples that met the following conditions were included in the assessment:

a) Reusable coffee cups, mugs, cups and bowls that are typically filled with hot liquid and are for daily use.
b) A clear distinction between whether the investigated samples were made from ‘conventional’ MFR or ‘’bamboo-ware’’ had to be clearly stated.
c) The migration investigation used 3% acetic acid as the food simulant and the test was conducted in accordance to Regulation (EU) No 10/2011 (‘Conventional’ MFR and ’bamboo-ware’ articles were filled with 3% acetic acid three times in succession at 70°C for 2 hours each)
d) The results were available for the third migration test and could be unambiguously related to the volume of the food simulant.

Formaldehyde migration

12. Migration experiments were conducted in accordance with Regulation (EU) No 10/2011 (on plastic materials and articles intended to come into contact with food). In this assessment the fillable articles (conventional

melamine formaldehyde and 'bamboo-ware') were carried out under hot-fill conditions of 2 hours at 70°C with 3% acetic acid (food simulant) and repeated three times. The exposure assessment assumed that adults consumed coffee beverages five days a week from a reusable coffee cup. Infants (12 – 36 months) were assumed to consume beverages such as tea, milk-based drinks or baby food from cups, mugs or bowls that were made out of MFR.

13. The BfR had derived a tolerable daily intake (TDI) of 0.6 mg/kg body weight/day using a NOAEL of 15 mg/kg body weight/day from a chronic toxicity rat study where rats were orally exposed to formaldehyde doses (Til *et al.*, 1989) and this was used to assess the findings.

14. Table 1 below shows the results for formaldehyde migration. One hundred and thirty-eight samples from 'conventional' MFR and 228 samples from 'bamboo-ware' were analysed in accordance with the criteria in paragraph 11. The migration of formaldehyde from 'Conventional' MFR was significantly lower than migration from 'bamboo-ware'. The total specific migration limit (SMLT)[1] for formaldehyde was 15 mg/kg. The median value, from 'bamboo-ware' items that released more than 50 mg/L, was 242 mg/L, which is 16 times higher than the SMLT. There was a high standard deviation of 236 mg/L indicating a high level of variation in formaldehyde migration from the individual articles. When all 'bamboo-ware' articles are taken into consideration, the formaldehyde migration exceeded the SMLT in 31% of the 70 samples.

Table 1: Release of formaldehyde from fillable food contact material products made from 'conventional' melamine formaldehyde resin (MFR) and ''bamboo-ware''; migration conditions: 2 h at 70°C in 3% acetic acid, 3rd migrate; LOQ = limit of quantification.

	'Conventional' MFR	'Conventional' MFR	'bamboo-ware'	'bamboo-ware'
		Total	Migration <50 mg/L simulant	Migration >50 mg/L simulant
No. of samples	138	228	173	55
Result in mg/L simulant				
Minimum	<LOQ	<LOQ	<LOQ	54.8
Maximum	32.7	912	33.0	912
Median	4.45	9.25	6.75	242
75th percentile	7.39	31.9	10.8	388
95th percentile	15.3	442	19.7	808

[1] Total specific migration limit (SMLT) : means the maximum permitted sum of particular substances released in food or food simulants expressed as total of moiety of the substances indicated;

Mean value	5.69	85.9	8.07	331
Standard deviation	5.47	180	6.15	236
Relative standard deviation (dimensionless)	0.98	2.1	0.76	0.71
No. of samples >15 mg/L (SMLT)	8 (5.8%)	70 (31%)	15 (8.7%)	55 (100%)

Melamine migration

15. Table 2 below shows the results for melamine migration. One hundred and eleven samples from 'conventional' MFR and 180 samples from 'bamboo-ware' were in accordance with the criteria in paragraph 11. All the results from the third migration test were below 25 mg/L. Nineteen of the samples were made from 'Conventional' MFR and 18 were 'bamboo-ware' samples. Seventeen 'Conventional' MFR and 63 'bamboo-ware' articles exceeded the melamine SMLT of 2.5 mg/kg.

Table 2: Release of melamine from fillable food contact material products from 'conventional' melamine formaldehyde resin (MFR) and ''bamboo-ware'.

	'Conventional' MFR	''bamboo-ware''
No. of samples	111	180
Result in mg/L simulant		
Minimum	<LOQ	<LOQ
Maximum	8.37	20.7
Median	0.69	1.55
75th percentile	1.88	3.53
95th percentile	4.29	7.71
Mean value	1.27	2.64
Standard deviation	1.58	3.06
Relative standard deviation (dimensionless)	1.24	1.16
No. of samples >2.5 mg/L (SML)	17 (15%)	63 (35%)

Exposure assessment for formaldehyde

16. For the exposure assessment in adults, a Monte Carlo simulation[2] was carried out using a programme called ConsExpo Web[3]. The results from the migration experiments were specified as the substance's concentration in the form of log-normal distributions with the respective median and relative standard deviation as seen in Table 1. In the initial step for 'bamboo-ware' articles, only the migration values that were <50 mg/L were used. The migration values that were >50 mg/L did not fit into the log-normal distribution of the values <50 mg/L and was therefore considered separately. The consumption quantities were specified as log-normal distributions. Two hundred and seventy eight consumption days per year were assumed. Migration from packaging and instant release were selected as simulation parameters. In accordance with Regulation (EU) no 10/2011, a body weight of 60 kg was assumed. The results of the Monte Carlo simulation are presented below in Table 3.

Table 3: Daily levels of formaldehyde exposure for adults (19-50 years) who use reusable coffee cups made from melamine formaldehyde resin. The calculation was done using a Monte Carlo simulation. For ''bamboo-ware'' articles, only the migration values <50 mg/L were included in the calculation (76% of all values).

		Exposure in	terms of all days	mg/kg bw*/day
Exposure to:	No. of days with consumption per year	Mean value	Median	95th percentile
Objects made from 'conventional' MFR**	278	0.056	0.036	0.17
''bamboo-ware''	278	0.079	0.055	0.22
Ratio of ''bamboo-ware'' to 'conventional' MFR**	-	1.4 (140%)	1.5 (150%)	1.3 (130%)

[2] 'Monte Carlo simulation is a method that attempts to find numerical solutions to complex, stochastic problem scenarios. For the problem scenario in question, a value is drawn randomly from the distribution of formaldehyde content values and multiplied by a consumption quantity value, also drawn randomly from the respective distribution. By repeating this process many times, a distribution curve is generated of the respective individual exposures, for which various percentiles and a standard deviation can then be calculated' (Bfr, 2019).

[3] https://www.consexpoweb.nl/

*Body weight = 60 kg
**Melamine formaldehyde resin

17. Daily levels of formaldehyde exposure for infants are presented in Table 4. For the exposure assessment a Monte Carlo simulation was carried out using a programme called 'ConsExpo Web' (version 1.0.6)[4]. For the exposure assessment a consumption value of 960 g of food product/day and a body weight of 12 kg was assumed (EFSA, 2012;2016). The daily intake was higher for infants in comparison to adults as seen above in table 3.

Table 4: Daily formaldehyde exposure for infants (12–36 months) who consume heated food products from fillable objects made from melamine formaldehyde resin. The calculation was done using a Monte Carlo simulation. For 'bamboo-ware' items, only the migration values <50 mg/L were included in the calculation (76% of all values).

		Exposure in terms of all days mg/kg bw*/day	
Exposure to	Mean value	Median	95th percentile
Objects made from 'conventional' MFR**	0.50	0.35	1.3
''bamboo-ware''	0.67	0.54	1.6
Ratio of 'bamboo-ware' to 'conventional' MFR**	1.4 (140%)	1.5 (150%)	1.3 (130%)

*body weight, daily quantity consumed = 80 g of food/kg body weight
**Melamine formaldehyde resin

Exposure assessments for melamine

18. The adult and infant exposure assessments for melamine were conducted using the same approaches that were used for formaldehyde. The melamine migration values as seen above in Table 2 were included in the exposure assessment calculation. The exposure assessment results are presented in Tables 5 and 6. The daily melamine exposure from 'bamboo-ware' for normally exposed adults (mean/median) and highly exposed adults (95th percentile) resulted in daily intakes that were roughly twice as high (Table 6). The daily intake for infants (Table 6) is higher in comparison to adults (Table 5). The average daily intake for infants was nearly three times higher in comparison to highly exposed adults (95th percentile).

[4] https://www.consexpoweb.nl/

Table 5: Daily melamine exposure for adults (19-50 years) who use reusable coffee cups made from melamine formaldehyde resin.

		Exposure in	terms of all days	mg/kg bw*/day
Exposure to	No. of days with consumption per year	Mean value	Median	95th percentile
Objects made from 'conventional' MFR**	278	0.010	0.006	0.033
''bamboo-ware''	278	0.021	0.013	0.069
Ratio of 'bamboo-ware' to 'conventional' MFR**	-	2.1 (210%)	2.2 (220%)	2.1 (210%)

*Body weight = 60 kg
**Melamine formaldehyde resin

Table 6: Daily melamine exposure for infants (12-36 months) who consume heated food products from fillable articles made from melamine formaldehyde resin.

		Exposure in terms of all days mg/kg bw*/day	
Exposure to	Mean value	Median	95th percentile
Objects made from 'conventional' MFR**	0.090	0.057	0.28
''bamboo-ware''	0.19	0.12	0.56
Ratio of 'bamboo-ware' to 'conventional' MFR**	2.1 (210%)	2.2 (220%)	2.0 (200%)

Results

Formaldehyde

19. For roughly 1 in 4 ''bamboo-ware'' articles, the amount of formaldehyde released under the tested conditions led to an exposure that was up to 30

times higher than the BfR TDI of 0.6 mg/kg bw 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). Although formaldehyde release was substantially lower for the rest of the investigated ‘’bamboo-ware’’, 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 could be almost three times higher than the TDI. The maximum tolerable formaldehyde concentration in food (simulant) was exceeded by the formaldehyde release from 12% of ‘conventional’ MFR tableware and 27% of ‘’bamboo-ware’’ articles (BfR, 2020). In the case of a long-term daily use of ‘’bamboo-ware’’ tableware with exceptionally high formaldehyde release, the BfR considered an increased risk to health to be likely.

20. These results suggest 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 food. Accordingly, the BfR recommended that hot meals or beverages should not be consumed from MFR tableware. This recommendation applies to both tableware made from ‘conventional’ MFR and ‘’bamboo-ware’’. The BfR stated that all articles made from MFR were unsuitable for use in microwave ovens. MFR tableware can be used to consume foodstuffs at room temperature safely as the release of melamine and formaldehyde at levels relevant for adverse health effects, occurred only at high temperatures. To ensure that consumer health was adequately protected, the BfR recommended 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).

21. Daily intakes were calculated based on the exposure scenarios and migration data for the articles with release of up to 50 mg formaldehyde/l food simulant. The 95th percentile infant group significantly exceed the TDI of 0.6 mg/kg body weight/day (up to 170%).

22. The results of the ‘Conventional’ MFR and ‘bamboo-ware’ migration are presented below in Table 7. As there is a possibility that formaldehyde exposure through food alone can exceed the TDI, the BfR considered the maximum formaldehyde intake which would result in exposures of 20% of the TDI, from the release from food contact materials, to be acceptable. The BfR used toxicological studies to derive a maximum tolerable formaldehyde concentration for chronic exposure from food consumption to protect from possible concentration-dependant local formaldehyde effects. The maximum tolerable formaldehyde concentration was 10.4 mg/L. Based on the results in Table 7,the tolerable maximum concentration was exceeded as a result of the formaldehyde release from 44% of articles made from ‘’bamboo-ware’’, It was concluded by the BfR that an increased health risk is possible for both adults and infants as a result of the daily usage of, particularly ‘’bamboo-ware’’, articles in contact with hot liquid food products.

Table 7: Results on the release of formaldehyde from fillable food contact materials made from 'conventional' melamine formaldehyde resin (MFR) and from ''bamboo-ware''; migration conditions: 2 h at 70 °C in 3% acetic acid, 3rd migrate; LOQ = limit of quantification; values in brackets are the % of the tolerable maximum concentration (C_{max}) of 10.4 mg/L food (simulant); values highlighted in **blue and bold** exceed C_{max}.

	'Conventional' MFR	''bamboo-ware''	''bamboo-ware'', migration <50 mg/L simulant	''bamboo-ware'', migration >50 mg/L simulant
No. of samples	138	228	173	55
Result in mg/L simulant				
Minimum	<LOQ (-)	<LOQ (-)	<LOQ (-)	**54.8 (527)**
Median	4.45 (43)	9.25 (89)	6.75 (65)	**242 (2330)**
Mean value	5.69 (55)	**85.9 (826)**	8.07 (78)	**331 (3178)**
75th percentile	7.39 (71)	**31.9 (307)**	**10.8 (104)**	**338 (3732)**
95th percentile	**15.3 (147)**	**442 (4252)**	**19.7 (190)**	**808 (7771)**
Maximum	**32.7 (314)**	**912 (8764)**	**33.0 (318)**	**912 (8764)**
No. of samples >10.4 mg/L (Cmax)	17 (12%)	101 (44%)	46 (27%)	55 (100%)

23. Table 8 below shows the daily formaldehyde exposure calculated from migration data and consumption data, shown in relation to the tolerable daily intake (TDI) value of 0.6 mg/kg body weight/day. Adult normal consumers (mean/median) who used 'bamboo-ware' articles that have an median formaldehyde release of 242 mg/L (see Table 1) on a daily basis are at risk at exceeding the TDI by approximately 2.5 times. High consumers (95th percentile) who used 'bamboo-ware' articles that have a maximum formaldehyde release of 912 mg/L (see Table 1) on a daily basis are at risk of taking formaldehyde at levels up to 30 times higher than the TDI. The BfR concluded that there is therefore an increased risk to health to likely occur from the daily use of 'bamboo-ware' under the conditions described in paragraph 11.

24. Infant consumers who used 'bamboo-ware' articles on daily basis under the selected conditions (2h, 70°C, 3% acetic acid) resulted in a TDI exceedance of 12,000% (Table 8). The BfR advised against the use of these articles (especially if they come into contact with hot liquid foods).

Table 8 - Daily formaldehyde exposure calculated from migration data and consumption data, shown in relation to the tolerable daily intake (TDI) value of 0.6 mg/kg body weight/day for adults (body weight = 60 kg) and infants (body weight = 12 kg); values highlighted in **blue and bold** exceed the TDI; q.c. = quantity consumed.

	Formaldehyde intake for adults (19–50 years) as a percentage of TDI (and in mg/kg body weight)	Formaldehyde intake for adults (19–50 years) as a percentage of TDI (and in mg/kg body weight)	Formaldehyde intake for infants (12–36 months) as a percentage of TDI (and in mg/kg body weight)	Formaldehyde intake for infants (12–36 months) as a percentage of TDI (and in mg/kg body weight)
	Normally exposed individuals (median)	Highly exposed individuals (95th percentile)	Normally exposed individuals (median)	Highly exposed individuals (95th percentile)
'Conventional'	melamine	formaldehyde	resin articles	
	6.0% (0.036)	28% (0.17)	59% (0.35)	**223% (1.3)**
''bamboo-ware''	articles with	migration <50	mg/L	
	9.2% (0.055)	37% (0.22)	89% (0.54)	**270% (1.6)**
''bamboo-ware''	articles with	migration >50	mg/L	
Migration value	Normal consumers (q.c. = 380 g/day	High consumers (q.c. = 1,200 g/day)	High consumers (q.c. = 80 g/kg body weight/day)	High consumers (q.c. = 80 g/kg body weight/day)
Median (242 mg/L)	**256% (1.5)**	**808% (4.9)**	**3231% (19)**	**3231% (19)**
95th percentile (808 mg/L)	**853% (5.1)**	**2694% (16)**	**10775% (65)**	**10775% (65)**
Maximum value (912 mg/L)	**962% (5.8)**	**3038% (18)**	**12153% (73)**	**12153% (73)**
Article with maximum level of migration allowed (SMLT) of 15 mg/kg of food product	16% (0.095)	50% (0.30)	200% (1.2)	**200% (1.2)**

Melamine

25. The BfR used the TDI of 0.2 mg melamine/kg day (EFSA 2010). The TDI is based on a rat study where the formation of stones in the efference urinary system was observed (NTP, 1983). The SML of 2.5 mg melamine/kg

food was set. The median and the 95th percentile of migration from 'bamboo-ware' were twice as high in comparison to the 'Conventional' MFR. 35% of the 'bamboo-ware' articles exceeded the SML of 2.5 mg melamine/kg.

26. Based on the exposure scenarios for adults and infants described in paragraph 12 and the available migration data, daily intakes for melamine were calculated. The 95th percentile infant group exceeded the TDI of 0.2 mg/kg body weight/day (by up to 180% for ''bamboo-ware'' and up to 40% for 'conventional' MFR). The 95th percentile exposure for the adult group was 35% of the TDI. The BfR concluded that an increased health risk was possible for infants as a result of the usage of, particularly ''bamboo-ware'', articles in contact with hot liquid food products especially if these articles were used on a daily basis.

27. With regard to melamine, average release from ''bamboo-ware'' 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 that consumed hot food products from MFR tableware and ''bamboo-ware'' had reported daily exposures that were up to three times the TDI. The BfR therefore considered an increased risk to health to be possible if consumers filled MFR tableware with hot liquid foodstuffs and consumed these foods on a daily basis.

28. It was observed that melamine can migrate from 'bamboo-ware' articles into food (1.16 – 20.7 mg/L as reported in Table 2). In table 9, the resulting daily intake did not exceed the TDI of 0.2 mg/kg body weight/day in normally exposed adults and infants. However, infant high consumers (95th percentile) who used 'bamboo-ware' articles that had a maximum melamine release of 20.7 mg/L (see Table 2) on a daily basis, exceeded the TDI (by up to 180%).

Table 9 - Daily melamine exposure calculated from migration data and consumption data, shown in relation to the tolerable daily intake (TDI) of 0.2 mg/kg body weight/day for adults (body weight = 60 kg) and infants; values highlighted in **blue and bold** exceed the TDI.

	Formaldehyde intake for adults (19–50 years) as a percentage of TDI (and in mg/kg body weight)	Formaldehyde intake for adults (19–50 years) as a percentage of TDI (and in mg/kg body weight)	Formaldehyde intake for infants (12–36 months) as a percentage of TDI (and in mg/kg body weight)	Formaldehyde intake for infants (12–36 months) as a percentage of TDI (and in mg/kg body weight)
	Normally exposed individuals (median)	Highly exposed individuals (95th percentile)	Normally exposed individuals (median)	Highly exposed individuals (95th percentile)
'Conventional'	melamine	formaldehyde	resin articles	

	3.0% (0.006)	17% (0.033)	29% (0.057)	**140% (0.28)**
‘‘bamboo-ware’’	articles			
	9.2% (0.055)	37% (0.22)	89% (0.54)	**280% (0.56)**
‘‘bamboo-ware’’	articles with	migration >50	mg/L	
Article with maximum level of migration allowed (SMLT) of 15 mg/kg of food product	16% (0.095)	50% (0.30)	200% (1.2)	100% (0.2)

BfR conclusions and recommendations

29. The BfR therefore considered an increased risk to health to be likely, in the case of long-term daily use of ‘’bamboo-ware’’ tableware with exceptionally high formaldehyde release was observed in the study.

30. Repeated tests (12 successive migration tests) on the exact same piece of tableware also showed an increase of melamine release and indicated that the food contact articles were not stable under the selected migration conditions (2h, 70°C, 3% acetic acid). The melamine migration results suggested that contact with hot liquids caused the material to be degraded and damaged during repeated used. The BfR, considered MFR as unsuitable for repeated usage should there be any contact with hot liquid food. The BfR has recommended that consumers should not consume hot meals or beverages from MFR tableware. This recommendation applied both to tableware made from ‘conventional’ MFR and to ‘’bamboo-ware’’.

31. The BfR concluded that all articles made from MFR were 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 only occur at high temperatures. To ensure that consumer health is adequately protected, the BfR recommended that the specific migration limit (SML)[5] should be lowered for formaldehyde from 15 to 6.0 mg per kg food (EU Plastics Regulation (Regulation (EU) No 10/2011).

NVWA/BURO report

32. A study conducted by the German consumer organisation Stiftung Warentest[6] and the German Federal Institute for Risk Assessment (BfR) found that not all bamboo/melamine cups were safe for consumers, this finding triggered media attention. Consequently, the NVWA conducted a

[5] Specific migration limit (SML): The specific migration limit is the maximum permitted amount of a substance in food. This limit is set to ensure that the food contact material does not pose risk to human health (Commission Regulation (EU) No 10/2011)

[6] https://www.test.de/Bambusbecher-im-Test-Die-meisten-setzen-hohe-Mengen-an-Schadstoffen-frei-5496265-0/

market study that investigated the migration of formaldehyde from bamboo cups.

33. Forty-six bamboo/melamine drinking items were sampled in duplicate and examined for the migration of formaldehyde. Nine cups were made of bamboo, 9 cups were made of bamboo and corn, 7 cups were labelled 'reinforced with melamine', 2 cups were made of bamboo, corn and melamine and 2 cups were labelled as biodegradable. As there was an increase in the number of excessive violations of the migration limit for formaldehyde, the Enforcement Directorate of the NVWA requested the Office for Risk Assessment & Research (BuRO) to advise on the following questions:

1. How severe is the health risk entailed by the observed migration of formaldehyde from bamboo/melamine consumer articles?
2. From what level of formaldehyde migration is there a health risk for adults?
3. From what level of formaldehyde migration is there a health risk for children (aged up to three years) if they eat from children's tableware made of bamboo/melamine?
4. From what level of melamine migration from bamboo/melamine food contact materials is there a health risk?

34. To address question 1, the BuRO stated that with a low level of background exposure via food and a realistic scenario of a daily intake of 2 cups of hot beverages per day, the health-based guidance value would be exceeded if the migration value is 19 mg/kg or higher. If the exposure level is higher than the health-based guidance limit, adverse health effects such as stomach irritation and the formation of stomach ulcers cannot be ruled out. Ten bamboo/melamine consumer articles (11%) failed to meet the value of 19 mg/kg.

35. To address question 2, the BuRO stated that the health-based guidance value is exceeded if a formaldehyde migration is 19 mg/kg or higher.

36. In relation to question 3, The BuRO stated that the maximum amount of formaldehyde that may migrate from bamboo/melamine children's tableware before the health-based guidance value is exceeded was 4.2 mg/kg. If a higher migration amount was reported, a health risk could not be ruled out. It was stated that the SML of 4.2 mg/kg did not provide adequate protection for children's tableware.

37. In relation to question 4, the BuRO emphasised that based on a daily intake of 2 cups of hot beverages from bamboo/melamine cups, the health-based guidance value would be exceeded if melamine migration was equal to or higher than 30 mg/kg. For children's tableware, the maximum migration is 6.7 mg/kg, therefore the health-based guidance value was not exceeded. Both the maximum migration values for melamine were above the SML of 2.5 mg/kg. The SML for melamine was declared sufficiently protective.

38. The migration tests were carried out in accordance with Annex V of Regulation (EU) No 10/2011. The bamboo cup test articles were filled with food simulant (3% acetic acid at 70°C) to 5 mm below the rim and then covered with a glass plate. The cups were then placed in an oven at 70°C for 2 hours. The test was repeated 3 times and the simulant was replaced each time. The migration fluid for the third migration test was analysed for formaldehyde levels.

39. In February 2021, the NVWA conducted a risk assessment of formaldehyde exposure in adults and young children from melamine crockery with bamboo fibre. The SML for formaldehyde was 15 mg/kg food. The exposure assessment was based on the consumption of hot beverages from bamboo/melamine cups; assumed that 2 cups of hot beverages would be consumed per day (0.4 kg/day); and the body weight of the adult consumer was assumed to be 60 kg.

40. For children's crockery, a daily intake of 200 g 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. A health risk is identified if the formaldehyde migration level is 19 mg/kg or higher.

Results

Formaldehyde

41. 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 used as the value for background exposure for this risk assessment. For a child that weighs 10.1 kg, the estimated background formaldehyde exposure would amount to 0.25 mg/day; for an adult that weighed 60 kg would amount to a daily exposure of 1.5 mg/day. EFSA has determined the tolerable daily intake (TDI) for oral exposure to formaldehyde based on the critical effect of stomach irritation. Based on the exposure values, there is an increased health risk as the TDI of 0.15 mg/kg bw/day is exceeded (Netherlands Food and Consumer Product Safety Authority, 2021).

42. A risk assessment on melamine was also conducted. For adults, the assumption was a daily intake of 0.4 kg of hot beverages from bamboo/melamine cups. The test is 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 used. 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. The TDI for melamine established by EFSA of 0.2 mg/kg bw based on the critical effect of the formation of stones in the kidneys or urinary tract was used in the assessment. The HBGV would be exceeded at migration levels of or greater than 6.6 mg/kg, which is greater than the SML of 2.5 mg/kg (NWVA, 2021).

43. Table 4 below shows an overview of the values found for the migration of formaldehyde. 88% of the products met the formaldehyde met the migration limit of 15 mg/kg. The highest reported value was 247 mg/kg formaldehyde .

Table 10 – Observed formaldehyde migration values from bamboo/melamine in NVWA study (n = 92).

	Formaldehyde migration (mg/kg)
Minimum	0.54
Median	3.82
Average	18.60
75th percentile	7.18
95th percentile	156
Maximum	247
Number of samples > SML (15 mg/L)	11 (88%)

Estimated exposure to formaldehyde from bamboo/melamine cups

44. From 2012-2016, The National Institute for Public Health and the Environment (RIVM) conducted food consumption surveys among the Dutch population on behalf of the Ministry of Health, Welfare and Sport (Van Rossum et al, 2016). Table 11 below shows the coffee and tea consumption data of the Dutch population.

Table 11: Overview of coffee and tea consumption in the Netherlands.

Hot beverage	Average (g/day)	95th percentile (g/day)
Coffee	455.0	1260.8
Tea	104.0	1141.7
Herbal tea	0.0	637.5
Coffee, tea and herbal tea	800.0	1800.0

45. The risk assessment assumed that a realistic worst-case scenario is when someone drinks 2 cups of hot beverages from such cups per day: 0.4 kg/day. A body weight of 60 kg was assumed. The maximum migration of formaldehyde, where the health-based guidance value is not exceeded, was calculated using the following formula below:

M_{max} = (TDI – AB) x LG / I = (0.15 x 0.025) x 60 / 0.4 = 18.8 mg/kg

M_{max} : migration (mg/kg food)
TDI : exposure (mg/kg body-weight/day)
AB : background exposure (mg/kg body-weight/day)
LG : body weight (kg)
I : daily consumption of hot beverages (kg food/day)

Estimated exposure to formaldehyde from bamboo/melamine tableware

46. For this assessment, it was assumed that infants at the age of 12 months would consume 200 g of warm food and 100 g of warm drinks (0.3 kg in total) in cups and tableware (cups, bowls, plates and cutlery). The weight of 10.1 kg was assumed. The maximum migration of formaldehyde is subsequently calculated using the formula below and the result shows that the health-based guidance value is not exceeded. The maximum migration of formaldehyde, where the health-based guidance value is not exceeded, was calculated using the following formula below:

M_{max} = (TDI – AB) x LG / I = (0.15 x 0.025) x 10.3 / 0.3 = 4.2 mg/kg

M_{max} : migration (mg/kg food)
TDI : exposure (mg/kg body-weight/day)
AB : background exposure (mg/kg body-weight/day)
LG : body weight (kg)
I : daily consumption of hot beverages (kg food/day)

Estimated exposure to melamine from bamboo/melamine cups

47. The NVWA had no data on the migration of melamine from bamboo/melamine FCM. Therefore, the intake data from the BfR opinion as presented above in Table 2 was used in their assessment. The maximum migration of melamine from bamboo/melamine consumers was calculated using the following equation below:

M_{max} = (TDI – AB) x LG / I = (0.2 x 0.0016) x 60/0.4 = 30 mg/kg

M_{max} : migration (mg/kg food)
TDI : exposure (mg/kg body-weight/day)
AB : background exposure (mg/kg body-weight/day)
LG : body weight (kg)
I : daily consumption of hot beverages (kg food/day)

Estimated exposure to melamine from bamboo/melamine cups

48. The tableware for babies and children intake from table 2 was used for this assessment. The maximum migration of melamine from bamboo/melamine consumers was calculated using the following equation below:

M_{max} = (TDI – AB) x LG / I = (0.2 x 0.0016) x 10.1/0.3 = 6.7 mg/kg

M_{max} : migration (mg/kg food)
TDI : exposure (mg/kg body-weight/day)
AB : background exposure (mg/kg body-weight/day)
LG : body weight (kg)
I : daily consumption of hot beverages (kg food/day)

Risk assessment of formaldehyde

Bamboo/melamine cups

49. The NVWA assumed a background exposure of 1.6 µg/kg body-weight/day daily intake of 0.4 kg of hot beverages from bamboo/melamine cups and a body weight of 60 kg. The NVWA found that the melamine health based guidance value of 0.2 mg/kg body-weight/day was exceeded in the case of a migration value that was 30 mg/kg or higher.

Tableware for babies and children

50. The NVWA assumed that a child (12 months) would consumed 0.3 kg/day of warm food and drinks from children's tableware. A body weight of 10.1 kg was assumed. The health-based guidance value for melamine was exceeded in case of a melamine migration higher than 6.7 mg/kg food.

NVWA/BuRO Conclusions

51. The majority of the bamboo/melamine FCM that was tested by the

NVWA was below the formaldehyde migration limit of 15 mg/kg. There is a significant level of formaldehyde background exposure via food, other consumer products and the environment. However, NVWA were not able to quantitatively determine the background exposure.

52. Based on the exposure assumptions stated in paragraph 38 for adults, 89% of the cups examined by NVWA exceeded the formaldehyde SML value of 19 mg/kg.

53. Based on the exposure assumptions stated in paragraph 39, the formaldehyde migration level of 4.2 mg/kg exceeded the formaldehyde SML value of 19 mg/kg. It was also stated that the SML for formaldehyde did not provide adequate protection.

54. Based on the exposure assumptions stated in paragraph 38 and the data from the BfR opinion (Table 2), the health-based guidance value for melamine was not exceeded. Based on the exposure assumptions stated in paragraph 29 and the data from the BfR opinion (Table 2), the health-based guidance and SML of melamine was exceeded. The data in the BfR was used as there were no melamine migration data available.

55. The NVWA concluded that a potential health risk to formaldehyde and melamine is more likely to be present for children's 'bamboo-ware' tableware (bowls, plates and cutlery) in comparison to cups, at which the health-based guidance value would not be exceeded due to the lower body weight of young children. The conclusions also applied to melamine FCMs.

56. The findings and conclusions for the migration of formaldehyde and melamine from bamboo/melamine FCM also apply to melamine FCM. Two of the cups tested claimed to be 'Biodegradable'. FCM must not bear any misleading claims such as 'biodegradable', 'environmentally friendly', 'organic', 'natural' or even '100% bamboo'. Bamboo and corn are not authorised for use as additives for plastic FCM. Plastic FCM such as cups and children's tableware in which bamboo fibre or corn has been processed may not be placed on the European market.

57. The BuRO advised the Minster for Medical Care and Sport that the current SML for formaldehyde (15 mg/kg) offered inadequate protection for children's tableware. It was recommended that the necessary action should be taken to adjust the SML to a level that offered sufficient protection. It was also advised that the advisory report should be bought to the attention of the Netherlands Nutrition Centre so that consumers and professionals are made aware of the various risks of bamboo FCM products pose to babies and children in particular.

58. The BuRO also advised the General of the NVWA that if there is no new SML, action should be taken against violations of the current SML for formaldehyde (15 mg/kg) and melamine (2.5 mg/kg) for FCM made out of melamine resin. It was emphasised that melamine and formaldehyde migration tests should be conducted on consumer articles used by young

children. The BuRO also stated that the risks from bamboo cups should be actively communicated on the NVWA website so that consumers and professionals are aware. Finally, the BuRO concluded that plastic FCM that contained unauthorised additives such as a bamboo and/corn should be banned from the Dutch market.

Overall recommendations

59. The BfR recommended that hot meals or beverages should not be consumed from 'bamboo-ware' as there is an increased health risk to both adults and infants. Lastly, the BfR concluded that work should be completed with international experts on devising a logical approach to the assessment of the health risks that arise from exposure to substances that only lead to local adverse effects following their chronic oral intake.

60. The BuRO recommended 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.

Questions on which the views of the Committee are sought

i) Do members agree with the methodologies used in both reports?
ii) Do members agree with the exposure scenario assumptions made in both reports were realistic or worst-case?
iii) Do members agree with the conclusions of the BfR and NVWA/BURO reports?
iv) Do members have any other comments?

Secretariat
October 2021

Abbreviations

AB: background exposure (mg/kg body-weight/day)

EFSA: European Food Safety Authority

BfR: German Federal Institute for Risk Assessment:

BURO: Office for Risk assessment & research

I : daily consumption of hot beverages (kg food/day)

LG : body weight (kg)

$\mathbf{M_{max}}$: Migration (mg/kg food)

NVWA: Netherlands Food and Consumer Product Safety Authority

SML: Specific migration limit

SMLT: Total specific migration limit

TDI : Total Daily Intake

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Secretariat
October 2021

Committee On Toxicity Of Chemicals In Food, Consumer Products And The Environment (COT)

Discussion paper on the German Federal Institute for Risk Assessment (BfR) and Office for Risk assessment & research (BURO)/ Netherlands Food and Consumer Product Safety Authority (NVWA) opinions on the potential health risks of bamboo food contact materials (FCMs)

Table A1: Data from the German National Food Consumption II on the consumption of coffee beverages in various age groups. Mean, median and 95th percentile values are calculated by taking into account data for days on which consumption took place.

Age group	No. of days with consumption (% of reported days)	Mean in g/day	Relative standard deviation	Median in g/day	95th percentile in g/day
Adolescents (14 – 18 years)	308 (15.2)	320	0.71	300	678
Adults (19 – 50 years)	15,895 (76.3)	578	0.69	500	1200
Older adults (50 – 65 years)	3,442 (85.8)	516	0.58	490	1060
Elderly adults (65 – 80 years)	804 (82.0)	453	0.56	386	900

Table A2: Data from the German National Food consumption II on the consumption of coffee beverages in various age groups. Mean, median and 95th percentile values are calculated by accounting from all days (not just those with consumption).

Age group	No. of days with consumption (% of reported days)	Mean in g/day	Relative standard deviation	Median in g/day	95th percentile in g/day
Adolescents (14 – 18 years)	308 (15.2)	48.7	2.0	0	300
Adults (19 – 50 years)	15,895 (76.3)	441	0.93	380	1200
Older adults (50 – 65 years)	3,442 (85.8)	443	0.74	380	1000
Elderly adults (65 – 80 years)	804 (82.0)	372	0.75	380	900

Annex B to TOX/2021/54

Committee On Toxicity Of Chemicals In Food, Consumer Products And The Environment (COT)

Discussion paper on the German Federal Institute for Risk Assessment (BfR) and Office for Risk assessment & research (BURO)/ Netherlands Food and Consumer Product Safety Authority (NVWA) opinions on the potential health risks of bamboo food contact materials (FCMs)

BfR opinion 046/2019- Fillable articles made from melamine formaldehyde resin, such as coffee-to-gocups sold as ‘‘bamboo-ware’’, may leak harmful substances into hot foods

This annex contains the BfR opinion and can be assessed at:
BfR opinion

Advisory report from the Director of the Office for Risk Assessment and Research concerning the ‘Health Risks of Bamboo cups’

The annex contains the advisory report can be assessed at:
Advisory report

Committee On Toxicity Of Chemicals In Food, Consumer Products And The Environment (COT)

Discussion paper on the German Federal Institute for Risk Assessment (BfR) and Office for Risk assessment & research (BURO)/ Netherlands Food and Consumer Product Safety Authority (NVWA) opinions on the potential health risks of bamboo food contact materials (FCMs)

Table C1 - Migration of formaldehyde from bamboo/melamine cups (result of third migration measurement (NVWA, 2021).

Article	Labelling	Formaldehyde migration (mg/kg) Sample[1]	Formaldehyde migration (mg/kg) Sample[2]
Cup		3.8	3.9
Cup		2.7	3.0
Cup		7.0	7.1
Cup		2.8	2.7
Cup	Bamboo	4.9	7.4
Cup	Bamboo	2.3	1.3
Cup	Bamboo and corn[1]	8.8	6.4
Cup	Bamboo and corn [2]	13.2	8.5
Bowl	Bamboo and corn [2]	2.7	1.4
Cup	Bamboo and corn [2]	3.7	6.0
Cup	Bamboo and corn [2]	11.5	**18.1**
up	Bamboo, corn, melamine	4.1	2.9
Cup	Bamboo, corn, melamine	3.0	2.8
Cup		2.8	2.3
Cup		2.0	2.9
Cup		3.3	6.7
Mug	Bamboo and corn [2]	13.2	8.1
Bowl		4.2	4.1
Bowl	Bamboo and corn[1]	0.5	1.8
Mug	Bamboo and corn[2]	2.8	4.1
Cup		1.9	2.4
Cup	Melamine	3.3	1.9
Cup		0.7	0.8
Cup	Bamboo	8.9	7.1

Bowl	Bamboo	3.6	3.2
Mug	Bamboo	1.7	2.1
Cup		10.6	10.6
Cup		3.2	2.8
Bowl		2.2	2.7
Bowl	Bamboo	8.8	9.3
Cup		3.5	4.2
Mug	Bamboo	9.3	8.2
Bowl		4.8	4.1
Mug		1.9	2.4
Bowl		**142**	**120**
Mug		5.5	4.8
Mug	Bamboo	2.1	2.2
Bowl	Bamboo and corn[2]	**82**	**65**
Cup		**232**	**247**
Cup		**150**	**163**
Bowl		2.0	2.2
Cup	Bamboo	4.6	5.2
Cup	Bamboo	5.3	3.0
Cup	Bamboo and corn[2]	3.4	1.9
Bowl		**213**	**177**
Cup		1.8	2.4

Blue and bold = the result is higher than the migration limit of 15 mg/kg