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The opinion of the French Food Safety Agency concerning the risk assessment of melamine exposure from the consumption of contaminated foodstuffs from China

I. Context and History

The food crisis involving the very high contamination of powdered infant formulae by melamine broke out on 11 September 2008 in China. This substance was added fraudulently to give the illusion of a higher protein content. The Chinese authorities revealed contamination levels as high as 2,563mg/kg.

Melamine is a chemical used in the manufacture of resins, plastics and glues. In Europe, melamine use is authorised in the manufacture of plastic.

The import of milk and milk products from China has been banned in the European Union because of animal diseases in China and insufficient controls by the Chinese authorities. But powdered milk is used in many industrial sectors other than the infant formulae industry, such as sweets, biscuits, chocolate, crackers, ice cream and some soft drinks.

After receiving an urgent request from the European Commission, the European Food Safety Authority (EFSA) published an initial quantitative risk assessment on 25 September 2008[1]. This assessment was based on the consumption of 3 types of product (milk toffee, chocolate and biscuits) and several contamination scenarios, including a very pessimistic one taking account of the highest contamination value reported in China: 2,563mg/kg. It concluded that there was no risk for adults and children with mean consumption levels, but that there was a risk of exceeding the Tolerable Daily Intake (TDI) of 0.5mg/kg bw/d in children with high daily consumption of one of the products concerned. Those consuming high quantities of biscuits and chocolate, at the highest contamination levels, exceeded the TDI by a factor of 3.

A maximum level of 2.5mg/kg for composite products imported from China has been set by the European Commission to guarantee a wide safety margin[2].
Several European countries, including France, then revealed varying levels of melamine in diverse products imported from China, including Chinese sweets called "White Rabbit".

[1] Statement of EFSA on risks for public health due to the presence of melamine in infant milk and other milk products in China. T***he EFSA Journal*** **(2008) 807, 1-10.**

Afssa received a request in this context on 1 October 2008 to conduct a risk assessment on the basis of national monitoring data of melamine levels in foodstuffs originating from China, with a view to building on EFSA's assessment by taking account of other milk-based products and the most exposed consumers.

It is important to highlight the fact that this assessment is retrospective and does not concern the current situation, since all milk-based products from China have been withdrawn from the market and destroyed.

II. Method

Due to the contamination of foodstuffs originating from China with melamine, it would have ideally been worth considering the dietary habits of regular consumers of foodstuffs originating from China or Asia. Indeed, there are specialist distribution sectors and probably consumers who regularly purchase products originating from Asia and especially China.

However, with no targeted consumption data for this type of consumer, we carried out "worst-case" simulations. These simulations make the protective assumption of an exclusive consumption of products from China for the food categories for which contamination data was gathered.

Moreover, we used food consumption data that was representative at the national level by assuming that variability between each person with the dietary habits gathered in the national studies was at least as high as within the population of regular consumers of Asian products. This assumption does not seem too high insofar as the consumption of categories of vector foodstuffs of melamine (sweets, crisps, biscuits, etc.) are not specific to a given consumer group.

II.1. Food consumption data

In order to take into account the exposure of infants as well as the exposure of children over the age of 3 and adults, we used two distinct food consumption surveys for the melamine exposure risk assessment. Given the difference between the food category lists used in these two surveys, we had to use different categories of products for infants under 3 years old and the population over the age of 3.

II.1.1. Infants aged 1 to 36 months

The survey was carried out in the field from 12 January to 10 March 2005 by TNS-SOFRES (French leader in market research and opinion polls) on behalf of the French Association of Childhood Foods,

[2] COMMISSION DECISION of 26 September 2008 imposing special conditions governing the import of products containing milk or milk products originating in or consigned from China. 2008/757/EC.

a member of Alliance 7. Consumption data was collected from the homes of 713 children (aged between 15 days and 36 months and 15 days) using a food diary for three days in a row, meal by meal, filled in by the children's carers (usually the mother, and/or the nanny, with help from the fathers).

Included in this study were infants or young children who were not breastfed (neither exclusively nor partially) and who did not attend nursery or school over the three days following the recruitment.

The actual number of children whose data could be analysed amounts to 706, as seven food diaries had to be excluded from the nutritional analysis because they did not contain enough information or posed too many problems to be considered. Moreover, melamine levels were only calculated for 705 children as information about the weight of one child was missing.

This consumption survey's list contains 32 main food categories, some of which contain sub-categories (e.g. the cereal category contained infant cereals and breakfast cereals).

Note than the average body weight of children in this survey was 9.2kg (95^{th} perc.^{3}=15 kg).

II.1.2. General population (3 years and over)

The Individual and National Survey on Food Consumption (INCA2) which was carried out between 2005 and 2007. This survey is based on the French National Institute for Statistics and Economic Studies (INSEE) census.

In total, more than 4,079 people were questioned over 4 survey periods from December 2005 to April 2007, including 1,455 children aged between 3 and 17 and 2,624 adults aged 18 years and over.

Consumption data was gathered through 7-day diaries, using a photo album to consult portion sizes distinguishing 1,342 different foods.

For the needs of this study, we created 3 age groups for the children aged 3 to 17 years: 3-10, 11-14 and 15-17 years old. Mean body weight for these age groups were 25.2kg (95^{th} perc.=40kg), 47.6kg (95^{th} perc.=70.3kg) and 60.4 (95^{th} perc.=83kg) respectively.

In adults, the mean body weight was 68.9kg (95^{th} perc.=94kg).

II.2. Contamination data and calculation scenarios

The contamination data used was obtained from the Directorate General for Competition, Consumer Affairs and Fraud Control (DGCCRF) and the Directorate General for Food (DGAL) following tests and samples carried out by the DGCCRF, Customs, National Brigade of Veterinary and Plant Health Surveys and Local Departments of Veterinary Services on Asian products, particularly originating from China, on shopkeepers and restaurant owners. On 3 November 2008, we received 56 pieces of exploitable data: 17 from the DGAL and 39 from the DGCCRF. The urgent nature of the situation meant that we could not wait for the results of other analyses that are still under way.

5 results from this data were positive: 3 samples on "White Rabbit" sweets (25, 52 and 290mg/kg) and 2 samples of cheese & onion crisps (5 and 30mg/kg). All other samples were below the limits of qunatification (LOQ), ranging from 0.17mg/kg to 2.5mg/kg.

Moreover, given the new alerts over the detection of melamine in eggs from China and the common consumption of eggs and egg products, we considered it important to estimate the potential intake of melamine from this source. This estimation is particularly protective with regard to the banned import of eggs for human consumption from China[4] and must be considered a conservative estimate of egg intake as an ingredient. Given the absence of national contamination data, we chose to use the only data available from the Center for Food Safety of Hong Kong[5] which publishes the results of analyses carried out on suspicious products daily online. According to data published on eggs, 3 results were found to be positive, with contamination values of 2.9, 3.1 and 4.7mg/kg.

Melamine was also recently detected in Taiwan in ammonium carbonate imported from China, sometimes at levels exceeding 2,000mg/kg. Ammonium carbonate is used as a raising agent in the biscuit and pastry industries, as well as in baby food and cereal-based foods for babies and young children. Unfortunately, in the absence of usage data concerning this additive and of French contamination data, it is currently difficult to assess the intake that this source of melamine would present. We have nevertheless made a rough estimate for potential intakes of melamine from ammonium carbonate for information.

The two scenarios presented in this assessment are worst-case scenarios as they are based on the assumption that all consumed foods are from China and are potentially contaminated:

1. Scenario 1: **Protective scenario following the conventional method**

All values<LOQ[6] are set at the corresponding LOQ and the contamination value attributed to the category is the mean content, including for eggs (3.6mg/kg).

This protective scenario is based on the conventional approach for taking account of upper contamination limits and on the fact that chronic exposure over a long period is calculated on the basis of mean contamination levels for each food category concerned. For example, a consumer of "White Rabbit" sweets cannot systematically consume them at the highest contamination level observed as, over a long period, s/he sometimes consumes "White Rabbit" sweets that are more contaminated than the mean, and sometimes consumes "White Rabbit" sweets that are less contaminated than the mean.

2. Scenario 2: **Worst-case scenario**

All values<LOQ are set at the corresponding LOQ and the contamination value attributed to the category is the maximum value, including for eggs (4.7 mg/kg).

According to this scenario, we assume that it is possible for a person to systematically consume the most contaminated products over a long period. This scenario is very unlikely as

[3] P95=95th percentile of the statistical distribution
[4] Commission Decision 2005/692/EC of 6 October 2005 amended
[5] http://www.cfs.gov.hk/english/whatsnew/whatsnew_fstr/whatsnew_fstr_Test_results_of_dairy_product_samples.html

it is the result of a combination of very unlikely events, namely a large number of consecutive and systematic purchases of the most contaminated foodstuffs. However, we mention it because it is one of those put forward by EFSA.

Tables 1 and 2 present the 59 contamination data (DGCCRF, DGAL and Center for Food Safety of Hong Kong), as well as the values that we consider for the calculation scenarios for each population studied.

Note that 57 data were considered in the assessment of exposure in children under 3 as we eliminated the samples on coffee drink and Chinese béchamel sauce, which did not exist in this consumption study.
For the same reasons, only of data in children over 3 and adults were considered, as the samples on milk with cereal were eliminated.

II.3. Food categories considered and assumptions drawn up

All of the data provided corresponds to Asian products imported from China, the consumption of which is not frequent enough in France to be assessed in the food surveys available. As a result, an exact correspondence between the food survey food category lists and these products is impossible, since no consumption corresponds. That said, these products can be grouped into the main food categories listed in the food surveys, except for crisps for which a more specific approach is necessary. This is because the cheese & onion crisps imported from China belong to the “Potato and potato products” category in the list of the “infants and young children" 2005 study, as this category does contain salted crisps, which are commonly consumed in France, but which represent a mere 0.4% of the consumption of this category, which comprises potato-based dishes (chips, mashed potato, boiled potatoes, etc.). The consumption of boiled potatoes is fairly high in under 3 year olds as it accounts for almost 60% of the consumption of this food category. Accordingly, we have attributed the consumption of common salted crisps to cheese & onion crisps as we cannot consider that all of the potatoes consumed by infants and young children are contaminated, even in the worst-case scenario.

The “sweet products” category in the baby survey contains all sugars and sweet products (jam, chocolate bars, sweets, ice cream, etc.). As a result, we have only kept sweets and ice cream, which correspond to the foods sampled.

This approach is preferable with a view to making as protective, but probable, an assumption as possible. We have therefore estimated melamine intake by attributing a contamination value to a wider food category than the foodstuffs actually sampled and analysed and by putting ourselves in the situation of someone who only buys products originating from China for these categories, and who consumes them in large amounts.

[6] LOQ=Limit of quantification

To estimate the contribution of eggs to melamine intake, we calculated the consumption of eggs in all forms (boiled, scrambled, omelette, fried and so on), bearing in mind that imported eggs from China are banned and that potential exposure would come from powdered egg used as an ingredient in processed foods at lower levels of use than these consumption levels.

Tables 3 and 4 present the consumption levels of the different food categories selected.

Table 1: Contamination data and values selected for estimating the exposure of infants under 3 years old (Baby survey, 2005)

Source of data	Origin of the product	Product	Food catégory (Alliance7 survey)	Melamine content	<LOQ=LOQ (mg/kg)	Occurrence value : scenario 1 (mg/kg)	Occurrence value : scenario 2 (mg/kg)
DGAL		Lemon waffle	Biscuits, cakes, croissant-type pastries	below 0.17 mg/kg	0.17	1.7	2.5
DGCCRF	China	Tomato flavored cracker	Biscuits, cakes, croissant-type pastries	below 2,5 mg/kg	2.5		
DGCCRF	China	Pizza flavored cracker	Biscuits, cakes, croissant-type pastries	below 2,5 mg/kg	2.5		
DGCCRF	China	Chive cracker	Biscuits, cakes, croissant-type pastries	below 2,5 mg/kg	2.5		
DGCCRF	China	Pepper cracker	Biscuits, cakes, croissant-type pastries	below 2,5 mg/kg	2.5		
DGCCRF	China	Pepper cracker	Biscuits, cakes, croissant-type pastries	below 2,5 mg/kg	2.5		
DGCCRF	China	Sesame biscuits	Biscuits, cakes, croissant-type pastries	below 0,2 mg/kg	0.2		
DGCCRF	China	Sesame biscuits	Biscuits, cakes, croissant-type pastries	below 0,2 mg/kg	0.2		
DGCCRF	China	Biscuits	Biscuits, cakes, croissant-type pastries	below 0,2 mg/kg	0.2		
DGCCRF	China	Almond biscuit	Biscuits, cakes, croissant-type pastries	below 2,5 mg/kg	2.5		
DGCCRF	China	Green tea biscuits	Biscuits, cakes, croissant-type pastries	below 2,5 mg/kg	2.5		
DGCCRF	China	Biscuits assortment	Biscuits, cakes, croissant-type pastries	below 2,5 mg/kg	2.5		
DGCCRF	Hong Kong	Strawberry flavored wafer	Biscuits, cakes, croissant-type pastries	below 2,5 mg/kg	2.5		
DGCCRF	China	Peanut flavored wafer	Biscuits, cakes, croissant-type pastries	below 2,5 mg/kg	2.5		
DGCCRF	China	Durian flavored wafer	Biscuits, cakes, croissant-type pastries	below 2,5 mg/kg	2.5		
DGCCRF	China	Strawberry flavored wafer	Biscuits, cakes, croissant-type pastries	below 2,5 mg/kg	2.5		
DGCCRF	China	Chocolate wafer	Biscuits, cakes, croissant-type pastries	below 2,5 mg/kg	2.5		
DGCCRF	China	White chocolate wafer	Biscuits, cakes, croissant-type pastries	below 2,5 mg/kg	2.5		
DGAL	China	Peanut biscuits	Biscuits, cakes, croissant-type pastries	below 0.17 mg/kg	0.17		
DGAL		Biscuits	Biscuits, cakes, croissant-type pastries	below 0.17 mg/kg	0.17		
DGAL		Cakes (lemon,strawberry,orange)	Biscuits, cakes, croissant-type pastries	below 0.17 mg/kg	0.17		
DGAL	China	Melon wifecake	Biscuits, cakes, croissant-type pastries	below 0.17 mg/kg	0.17		
DGCCRF	China	Nutrition milky cereal	Milk drinks	below 2,5 mg/kg	2.5	2.5	2.5
DGCCRF	China	Instant milky cereal	Milk drinks	below 2,5 mg/kg	2.5		
DGAL		Cereal porridge with milk	Cereals	below 0.17 mg/kg	0.17	0.17	0.17
DGAL	Singapour	Chocolate cereals	Cereals	below 0.17 mg/kg	0.17		
DGAL		Cereals	Cereals	below 0.17 mg/kg	0.17		
DGCCRF	Netherlands	Condensed milk, sweetened	Milk	below 2,5 mg/kg	2.5	1.7	2.5
DGCCRF	China	Dry milk	Milk	below 2,5 mg/kg	2.5		
DGAL	China	Dry milk	Milk	below 0.17 mg/kg	0.17		
DGCCRF	China	Onion and cheese crisps	Crisps	30mg/kg	30.0	10.0	30
DGCCRF	China	Onion and cheese crisps	Crisps	5mg/kg	5.0		
DGCCRF	China	Onion and cream crisps	Crisps	below 2,5 mg/kg	2.5		
DGCCRF	China	Onion and cheese crisps	Crisps	below 2,5 mg/kg	2.5		
DGCCRF	Taiwan	Milk tea beverage with tapioca	Fizzy drinks, cordials, flavoured water	below 2,5 mg/kg	2.5	1.9	2.5
DGCCRF	China	Cereal flavored tea	Fizzy drinks, cordials, flavoured water	below 2,5 mg/kg	2.5		
DGCCRF	China	Tea beverage	Fizzy drinks, cordials, flavoured water	below 2,5 mg/kg	2.5		
DGAL		Milk tea beverage	Fizzy drinks, cordials, flavoured water	below 0.17 mg/kg	0.17		
DGCCRF	China	White rabbit candies	Sweet products	25 mg/kg	25.0	23.7	290
DGCCRF	China	White rabbit candies	Sweet products	290mg/kg	290.0		
DGCCRF	China	White rabbit candies	Sweet products	52 mg/kg	52.0		
DGCCRF	China	Sunflower seed candy	Sweet products	below 0,2 mg/kg	0.2		
DGCCRF	China	Coconut candy	Sweet products	below 0,2 mg/kg	0.2		
DGCCRF	China	Coconut candy	Sweet products	below 0,2 mg/kg	0.2		
DGCCRF	China	Lollipop	Sweet products	below 2,5 mg/kg	2.5		
DGCCRF	China	Peanut candy	Sweet products	below 2,5 mg/kg	2.5		
DGCCRF	China	Sunflower seed candy	Sweet products	below 2,5 mg/kg	2.5		
DGAL		Milky candy	Sweet products	below 0.17 mg/kg	0.17		
DGAL		Coffee and cream candy	Sweet products	below 0.17 mg/kg	0.17		
DGAL		Sesame crisp flakes (candy)	Sweet products	below 0.17 mg/kg	0.17		
DGAL		Peanut crisps (candy)	Sweet products	below 0.17 mg/kg	0.17		
DGAL		Kidney bean sweet paste	Sweet products	below 0.17 mg/kg	0.17		
DGAL	China	Marshmallow candy	Sweet products	below 0.17 mg/kg	0.17		
DGCCRF	China	Ice cream bar	Sweet products	below 2,5 mg/kg	2.5		
CFS Hong Kong	China	Fresh eggs	Eggs and egg products	2.9 mg/kg	2.9	3.6	4.7
CFS Hong Kong	China	Fresh eggs	Eggs and egg products	3.1 mg/kg	3.1		
CFS Hong Kong	China	Fresh eggs	Eggs and egg products	4.7 mg/kg	4.7		
DGCCRF	Taiwan	Vanilla flavored coffee beverage		below 2,5 mg/kg	2.5		
DGAL		Chinese bechamel		below 0.17mg/kg	0.17		

Table 2: Contamination data and values selected for estimating the exposure of children and adults over 3 years old (INCA 2 Survey)

Source of data	Origin of the product	Product	Food catégory (Inca survey)	Melamine content	<LOQ=LOQ (mg/kg)	Occurrence value : scenario 1 (mg/kg)	Occurrence value : scenario 2 (mg/kg)
DGCCRF	Taiwan	Milk tea beverage with tapioca	Other soft drinks	below 2,5 mg/kg	2.5	1.9	2.5
DGCCRF	China	Cereal flavored tea	Other soft drinks	below 2,5 mg/kg	2.5		
DGCCRF	China	Tea beverage	Other soft drinks	below 2,5 mg/kg	2.5		
DGAL		Milk tea beverage	Other soft drinks	below 0.17 mg/kg	0.17		
DGAL		Cereal porridge with milk	Other cereals	below 0.17 mg/kg	0.17	0.17	0.17
DGAL		Lemon waffle	Doughnuts, pancakes and waffles	below 0.17 mg/kg	0.17	0.17	0.17
DGCCRF	China	Tomato flavored cracker	Crackers	below 2,5 mg/kg	2.5	5.8	30.0
DGCCRF	China	Pizza flavored cracker	Crackers	below 2,5 mg/kg	2.5		
DGCCRF	China	Chive cracker	Crackers	below 2,5 mg/kg	2.5		
DGCCRF	China	Pepper cracker	Crackers	below 2,5 mg/kg	2.5		
DGCCRF	China	Pepper cracker	Crackers	below 2,5 mg/kg	2.5		
DGCCRF	China	Onion and cheese crisps	Crackers	30 mg/kg	30.0		
DGCCRF	China	Onion and cheese crisps	Crackers	5 mg/kg	5.0		
DGCCRF	China	Onion and cream crisps	Crackers	below 2,5 mg/kg	2.5		
DGCCRF	China	Onion and cheese crisps	Crackers	below 2,5 mg/kg	2.5		
DGCCRF	China	Sesame biscuits	Sweet biscuits	below 0,2 mg/kg	0.2	1.7	2.5
DGCCRF	China	Sesame biscuits	Sweet biscuits	below 0,2 mg/kg	0.2		
DGCCRF	China	Biscuits	Sweet biscuits	below 0,2 mg/kg	0.2		
DGCCRF	China	Almond biscuit	Sweet biscuits	below 2,5 mg/kg	2.5		
DGCCRF	China	Green tea biscuits	Sweet biscuits	below 2,5 mg/kg	2.5		
DGCCRF	China	Biscuits assortment	Sweet biscuits	below 2,5 mg/kg	2.5		
DGCCRF	Hong Kong	Strawberry flavored wafer	Sweet biscuits	below 2,5 mg/kg	2.5		
DGCCRF	China	Peanut flavored wafer	Sweet biscuits	below 2,5 mg/kg	2.5		
DGCCRF	China	Durian flavored wafer	Sweet biscuits	below 2,5 mg/kg	2.5		
DGCCRF	China	Strawberry flavored wafer	Sweet biscuits	below 2,5 mg/kg	2.5		
DGCCRF	China	Chocolate wafer	Sweet biscuits	below 2,5 mg/kg	2.5		
DGCCRF	China	White chocolate wafer	Sweet biscuits	below 2,5 mg/kg	2.5		
DGAL	China	Peanut biscuits	Sweet biscuits	below 0.17 mg/kg	0.17		
DGAL		Biscuits	Sweet biscuits	below 0.17 mg/kg	0.17		
DGCCRF	Taiwan	Vanilla flavored coffee beverage	Coffee	below 2,5 mg/kg	2.5	2.5	2.5
DGAL	Singapour	Chocolate cereals	Cereales with chocolate	below 0.17 mg/kg	0.17	0.17	0.17
DGAL		Cereals	Sweet cereals, coated cereals or with honey	below 0.17 mg/kg	0.17	0.17	0.17
DGCCRF	China	White rabbit candies	Confectionery	25 mg/kg	25.0	25.1	290.0
DGCCRF	China	White rabbit candies	Confectionery	290 mg/kg	290.0		
DGCCRF	China	White rabbit candies	Confectionery	52 mg/kg	52.0		
DGCCRF	China	Sunflower seed candy	Confectionery	below 0,2 mg/kg	0.2		
DGCCRF	China	Coconut candy	Confectionery	below 0,2 mg/kg	0.2		
DGCCRF	China	Coconut candy	Confectionery	below 0,2 mg/kg	0.2		
DGCCRF	China	Lollipop	Confectionery	below 2,5 mg/kg	2.5		
DGCCRF	China	Peanut candy	Confectionery	below 2,5 mg/kg	2.5		
DGCCRF	China	Sunflower seed candy	Confectionery	below 2,5 mg/kg	2.5		
DGAL		Milky candy	Confectionery	below 0.17 mg/kg	0.17		
DGAL		Coffee and cream candy	Confectionery	below 0.17 mg/kg	0.17		
DGAL		Sesame crisp flakes (candy)	Confectionery	below 0.17 mg/kg	0.17		
DGAL		Peanut crisps (candy)	Confectionery	below 0.17 mg/kg	0.17		
DGAL		Kidney bean sweet paste	Confectionery	below 0.17 mg/kg	0.17		
DGAL	China	Marshmallow candy	Confectionery	below 0.17 mg/kg	0.17		
DGAL		Cakes (lemon,strawberry,orange)	Cakes	below 0.17 mg/kg	0.17	0.17	0.17
DGAL	China	Melon wifecake	Cakes	below 0.17 mg/kg	0.17		
DGCCRF	China	Ice cream bar	Ice-cream	below 2,5 mg/kg	2.5	2.5	2.5
DGCCRF	Netherlands	Condensed milk, sweetened	Condensed or powdered milk	below 2,5 mg/kg	2.5	1.7	2.5
DGCCRF	China	Dry milk	Condensed or powdered milk	below 2,5 mg/kg	2.5		
DGAL	China	Dry milk	Condensed or powdered milk	below 0.17 mg/kg	0.17		
DGAL		Chinese bechamel	Sauces	below 0.17 mg/kg	0.17	0.17	0.17
CFS Hong kong		Fresh eggs	Eggs and egg products	2.9 mg/kg	2.9	3.6	4.7
CFS Hong kong		Fresh eggs	Eggs and egg products	3.1 mg/kg	3.1		
CFS Hong kong		Fresh eggs	Eggs and egg products	4.7 mg/kg	4.7		
DGCCRF	China	Nutrition milky cereal		below 2,5 mg/kg	2.5		
DGCCRF	China	Instant milky cereal		below 2,5 mg/kg	2.5		

Table 3. Food consumption in infants and young children (1 to 36 months)

	Whole of the population			Consumers only			
	Average	Standard dev.	97.5th perc.	Rate*	Mean	Standard dev.	97.5th perc.
	g/d	g/d	g/d	%	g/d	g/d	g/d
Biscuits, cakes, croissant-type pastries	10.5	22.5	72.0	36.9	28.5	29.4	72.0
Milk drinks	22.6	75.4	250.0	12.6	179.3	130.4	250.0
Cereals	1.9	7.4	21.4	13.9	13.4	15.6	21.4
Milk	113.1	202.8	680.0	36.3	311.5	226.9	680.0
Crisps	0.1	1.1	0.0	0.9	8.6	8.8	0.0
Fizzy drinks, cordials, flavoured water	5.7	30.6	50.8	12.5	45.7	75.8	50.8
Sweet products	0.6	2.8	9.3	7.5	8.0	6.9	9.3
Eggs and Egg products	1.7	6.0	17.8	14.0	12.4	11.1	17.8
Total consumption	**156.3**	**222.0**	**733.3**	**56.6**	**276.1**	**232.5**	**733.3**

*Consumer rate

Table 4. Food consumption in children and adults over 3 years old

		Whole of the population			Consumers only			
		Average	Standard dev.	97.5th perc.	Rate*	Mean	Standard dev.	97.5th perc.
Food category	**Age group**	g/d	g/d	g/d	%	g/d	g/d	g/d
Sweet cereals, coated cereals or cereals with honey	3-10 years	5.0	13.9	42.9	30.7	16.3	19.6	60.0
	11-14 years	5.1	10.1	38.6	30.4	18.0	12.6	51.4
	15-17 years	5.9	11.1	49.3	25.9	19.7	16.0	64.3
	18 years & over	2.1	9.6	30.0	8.9	23.0	23.5	75.0
Cereals with chocolate	3-10 years	6.1	12.5	36.4	37.7	15.3	14.6	45.0
	11-14 years	8.5	16.9	53.6	32.0	24.8	23.1	74.6
	15-17 years	5.5	11.6	42.9	26.2	19.6	17.4	66.4
	18 years & over	1.0	6.2	10.7	4.2	20.8	21.7	100.0
Other cereals	3-10 years	0.2	2.0	0.0	1.2	13.6	8.0	21.4
	11-14 years	0.5	4.2	0.0	2.2	25.9	18.9	78.6
	15-17 years	0.5	3.9	0.0	1.7	30.7	17.5	64.3
	18 years & over	0.7	5.9	3.6	3.2	26.5	22.6	111.4
Sweet biscuits	3-10 years	14.9	20.5	64.0	77.5	18.7	21.0	64.3
	11-14 years	11.6	22.8	62.6	60.7	19.5	27.1	84.0
	15-17 years	11.2	16.5	79.9	53.5	20.3	19.4	87.7
	18 years & over	6.6	16.7	50.0	41.4	16.5	22.7	74.6
Crackers	3-10 years	2.1	5.2	15.7	37.7	5.5	6.7	22.9
	11-14 years	2.6	5.6	17.9	35.6	7.1	7.7	28.6
	15-17 years	2.0	3.8	14.3	29.2	6.9	5.1	30.0
	18 years & over	1.9	4.9	14.3	29.4	6.2	7.2	28.6
Cakes	3-10 years	17.5	25.0	75.0	71.1	24.7	25.4	87.9
	11-14 years	19.0	24.0	82.9	60.9	31.4	25.0	104.3
	15-17 years	17.4	22.0	85.0	56.6	30.5	23.9	91.4
	18 years & over	15.9	25.0	90.0	55.5	30.4	26.8	107.1
Doughnuts, pancakes and waffles	3-10 years	8.2	16.9	50.0	37.4	22.0	18.9	64.3
	11-14 years	11.3	20.7	79.3	37.8	30.3	25.8	110.7
	15-17 years	8.5	14.5	53.6	32.5	25.4	18.2	85.7
	18 years & over	5.3	15.1	50.0	21.4	26.4	23.5	89.3
Condensed or powdered milk	3-10 years	0.1	2.1	0.0	0.9	19.1	14.2	37.1
	11-14 years	0.0	0.3	0.0	0.7	3.7	2.1	5.7
	15-17 years	0.0	0.0	0.0	.	.	.	.
	18 years & over	0.3	3.1	0.0	1.7	17.3	16.6	72.9

		Whole of the population			Consumers only			
		Average	Standard dev.	97.5th perc.	Rate*	Mean	Standard dev.	97.5th perc.
Food category	Age group	g/d	g/d	g/d	%	g/d	g/d	g/d
Ice cream	3-10 years	8.7	18.3	55.7	35.8	22.7	21.8	72.1
	11-14 years	10.6	17.9	65.7	35.8	27.9	21.8	90.0
	15-17 years	8.2	14.7	57.9	31.1	27.8	18.1	85.7
	18 years & over	7.2	17.6	51.4	26.4	25.5	26.1	102.9
Confectionery	3-10 years	2.8	6.0	19.3	48.8	5.4	7.2	22.9
	11-14 years	2.8	4.7	20.7	39.8	6.5	5.9	22.9
	15-17 years	2.7	5.7	20.0	37.5	7.2	7.9	32.4
	18 years & over	1.2	4.6	14.0	18.9	6.8	8.9	32.6
Other soft drinks	3-10 years	35.1	107.0	257.1	47.2	73.0	143.2	376.6
	11-14 years	36.0	84.3	300.0	41.8	81.6	117.5	544.3
	15-17 years	28.6	62.6	250.0	37.3	87.0	85.7	354.3
	18 years & over	20.4	69.1	230.0	20.5	93.7	126.9	428.6
Coffee	3-10 years	4.1	37.2	22.9	3.3	130.6	147.2	462.9
	11-14 years	7.5	38.5	107.1	7.1	127.3	103.5	450.0
	15-17 years	25.6	57.7	285.7	23.6	103.9	90.0	350.0
	18 years & over	251.6	283.2	958.6	81.5	314.3	281.5	1050.0
Sauces	3-10 years	8.0	10.3	30.9	80.0	10.0	10.3	34.7
	11-14 years	10.4	9.4	35.6	78.9	12.7	9.3	36.1
	15-17 years	10.8	10.8	42.4	80.4	13.3	11.0	51.1
	18 years & over	14.3	13.3	50.1	84.6	16.7	13.0	52.6
Eggs and egg products	3-10 years	10.2	15.5	42.9	56.7	17.6	15.6	51.4
	11-14 years	10.1	12.0	47.0	52.7	19.1	11.5	54.7
	15-17 years	10.5	12.2	48.6	48.6	19.9	12.7	65.2
	18 years & over	15.2	17.3	57.8	62.4	23.7	16.6	67.6
TOTAL CONSUMPTION	3-10 years	**123.2**	**125.8**	**403.4**	**99.8**	**123.4**	**125.7**	**403.4**
	11-14 years	**136.1**	**100.0**	**420.7**	**99.6**	**136.8**	**99.8**	**420.7**
	15-17 years	**137.4**	**103.8**	**535.8**	**99.5**	**137.7**	**103.9**	**535.8**
	18 years & over	**343.7**	**297.3**	**1080.7**	**99.7**	**344.5**	**297.3**	**1082.6**

*Consumer rate

III. Results

Tables 5 to 9 present the results obtained in the 5 age groups studied (under 3 years old, 3-10, 11-14, 15-17 years old and adults over 18 years old).

II.1. Scenario 1: Values<LOQ=LOQ; Contamination value selected for the calculation=mean; Contamination value for eggs=mean (3.6mg/kg).

This scenario does not present results exceeding the TDI for melamine.

In children under 3 years old, total intake is 0.030mg/kg bw/d on average (6% of the TDI) and 0.145mg/kg bw/d at the 97.5th percentile (29% of the TDI).

In children aged 3 to 17 years old, average intake ranges from 0.005mg/kg bw/d (15-17 years old) to 0.011mg/kg bw/d (3-10 years old). In the highest consumers, intake ranges from 0.022mg/kg bw/d (11-14 years old) to 0.041mg/kg bw/d (3-10 years old).

In adults, intake is 0.012mg/kg bw/d on average and 0.040mg/kg bw/d at the 97.5th percentile.

III.2. Worst-case scenario 2: Values<LOQ=LOQ; Contamination value selected for the calculation=maximum level for the category; Contamination value for eggs=maximum (4.7 mg/kg).

In this maximalist scenario, no results exceeding the TDI were observed, despite the high assumptions drawn up.

In children under 3 years old, mean intake is 0.052mg/kg bw/d (10.4% of the TDI) and 0.325mg/kg bw/d in high consumers, or 65% of the TDI.

In children and adults over 3 years old, melamine intakes did not exceed the TDI. Total intake in high consumers amount to between 18% of the TDI in adults and 57.4% of the TDI in 3-10 year old children.

Comment on ammonium carbonate: Alliance 7's "biscuit/crispbread industry training" report recommends using 0.75% ammonium carbonate in flour.

Assuming an ammonium carbonate level of 1% in flour, a contamination of 2,000mg/kg[7], the consumption of risen foodstuffs (biscuits, cakes and pastries) would represent an intake of 0.02mg/kg of body weight for an infant under 3 years old, 0.03mg/kg of body weight for a child aged 3 to 10 years, 0.02mg/kg of body weight for a child aged 11 to 14 years and 0.01mg/kg of body weight for a child aged 15 to 17 years and adult aged 18 years or over (see Table 10). This data does not significantly alter how the exposure scenarios presented in this paper are interpreted, as the simulation made shows that even in the worst-case scenario, total intake would not exceed the TDI.

[7] Assuming the same level of contamination as detected in Taiwan.

Table 5: Melamine intakes in infants under 3 years old

		Scenario 1				Scenario 2			
	Consumer rate	Mean	Std	97.5th perc.	Percentage TDI	Mean	Std	97.5th perc.	Percentage TDI
	%	mg/kg bw/d	mg/kg bw/d	mg/kg bw/d	%	mg/kg bw/d	mg/kg bw/d	mg/kg bw/d	%
Biscuits, cakes, croissant-type pastries	36.9	0.001	0.003	0.011	0.3	0.002	0.005	0.016	0.4
Milk drinks	12.6	0.007	0.026	0.078	1.4	0.007	0.026	0.078	1.4
Cereals	13.9	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Milk	36.3	0.018	0.038	0.121	3.6	0.027	0.056	0.178	5.4
Crisps	0.9	0.000	0.001	0.000	0.0	0.000	0.003	0.000	0.0
Fizzy drinks, cordials, flavoured water	12.5	0.001	0.005	0.008	0.2	0.001	0.006	0.011	0.2
Sweet products	7.5	0.001	0.005	0.016	0.2	0.014	0.066	0.193	2.8
Eggs and egg products	14.0	0.001	0.002	0.006	0.1	0.001	0.002	0.008	0.2
TOTAL INTAKE	**56.6**	**0.030**	**0.046**	**0.145**	**6.0**	**0.052**	**0.092**	**0.325**	**10.4**

Table 6: Melamine intakes in children aged 3 to 10 years

		Scenario 1				Scenario 2			
Food category	**Consumer rate**	**Mean**	**Std**	**97.5th perc.**	**Percentage TDI**	**Mean**	**Std**	**97.5th perc.**	**Percentage TDI**
	%	mg/kg bw/d	mg/kg bw/d	mg/kg bw/d	%	mg/kg bw/d	mg/kg bw/d	mg/kg bw/d	%
Sweet cereals, coated cereals, or cereals with honey	30.7	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Cereals with chocolate	37.6	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Other cereals	1.2	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Sweet biscuits	77.5	0.001	0.002	0.005	0.2	0.002	0.002	0.007	0.4
Crackers	37.6	0.001	0.001	0.004	0.2	0.003	0.006	0.018	0.6
Cakes	71.0	0.000	0.000	0.001	0.0	0.000	0.000	0.001	0.0
Doughnuts, pancakes and waffles	37.4	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Condensed or powdered milk	0.9	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Ice cream	35.7	0.001	0.002	0.006	0.2	0.001	0.002	0.006	0.2
Confectionery	48.8	0.003	0.006	0.022	0.6	0.035	0.075	0.253	7.0
Other soft drinks	47.2	0.003	0.008	0.022	0.6	0.004	0.011	0.030	0.8
Coffee	3.3	0.000	0.003	0.003	0.0	0.000	0.003	0.003	0.0
Sauces	80.0	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Eggs and egg products	56.6	0.002	0.003	0.007	0.4	0.002	0.003	0.009	0.4
TOTAL INTAKE	**84.0**	**0.011**	**0.012**	**0.041**	**2.2**	**0.046**	**0.078**	**0.287**	**9.2**

Table 7: Melamine intakes in children aged 11 to 14 years

		Scenario 1				Scenario 2			
Food category	**Consumer rate**	**Mean**	**Std**	**97.5th perc.**	**Percentage TDI**	**Mean**	**Std**	**97.5th perc.**	**Percentage TDI**
	%	**mg/kg bw/d**	**mg/kg bw/d**	**mg/kg bw/d**	**%**	**mg/kg bw/d**	**mg/kg bw/d**	**mg/kg bw/d**	**%**
Sweet cereals, coated cereals, or cereals with honey	30.4	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Cereals with chocolate	31.7	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Other cereals	2.2	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Sweet biscuits	60.7	0.000	0.001	0.003	0.0	0.001	0.001	0.004	0.2
Crackers	35.6	0.000	0.001	0.003	0.0	0.002	0.004	0.014	0.4
Cakes	60.8	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Doughnuts, pancakes and waffles	37.6	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Condensed or powdered milk	0.7	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Ice cream	35.6	0.001	0.001	0.004	0.2	0.001	0.001	0.004	0.2
Confectionery	39.6	0.002	0.003	0.011	0.4	0.019	0.034	0.132	3.8
Other soft drinks	41.8	0.001	0.003	0.011	0.2	0.002	0.004	0.015	0.4
Coffee	7.1	0.000	0.002	0.006	0.0	0.000	0.002	0.006	0.0
Sauces	78.8	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Eggs and egg products	52.5	0.001	0.001	0.004	0.2	0.001	0.001	0.005	0.2
TOTAL INTAKE	**80.0**	**0.006**	**0.005**	**0.022**	**1.2**	**0.026**	**0.035**	**0.138**	**5.2**

Table 8: Melamine intakes in children aged 15 to 17 years

		Scenario 1				Scenario 2			
Food category	**Consumer rate**	**Mean**	**Std**	**97.5th perc.**	**Percentage TDI**	**Mean**	**Std**	**97.5th perc.**	**Percentage TDI**
	%	**mg/kg bw/d**	**mg/kg bw/d**	**mg/kg bw/d**	**%**	**mg/kg bw/d**	**mg/kg bw/d**	**mg/kg bw/d**	**%**
Sweet cereals, coated cereals, or cereals with honey	25.8	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Cereals with chocolate	26.2	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Other cereals	1.7	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Sweet biscuits	53.4	0.000	0.000	0.002	0.0	0.000	0.001	0.003	0.0
Crackers	29.2	0.000	0.000	0.001	0.0	0.001	0.002	0.008	0.2
Cakes	56.5	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Doughnuts, pancakes and waffles	32.4	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Condensed or powdered milk	.	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Ice cream	31.1	0.000	0.001	0.003	0.0	0.000	0.001	0.003	0.0
Confectionery	37.4	0.001	0.002	0.009	0.2	0.013	0.027	0.099	2.6
Other soft drinks	37.3	0.001	0.002	0.009	0.2	0.001	0.003	0.012	0.2
Coffee	23.4	0.001	0.002	0.011	0.2	0.001	0.002	0.011	0.2
Sauces	80.3	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Eggs and egg products	48.5	0.001	0.001	0.003	0.2	0.001	0.001	0.004	0.2
TOTAL INTAKE	**72.2**	**0.005**	**0.005**	**0.024**	**1.0**	**0.018**	**0.028**	**0.110**	**3.6**

Table 9: Melamine intakes in adults aged 18 years and over

		Scénario 1				Scénario 2			
Food category	**Consumer rate**	**Mean**	**Std**	**97.5th perc.**	**Percentage TDI**	**Mean**	**Std**	**97.5th perc.**	**Percentage TDI**
	%	**mg/kg bw/d**	**mg/kg bw/d**	**mg/kg bw/d**	**%**	**mg/kg bw/d**	**mg/kg bw/d**	**mg/kg bw/d**	**%**
Sweet cereals, coated cereals, or cereals with honey	8.9	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Cereals with chocolate	4.2	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Other cereals	3.2	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Sweet biscuits	41.4	0.000	0.000	0.001	0.0	0.000	0.001	0.002	0.0
Crackers	29.4	0.000	0.000	0.001	0.0	0.001	0.002	0.006	0.2
Cakes	55.5	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Doughnuts, pancakes and waffles	21.4	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Condensed or powdered milk	1.7	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Ice cream	26.4	0.000	0.001	0.002	0.0	0.000	0.001	0.002	0.0
Confectionery	18.9	0.000	0.002	0.005	0.0	0.006	0.021	0.062	1.2
Other soft drinks	20.5	0.001	0.002	0.007	0.2	0.001	0.003	0.009	0.2
Coffee	81.5	0.009	0.011	0.037	1.8	0.009	0.011	0.037	1.8
Sauces	84.5	0.000	0.000	0.000	0.0	0.000	0.000	0.000	0.0
Eggs and egg products	62.3	0.001	0.001	0.003	0.2	0.001	0.001	0.004	0.2
TOTAL INTAKE	**77.5**	**0.012**	**0.012**	**0.040**	**2.4**	**0.018**	**0.025**	**0.090**	**3.6**

Table 10: Simulation of melamine intake from risen foods containing 1% ammonium carbonate contaminated at 2,000mg/kg

Age group	Consumption* (g)	Mean weight of age group (kg)	Intake (mg/kg bw)
1-36 months	10.5	9.2	0.02
3-10 years	40.6	25.2	0.03
11-14 years	41.9	47.6	0.02
15-17 years	37.1	60.4	0.01
18 years & over	27.8	68.9	0.01

* Mean consumption of sweet biscuits, cakes, croissant-type pastries and doughnuts, pancakes and waffles

IV. Discussion

Melamine intakes in the population regularly consuming products originating from China are still encouraging, despite the protective assumptions made in this assessment. This is because we attributed the consumption levels of wide food categories consumed in France to rarely consumed products, and we corresponded often very high contamination levels to these wide categories.

The consumption models used were intended to be widely protective and to cover the scenarios of populations regularly consuming foodstuffs originating from China.
The validity of this study does depend, however, on no new source of food contamination being discovered.

IV. Conclusion

Afssa received a request to assess the retrospective risk of consuming Chinese products adulterated with melamine. Several exposure scenarios were considered, including a highly unlikely “worst-case” scenario, similar to the one put forward by EFSA. Assuming that people can consume products originating from China only, the results are encouraging since no results exceeding the TDI were observed, including in the maximalist scenario.