

**Risk Assessment Studies**

**Report No. 35**

**Chemical Hazard Evaluation**

# **ALUMINIUM IN FOOD**

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Centre for Food Safety

Food and Environmental Hygiene Department

The Government of the Hong Kong Special Administrative Region

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**ALUMINIUM IN FOOD**

## **EXECUTIVE SUMMARY**

The Centre for Food Safety (CFS) has conducted a study on aluminium in food aiming to examine the levels of aluminium in various food products in relation to the use of aluminium-containing food additives, to estimate the potential dietary exposure to aluminium of the population in Hong Kong and to assess the associated health risk, and to examine the local situation of aluminium content in soya milk powder including soya-based formula.

Aluminium-containing food additives have been used in food processing for over a century, as firming agent, raising agent, stabiliser, anticaking agent and colouring matter, etc. and some are permitted to be used in food in many countries. Aluminium is also present in food naturally (normally at low levels).

In 2006, the Joint Food and Agriculture Organization / World Health Organization Expert Committee on Food Additives (JECFA) has re-evaluated the safety of aluminium and concluded to lower the Provisional Tolerable Weekly Intake (PTWI) by seven folds to 1 mg/kg body weight (bw) for aluminium (including additives) due to the potential to affect the reproductive and developing nervous system in experimental animals at doses lower than those used in establishing the previous PTWI. The dietary exposure patterns reported in various countries may exceed this new PTWI. JECFA also noted that dietary exposure to aluminium was expected to be very high for infants fed on soya-based formula due to the high levels of aluminium in soya-based formula.

## Results

During August 2007 and October 2008, the CFS collected from the local retail markets a total of 256 food samples, including (i) steamed bread/bun/cake, (ii) bakery products, (iii) jellyfish, (iv) confectionery with coating, (v) snack including fried snack product, (vi) other food products including pickles, mung bean vermicelli and cheese products, and (vii) powder mix, salt and sugar; and 10 soya milk powder samples including soya-based formula. Laboratory analysis for aluminium was conducted by the Food Research Laboratory of the CFS. Except mung bean vermicelli samples which have been cooked prior to analysis, all other food samples were analysed as they were.

The results showed that high aluminium levels were found in steamed bread/bun/cake (mean: 100 – 320 mg/kg), some bakery products such as muffin (mean: 250 mg/kg), pancake/waffle (mean: 160 mg/kg), coconut tart (mean: 120 mg/kg) and cake (mean: 91 mg/kg), and jellyfish (ready-to-eat form) (mean: 1200 mg/kg). The results demonstrated that aluminium-containing food additives have been widely used in such products.

The average dietary exposure to aluminium of a 60-kg adult was estimated to be 0.60 mg/kg bw/week, which amounted to 60% of the new PTWI established by JECFA. However, the potential health risk of aluminium to high consumers cannot be ruled out. Moreover, some population who

consume large amount of steamed bread/bun/cake, bakery products such as muffins, pancake/waffle, and jellyfish may be of particular risk.

The main dietary source was “steamed bread/bun/cake” which contributed to 60% of the total exposure, and was followed by “bakery products” and “jellyfish” which contributed to 23% and 10% of the total exposure, respectively.

The above estimation was based on the average consumption data of food group and the corresponding average aluminium concentrations, which might lead to under-estimation, particularly exposure from foods that were found to contain high levels of aluminium. Moreover, the estimation did not include the intake of aluminium from natural food sources, food contact materials and other sources (e.g. drinking water). Furthermore, the current study might not cover all food products with aluminium-containing food additives added.

The results also revealed that aluminium contents in soya-based formula samples (mean: 5 mg/kg) fell within the lower end of the reported range, and the average dietary exposure to aluminium of a 6-kg infant fed on soya-based formula was estimated to be 0.76 mg/kg bw/week, which amounted to 76% of the PTWI. In addition, the aluminium contents in soya milk powder samples (mean: 5 mg/kg) were comparable with those in soya-based formula.

## Conclusions and recommendations

Aluminium-containing food additives are widely used in the production of steamed bread/bun/cake, some bakery products such as muffin, pancake/waffle, coconut tart and cake, and jellyfish. Although the results indicated that it is unlikely to cause adverse health effect of aluminium for the general population, the adverse health effect of aluminium for some population, who regularly consume foods added with aluminium-containing food additives such as steamed bread/bun/cake, bakery products and jellyfish, cannot be ruled out. On the other hand, the results indicated that the infants fed on soya-based formula were unlikely to experience major toxicological effects of aluminium.

The trade is advised to reduce the use of aluminium-containing food additives in preparing food or replace them with other alternatives as far as possible. Information on label including specific food additives used should be accurate. The trade is also advised to develop alternative technique to reduce the use of aluminium-containing food additives during food processing, e.g. production of salted jellyfish. The CFS will work with the trade to reduce the population exposure to aluminium.

The public is advised to maintain a balanced diet so as to avoid excessive exposure to aluminium from a small range of food items. The public is also advised to make reference to the information in the ingredient list on the label to make informed food choices.



## **Aluminium in Food**

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### **OBJECTIVE**

This study aims (i) to examine the levels of aluminium in various food products in relation to the use of aluminium-containing food additives; (ii) to estimate the potential dietary exposure to aluminium of the population in Hong Kong and to assess the associated health risk; and (iii) to examine the local situation of aluminium content in soya milk powder including soya-based formula.

### **BACKGROUND**

2. The Joint Food and Agriculture Organization / World Health Organization Expert Committee on Food Additives (JECFA) has re-evaluated the safety of aluminium in June 2006 and concluded that aluminium compounds have the potential to affect the reproductive and developing nervous system in experimental animals at doses lower than those used in establishing the previous safety reference and hence reduced the safety reference to a lower value (i.e. the Provisional Tolerable Weekly Intake (PTWI) was reduced to 1 mg/kg body weight (bw)). Following the setting of a lowered PTWI, JECFA has recommended Codex that the provisions for aluminium-containing food additives included in the Codex General Standard for Food Additives (GSFA) should be compatible with the newly established

safety reference for aluminium compounds. JECFA also confirmed that dietary exposure, particularly through foods containing aluminium-containing food additives, was found to represent the major route of aluminium exposure for the general population.<sup>1</sup> The dietary exposures reported in various countries<sup>2</sup> would be likely to exceed this new safety reference to a large extent by some population groups who regularly consume foods added with aluminium-containing food additives.<sup>1</sup> JECFA also noted that dietary exposure to aluminium was expected to be very high for infants fed on soya-based formula.<sup>1</sup>

3. There have been reports about high levels of aluminium being detected in various food products such as steamed bread/bun/cake, bakery products (e.g. muffin, cake and pancake), fried snacks, leavening product, jellyfish and mung bean vermicelli. The high levels of aluminium were probably due to the use of aluminium-containing food additives as firming agent, raising agent or stabiliser in food.<sup>3,4,5,6</sup>

4. In view of the new toxicological data of aluminium, public concern and a lack of local data on the situation of food containing aluminium-containing food additives, there is a need to conduct a study to examine the local situation.

## Aluminium

### *Nature of aluminium*

5. Aluminium is a silvery-white metal with light weight and is the most abundant metallic element of the earth's crust. It does not occur naturally in the metallic, elemental state but normally combined with other elements such as oxygen, silicon, and fluorine.<sup>1</sup>

### *Uses of aluminium*

6. Aluminium metal has a wide variety of uses including cooking utensils, food packaging such as beverage cans and foil, and structural material for construction, automobiles and aircraft, and other industrial uses such as corrosion-resistant chemical equipment and solid fuel rocket propellants, etc. Aluminium compounds such as sulphate, phosphate, hydroxide and silicate, have a wide variety of uses such as food processing (e.g. food additives), water treatment, cosmetics (e.g. antiperspirants), medicinal (e.g. antacids) and industrial uses.<sup>2,7</sup>

### *Sources of aluminium*

7. Aluminium is present in drinking water at usual levels of less than 0.2 mg/L, and is also present in most foods naturally (normally at levels of less than 5 mg/kg) or due to the use of aluminium cooking utensils and foil, in which the magnitude of this increase is generally not of practical importance.

But, some foods such as potatoes, spinach and tea may contain high levels of aluminium naturally. Aluminium is also present in food owing to the use of aluminium-containing food additives, which has been regarded as the main dietary source.<sup>1,7</sup> Moreover, it has been reported that soya-based formulae were found to contain high levels of aluminium, leading to concentrations of 0.4 – 6 mg/L in the ready-to-drink products.<sup>1</sup>

8. Aluminium-containing food additives have been used in food processing for over a century, as firming agent, raising agent, stabiliser, anticaking agent and colouring matter,<sup>1,7</sup> and some are permitted to be used in food in many countries such as the United States (US), the European Union (EU), Australia, New Zealand, Japan and Mainland China, etc. Some aluminium-containing food additives have been included in the Codex General Standard for Food Additives. According to the Colouring Matter in Food Regulations, the Public Health and Municipal Services Ordinance (PHMSO) (Cap.132), the aluminium salts (lakes) of any of the permitted water-soluble colours and aluminium in leaf or powder form solely for external colouring of dragees and decoration of sugar-coated flour confectionery are permitted colouring matters in Hong Kong. As for the other aluminium-containing food additives, there is no specific subsidiary legislation to govern their uses. However, the PHMSO stipulates that all food on sale in Hong Kong must be fit for human consumption.

9. The following are some examples of the use of aluminium-containing

additives in food. Aluminium sodium sulphate (INS\* no. 521) and sodium aluminium phosphate-acidic (INS no. 541(i)) can be used as raising agent and are common ingredients in baking powder, which in turn, is used in bakery and steamed bread/bun/cake products, and their use levels can be ranged from 21% to 26% in baking powder. Alum (明礬), the common name of aluminium potassium sulphate (INS no. 522), is used as firming agent during the processing of jellyfish and pickles. Sodium aluminium phosphate-basic (INS no. 541(ii)) is used as emulsifier in processed cheese. Sodium aluminosilicate (INS no. 554) is used as anticaking agent in powder mix such as non-dairy creamer and beverage mix. Aluminium powder and aluminium salts (lakes) are also used as colouring matters in decoration of sugar-coated flour confectionery, and candy and coatings.<sup>6,8,9,10</sup>

10. Apart from dietary source, air, the use of cosmetic and toiletry products such as antiperspirants, and medicines may also contribute to aluminium exposure. Aluminium from air and the use of cosmetic and toiletry products constituted a minor source of exposure. The aluminium-containing medications such as antacids, phosphate-binders and buffered analgesics may lead to long-term exposure. For an individual who regularly ingests aluminium-containing medications for long term, exposure to aluminium from medication could be much higher than that from the diet.<sup>1</sup>

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\* “INS” in full is “International Numbering System for Food Additives” adopted by Codex Alimentarius Commission (Codex).

## *Toxicity*

### *Kinetics and metabolism*

11. Absorption appears to be influenced by the speciation of aluminium, and it is widely assumed that soluble aluminium compounds such as the chloride and lactate salts are more bioavailable than insoluble compounds such as the hydroxide or silicates. Absorption of aluminium is usually less than 1% from gastrointestinal tract in experimental animals, and is also poor in humans although the rate and extent of absorption have not been adequately studied. Absorption can be increased in the presence of citrate (one of the main organic acids present in fruits), while it may be reduced in the presence of other compounds, such as silicates and phosphate.<sup>1,7</sup>

12. It has been reported that aluminium, once absorbed, is distributed in most organs within the body of the experimental animals, with accumulation at high dose mainly in bone. Furthermore, aluminium concentrations are increased in blood and selected tissues such as brain, bone, muscle, kidney and lung of human after ingestion or inhalation of aluminium compounds. Aluminium is excreted mainly via the route of faeces and the urine in both experimental animals and human.<sup>1,2,7</sup>

### *Acute toxicity*

13. It was reported that in experimental animals, the oral median lethal dose (LD<sub>50</sub>) values of aluminium compounds ranged from several hundred to

1000 mg /kg bw, expressed as aluminium. No acute toxic effects by the oral exposure to aluminium in the general population have been reported despite its widespread occurrence in foods, drinking water and many antacid preparations.<sup>2</sup>

#### Genotoxicity and carcinogenicity

14. Although aluminium can form complexes with deoxyribonucleic acid (DNA) and cross-link chromosomal proteins and DNA, it has not been shown to be mutagenic in bacteria and mammalian cells *in vitro*.<sup>7</sup> Moreover, no reports have indicated that aluminium is genotoxic to human following oral exposure. There is no indication that aluminium is a carcinogen to animals and the available data is insufficient to classify the carcinogenic risk to humans from exposure to aluminium and aluminium compounds.<sup>2</sup>

#### Reproductive and developmental toxicity

15. Soluble aluminium compounds have demonstrated reproductive toxicity (including histopathological changes in the testes and effect on gestation length) and developmental toxicity (including increased pup mortality, decreased growth, delayed maturation, and impaired neurodevelopment) in experimental animals. However, it has been reported that the developmental toxicity of aluminium by the oral route would be highly dependent on the form of aluminium and the presence of organic compounds that influence bioavailability.<sup>1,2,7</sup>

### Neurotoxicity

16. The neurotoxicity potential for aluminium has received particular attention due to a speculated association with Alzheimer's disease.<sup>7</sup> There have been a lot of researches into this area during the past decades. In the recent evaluation by JECFA in 2006, there was minimal information from the epidemiology literature about the association between intake of aluminium in food and neurological conditions and the current information from a pilot study evaluating Alzheimer's disease was considered to be preliminary. JECFA expressed that no crucial epidemiology studies were available for the risk assessment at the time of the evaluation.<sup>1</sup> In an opinion published by the European Food Safety Authority (EFSA) in July 2008, they did not consider exposure to aluminium through food to present a risk for developing Alzheimer's disease, based on the available scientific data.<sup>11</sup>

### Other toxicological effects

17. Osteomalacia has been reported in humans following daily intake of several grams of aluminium-containing antacids for several months and in patients with chronic renal failure after exposed to aluminium in dialysis fluids.<sup>12</sup>



### Safety reference value

18. JECFA has evaluated the safety of various aluminium compounds in various meetings since 1969, and a PTWI of 0 – 7.0 mg/kg bw for aluminium, including food additive uses, has been set in 1988. In June 2006, JECFA re-evaluated the safety of aluminium and concluded that aluminium compounds have the potential to affect the reproductive and developing nervous system in experimental animals at doses lower than those used in establishing the previous PTWI, and, therefore, lowered the PTWI by seven folds to 1 mg/kg bw, which applies to all aluminium compounds in food, including additives.<sup>1</sup>

19. PTWI is an estimate of the amount of a chemical that can be ingested over a lifetime without appreciable risk. An intake above the PTWI does not automatically mean that health is at risk. Transient excursion above the PTWI would have no health consequences provided that the average intake over long period is not exceeded as the emphasis of PTWI is a lifetime exposure.

### *Sources of human exposure*

20. The main source of exposure to aluminium for the general population is food, which contributed to more than 95% of total exposure, particularly through foods added with aluminium-containing food additives, but the intake can be increased 10 to 100 times through the use of aluminium-containing medicinal products such as antacids.<sup>1,2</sup>

21. Dietary sources of exposures to aluminium include drinking water, natural food sources, migration from food-contact material and food additives. JECFA indicated that the PTWI is likely to be exceeded to a large extent by some population groups, particularly children, who regularly consume foods added with aluminium-containing food additives.<sup>1</sup> The mean exposures of the adult population to aluminium from overall diet including additives varied a lot among different countries, ranged from 1.6 mg/day in most recent French study<sup>13</sup> to more than 34 mg/day in Mainland China<sup>14</sup> (which contributed to about 20 – 400% of PTWI, assuming a body weight of 60 kg). In fact, the dietary exposures to aluminium of some population groups were found to exceed the PTWI in some countries such as the UK (1.3 mg/kg bw/week for toddlers (1.5 – 4.5 years))<sup>15</sup>, Sweden (1.5 mg/kg bw/week for 60-kg females)<sup>2</sup>, and Mainland China (4.0 mg/kg bw/week for 60-kg adults)<sup>14</sup>.

22. In dietary exposures studies in Mainland China and the UK, cereals and cereal products were found to be the main dietary sources of aluminium, which contributed 79.5% and 49% of total dietary exposures, respectively. The relatively high aluminium intake from the cereal products might be attributed to the use of aluminium-containing food additives.<sup>14,15</sup>

23. Overseas report revealed that high levels of aluminium were found in soya-based formulae and dietary exposure to aluminium was expected to be very high, up to 1 mg/kg bw/day, for infants fed on soya-based formula.<sup>1</sup>

## **SCOPE OF STUDY**

24. This study focused on seven groups of food products, which have been reported to contain high level of aluminium due to the use of aluminium-containing food additives, namely (i) steamed bread/bun/cake (蒸包或蒸糕), (ii) bakery product (烘焙食品), (iii) jellyfish, (iv) confectionery with coating, (v) snack including fried snack product (油炸小食), (vi) other food products including pickles, mung bean vermicelli, and cheese products, and (vii) powder mix, salt and sugar. Moreover, the study also covered the soya milk powder including soya-based formula, which has been reported to contain high level of aluminium.

## **METHODOLOGY**

### Sampling plan

25. The food samples for the study were taken from the local market from August 2007 to October 2008. A total of 256 food samples (including 60 prepackaged and 196 non-prepackaged samples) were collected for testing from the seven groups of food products as mentioned in para. 24. About five samples for each food product from the seven groups were taken from various locations. Basically, for prepackaged products, only food items labelled with aluminium-containing food additives in the ingredient list were selected for the testing of aluminium. The number of samples taken in each group of food

products is shown in Table 1. Moreover, another 10 samples of soya milk powder including soya-based formula were taken for testing.

**Table 1: Number of samples taken from the seven food groups in the study**

<b>Food groups</b>	<b>Number of samples taken</b>
(i) Steamed bread/bun/cake	61
(ii) Bakery product	97
(iii) Jellyfish (ready-to-eat form)	15
(iv) Confectionery with coating	9
(v) Snack including fried snack product	30
(vi) Other food products including pickles, mung bean vermicelli, and cheese products	19
(vii) Powder mix, salt and sugar	25
<b>Total</b>	<b>256</b>

### Laboratory analysis

26. Laboratory analysis was conducted by the Food Research Laboratory (FRL) of the CFS. All food samples were analysed in individual sample basis. The mung bean vermicelli samples have been cooked prior to analysis, while the other food samples were analysed as they were. The sample was homogenised and digested sequentially with concentrated nitric acid and hydrogen peroxide at 95°C, followed by dilution with deionised water and then determination of aluminium by Inductively Coupled Plasma / Optical Emission Spectrophotometry (ICP-OES). For those results detected by ICP-OES with aluminium content below 5 mg/kg, the sample would then be determined by Graphite Furnace Atomic Absorption Spectrophotometry (GFAAS). The limit of detection (LOD) and the limit of quantification (LOQ) were 0.5 mg/kg and 2 mg/kg respectively.

## Dietary exposure

27. Average daily dietary exposure from each food group was roughly estimated by combining the average aluminium concentration of a food group and the average consumption data of the corresponding food group from the Hong Kong Adult Dietary Survey 1995<sup>16</sup>. Total average daily dietary exposure was obtained by summing up average daily exposures from all food groups, and was then multiplied by seven and divided by the body weight of an adult to obtain the average weekly dietary exposure level. Food group “powder mix, salt and sugar”, which is non-ready-to-eat food, was excluded in the exposure estimation. The body weight of an adult was assumed to be 60 kg. The estimated average weekly exposure level was then compared with the PTWI established by JECFA.

28. The possible dietary exposures from individual food items which were found to contain high levels of aluminium and may be commonly consumed by the population would also be estimated based on the assumption that a 60-kg adult consumes a piece of such food once a week.

29. The dietary exposure for infants fed on soya-based formula was estimated based on an infant aged 3 months weighing an average of 6 kg, taking 1 litre of soya-based formula as his daily consumption.<sup>1</sup> For the other soya milk powder, the possible dietary exposure of 3-year-old child would also be estimated based on the assumption that a child with a body weight of 10 kg consumes two glasses (250 ml each) of soya milk prepared from the soya milk powder daily.

## RESULTS

### Concentrations of aluminium in food

30. A total of 256 samples were tested for aluminium and the test results are summarised in Table 2 and the breakdown results are shown in Annex. Aluminium was detected in most of the samples (97%).

**Table 2: Concentrations of Aluminium in the Seven Food Groups**

Food groups	Number of samples taken	Mean aluminium level in mg/kg [range]
<b><u>(i) Steamed bread/bun/cake</u></b>	<b>61</b>	
<input type="checkbox"/> Steamed bread (without filling)	14	100 [3 – 230]
<input type="checkbox"/> Steamed bun (with filling)	36	130 [4 – 270]
<input type="checkbox"/> Steamed cake	11	320 [200 – 570]
<b><u>(ii) Bakery product</u></b>	<b>97</b>	
<input type="checkbox"/> Bread /roll	15	5 [1 – 28]
<input type="checkbox"/> Tart other than coconut tart	16	12 [1 – 87]
<input type="checkbox"/> Cookies/biscuits	15	16 [1 – 88]
<input type="checkbox"/> Chinese pastry	10	33 [1 – 180]
<input type="checkbox"/> Doughnut	5	59 [1 – 160]
<input type="checkbox"/> Cake	15	91 [1 – 220]
<input type="checkbox"/> Coconut Tart	6	120 [65 – 180]
<input type="checkbox"/> Pancake / Waffle	10	160 [1 – 710]
<input type="checkbox"/> Muffin	5	250 [6 – 510]
<b><u>(iii) Jellyfish (ready-to-eat form)</u></b>	<b>15</b>	1200 [400 – 1800]
<b><u>(iv) Confectionery with coating</u></b>	<b>9</b>	82 [1 – 210]
<b><u>(v) Snack including fried snack product</u></b>	<b>30</b>	
<input type="checkbox"/> Leavening products	15	20 [1 – 110]
<input type="checkbox"/> Deep fried dough	15	46 [2 – 330]
<b><u>(vi) Other food products</u></b>	<b>19</b>	
<input type="checkbox"/> Mung bean vermicelli (cooked)	4	1 [1]
<input type="checkbox"/> Cheese products	10	4 [ND – 20]*
<input type="checkbox"/> Pickles	5	100 [5 – 320]
<b><u>(vii) Powder mix, salt and sugar</u></b>	<b>25</b>	
<input type="checkbox"/> Sugar	5	1 [ND – 2]*
<input type="checkbox"/> Salt	5	52 [ND – 260]*
<input type="checkbox"/> Beverage mix and non-dairy creamer	5	110 [54 – 180]
<input type="checkbox"/> Powder mix for bakery/fried food	10	2600 [180 – 16000]
<b>Total</b>	<b>256</b>	

ND: not detected

\* A value of 1/2 LOD is assigned for samples with aluminium concentration below LOD when calculating the mean concentration.

### *Steamed bread/bun/cake*

31. Among all 61 steamed bread/bun/cake samples, steamed cake was found to contain the highest aluminium level (mean: 320 mg/kg), and was followed by steamed bun (with filling) (mean: 130 mg/kg) and steamed bread (without filling) (mean: 100 mg/kg). Only two samples (3%) were found to contain low levels of aluminium ( $\leq 10$  mg/kg).

### *Bakery product*

32. Among all 97 bakery samples, aluminium levels varied widely among samples of the different product types (mean: 5 mg/kg for bread/roll to 250 mg/kg for muffin), as well as samples of the same product type (range: 1 – 710 mg/kg for pancake/waffle; 6 – 510 mg/kg for muffin).

33. Muffin was found to contain the highest aluminium level (mean: 250 mg/kg), and was followed by pancake/waffle (mean: 160 mg/kg), coconut tart (mean: 120 mg/kg) and cake (mean: 91 mg/kg). Only 25% of samples from those product types were found to contain low levels of aluminium ( $\leq 10$  mg/kg). Moreover, a pancake sample (which was served with breakfast meal) was found to contain the highest aluminium level of 710 mg/kg among bakery samples.

34. On the other hand, most of the samples of the remaining product types (i.e. bread/roll, Chinese pastry, cookies/biscuits, doughnut, and tart other than coconut tart) within this group were found to contain low levels of aluminium (82% of such samples were  $\leq 10$  mg/kg).

#### *Jellyfish*

35. All 15 samples of jellyfish (ready-to-eat form) were found to contain very high levels of aluminium, ranged from 400 to 1800 mg/kg with a mean of 1200 mg/kg.

#### *Confectionery with coating*

36. The nine samples of confectionery with coating were found to contain aluminium at levels from 1 to 210 mg/kg with a mean of 82 mg/kg.

#### *Snack including fried snack product*

37. Among the 30 samples of snack products, aluminium levels varied widely (range: 1 – 330 mg/kg), including samples of the same food type, but the majority of samples (70%) were found to contain low levels of aluminium ( $\leq 10$  mg/kg).



### *Other food products*

38. Cooked mung bean vermicelli samples and cheese products were found to contain average aluminium levels at 1 and 4 mg/kg, respectively. The aluminium levels in pickles varied a lot, ranged from 5 to 320 mg/kg.

### *Powder mix, salt and sugar*

39. The five samples of beverage mix and non-dairy creamer samples were found to contain aluminium at levels from 54 to 180 mg/kg with a mean of 110 mg/kg. If the samples were used to prepare the drink according to the directions on the packages, the aluminium levels in the drinks would range from 6 to 31 mg/kg with a mean of 12 mg/kg.

40. High levels of aluminium were found in the ten powder mix samples for bakery/fried food, ranged from 180 to 16000 mg/kg. Except a baking powder sample which was found to have the highest level of aluminium (16000 mg/kg), the aluminium levels of remaining powder mix samples ranged from 180 to 1900 mg/kg. According to the recommended recipes on the packages of the samples, the use levels of pancake /cake mix, self-raising flour and baking powder could be about 40 – 70%, 20 – 30%, and less than 2%, respectively. Home-made bakery or fried food made from these samples may still contain high levels of aluminium (up to several hundreds mg/kg) when foods are prepared according to the recommended recipes on the package.

41. Among salt and sugar samples, only a salt sample was found to contain aluminium at 260 mg/kg due to the use of aluminium-containing food additive as anticaking agent. All remaining nine samples of salt and sugar were found to contain very low levels of aluminium (less than 2 mg/kg).

### Dietary Exposure

#### *Average adult*

42. The average dietary exposure to aluminium for an adult was estimated to be 0.60 mg/kg bw/week. Dietary exposures to aluminium from different food groups are shown in Table 3.

**Table 3: Average Dietary Exposure to Aluminium for an Adult**

<b>Food group</b>	<b>Dietary exposure to aluminium in mg/kg bw/week (% contribution of total exposure)</b>	
Steamed bread /bun/cake	0.36	(60%)
Bakery product	0.14	(23%)
Jellyfish	0.06	(10%)
Confectionery	0.02	(3%)
Snack including fried snack product	0.01	(1%)
Other food products	0.01	(2%)
<b>Total</b>	<b>0.60</b>	<b>(100%)*</b>

(\* Figures may not add up to total due to rounding)

#### *Possible exposures from individual foods containing high levels of aluminium*

43. Possible exposures to aluminium from steamed bread/bun/cake and some bakery products were estimated to be ranged from 0.09 to 0.63 mg/kg

bw/week, if a 60-kg adult consumed a piece of such food once a week (Table 4).

**Table 4: Possible Exposures to Aluminium from Consumption of Steamed Bread/bun/cake and some Bakery Products for an Adult**

<b>Food items</b>	<b>Average weight of a piece of food (g/unit)</b>	<b>Average exposure to aluminium* (mg/kg bw/week)</b>
Steamed cake	112	0.63
Muffins	100	0.47
Pancake/waffle	100	0.21
Steamed bun (with filling)	68	0.15
Coconut tart	70	0.14
Cake	62	0.09
Steamed bread (without filling)	69	0.09

\* Assuming that a 60-kg adult consumed a piece of the product once a week

44. Regarding the pancake sample with the highest aluminium level of 710 mg/kg, the usual serving size for the breakfast meal with the pancake would be three pieces (about 130 g) of pancake. The exposure to aluminium from this breakfast meal would be estimated to be 1.54 mg/kg bw/week, if a 60-kg adult consumed this breakfast meal once a week. Moreover, jellyfish samples (ready-to-eat form) were found to contain the highest mean aluminium level (at 1200 mg/kg) among all the ready-to-eat samples. If a 60-kg adult consumes 50 g of jellyfish weekly, exposure to aluminium would reach the PTWI.

### Soya milk powder including soya-based formula

45. The mean aluminium concentrations in both soya-based formula samples and soya milk powder samples were found to be 5 mg/kg, leading to mean concentrations of 0.6 mg/L in both ready-to-drink products. The test results are summarised in Table 5.

**Table 5: Concentrations of Aluminium in soya-based formula and soya milk powder**

	Number of samples taken	Mean aluminium level [range]	
		Powder in mg/kg	Ready-to-drink products in mg/L
Soya-based formula	4	5 [3 – 6]	0.6 [0.4 – 0.8]
Soya milk powder	6	5 [2 – 12]	0.6 [0.2 – 1.5]

46. The average weekly dietary exposure to aluminium for infants fed on soya-based formula was estimated to be 0.76 mg/kg bw/week [ranged from 0.46 – 0.92 mg/kg bw/week]. On the other hand, the possible exposure to aluminium for a 3-year-old child with a body weight of 10 kg was estimated to be 0.21 mg/kg bw/week [ranged from 0.08 to 0.53 mg/kg bw/week], if the child consumed two glasses (250 ml each) of soya milk prepared from the soya milk powder per day.

## DISCUSSION

### Use of aluminium-containing food additives

47. Results of the present study revealed that aluminium levels varied quite a lot among the products tested. The low levels of aluminium found in some products might be due to the amount naturally present in the food. Variation in aluminium levels not only existed in different products, but also among products of the same type. Their presence would be probably due to the use of aluminium-containing food additive, while the variation in levels might be due to the differences in food recipes used for the production.

48. Results of the present study revealed that aluminium-containing food additives were widely used in steamed bread/bun/cake and some bakery products such as muffin, pancake/waffle, coconut tart and cake available in the local market. On the other hand, such products could also be prepared from other raising agent, instead of aluminium-containing food additives. The findings were consistent with those reported elsewhere.<sup>3,4,6</sup>

49. High levels of aluminium residues were found in jellyfish (ready-to-eat form). This may be due to the use of alum as firming agent in processing salted jellyfish. According to the aquatic industrial standard for “Salted jellyfish and salted jellyfish head” in Mainland China, the standard for alum in these products is set at 1.2 – 2.2% (i.e. 12000 – 22000 mg/kg), which

corresponds to 684 – 1250 mg/kg as aluminium. Hence, high levels of aluminium residues would be expected in the end products.

50. Our results revealed that among snack samples including fried snack products, a small proportion of them have been added with aluminium-containing food additives. On the other hand, our results revealed that if the powder mix for bakery/fried food contained aluminium-containing food additives, high levels of aluminium would be expected in the products made from them.

#### Dietary Exposures to Aluminium

51. Average dietary exposure to aluminium for adult was estimated to be 0.60 mg/kg bw/week, which amounted to 60% of PTWI. On the other hand, possible exposures to aluminium from steamed bread/bun/cake and some bakery products were estimated to be ranged from 0.09 to 0.63 mg/kg bw/week, assuming that a piece of such product was consumed by a 60-kg adult once a week, which amounted to 9 – 63 % of PTWI.

52. Therefore, the general population was unlikely to experience major undesirable health effects of aluminium. Due to the lack of individual consumption pattern for the population, the exposures of the high consumers could not be estimated. According to the literatures, generally, high consumers may approximate three times the average consumption amount for

individual foods and up to twice the total amount consumed as a whole.<sup>17</sup> Therefore, the potential health risk of aluminium to a high consumer cannot be ruled out. Moreover, some people who consume large amount of steamed bread/bun/cake, bakery products such as muffins, pancake/waffle, and jellyfish may be of particular risk.

53. In our findings, the main dietary source of aluminium was “steamed bread/bun/cake” which contributed to 60% of the total exposure, and was followed by “bakery product” which contributed to 23% of the total exposure. Although high levels of aluminium residues were found in “jellyfish”, “jellyfish” only contributed to 10% of the total exposure and was less than that of “steamed bread/bun/cake”. It would be because the consumption amount of jellyfish was less than that of steamed bread/bun/cake. The findings are consistent with those conducted in dietary exposure studies such as those conducted in the UK and Mainland China.

54. The sensitive subgroup of the population regarding the adverse effect of developing nervous system for aluminium would be children. As the data of local consumption pattern for children is not available, the health risk of aluminium resulting from dietary exposure of children cannot be assessed.

### *International Comparison*

55. Estimates of dietary exposure to aluminium were compared with findings in other places and presented in Table 6. The dietary exposure estimated in our study fell within the range of the exposure patterns obtained from other places. However, direct comparison of the data has to be done with caution due to the differences in time when the studies were carried out, research methodology, food group categorisation, methods of collection of consumption data, methods of analysis and methods of treating results below detection limits.

**Table 6: A Comparison of Average Weekly Dietary Exposure to Aluminium**

<b>Places</b>	<b>Average weekly dietary exposure (mg/ person /week)</b>
France <sup>13</sup>	11
Australia <sup>2</sup>	16.8 (male), 13.3 (female)
Netherlands <sup>2</sup>	21.7
Switzerland <sup>2</sup>	30.8
Japan <sup>2</sup>	31.5
Hong Kong *	36
UK <sup>15</sup>	37.8
Finland <sup>2</sup>	46.9
US <sup>18</sup>	56 - 63 (male), about 49 (female)
Germany <sup>2</sup>	77 (males), 56 (female)
Sweden <sup>2</sup>	91 (female)
Mainland China <sup>14</sup>	238

\* The exposure data in Hong Kong is extracted from our current study.



### Soya milk powder including soya-based formula

56. Our results revealed that aluminium contents in soya-based formula samples fell within the lower end of the reported range of soya-based formula.<sup>1</sup> Exposure to aluminium for infants fed on soya-based formula was estimated to be 0.76 mg/kg bw/week, which amounted to 76% of PTWI, and, therefore, suggested that the infants fed on soya-based formula were unlikely to experience major toxicological effects of aluminium. Moreover, the aluminium contents in other soya milk powder samples were comparable with those in the soya-based formula. Soya milk powder could also be a source of aluminium exposure for children.

### Other Sources of Aluminium Exposure

57. Apart from food, water, air, the use of cosmetic and toiletry products and medicines may also contribute to aluminium exposure. According to data from the Water Supplies Department, the average level of aluminium in local drinking water was 0.02 mg/L in water for the period from April 2007 to March 2008.<sup>19</sup> Assuming that a 60-kg adult consumed 2 litres of water per day, exposure to aluminium was estimated to be 0.0047 mg/kg bw/week and therefore constituted a minor source of exposure. Aluminium from air, in urban area, contributed about 0.04 mg/day<sup>2</sup> and therefore constituted a minor source of exposure. Aluminium compounds are widely used in the preparation of antiperspirants, but dermal absorption of aluminium was estimated to be only about 0.004 mg from a single use of the antiperspirants on both underarms.<sup>1</sup>

58. The aluminium-containing medications such as antacids, phosphate-binders and buffered analgesics may lead to long-term exposure. If taken as directed, the daily intake of aluminium in antacids and buffered aspirin could be as much as 5 g and 0.7 g respectively.<sup>1</sup> For an individual who regularly ingests aluminium-containing medications for long term, exposure to aluminium from medication could be much higher than that from the diet.

## **LIMITATIONS OF STUDY**

59. The study showed that food contains aluminium. It is believed that the majority of aluminium came from food additives. However, it is not possible to distinguish the proportion of aluminium coming from natural source or aluminium-containing food additives.

60. The methodology for collection of consumption data may influence the accuracy of the estimates on dietary exposure. In the food consumption survey applied in the current study, the food consumption pattern of adult was collected using a food frequency questionnaire, which did not cover some food items, which might be relevant to aluminium exposure. Moreover, the individual consumption pattern of the population is not available. Hence the exposure could only be estimated based on the average consumption data and

average aluminium concentrations of the food groups. The exposures may lead to underestimation, particularly from foods that were found to contain high levels of aluminium. Furthermore, the estimation did not include the intake of aluminium from natural food sources and food contacting materials.

61. Only food products reported with high aluminium levels due to the use of aluminium-containing food additives were covered in the current study, therefore, some other food products with aluminium-containing food additives might not have been covered in the current study, which would also lead to under-estimation of dietary exposure.

## **CONCLUSIONS AND RECOMMENDATIONS**

62. Aluminium-containing food additives were widely used in the production of steamed bread/bun/cake, some bakery products such as muffin, pancake/waffle, coconut tart and cake, and jellyfish. High levels of aluminium residues were found in such products.

63. The potential dietary exposure to aluminium of the population was estimated to be 0.60 mg/kg bw/week, which amounted to 60% of the PTWI established by JECFA. The general population is unlikely to experience major toxicological effect of aluminium but the adverse health effect of aluminium for some population, who regularly consume foods added with

aluminium-containing food additives such as steamed bread/bun/cake, bakery products and jellyfish, cannot be ruled out.

64. Soya-based formula products available in the market contain aluminium at a lower level as compared with reported levels in other places. Exposure to aluminium for infants fed on soya-based formula fell below the PTWI established by JECFA, and, therefore, suggested that the infants fed on soya-based formula were unlikely to experience major toxicological effects of aluminium. Moreover, other soya milk powder products contain similar aluminium levels of the soya-based formula and thus soya milk powder could also be a source of aluminium exposure for children.

65. Food, particularly those with the use of aluminium-containing food additives, is recognised as the major source of aluminium exposure. Codex Committee on Food Additives in April 2007 started to review the GSFA in this aspect. In the subsequent meeting held in April 2008, the committee noted that the proposed levels for aluminium-containing food additives seemed high, which might result in the PTWI being exceeded, and requested further information about the use of aluminium-containing food additives, which would be used to request JECFA to conduct an exposure assessment.<sup>20</sup> In the recent meeting held in March 2009, the committee has discontinued the work on some proposed levels for aluminium-containing food additives as no technological justification / information had been provided or submitted. The committee also requested clarification on the reporting basis (e.g. as aluminium

or aluminium compounds) of all levels for aluminium-containing food additives, otherwise the levels would be revoked. Furthermore, the committee has maintained the aluminium compounds in the priority list proposed for safety evaluation by JECFA.<sup>21</sup>

66. Moreover, EFSA has released their study on the safety of aluminium from dietary intake recently, and concluded that the dietary intake of aluminium in a significant part of European population may exceed the PTWI but it was unable to conclude the contribution of the various sources such as the amount naturally present, the contributions from food additives and food contact materials. EFSA also commented that there was a need to have better data on the sources and extent of use of aluminium in food. Other food authorities such as Canada, Japan and Australia have also conducted or planned to conduct exposure assessment studies on aluminium but their results are not yet available.

67. Effort should be made to reduce exposure to aluminium for the population. The trade is advised to reduce the use of aluminium-containing food additives in preparing food or replace them with other alternatives as far as possible. The trade is also advised to develop alternative techniques to reduce the use of aluminium-containing food additives during food processing, e.g. production of salted jellyfish. Furthermore, the trade should ensure that accurate information on label including specific food additives used is made

available to the consumers. CFS will work with the trade to reduce the population exposure to aluminium.

68. The public is advised to maintain a balanced diet so as to avoid excessive exposure to aluminium from a small range of food items, particularly jellyfish, steamed cakes and muffins. Members of the public are also advised to make reference to the information in the ingredient list on label to make informed food choices.

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## Concentrations of aluminium in food samples

Food Group	Food item	No of samples		Mean conc /mg/kg (range)	
		Food item	Food sub-group	Food item	Food sub-group
<b>(i) Steamed bread/bun/cake</b>					
Steamed bread (without filling) (蒸包 [沒有餡料])		14		100 (3 – 230)	
	Twisted rolls (花卷)	5		80 (59 – 100)	
	Steamed bread (饅頭)	9		110 (3 – 230)	
Steamed bun (with filling) (蒸包[有餡料])		36		130 (4 – 270)	
	Pork and vegetable bun (菜肉包)	5		100 (4 – 220)	
	Egg custard bun (奶黃包)	5		120 (67 – 170)	
	Roasted pork bun (燒腩卷)	5		130 (58 – 200)	
	Lotus seed bun (蓮蓉包)	5		130 (40 – 270)	
	Longevity bun (壽包)	5		140 (69 – 170)	
	Barbecue pork bun (叉燒包)	5		150 (37 – 220)	
	Sesame paste bun (麻蓉包)	6		150 (91 – 190)	
Steamed cake (蒸糕)		11		320 (200 – 570)	
	Thousand layer steamed cake (千層糕)	5		260 (200 – 380)	
	"Mai Lai" cake (馬拉糕)	6		380 (240 – 570)	
<b>(ii) Bakery product</b>					
Bread/roll		15		5 (1 – 28)	
	White bread	5		3 (1 – 4)	
	Wheat bread	5		4 (3 – 6)	
	Roll	5		7 (1 – 28)	
Tart other than coconut tart		16		12 (1 – 87)	
	Egg custard tart (蛋撻)	5		4 (1 – 6)	
	Fruit tart	8		20 (1 – 87)	
	Other tart	3		3 (2 – 3)	
Cookies/biscuits		15		16 (1 – 88)	
	Wafers (威化餅)	5		7 (6 – 7)	
	Cookies and biscuits	10		21 (1 – 88)	
Chinese pastry		10		33 (1 – 180)	
	Baked barbecue pork puff (叉燒酥)	5		4 (3 – 5)	
	Chinese walnut cookie (合桃酥) or similar products	5		61 (1 – 180)	
Doughnut		5		59 (1 – 160)	
Cake		15		91 (1 – 220)	
	Soft cake	5		75 (3 – 210)	
	Butter cake	5		99 (53 – 140)	
	Swiss cake	5		100 (1 – 220)	
Coconut tart (椰撻)		6		120 (65 – 180)	
Pancake/Waffle		10		160 (1 – 710)	
	Pancake	5		150 (4 – 710)	
	Waffle	5		180 (1 – 430)	
Muffin		5		250 (6 – 510)	
<b>(iii) Jellyfish (ready-to-eat form)</b>		15		1200 (400 – 1800)	
<b>(iv) Confectionery with coating</b>		9		82 (1 – 210)	

Food Group	Food item	No of samples		Mean conc /mg/kg (range)	
		Food item	Food sub-group	Food item	Food sub-group
<b>(v) Snack including fried snack product</b>					
Leavening products			15		20 (1 – 110)
	Crispy egg floss (蛋散)	5		2 (1 – 3)	
	Prawn cracker	5		25 (10 – 65)	
	Other leavening products	5		33 (1 – 110)	
Deep fried dough			15		46 (2 – 330)
	Deep fried sweet cruller (牛蒡酥)	5		3 (2 – 5)	
	Deep fried dough cake (鹹煎餅)	5		30 (2 – 140)	
	Fried fritters (油條)	5		100 (3 – 330)	
<b>(vi) Other food products</b>					
Mung bean vermicelli (cooked)			4		1 (1)
Cheese products			10		4 (ND – 20)*
Pickles			5		100 (5 – 320)
<b>(vii) Powder mix, salt and sugar</b>					
Sugar			5		1 (ND – 2)*
Salt			5		52 (ND – 260)*
Beverage mix and non-dairy creamer			5		110 (54 – 180)
Powder mix			10		2600 (180 – 16000)
	Cake mix/Pancake mix	5		850 (180 – 1500)	
	Powder mix for bakery /fried food	5		4300 (820 – 16000)	
Total			256		

ND: not detected

\* A value of 1/2 LOD is assigned for samples with aluminium concentration below LOD when calculating the mean concentration.

