


A Short Critique on the Stance of the Netherlands Food and Consumer Product Safety Authority on Melamine Polymer Formaldehyde Exposures

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Abstract

In February 2021, the Netherlands Food and Consumer Product Safety Authority came out with their risk assessment on formaldehyde exposure from melamine crockery with bamboo fiber to especially young children. In this short commentary, I will critique their assessment of this type of food-contact material (FCM). The main flaws are at least: (i) absence of a proper valuation of the available principal scientific literature yielding a biased risk assessment; (ii) discounting the endogenous formaldehyde formation that outweighs background exposure substantially; (iii) ad hoc positing of an unjustifiable and unfounded low background exposure levels to formaldehyde whereby risks of exposure to melamine formaldehyde is grossly exaggerated. This biased assessment has created societal unrest that is wholly uncalled for. Additionally, it has wide-ranging European consequences for the use of all melamine FCM.

Keywords

formaldehyde exposure, melamine FCM, Netherlands Food and Consumer Product Safety Authority, risk assessment

Introduction

The risks of formaldehyde-exposure to, particularly, toddlers (age 1-3 years) from melamine crockery will be considered in the below-presented critical evaluation of BuRO-report TRCVWA/2021/768¹ “Advisory Report from the Director of the Office for Risk Assessment and Research concerning the Health Risks of Bamboo Cups” of the Netherlands Food and Consumer Product Safety Authority (henceforth report). This report has caused quite the political and regulatory stir, both in the Netherlands and Europe. In this commentary, we will take a closer look at the toxicological aspects of formaldehyde and the subsequent risk assessment as presented in the report.

The Report’s Main Findings on Formaldehyde Risks of Exposure From Melamine (Bamboo Fiber) Crockery

The report is on food-contact material (FCM) that is melamine polymers containing bamboo fiber and the risks that type of material could engender toward especially children. The main report’s questions are (p.1):

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 3 years) if they eat from children’s tableware made of bamboo/melamine? . . .”

Again, we will limit our analysis tot formaldehyde migration from FCM made of bamboo/melamine. The results of the

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analysis presented by the authors of the report will have its repercussions on pure melamine FCM, as stated on p. 14: "The findings and conclusions for the migration of formaldehyde and melamine from bamboo/melamine FCM also apply to melamine FCM." So whether or not melamine FCM contains bamboo fiber is irrelevant to the question of the risks of formaldehyde migration.

The Specific Migration Limit (SML) for formaldehyde is 15 mg/kg food. The report's exposure assessment is based on the consumption of hot beverages 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 melamine bamboo crockery, a daily intake of 200 g of warm food and 100 g of warm drinks is assumed for a child 1-3 years old. The body weight is assumed to be 10.1 kg.

The report (p. 9) details on melamine crockery that "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 lowest reported ingestion via food -0.025 mg/kgbw/day- has been used as background exposure in the report. For a child weighing 10.1 kg that would amount to 0.25 mg/day; for an adult weighing in at 60 kg that would result in a daily exposure of 1.5 mg. The report (p. 8) furthermore suggests that there "certainly [is] an increased health risk if the TDI [0.15 mg/kgbw/day; see below] is exceeded at this background exposure value."

For adults (60 kg), the report (p.13) concludes that 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." For toddlers between 1-3 (10.1 kg), the report concludes that 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."

Oral Toxicology

As a toxicological benchmark for formaldehyde, the report takes the well-known TDI of 0.15 mg/kgbw/day for oral exposure as published by Til et al.² Very briefly, formaldehyde was administered in drinking-water to groups of 70 male and 70 female Wistar rats for up to 24 months. Survivors of subgroups of 10 rats/sex/group each were killed after 12 or 18 months. The mean formaldehyde doses administered were 0, 1.2, 15 or 82 mg/kgbw/day for males, and for females the doses were 0, 1.8, 21 or 109 mg/kgbw/day. The authors observations were (italics added):

Oral administration of formaldehyde at doses of 82 and 109 mg/kg/day to male and female rats, respectively, caused severe damage to the gastric mucosa but did not result in gastric tumours or tumours at other sites. The study did not provide any evidence of carcinogenicity of formaldehyde after oral administration... The general health and behaviour of the animals did not appear to be affected by any of the

formaldehyde treatments... There was no toxicologically significant difference in mortality between controls and treated animals....

Til et al determined the formaldehyde No-Observed-Adverse-Effect Level (NOAEL; keeping in mind the sizeable jump between the NOAEL and the highest experimental dose applied) to be 15 and 21 mg/kgbw/day for male and female rats, respectively. The critical effect is stomach irritation. The NOAEL of 15 mg/kgbw/day was chosen to formulate the human oral Tolerable Daily Intake (TDI) of 0.15 mg/kgbw/day.

Gelbkea et al³ used the NOAEL of Til et al to calculate the *actual* drinkingwater concentrations of formaldehyde that were fed to the rats in their experiment. Gelbkea et al state:

After 2 years of exposure the NOAEL for irritation in the stomach was 15 mg/kg bw/d for males and 21 mg/kg bw/d for females, corresponding to 260 mg/l drinking water on average.²

From this average of 260 mg/l drinkingwater that corresponds to the NOAEL dose, Gelbkea et al, proposed a *safe exposure level of formaldehyde via foods*, which they calculated to be at 32.5 mg/kg food per day.

Critical Reflections

A number of concerns stand out. *Firstly*, endogenously produced formaldehyde in humans, as a result of many different physiological processes, only receives cursory reflection in the report. A daily turnover of formaldehyde in humans of an estimated 878-1310 mg/kgbw (kg bodyweight) per day, with a half-life of only minutes, remains unmentioned (EFSA).⁴ Considering this high metabolic turnover, formaldehyde does not accumulate in the body. Human physiology is well-equipped to deal with large (endogenous) loads of formaldehyde.⁵

Secondly, the background exposure of 0.025 mg/kgbw/day proposed in the report is unrealistically low and is devoid of any scientific rationale. *Contrary to* the report, European Food Safety Authority (EFSA) estimates exposure to formaldehyde from dietary sources maximally will be 100 mg formaldehyde per day when no more than 1 kg of food per day is consumed. EFSA, subsequently, considers daily intake to be approximately 1.4 – 1.7 mg/kgbw depending on chosen default adult bodyweights (70 and 60 kg, respectively).

Indeed, a myriad of foodstuffs naturally contain formaldehyde, which via a normal diet would add to the daily background exposure way beyond the report's chosen quantity. Fruit and vegetables contain roughly between 3 and 60 mg/kg product.⁶ Cow's milk can contain up to 3.3 mg/kg product. Meats contain between 0.1 – 20 mg formaldehyde/kg, beef sitting at the lower end of the scale and pork at the higher end.⁷ Fish of different varieties, its consumption generally regarded as adding to a healthy diet, contain between roughly 1–293 mg/kg. Cod, haddock, whiting and other fish belonging to the

Gadidae family show the highest concentrations, even after roasting or boiling.⁸

Estimating a children's ballpark formaldehyde exposure through a normal diet, total food-intake is appraised by the EFSA⁹ at 114.4 g/kgbw per day. For dietary exposure assessments, a body weight of 12 kg should be used as default for European toddlers (1-3 years). A toddler consuming 'one piece of fruit' or a mixture thereof per day -e.g. made from apples, grapes, bananas or pears, weighing in at some 200 gr., would amount to a formaldehyde intake between $\pm 2 - 11$ mg. Vegetables, say some 150 gr., per day, would add to this intake between $\pm 1 - 5$ mg of formaldehyde. Some 100 gr. of meat will add up to ± 2 mg of formaldehyde to the toddler's intake. Consumption of 100 gr of fish, instead of meat, could add to the overall intake between ± 0.1 mg – 29 mg/day. The higher values are certainly not impossible considering the popularity of e.g. cod and haddock. Fresh dairy products will add little to the formaldehyde intake, and will not be considered here. Also, bread and related products such as crackers are not considered. Even this cursory glance at a toddler's diet shows that natural formaldehyde intake via foods is, on average, at least ± 10 mg per day. This is much higher than the report's formaldehyde background of 0.25 mg/day.

Thirdly, the report's statement (p. 8) that there is an increased health risk if the TDI is exceeded at the background exposure is false and without merit. That is firstly related to the NOAEL-derived TDI with a factor 100. That makes for a very conservative TDI that will not indicate hazard if exceeded. Secondly, average food-intake of *maximally* 100 mg/day is only 0.1-0.2% of the daily endogenous formaldehyde production and turnover, which, again, remains deceptively undiscussed in the report.

Fourthly, the inference made in the report that the existing SML of 15 mg formaldehyde/kg is insufficiently protective is false for the following reasons:

1. Migration tests are expressly maximized for leaching formaldehyde from melamine crockery. Warm solid foods will have a lower migration-potential than a 2 h experiment with a 70°C acetic acid 3% watery solution.
2. Formaldehyde migration is limited by the total load present in the melamine crockery. Over time, leaching will decline to nil so that formaldehyde leaching is not a permanent fixture of melamine crockery use.
3. Migrated formaldehyde into warm solid consumables will bind, to some extent, to food-content chemicals, making them less biologically available.
4. The TDI derived from Til et al² translates into 32.5 mg/kg food per day as done by Gelbkea et al,³ which is substantially higher than even the current SML of 15 mg formaldehyde/kg that would need to leach into warm consumables in contact with melamine crockery on a daily basis.
5. The scientifically unmotivated and arbitrarily low formaldehyde background exposure unrealistically

emphasizes formaldehyde migration levels from melamine crockery.

6. The disregarded high natural endogenous production turnover of formaldehyde unrealistically emphasizes formaldehyde migration levels and its purported risks from melamine crockery.

In Conclusion

Summarizing, the report's assessment of the risks of formaldehyde exposure from melamine crockery is biased, lacks thoroughgoing analysis -e.g. no exposure assessment from foods is presented- and neglects important and recent literature. This bias is exacerbated by choosing unrealistically low formaldehyde background exposures from foods and discounts the substantial endogenous formaldehyde production. As a result, unrealistic and unfounded worst-case scenarios are pandered to regulators and the media.

Finally, the report exudes archetypal precautionary reflections superficially donned in toxicological vernacular, inexcusably publicizing fear toward the general public. The latter has no basis in the known physiology and toxicology of formaldehyde, establishing the report to be incompatible with the known science of formaldehyde.


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References

1. The Netherlands Food and Consumer Product Safety Authority (NVWA). *Advice From BuRO on the Health Risks of Bamboo Cups*. BuRO-report TRCVWA/2021/768. Published 2021. Accessed October 3, 2021. <https://english.nvwa.nl/documents/consumers/food/safety/documents/advice-from-buro-on-the-health-risks-of-bamboo-cups>
2. Til HP, Woutersen RA, Feron VJ, Hollanders VHM, Falke HE, Clary JJ. Two-year drinking-water study of formaldehyde in rats. *Food Chem Toxicol*. 1989;27(2):77-87.
3. Gelbkea HP, Buist H, Eisert R, Leibold E, Sherman JH. Derivation of safe exposure levels for potential migration of formaldehyde into food. *Food Chem Toxicol*. 2019;132:110598.
4. European Food Safety Authority (EFSA). Endogenous formaldehyde turnover in humans compared with exogenous contribution from food sources. *EFSA J*. 2014;12(2):3550.

5. Burgos-Barragan G, Wit N, Meiser J, et al. Mammals divert endogenous genotoxic formaldehyde into one-carbon metabolism. *Nature*. 2017;548(7669):549-554.
6. Nowshad F, Islam MN, Khan MS. Concentration and formation behavior of naturally occurring formaldehyde in foods. *Agric Food Secur*. 2018;7:17.
7. Claeys W, Vleminckx C, Dubois A, et al. Formaldehyde in cultivated mushrooms: a negligible risk for the consumer. *Food Addit Contam*. 2009;26(9):1265-1272.
8. Bianchi F, Careri M, Musci M, Mangia A. Fish and food safety: determination of formaldehyde in 12 fish species by SPME extraction and GC-MS analysis. *Food Chem*. 2007;100(3):1049-1053.
9. European Food Safety Authority (EFSA). Guidance on selected default values to be used by the EFSA scientific committee, scientific panels and units in the absence of actual measured data. *EFSA J*. 2012;10(3):2579.