



Codex Community Event

OPEN TO CCNASWP MEMBERS

26 – 28 February 2024

Sofitel Fiji, Nadi, Fiji

Codex Guidance to Manage Chemical Contaminants in Food

Case Study

Melamine in Food

2ND NORTH AMERICA SOUTH WEST PACIFIC CODEX COLLOQUIUM

Supporting the Enhancement of Food Control Systems in the SWP Region

Event Partner Organizations



Prof. Samuel Godefroy, Laval University, Québec, QC. Canada

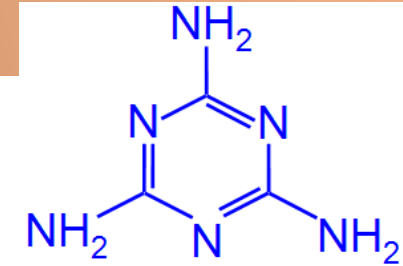
MELAMINE CRISIS

- ❑ March 2007 : Reports from China indicated the adulteration of pet food in China with Melamine with possible implication on feed.
- ❑ Gluten protein in pet foods sourced from China were adulterated – over 1000 products recalled by Canadian pet food manufacturer “Menu Foods”.
- ❑ In September 2008: Reports from China indicated findings of levels of Melamine from 20 to 900 ppm (mg/kg) in milk powder (included in infant formula)





WHAT IS MELAMINE



Melamine

(1,3,5-triazine-2,4,6-triamine)

- ❑ Melamine is 1,3,5-triazine-2,4,6-triamine, a **Synthetic chemical** used in industrial applications, including resins and foams, cleaning products, fertilizers and pesticides.
- ❑ **67% nitrogen by weight**
- ❑ Protein content of food measured through readings of Nitrogen content (derivative of Kjeldhal method that dates back to 1883)
- ❑ Low ppm range of melamine would increase the apparent protein content by a few %
- ❑ Milk contains about **3.0–3.4% protein content**
- ❑ **Addition of Melamine increases substantially “false readings” of protein : FOOD FRAUD**



THE ISSUE NATIONALLY

Identifying the Issue:

❑ Possible presence of Melamine in food as a result of deliberate addition:

- Expecting high levels in foods rich in dairy components (e.g. infant formula)
- Expecting some levels in other products
- Milk is a common ingredient in processed foods (particularly those destined to children!) = vulnerable population possibly at risk





REVIEW OF MAIN FINDINGS – HAZARD CHARACTERIZATION

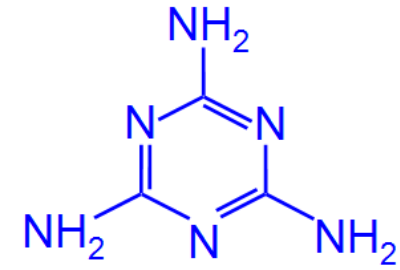
❑ Approach Adopted: BMDL10 : 35mg/kgbw/day

❑ Safety factors: 100

❑ TRD: 0.35 mg/kgbw/day (In Canada)

❑ Uncertainties:

- Differences between epi observations: kidney effects in children and bladder effects in animal studies
- Possible synergetic effects related to compounds with similar structure (renal crystal formation) – not quantitatively assessed.



Melamine

(1,3,5-triazine-2,4,6-triamine)



EXPOSURE ASSESSMENT WAS MADE USING....

❑ Theoretical approaches

❑ Worse case scenarios (maximum infant formula intake)

Table 1. Maximum infant formula intakes and estimated melamine intakes based on various theoretical melamine concentrations (1.0, 2.5, and 20 ppm)

Age Group	Infant BW (kg) ¹	Maximum Infant Formula Intake (g/day) ²	Melamine Intakes (mg/kg bw/day) at various melamine concentrations (µg/g)		
			1.0 ppm	2.5 ppm	20.0 ppm
Premature infants	1.5	100	0.066	0.167	1.330
0-1 month	3.9	1080	0.277	0.693	5.540
2-3 month	5.5	1470	0.267	0.668	5.340
4-7 month	7.2	1440	0.200	0.500	4.000
8-12 month	9.0	960	0.107	0.267	2.140
12-18 month	10.6	900	0.085	0.213	1.700

Recreating the figures:

For premature infants at 1 ppm melamine

1µg/g – in 100 g we have 100 µg
100 µg divided by body weight
1.5kg

Intake 66 µg/kgbw/day or 0,066 mg/kgbw/day in comparison with 0.35 mg/kgbw/day

EXPOSURE ASSESSMENT FOR OTHER FOODS

- Choice of Mean and 90th percentile consumption / intake values – calculation with 2.5 ppm melamine

Recreating the figures:

For 1 year olds at 2.5 ppm melamine in dairy-containing foods

2.5ug/g – in 53.16 g(per kgbw)
we have 132.9 ug /kgbw

Intake 0.132mg/kgbw/day
represents **37 or 38% of the TRD**

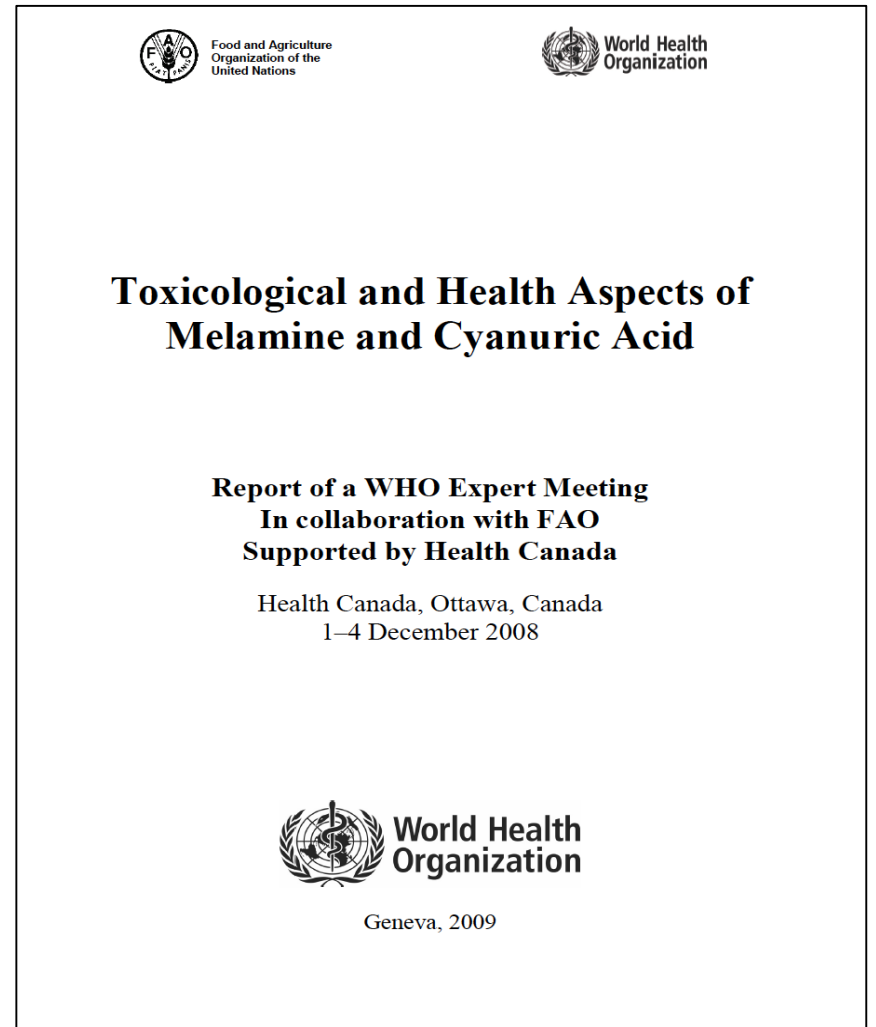
Age group	mean consumption of foods containing milk ingredients (g/kg bw) ¹	mean melamine intake (mg/kg bw/day) assuming a concentration of 2.5 ppm melamine	% of TRD ²	90 th percentile consumption of foods containing milk ingredients (g/ kg bw)	90 th percentile melamine intake (mg/kg bw/day) assuming a concentration of 2.5 ppm melamine	% of TRD
1 yr	53.16	0.13	38.0	84.82	0.21	60.6
2-3 yr	48.56	0.12	34.7	72.42	0.18	51.7
4 yr	41.38	0.10	29.6	62.74	0.16	44.8
5-6 yr	36.93	0.09	26.4	55.44	0.14	39.6
7-11 yr	26.37	0.07	18.8	41.51	0.10	29.6
12-18 yr M	18.95	0.05	13.5	30.81	0.08	22.0
12-18 yr F	16.50	0.04	11.8	27.13	0.07	19.4
19-35 yr M	17.29	0.04	12.3	27.56	0.07	19.7
19-35 yr F	15.52	0.04	11.1	25.09	0.06	17.9
36-50 yr M	16.08	0.04	11.5	24.66	0.06	17.6
36-50 yr F	15.75	0.04	11.3	24.91	0.06	17.8
51+ yr M	14.75	0.04	10.5	22.43	0.06	16.0
51+ yr F	14.70	0.04	10.5	23.24	0.06	16.6

A 3D maze background with the text "Need for An International Guidance" overlaid. The maze is composed of white walls and paths, creating a complex, winding structure. The text is in a bold, blue, sans-serif font with a slight shadow effect, centered over the maze.

Need for An International Guidance

NEED FOR A COMMON FOUNDATION OF RISK ASSESSMENT

- ❑ Canada supported an expert consultation under the auspices of FAO/WHO to lead to a global risk assessment
- ❑ Common Risk Assessment used the latest information available internationally



CALL FOR CODEX GUIDANCE

- ❑ Dairy products and milk powder are part of several processed foods.
- ❑ Guidance was needed to mitigate possible multiplication of Tolerances for Melamine
- ❑ Maximum Levels were developed **to help discriminate products where Melamine is present as a result of “background / environmental” occurrence and instances of deliberate addition** : adulteration.
- ❑ Melamine standards were amongst the fastest moving Codex standards to date.
 - 2.5 PPM standard developed and adopted in **one year**





**Standard was based on
FAO/WHO Expert
Consultation
Standard Based on TDI –0.2
mg/kgbw/day**



**What happens if We Follow
International Guidance ??**

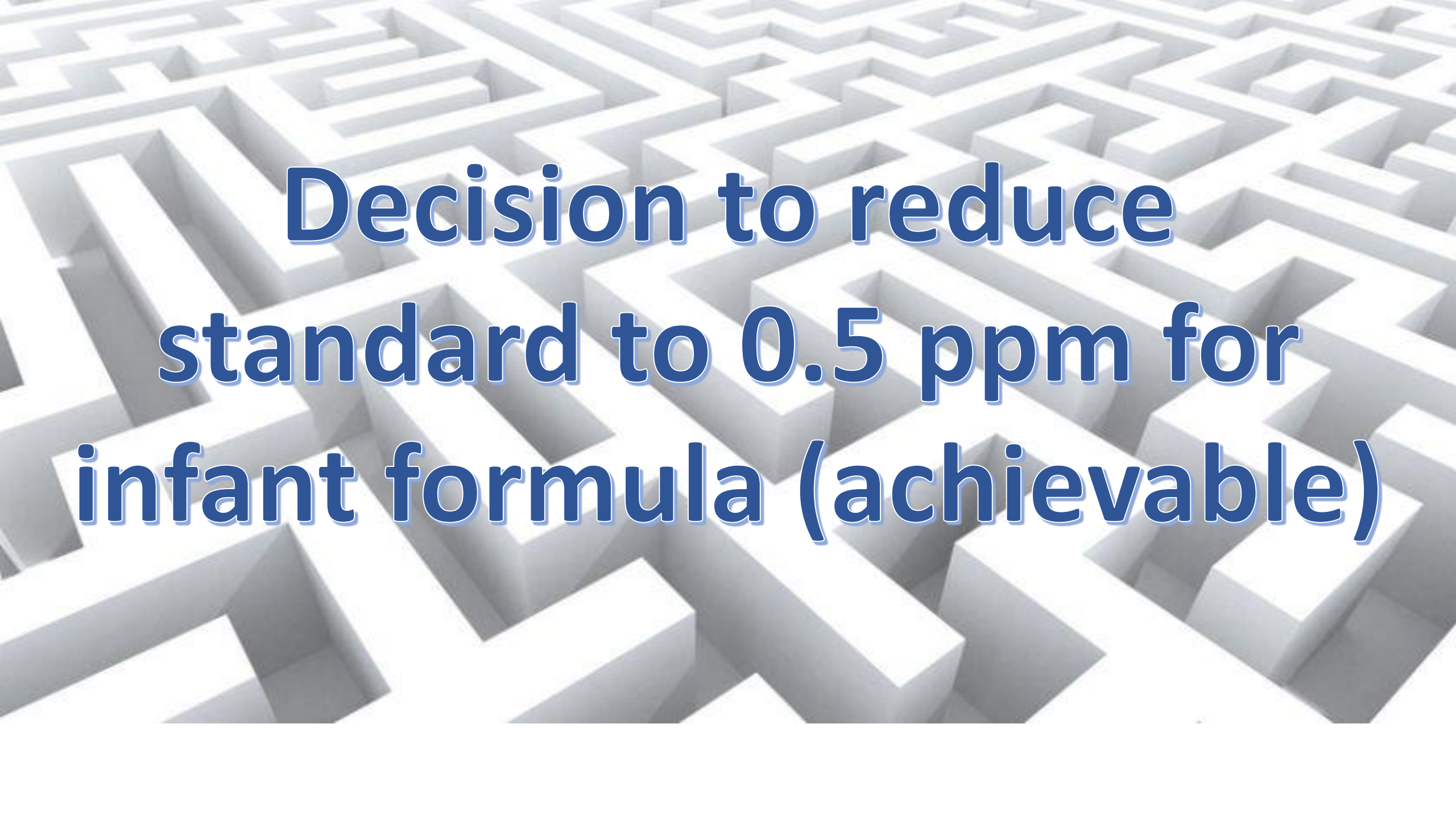


THE COMPARISON IS MADE WITH 0.2MG/KGBW/DAY

- ❑ Some age groups will no longer be as much protected
- ❑ **Worse case scenarios (maximum infant formula intake)**

Table 1. Maximum infant formula intakes and estimated melamine intakes based on various theoretical melamine concentrations (1.0, 2.5, and 20 ppm)

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A 3D maze background with blue text overlaid. The maze is composed of white walls and paths, creating a complex, winding pattern. The text is centered and reads:

**Decision to reduce
standard to 0.5 ppm for
infant formula (achievable)**

