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To the Minister for Medical Care and Sport

To the Inspector-General of the Netherlands Food and Consumer Product Safety Authority

Advisory Report from the Director of the Office for Risk Assessment and Research concerning the

Health Risks of Bamboo Cups

Office for Risk Assessment & Research

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Background

Consumer articles containing bamboo fibres have been in the news recently because it has come to light that although these are advertised as 'green' products, in reality they are not easily biodegradable and release excessive amounts of formaldehyde and melamine. The media attention was triggered by a study conducted by the German consumer organisation Stiftung Warentest[1] and the German Federal Institute for Risk Assessment (BfR). This study revealed that not all bamboo/melamine cups are safe for public health. It has also drawn the attention of Consumentenbond, the Dutch consumers' association[2].

Consequently, the Netherlands Food and Consumer Product Safety Authority (NVWA) conducted a market study at the end of 2019 to investigate the migration of formaldehyde from bamboo cups. This study involved takeaway cups as well as normal crockery. A total of 46 cups, bowls and mugs were sampled and examined in duplicate. Since a number of excessive violations of the migration limit for formaldehyde were found, the Enforcement Directorate of the NVWA requested the Office for Risk Assessment & Research (BuRO) for its advice.

The study conducted by the Enforcement Directorate had has led to the following research questions regarding the bamboo/melamine cups:

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?

Furthermore, bamboo/melamine consumer articles for young children are also available in the market. These were not included in the 2019 market study. The Enforcement Directorate has formulated an additional research question about these products:

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?

BuRO itself has added another research question regarding melamine:

[1] https://www.test.de/Bambusbecher-im-Test-Die-meisten-setzen-hohe-Mengen-an-Schadstoffen-frei-5496265-0/
[2] https://www.consumentenbond.nl/voedingstests/schadelijke-stoffen-in-bamboebekers

4. From what level of melamine migration from bamboo/melamine food contact materials is there a health risk?

Approach

BuRO has used the results of the NVWA study of the migration of formaldehyde as the basis for this Advisory Report. In addition, European RASFF (Rapid Alert System for Food and Feed) notifications on bamboo/melamine food contact materials (FCM) and publications from other Member States have been consulted. A literature study was conducted in PubMed to look for publications on melamine and formaldehyde migration from FCM made of bamboo/melamine. The following search terms and combinations were used for this: 'food contact materials', 'bamboo', 'melamine', 'formaldehyde' and 'migration'. To find out more about the toxicological properties of these substances, publications from the European Food Safety Authority (EFSA), European Chemicals Agency (ECHA) and other international governmental bodies have been consulted. Based on the Food Consumption Survey (*Voedselconsumptiepeiling, VCP*) for hot beverages and migration data, an estimate was subsequently made of the exposure to formaldehyde resulting from the consumption of foodstuff that has come in contact with these consumer articles.

Findings

Hazard identification

- For bamboo/melamine consumer articles, formaldehyde and melamine have been identified as hazards based on market studies from other Member States and RASFF notifications. Both these raw materials are used to produce melamine-formaldehyde resin from which these cups are made.

Hazard characterisation

- EFSA has determined the Tolerable Daily Intake (TDI)[3] for oral exposure to formaldehyde to be 0.15 mg/kg body-weight/day. The critical effect is stomach irritation. Due to the high migration values observed, an Acute Reference Dose (ARfD)[4] was sought for formaldehyde but this has not been found.
- For formaldehyde, there is a significant background exposure via food, smoking, other consumer products and the environment. There is a wide range in the estimated background exposure: from 0.025 to 0.7 mg/kg body-weight/day. The lowest value has been taken into account for this risk assessment so that, if the total exposure exceeds the health-based guidance value, an increased health risk can be assumed.
- EFSA has derived a TDI of 0.2 mg/kg body-weight/day for melamine, where the formation of stones in the kidneys or urinary tract is the critical effect. It has estimated the Dutch consumer's background exposure to melamine from food as 1.6 µg/kg body-weight/day.

Legal aspects

- Plastic FCM fall within the scope of Regulation (EU) No 10/2011[5]. Some of the cups indicate that they are made of bamboo or bamboo and corn. Bamboo fibres and corn are not authorised for use as additives in plastic FCM. Therefore, bamboo/melamine FCM are not permitted to be placed on the European

[3] Tolerable Daily Intake (TDI) is an estimate of the amount of a substance that can be ingested on a daily basis over a lifetime without it having a noticeable effect on one's health.

[4] Acute Reference Dose (ARfD) is an estimate of the amount of a substance in food or drinking water that can be ingested within a 24-hour period without any appreciable health risk.

[5] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. OJ L12, 15.1.2011, p. 1-89.

market. Formaldehyde is authorised as a raw material under Regulation (EU) No 10/2011, with a specific migration limit (SML) of 15 mg/kg food for the sum of formaldehyde, hexamethylenetetramine and 1,4-butanediol formal (expressed as formaldehyde). Melamine is authorised as a raw material for plastic FCM, where the SML is 2.5 mg/kg of food.

Exposure assessment
- The NVWA study showed that 88% of the cups tested complied with the SML for formaldehyde (15 mg/kg food). Twelve per cent exceeded the migration limit, where the violation was by a factor of 10 or more in 5 cases.
- The exposure assessment is based on the consumption of hot beverages (tea and coffee) from bamboo/melamine cups. A realistic assumption for this is 2 cups of hot beverages per day (0.4 kg/day). The body weight is assumed to be 60 kg.
- For children's tableware, a daily intake of 200 g of warm food and 100 g of warm drinks is assumed for a child aged 1 year or above, where this food and drink have come in contact with bamboo/melamine tableware. The body weight is assumed to be 10.1 kg.

Risk characterisation
- For bamboo/melamine cups, the health-based guidance value is exceeded in case of a formaldehyde migration of 19 mg/kg or higher. This is slightly higher than the SML. A formaldehyde migration of below 19 mg/kg was observed in 89% of the cups examined by the NVWA. However, very high values have also been found (> 200 mg/kg). Therefore, there is an increased health risk with respect to these products.
- For melamine migration from these bamboo/melamine cups, the health-based guidance value is exceeded if the migration value is 30 mg/kg or higher. This is well above the SML of 2.5 mg/kg. Such high migration values have not yet been published in the RASFF notifications.
- For children's tableware, the health-based guidance value is exceeded from a migration value equal to or higher than 4.2 mg/kg formaldehyde and 6.7 mg/kg melamine. For formaldehyde, the current SML (15 mg/kg) offers insufficient protection for children.
- Research by the BfR has shown that, in general, a significantly higher amount of formaldehyde and melamine is released from bamboo/melamine FCM than from FCM made of melamine. This indicates that the bamboo fibres affect the plastic matrix such that the level of migration increases.
- Substantiation for the derivation of the SML of formaldehyde could not be found. Normally, EFSA uses the following standard values for making the conversion to an SML: intake of 1 kg of food per day and a body weight of 60 kg. In that case, a TDI of 0.15 mg/kg body-weight/day corresponds to an SML of 0.15*60/1 = 9 mg/kg. This is lower than the current SML (15 mg/kg).
- Although this Advisory Report focuses on bamboo/melamine FCM, the findings and recommendations also apply to FCM made of melamine-formaldehyde resin (without the addition of bamboo or corn).

Answers to the research questions
Research question 1. How severe is the health risk entailed by the observed migration of formaldehyde from bamboo/melamine consumer articles?
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 is exceeded if the migration value is 19 mg/kg or higher. Ten products (11%) failed to meet this value of 19 mg/kg. 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.

Research question 2. From what migration level onwards is there a health risk for adults?
The health-based guidance value is exceeded in case of a formaldehyde migration of 19 mg/kg or higher. The products that did not meet this requirement often had much higher migration values of formaldehyde: 65-247 mg/kg. For some high migration values, the health-based guidance value is exceeded by a factor of 10 or more.

Research question 3. From what migration level onwards is there a health risk for children (aged up to three years) due to formaldehyde from children's tableware made of bamboo/melamine?
The maximum amount of formaldehyde that may migrate from bamboo/melamine children's tableware before the health-based guidance value is exceeded is 4.2 mg/kg. With higher migration, a health risk cannot be ruled out. The SML does not provide adequate protection for children's tableware.

Research Question 4: From what level of melamine migration is there a health risk?
With a daily intake of 2 cups of hot beverages from bamboo/melamine cups, the health-based guidance value is exceeded if melamine migration is equal to or higher than 30 mg/kg. For children's tableware, the maximum migration is 6.7 mg/kg, whereby the health-based guidance value is not exceeded. Both the maximum migration values for melamine are well above the SML of 2.5 mg/kg. Hence, the SML for melamine is sufficiently protective.

Advices BuRO
To the Minister for Medical Care and Sport
- The current SML for formaldehyde (15 mg/kg) offers insufficient protection for children's tableware. The necessary action should be taken to adjust this SML so that it offers sufficient protection.
- The results of this Advisory Report should be brought to the attention of the Netherlands Nutrition Centre (*Voedingscentrum*) so that it can inform consumers and professionals about the various risks and particularly about those affecting babies and children.

To the Inspector-General of the NVWA
- As long as 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) in FCM made of melamine resin.
- Moreover, consumer articles for young children should be tested for the migration of melamine and formaldehyde.
- The risks of bamboo cups should be actively communicated on the NVWA website.
- Plastic FCM containing the unauthorised additives bamboo and/corn should be banned from the Dutch market.

Yours sincerely,

Prof. Antoon Opperhuizen
Office for Risk Assessment & Research

Substantiation

Introduction

The use of bamboo food contact materials (FCM) is on the rise, partly because of their eco-friendly image and sustainability (reusable). Although sold as 'bamboo', these materials are made of melamine plastic to which bamboo fibres are added. Melamine FCM are made of melamine and formaldehyde resin. Such FCM can release formaldehyde and melamine into the food. Formaldehyde and melamine can also migrate from bamboo/melamine FCM.

The number of RASFF (Rapid Alert System for Food and Feed) notifications for bamboo/melamine FCM is worrying because of the violation of the migration limit of formaldehyde and/or melamine. From June 2018, there has been an increase in the number of RASFF notifications. In the period from June 2018 to 10 April 2020, 55 RASFF notifications concerning bamboo FCM were published. These RASFF notifications were published by Austria, Belgium, Croatia, Cyprus, Germany, Poland, Greece, Luxembourg, Slovenia, the Czech Republic, Norway and France. Almost all of these bamboo/melamine FCM came from China. Table 1 contains an overview of the observed migrations of formaldehyde and melamine. The highest reported values for formaldehyde and melamine migrations are 470 mg/kg and 16.7 mg/kg, respectively. In March 2020, Austria has published a RASFF notification about a consumer article made of bamboo, corn and melamine that has been placed illegally on the market.

Table 1: Formaldehyde and melamine migrations for bamboo/melamine consumer articles published in RASFF (n = 55) (June 2017-April 2020).

Formaldehyde migration (mg/kg) (Limit is 15)	Number of RASFF notifications	Melamine migration (mg/kg) (Limit is 2.5)	Number of RASFF notifications
15-100	21	2.5-5	12
100-200	7	5-7.5	11
200-300	5	7.5-10	2
>300	4	>10	3

Stiftung Warentest[6], the German Federal Institute for Risk Assessment (BfR) (BfR, 2019) and Bundesambt für Gebraucherschutz und Lebensmittelsicherheit[7] have conducted market studies that have found high levels of formaldehyde and/or melamine being released. According to the BfR, the health-based guidance value for formaldehyde (0.12 mg/kg body-weight/day) derived by them is exceeded by a factor of three in case of a frequent use of bamboo/melamine cups. Research by BfR showed that the migration of formaldehyde from bamboo/melamine cups is as much as 30% higher than that from normal melamine cups (without added bamboo fibres) (BfR, 2019).

In 2019, the NVWA conducted a market study on bamboo/melamine consumer articles and found that formaldehyde was being released. The results are described in Appendix 1. This Advisory Report focuses on drinkware because that is what the research question of the Enforcement Directorate asks about. Some

[6] https://www.test.de/Bambusbecher-im-Test-Die-meisten-setzen-hohe-Mengen-an-Schadstoffen-frei-5496265-0/
[7] https://iegpolicy.agribusinessintelligence.informa.com/PL222659/Germany-warns-about-migration-of-melamine-from-coffeetogo-cups

plates and cutlery were also included in the market study but they have been excluded from this Advisory Report.

Legal framework

Plastic FCM, including melamine, must comply with Regulation (EU) No 10/2011[8]. The specific migration limit (SML) for formaldehyde, hexamethylenetetramine and 1,4-butanediol formal (expressed as formaldehyde) together is 15 mg/kg. For melamine, the SML is 2.5 mg/kg.

The FCM Expert Working Group of the European Food Safety Authority (EFSA) has discussed the legal aspects and the safety of bamboo/melamine FCM[9]. Wood flour and fibres, if untreated, are authorised for use as additives for plastic FCM (EFSA, 2019). Bamboo fibres and corn do not fall under the definition of wood. Bamboo and corn are not included on the positive list and therefore may not be added to plastic FCM.

Additives of natural origin may pose a health risk if they contain impurities or contaminants. Another possible aspect to be considered is the compatibility with the matrix. The bamboo fibres can cause a swelling in the plastic matrix or a change in the surface, thereby encouraging the migration of components from the plastic.

Bamboo FCM are often marketed as sustainable, recyclable and natural with endorsements such as 'biodegradable', 'environmentally friendly', 'organic', 'natural' or even '100% bamboo'. It is suggested that the products are made exclusively from bamboo, whereas they are largely made of plastic materials. According to the Framework Regulation (EC) No 1935/2004[10], the labelling, advertising and designation of FCM should not be misleading.

Toxicology

Formaldehyde

Formaldehyde occurs naturally in low concentrations in a wide variety of foods such as vegetables and fruit and is also present in low levels as an endogenous substance in humans (IARC, 2009). Formaldehyde has a high so-called first-pass effect, as a result of which the systemic availability is very low (BfR, 2006). Due to its strong reactivity, formaldehyde mainly affects the site of first contact such as the respiratory epithelium, gastrointestinal tract and skin. After absorption by various enzyme systems, it is rapidly metabolised via conversion to formic acid (Pandey et al., 2000). Formic acid is converted into water and carbon dioxide at a relatively slow pace in humans (compared to rodents) via an enzymatic reaction that is dependent on folate (anionic form of folic acid). Accumulation of formic acid can lead to metabolic acidosis. The surplus formic acid is then excreted via urine as sodium salt. Formic acid has a half-life of 90 minutes.
On account of the high migration values reported in the RASFF (Table 1) and the NVWA study, an Acute Reference Dose (ARfD)[11] for formaldehyde was sought, for examining whether there could be an acute health risk. For this, the EFSA

[8] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. OJ L12, 15.1.2011, p. 1-89.
[9] https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_meeting-ind_20200623.pdf
[10] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. PB L 338, 13.11.2004, p. 4-17.
[11] Acute Reference Dose (ARfD) is an estimate of the amount of a substance in food or drinking water that can be ingested within a 24-hour period without any appreciable health risk.

website, ECHA's database on biocidal products, EU Pesticides Database and the WHO website were consulted. No ARfD value has been found for formaldehyde.

The International Agency for Research on Cancer (IARC) classifies formaldehyde as a human carcinogen via inhalation exposure (IARC, 2009). According to EFSA, there is no indication that formaldehyde is carcinogenic via oral exposure (EFSA, 2006). EFSA applies a Tolerable Daily Intake (TDI)[12] of 0.15 mg/kg body-weight per day for formaldehyde (EFSA, 2006). This TDI value has been taken over from the World Health Organization (WHO, 2005). The WHO has derived the TDI from the No Observed Adverse Effect Level (NOAEL)[13] of 15 mg/kg body-weight/day. This NOAEL is based on a 2-year study in rats, in which formaldehyde was administered via the drinking water (Til et al., 1989). When exposed to formaldehyde, the negative effects occur mainly in the first-contact tissues or organs. This is caused due to the rapid conversion of formaldehyde into formic acid. The critical effect was damage to the gastric mucosa, often leading to hyperkeratosis and gastric ulcer. For the conversion of the NOAEL to the TDI, EFSA applied a safety factor of 100 to correct for intra- and interspecies variation.

Melamine
Melamine (2,4,6-triamino-1,3,5-triazine, CAS no. 108-78-1) is a chemical that is produced in large volumes. Food fraud via the addition of melamine to food and animal feed has led to illness and death in infants and household pets (cats and dogs), mainly as a result of kidney damage caused by the formation of crystals or stones in the urinary tract. Melamine is rapidly absorbed from the gastrointestinal tract and excreted in mostly unchanged form. If the melamine concentration in the urine is high enough to form crystals, it can cause damage to the proximal tubule in the kidney.

According to EFSA's assessment, stone formation in the kidneys or urinary tract is the critical effect (EFSA, 2010). Using the Benchmark Dose (BMD)[14] approach, a $BMDL_{10}$ (benchmark dose lower confidence limit)[15] of 19 mg/kg body-weight/day has been derived for melamine. This $BMDL_{10}$ has been derived based on a 13-week study involving dietary exposure of male rats to melamine (National Toxicology Program, 1983). EFSA has converted this $BMDL_{10}$ value to a TDI of 0.2 mg/kg body-weight/day by applying a safety factor of 100 (a factor of 10 for interspecies variation and a factor of 10 for intraspecies variation).

Exposure to formaldehyde
Background exposure to formaldehyde

In the case of formaldehyde, there is a significant level of exposure via food and the environment. The Joint Research Centre (JRC) of the European Commission has identified smoking, food and drink as the main sources of exposure to formaldehyde (JRC, 2005). Formaldehyde is naturally present in fruits and vegetables at levels of 3 to 60 mg/kg. Ingestion of formaldehyde via food is estimated to be 4 to 40 mg/day (JRC, 2005). Assuming a body weight of 60 kg, this is converted into an exposure of 0.07 to 0.7 mg/kg body-weight per day. It should be noted that this calculation is based on information obtained from various countries around the world that is sometimes more than 30 years old.

[12] Tolerable Daily Intake (TDI) is an estimate of the amount of a substance that can be ingested on a daily basis over a lifetime without it having a noticeable effect on one's health.
[13] The highest level of ingestion at which no harmful effects occur.
[14] BMD is the dose estimated based on the dose-response curve at which a specified change in response occurs, i.e. the so-called benchmark response.
[15] $BMDL_{10}$ is the 95% lowest confidence interval of the estimated dose that carries an additional 10% risk.

WHO has arrived at a lower estimate of formaldehyde ingestion via food of between 1.5 and 14 mg/day for an adult, most of which occurs in a bound and unavailable form (WHO, 1989). After conversion, this amounts to an ingestion of 0.025 to 0.23 mg formaldehyde/kg body-weight per day (based on a body weight of 60 kg).

Formaldehyde is present in various consumer products such as furniture, floors, textiles, cleaning products and cosmetics. Exposure to formaldehyde occurs via inhalation and dermal absorption. The question is whether ingestion via these routes of exposure can be added together since inhalation and dermal exposure have different toxicological effects, although they do contribute to the total exposure. An evaluation of formaldehyde by the European Chemicals Agency (ECHA) has resulted in a report that includes information on consumer exposure (ECHA, 2019). Open fireplaces, cooking, candles and incense were identified as the most important temporary sources. Continuous exposure may occur via home textiles, carpeting, walls, doors and furniture. This ECHA report does not contain any value for the cumulative exposure to formaldehyde indoors. For inhalation exposure via indoor air, outdoor air and traffic, the daily ingestion is estimated at 24 µg/kg body-weight per day (JRC, 2005). For smokers, the estimated exposure to formaldehyde for 20 cigarettes per day is 0.5 mg/kg body-weight per day (JRC, 2005).

The level of exposure to formaldehyde via food or other sources is very significant and may even exceed the health-based reference value. The lowest reported ingestion via food has been used for the calculations in this Advisory Report: 0.025 mg/kg body-weight per day. There is certainly an increased health risk if the TDI is exceeded at this background exposure value.

Migration results for formaldehyde based on market study of bamboo/melamine cups

A total of 46 bamboo/melamine drinkware items have been sampled in duplicate and examined for the migration of formaldehyde (see Appendix 1). This includes takeaway cups as well as normal crockery. The following labelling was present:

- 9 cups made of bamboo
- 9 cups made of bamboo and corn, of which 7 cups were labelled 'Reinforced with melamine'
- 2 cups made of bamboo, corn and melamine
- 2 cups labelled 'Biodegradable'

The tested products are cups suitable for hot beverages and intended for repeated use. Since they are coffee or tea cups, the target group was adults. Although children may also drink tea from these cups, the risk assessment has been initially carried out for adults. The third research question is specifically aimed at bamboo/melamine products intended for the target group of children.

The migration tests have been carried out in accordance with Annex V of Regulation (EU) No 10/2011. For kitchenware, a specific guideline has been published by the network of European and National Reference Laboratories (EURL-NRL) for FCM (Beldi et al., 2019). The following test conditions are prescribed for melamine FCM intended for hot beverages:

- 3% acetic acid solution in water as a food simulant
- Temperature of 70°C
- Migration time of 2 hours
- -3 consecutive migration tests

Since the tested cups are 'fillable items', they are filled with food simulant (3% acetic acid at 70°C) to 5 mm below the rim and then covered with a glass plate.

The beakers are placed in an oven at 70°C for 2 hours. This migration test is repeated 3 times with fresh simulant. The migration fluid of the third migration test is analysed for the level of formaldehyde contained therein. This value is checked against the specific migration limit.

Figure 1 displays the frequency distribution of the observed migration values. Table 2 contains an overview of the values found for the migration of formaldehyde.

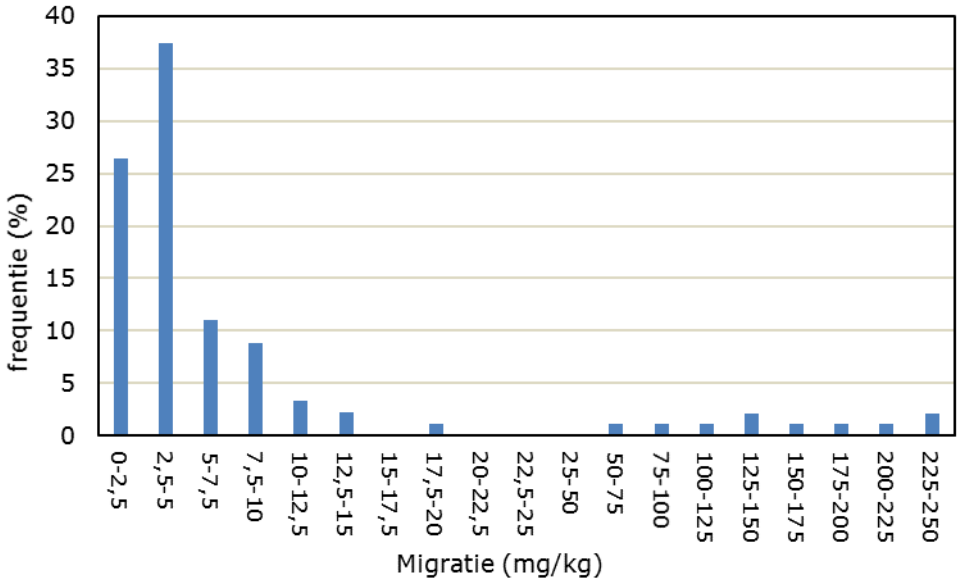

Figure 1: Distribution of formaldehyde migration from bamboo/melamine cups (n = 92) (result of third migration measurement)

Most of the products (88%) met the migration limit of 15 mg/kg. However, some very high migration values - higher than 200 mg/kg - have also been found. The highest migration value found for formaldehyde is 247 mg/kg. The migration values of the duplicate measurement are reasonably comparable. All the values have been used for this risk assessment. It is a known fact that melamine FCM are not always homogeneous, which can have a significant effect on the migration of substances. This may explain the difference in results between duplicates. For one type of product, the first result is lower than the migration limit, while the result for the duplicate sample is higher. For the other products, there is no difference in the results (whether or not they meet the legal requirement).

Table 2: 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%)

Migration results from other studies
Various German market studies show that violations of the migration limit of formaldehyde (up to more than 200 mg/kg) have also been found for bamboo/melamine cups. The BfR has compared the migration of formaldehyde from bamboo/melamine cups and melamine FCM (BfR, 2019), see Table 3. This shows that the release of formaldehyde from bamboo/melamine cups is, in general, significantly higher than that from melamine cups and the specific migration limit for formaldehyde is also more often exceeded in bamboo/melamine cups. The addition of bamboo fibres has a negative effect on formaldehyde migration.

The results of the German market study of formaldehyde migration from bamboo/melamine cups are higher than the values found by the NVWA (see Table 2).

Table 3: Formaldehyde migration (mg/l) from bamboo/melamine (n = 228) and melamine FCM (n = 138) in the German market study (BfR, 2019)

	Melamine cups	Bamboo/melamine cups
Minimum	<LOQ	<LOQ
Median	4.45	9.25
Average	5.69	85.9
75th percentile	7.39	31.9
95th percentile	15.3	442
Maximum	32.7	912
Number of samples > SML (15 mg/L)	17 (12%)	101 (44%)

For FCM intended for repeated use, it is prescribed that the result of the third migration test should be checked against the limit value. Bamboo/melamine cups are expected to be used multiple times. Therefore, in terms of chronic exposure, it is relevant to know the level of migration over time. The BfR has investigated the migration of formaldehyde during 12 consecutive migration tests (BfR, 2019). These tests show that the migration level appears to be approximately the same. Hydrolysis of the polymer releases both formaldehyde and melamine. This also leads to a deterioration of the contact surface. This is also visible after migration tests because the surface looks matte and rough.

Estimated exposure to formaldehyde from bamboo/melamine cups
The National Institute for Public Health and the Environment (RIVM) conducts food consumption surveys among the Dutch population on behalf of the Ministry of Health, Welfare and Sport. The last survey dates from 2012-2016 (Van Rossum et

al., 2016). A refillable cup is usually used for coffee or tea. Table 4 displays coffee and tea consumption data of the Dutch population.

Table 4: 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

The entire consumption of hot beverages such as coffee and tea will not be from bamboo/melamine cups. 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[8] is assumed. The maximum migration of formaldehyde, where the health-based guidance value is not exceeded, is calculated according to the formula given below.

$$M_{max} = \frac{(TDI\text{-}AB) \times LG}{I} = \frac{(0.15 \times 0.025) \times 60}{0.4} = 18.8 \text{ mg/kg}$$

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
Bamboo/melamine tableware for young children is also available on the market. This includes cups, bowls, plates and cutlery. For the purpose of this risk assessment, the age of 12 months is assumed as the starting point for the consumption of warm food from bamboo/melamine FCM. From this age on, it is assumed that children eat at the table, using their own tableware. Young children may also drink hot beverages from bamboo/melamine cups, including hot milk, chocolate milk or tea. This risk assessment assumes a daily intake of 200 grams of warm food and 100 grams of warm drinks (0.3 kg in total), where this food and drink have come in contact with bamboo/melamine tableware. The General Fact Sheet is used for the standard values for a child aged 1 year and older (Te Biesebeek et al., 2014). The 25th percentile for body weight is 10.1 kg for a Dutch child aged 1-2 years old. 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.

$$M_{max} = \frac{(TDI\text{-}AB) \times LG}{I} = \frac{(0.15 \times 0.025) \times 10.1}{0.3} = 4.2 \text{ mg/kg}$$

Exposure to melamine
Background exposure to melamine

EFSA has estimated the level of exposure to melamine via food (EFSA, 2010). To do this, it has used the food consumption data for different food groups obtained from various Member States. The food industry has provided data on the melamine levels in food. Based on this, an estimate has been made of exposure via food. With average consumption and average levels of melamine per food group, the Dutch consumer's exposure was estimated as being 1.58 µg/kg body-

weight/day. With extremely high consumption (P95) and high levels of melamine (P95), the worst-case exposure to melamine via food was estimated as being 7.97 µg/kg body-weight/day. Both values are well below the TDI of 0.2 mg/kg body-weight/day (200 µg/kg body-weight/day).

Estimated exposure to melamine from bamboo/melamine cups
The NVWA has no data on the migration of melamine from bamboo/melamine FCM. Table 1 contains an overview of the observed melamine migration values based on the published RASFF notifications. However, this does not give a representative picture of the market, since only violations are published in the RASFF. The highest value found for melamine migration from bamboo/melamine FCM was 16.7 mg/kg.

A study of the relevant literature mainly yielded results for melamine FCM and only the BfR has published a market study of bamboo/melamine cups (BfR, 2019). The BfR has determined the migration values of melamine for 180 bamboo/melamine cups and 111 melamine cups. Table 5 displays an overview of the migration values observed. This table shows that, in general, significantly higher migration values and more violations of the migration limit are found for bamboo/melamine FCM than for melamine FCM. These results indicate that the addition of bamboo fibres changes the plastic matrix such that there is an increase in migration.

Table 5: Melamine migration from bamboo/melamine (n = 180) and melamine FCM (n = 111) in the German market study (BfR, 2019)

	Melamine: melamine migration (mg/L)	Bamboo/melamine: melamine migration (mg/L)
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
Average	1.27	2.64
Number of samples > SML (2.5 mg/L)	17 (15%)	63 (35%)

For a number of cups made of both bamboo/melamine and melamine, the BfR has determined the level of migration in case of repeated use (BfR, 2019). In total, 12 consecutive migration tests were performed. The results showed that the migration of melamine increased with an increase in the number of tests. There was a higher rate of increase for bamboo/melamine FCM than for melamine FCM. This indicates progressive material degradation under the applied test conditions. Melamine (melamine-formaldehyde resin) is a polycondensate. Through reaction with water, it can be broken down into the two monomers (melamine and formaldehyde). The results in Table 5 have been obtained after the third migration test and possibly give an excessively low migration value for prolonged use.

The calculation of the maximum migration of melamine from bamboo/melamine consumer articles is performed in a similar way as for formaldehyde. The maximum migration value for melamine, where the health-based guidance value is not exceeded, is 30 mg/kg.

$$M_{max} = \frac{(TDI\text{-}AB) \times LG}{I} = \frac{(0.2\text{-}0.0016) \times 60}{0.4} = 30 \text{ mg/kg}$$

Estimated exposure to melamine from bamboo/melamine children's tableware
The same intake data are used as for the formaldehyde exposure estimation. For the purpose of this risk assessment, the age of 12 months is taken as the starting point for the consumption of warm food and drinks from bamboo/melamine FCM. The intake amount is assumed to be 0.3 kg of food per day that has come in contact with bamboo/melamine tableware. The General Fact Sheet is used for the standard values for a child aged 1 year and older (Te Biesebeek et al., 2014). The 25th percentile for body weight is 10.1 kg for a Dutch child aged 1-2 years old.

No migration data are available for bamboo/melamine children's tableware. The maximum migration of Melamine, where the health-based guidance value is not exceeded, is calculated according to the following formula:

$$M_{max} = \frac{(TDI\text{-}AB) \times LG}{I} = \frac{(0.2\text{-}0.0016) \times 10.1}{0.3} = 6.7 \text{ mg/kg}$$

Risk assessment of formaldehyde

Bamboo/melamine cups
It is assumed that 0.4 kg/day of hot beverages is consumed from bamboo/melamine cups per day. The test is based on the health-based guidance value of 0.15 mg of formaldehyde/kg body-weight/day. A body weight of 60 kg is assumed. The lowest reported ingestion of formaldehyde via food of 0.025 mg/kg body-weight/day is taken into account. Realistic values are selected for the daily intake of hot beverages from bamboo/melamine cups and the intake via food. In case of a formaldehyde migration of 19 mg/kg or higher, the health-based guidance value is exceeded and a health risk is involved.

Tableware for babies and children
The assumptions are a daily intake of 0.3 kg of warm food and drink that have come in contact with bamboo/melamine children's tableware; a body weight of 10.1 kg; and a dietary intake of formaldehyde of 0.025 mg/kg body-weight/day. These are realistic assumptions. The health-based guidance value is exceeded in case of a formaldehyde migration higher than 4.2 mg/kg. The SML of 15 mg/kg offers insufficient protection.

Risk assessment of melamine

Bamboo/melamine cups
The assumption is 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 body-weight/day and a background exposure of 1.6 µg/kg body-weight/day. A body weight of 60 kg is taken into account. The health-based guidance value for melamine is exceeded in case of a migration value of 30 mg/kg or higher. Such a high value was not found either in the RASFF notifications or the German market study.

Tableware for babies and children
The assumption is that a child (from the age of 1 year) will consume 0.3 kg/day of warm food and drinks that have come in contact with bamboo/melamine children's tableware. A body weight of 10.1 kg is assumed. The health-based guidance value for melamine is exceeded in case of a melamine migration higher than 6.7 mg/kg food.

Conclusions

Formaldehyde
Most of the bamboo/melamine FCM tested by the NVWA meet the formaldehyde migration limit of 15 mg/kg. A number of excessive violations have been found. For formaldehyde, there is a significant background exposure via food, other consumer products and the environment, which itself may exceed the TDI. However, this cannot be quantitatively determined for the Dutch situation.

Hence, certain realistic assumptions have been made in this Advisory Report, i.e. 2 cups of hot beverages are drunk from bamboo/melamine cups per day (0.4 kg/day). The lowest reported ingestion via food is taken into account as background exposure because a health risk is certainly involved as soon as the total exposure exceeds the health-based exposure limit. There is a health risk if the formaldehyde migration level is 19 mg/kg or higher. This is slightly higher than the SML (15 mg/kg). A migration value lower than 19 mg/kg was detected for 89% of the cups examined by the NVWA.

For tableware for babies and children, it is assumed that 200 g of warm food and 100 g of warm drinks are consumed daily, where this food and drink have come in contact with bamboo/melamine tableware. Children aged 1 year or older have been taken into account. In case of a migration value of 4.2 mg/kg or higher, the health-based guidance value is exceeded. The SML for formaldehyde does not provide sufficient protection.

The scientific basis for deriving an SML of 15 mg/kg for formaldehyde cannot be found. For FCM, an SML is normally derived based on the TDI, a daily intake of 1 kg of food into which this substance has migrated and a body weight of 60 kg. For formaldehyde, a TDI of 0.15 mg/kg body-weight/day would then result in an SML of 9 mg/kg.

Melamine
For bamboo/melamine cups, a daily consumption of 2 cups (0.4 kg/day) will not cause the health-based guidance value for melamine to be exceeded. This exposure limit for melamine is exceeded with a migration of 30 mg/kg or higher. This extremely high value has not been found in the relevant literature or the RASFF notifications.

For tableware for babies and children, it is assumed that 0.2 kg of warm food and 0.1 kg of warm drinks are consumed daily, where this food and drink have come in contact with bamboo/melamine tableware. From a migration of 6.6 mg/kg or higher, the health-based guidance value is exceeded. This value is well above the specific migration limit of 2.5 mg/kg.

In view of the results from the German market study and the reported values in the RASFF notifications, it is likely that non-compliant bamboo/melamine products are also present in the Dutch market.

General
A potential health risk is more likely to be present for children's tableware than for cups because the maximum migration value, at which the health-based guidance value is not exceeded, is lower. This is mainly due to the lower body weight of young children.

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.

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Appendix I: Migration of formaldehyde from bamboo/melamine cups

Table 6: Migration of formaldehyde from bamboo/melamine cups (result of third migration measurement)

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**
Cup	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
Cup	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**

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Our reference
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Article	Labelling	Formaldehyde migration (mg/kg) Sample 1	Formaldehyde migration (mg/kg) Sample 2
Mug		5.5	4.8
Mug		2.1	2.2
Bowl		**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

Red colour and bold type indicate that the result is higher than the migration limit of 15 mg/kg

[1] Based on biodegradable materials

[2] Reinforced with melamine resin