

## CRD 10

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PROPOSED DRAFT MAXIMUM LEVELS FOR MELAMINE IN FOOD AND FEED  
(N13-2009)

COMMENTS BY THE NATIONAL HEALTH FEDERATION

**[SUMMARY: Melamine is a synthetic chemical, deliberately added to foods. It is cumulative, deadly to humans and animals, and, as such, has no place in the food chain. Its acceptable limit for human consumption should be set at zero. Unlike naturally-occurring toxins, such as arsenic and lead, melamine is an intentional contaminant, whether directly or indirectly added to foods.**

**Setting any acceptable limit would only encourage its continued addition to foods. Nor should its permitted use in tableware, a cleanser, and a pesticide excuse human and animal exposure and contamination, any more than the use of lead tableware (such as in Roman times) would excuse human and animal exposure to and contamination by lead.]**

Melamine is an organic base and a trimer of cyanamide, with a 1,3,5-triazine skeleton. As with cyanamide, it contains 66% nitrogen by mass and, if mixed with resins, has fire-retardant properties due to its release of nitrogen gas when burned or charred, and has several other industrial uses. It is synthetic and not found in nature unless deliberately added into food or food items. It is deadly to humans and animals.

### **Toxicity**

Melamine is described as being "Harmful if swallowed, inhaled or absorbed through the skin. Chronic exposure may cause cancer or reproductive damage. Eye, skin and respiratory irritant."<sup>[1]</sup> U.S. Food and Drug Administration (FDA) scientists explained that when melamine and cyanuric acid are absorbed into the bloodstream, they concentrate and interact in the urine-filled renal microtubules, then crystallize and form large numbers of round, yellow crystals, which in turn block and damage the renal cells that line the tubes, causing the kidneys to malfunction.<sup>[2]</sup>

The European Union itself set a standard for acceptable human consumption of melamine at 0.5 milligrams per kg of body mass (based upon a relatively short period of time, i.e., not enough time for cumulative effects), Canada declared a limit of 0.35 mg, and the US FDA's limit was put at 0.63 mg (based upon a *13-week* rat study), but was later reduced to 0.063 mg daily.

The World Health Organization's food-safety director estimated that the amount of melamine a person could stand per day without incurring a *bigger* health risk, the "tolerable daily intake" (TDI), was 0.2 mg per kg of body mass.<sup>[3]</sup>

Note that the above studies were short-term studies and cannot in any way be used as a basis for determining the cumulative effects of melamine on humans and animals.

A toxicology study conducted after recalls of contaminated pet food concluded that the combination of melamine and cyanuric acid in diet does lead to acute renal failure in cats.<sup>[4]</sup> A 2008 study produced similar experimental results in rats and characterized the melamine and cyanuric acid in contaminated pet food from the 2007 outbreak.<sup>[5]</sup>

### **Toxicity Cumulative**

Very importantly, though, a recent study conducted by the School of Public Health (Beijing, China) and the Beijing Center for Disease Prevention and Control,<sup>[6]</sup> found dangerous cumulative effects from exposure to melamine. This study should be given great weight in that it considered the long-term effects of melamine consumption.

As reported by the Chinese researchers, "In general, the adjusted odds ratios between melamine dose and nephrolithiasis **increased** with an increasing daily level of melamine intake per kilogram of body weight. The risk of nephrolithiasis **also increased** with the increasing duration of exposure. Preterm infants, urinary malformation, and parents with a history of urinary stones were independent risk factors. In children exposed to melamine levels <0.2 mg/kg per day, the adjusted odds ratio expressing the risk for nephrolithiasis was still 1.7 times higher than in those without melamine exposure. **These findings suggest that the risk of melamine-induced nephrolithiasis in young children starts at a lower intake level than the levels recommended by the World Health Organization.**" (emphasis added)

Given the European Union's and other countries' penchant for adhering to the Precautionary Principle, one would think that when a proven-dangerous, cumulative, man-made substance such as melamine is present in the food supply, these countries would be just as strict in applying safety limits to melamine as they have quite correctly been with GM foods and crops.

### **Recent History**

In 2007, a pet-food recall was initiated by Menu Foods and other pet-food manufacturers who had found their products had been contaminated and caused serious illnesses or deaths in some of the animals that had eaten them. In March 2007, the US FDA reported finding white granular melamine in the pet food, in samples of white granular wheat gluten imported from a single source in China, Xuzhou Anying Biologic Technology<sup>[7]</sup> as well as in crystalline form in the kidneys and in urine of affected animals.<sup>[8]</sup> Further vegetable protein imported from China was later implicated.

In April 2007, the *New York Times* reported that the addition of "melamine scrap" into fish and livestock feed to give the false appearance of a higher level of protein was an "open secret" in many parts of mainland China, reporting that this melamine scrap was being produced by at least one plant processing coal into melamine.<sup>[9]</sup> Four days later, the same newspaper reported that, despite the widely-reported ban on melamine use in vegetable proteins in mainland China, at least some chemical manufacturers continued to report selling it for use in animal feed and in products for human consumption.

Another recall incident in 2007 involved melamine that had been purposely added as a binder to fish and livestock feed manufactured in the United States. This was traced to suppliers in Ohio and Colorado.<sup>[10]</sup>

On September 12, 2008, just weeks after the closing of the Beijing Olympics, the largest Chinese food-safety scandal broke, leading to global ramifications well beyond the latest problem's dairy origins. The melamine contamination of Chinese-made infant formula – which killed four babies, sickened more than 50,000 others, and involved 22 Chinese and 10 global manufacturers – has led to increased scrutiny of the entire international food and ingredient supply chain.

### **Presence in the Environment**

Food Standards – Australia, New Zealand has taken the well-expressed position that, "It is recognised that trace quantities of melamine and related compounds that are of no toxicological importance may legitimately be present in food. This may arise during processing through leaching from food-grade melamine contact material. Published reports, which specify the likely leached levels of melamine in foods, are not available but there are studies reporting levels of melamine that can be leached from melamine kitchenware under very severe conditions. Melamine may be detected in beverages at levels of 0.5, 0.7, 1.4 and 2.2 mg/kg in coffee, orange juice, fermented milk and lemon juice respectively<sup>5</sup>. These levels originate from migration of melamine from the cup, made of melamine-formaldehyde resin, into the beverage under experimental hot and acidic conditions (95°C for 30 min). Given the extreme use conditions used to generate these data it is considered that a level of 2.5 mg melamine/kg food would represent the *upper levels* likely to be legitimately found in foods. Melamine levels in food exceeding 2.5 mg/kg would be indicative of food adulteration."<sup>[11]</sup> (emphasis added)

It is important to note, though, that the Food Standards agency itself speaks in terms of 2.5 mg/kg of melamine as being the "upper levels likely to be 'legitimately' found in foods," thereby acknowledging that safety would be better established at limits *less than* 2.5 mg/kg. Indeed, at the 2009 CCNFSDU meeting in Düsseldorf, Germany, during one debate over NRV levels, the Australian delegate herself spoke of wanting to strive for "an extra degree of comfort" in safety. The NHF strongly suggests that that "extra degree of comfort" can be found in setting any upper level for melamine at an amount **far below** 2.5 mg/kg.

Indeed, even taking into account the senseless use of melamine in tableware, one pesticide, and in a food-utensil cleanser, the actual baseline concentration of melamine in the environment and, thus, the food chain is around **0.002 to 13 ug/Kg (ppb)** <sup>[12]</sup>

## Conclusion

Dr. Reto Battaglia, a food and melamine expert based in Switzerland, was quite firm in his opinion that the only acceptable limit for melamine in food would be a zero level. As he recently wrote:

“A melamine discussion has no place in Codex. It is neither an ingredient, additive nor residue of a legal application. It is just simply FORBIDDEN to use in the preparation and processing of food. If Codex should be so stupid as to issue a ‘limit,’ the presence of melamine up to that limit would be legal. Therefore: if melamine can be detected, the sample in question is illegal. If a common understanding of the achievable detection limit can be reached (internationally), legal disputes caused by different performance levels of laboratories may be excluded.” <sup>[13]</sup>

It has been argued that because melamine is used in tableware, a food-equipment cleanser, and one pesticide, Codex should permit an “acceptable limit.” This is an absurd argument, akin to arguing during the Roman Empire that there should be acceptable limits for lead in food because Romans ate with lead tableware.

Codex should set a limit of zero tolerance and force these dangerous products off the market. At the very least, due to its cumulative nature, the “acceptable limit” should be no higher than the U.S. FDA limit of 0.063 mg/kg, across the board and for both adults and infants. A zero level, however, would be more prudent and in line with Codex’s true mission here.

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