Policy Forum

The Revision of Aluminum-containing Food Additive Provisions in China

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The aim of this study was to revise the provisions for aluminum-containing food additives in GB 2760-2011 (The National Food Safety Standard for Use of Food Additives), in order to reduce aluminum exposure among the Chinese population. According to the latest risk assessment results of JECFA and China on aluminum and the actual use of aluminum-containing food additives in certain products, the aluminum-containing food additive-related provisions in GB 2760-2011 were revised. Those revisions included narrowing down the applicable food categories and adjusting the maximum use level of aluminum potassium sulfate and aluminum ammonium sulfate, repealing nine aluminum-containing food additives in puffed food and repealing the use of sodium aluminum phosphate, sodium aluminosilicate and starch aluminum octenylsuccinate in all food. After revision of the use of aluminum food additive provisions, the weekly dietary intake of aluminum in the Chinese population can be reduced to a safe level.

Aluminum is the third most abundant element and a major constituent of the earth's crust[1], which can be released into the environment both by natural processes and from anthropogenic sources. On the one hand, it is naturally present in varying amounts in most foodstuffs and may concentrate in food crops in some regions. On the other hand, a number of aluminum salts are used as food additives. In general, the foods that contain the highest concentration of aluminum are those that contain aluminum additives[1].

Various aluminum compounds were evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The committee evaluated aluminum as a contaminant at its 33rd meeting held in 1988 and established a Provisional Tolerable Weekly Intake (PTWI) of 0-7.0 mg/kg bw for aluminum. The committee concluded that there was no need to set a separate acceptable daily intake (ADI) for the aluminum-containing food additives because the PTWI included aluminum exposure arising from food additive uses. At its 67th meeting held in 2006, the committee reevaluated aluminum use in food additives and other sources and established a PTWI of 1 mg/kg bw, the new PTWI applied to all aluminum compounds in food, including food additives, and the previous PTWI was withdrawn. Finally, at its 74th meeting held in 2011, the committee established a PTWI of 2 mg/kg bw and the previous PTWI of 1 mg/kg bw was withdrawn[1].

In China, aluminum-containing food additives are listed in GB 2760 (*The Standard for Use of Food Additives*) and are commonly used in wheat flour and its product, puffed food and jelly fish, to aid dough fermentation or act as preservatives[2]. According to GB 2760-2011[2], aluminum-containing food additives included 14 food additives, which were listed as aluminum potassium sulfate, aluminum ammonium sulfate, sodium aluminum phosphate, sodium aluminosilicate, starch aluminum octenylsuccinate, and the aluminum lake of erythrosine, tartrazine, sunset yellow, allura red, brilliant blue, ponceau 4R, new red, indigotine, and amaranth. For these additives' usage level, reference is made to the PTWI of 7.0 mg/kg bw for aluminum established in 1988 by the JECFA Committee. As the new PTWI of 2 mg/kg bw was established by JECFA, it is necessary to reevaluate and revise the provisions of aluminum-containing food additives in China.

Data Resources

Risk assessment for aluminum based on the PTWI of 2 mg/kg bw was conducted by the China National Center for Food Safety Risk Assessment (CFSA) in 2011[3]. The risk assessment result showed that China's current aluminum residue limit (100 mg/kg) would lead to aluminum intake more than the PTWI among 39.7% of the population under current food consumption patterns. Food

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consumption data from the Nutrition and Health Survey of Chinese Residents in 2002 and the Nutrition and Health Monitoring of Chinese Residents in 2009 were used in this risk assessment to calculate the aluminum dietary intake. Table 1 listed the aluminum intake through different foods, which indicated that food categories 06.03.01 *Wheat flour*, 06.03.02 *Wheat flour products*, 16.06 *Puffed food* and 06.05.02 *Starch products* contributed the most to aluminum intake.

According to the assessment, the average dietary intake of aluminum was 1.795 mg/kg bw, which was lower than the PTWI of 2 mg/kg bw. But for children under 14 years old or people in north China or high consumption consumers, the exposure to aluminum was found to be higher than the PTWI. The conclusion of the risk assessment suggested that certain measures should be taken to reduce the intake of aluminum among people in China. Moreover, it is estimated that 75% of aluminum dietary sources among Chinese people were aluminum-containing food additives. Since the aluminum-containing food additives are the main contribution of aluminum intake, it is crucial to restrict the use of these additives to reduce aluminum exposure[3].

An industrial survey was conducted to collect the actual use data on aluminum-containing food additives, including usage level, the food categories in which aluminum-containing food additives were used, and technological necessity. According to the survey results, some additives, such as sodium aluminum phosphate, sodium aluminosilicate, and starch aluminum octenylsuccinate, were not unique in their function and could be replaced, while others were irreplaceable in certain food categories, such as aluminum potassium sulfate and aluminum ammonium sulfate used for jellyfish products.

Table 1. Aluminum Intake through Different Foods in the Total Population (mg/kg bw·w)*

Food Categories	Aluminum Intake	
	Average Value	P97.5
Wheat flour	0.787	4.835
Fried bread stick	0.184	2.572
Steamed bread	0.424	3.948
Noodle	0.133	0.859
Jellyfish product	0.022	0
Vermicelli	0.053	0.631
Fried dough cake	0.037	0
Bread	0.007	0.112
Fried dough twist	0.003	0
Fried cake	0.001	0
Puffed food	0.076	0.799
Other wheat flour product	0.074	0.811
In total	1.795	7.660

Note. **Source:* Risk assessment of dietary exposure to aluminum in Chinese Population, 2011.

Laboratory tests and field research were used to obtain the aluminum content and the actual processing technology of certain food. These data were used to verify the industrial survey results and provide reference to the formulation of aluminum residue restrictions.

Revision Principle

The revision of aluminum-containing food additives was based on the scientific risk assessment, while other factors, such as industry status, consumption patterns, technological necessity, and public acceptance, were also taken into account. The risk assessment data of aluminum exposure in the Chinese population and industrial survey results were used for the revision. CFSA's aluminum risk assessment suggested that the use of aluminum-containing food additives should be restricted to ensure that the Chinese population's intake of aluminumis lower than the PTWI[3]. Therefore, additives with no technological necessity should be removed, while those with substitutes should be restricted.

International standards have important referential value in the establishment of control measures. The use of aluminum-containing food additives in the Codex General Standard for Use of Food Additives (GSFA)[4], EU food additives regulations[5], Code of Federal Regulations of the USA[6], and food additive standards of Japan[7] and Australia[8] were referenced in the study.

Expert advice, public comments, and relevant ministries' opinions were also important during the revision. Academic seminars, survey forms and official letters were used to collect opinions from different groups. All of these opinions were considered and analyzed to protect the essential interests of all stakeholders.

Aluminum Potassium Sulfate and Aluminum Ammonium Sulfate

Aluminum potassium sulfate and aluminum ammonium sulfate were traditional food additives, and were commonly used in wheat flour products, puffed food, and aquatic products as a leavening agent and stabilizer. According to GB 2760-2011[2], the aluminum potassium sulfate and aluminum ammonium sulfate were permitted for use in six different food categories, including 04.04 *Bean products,* 06.03 *Wheat flour and its products,* 06.05.02.02 *Shrimp-flavored starch flakes*, 07.0 *Bakery wares*, 09.0 *Aquatic products (including fish, crustaceans, shellfish, mollusks, and echinoderms, and their processed products)* and 16.06 *Puffed food*. They should be used under GMPs and the aluminum residual level in finished food products should be no more than 100 mg/kg.

Aluminum potassium sulfate and aluminum ammonium sulfate were considered to contribute most to the aluminum intake due to their wide food application. Thus, the aluminum intake of the Chinese population would be decreased by restricting the use of these two additives.

Wheat Flour and its Products According to GB 2760-2011[2], food category 06.03 can be divided into 06.03.01 *Wheat flour* and 06.03.02 *Wheat flour products*. Each of them contained many detailed categories, such as 06.03.02.01 *Fresh pastas and noodles and similar products*, 06.03.02.02 *Dried pastas and noodles and similar products*, 06.03.02.03 *Fermented wheat flour products*, 06.03.02.04 *Batters (e.g., for breading or batters for fish or poultry)* and 06.03.02.05 *Fried flour products.*

The results of industry surveys showed that aluminum potassium sulfate and aluminum ammonium sulfate were not necessary in the production of food categories 06.03.01, 06.03.02.01, 06.03.02.02, and 06.03.02.03 under food category 06.03. The use of these two additives can be replaced by other substances, such as yeast, sodium carbonate or sodium bicarbonate. Therefore, the use of aluminum potassium sulfate and aluminum ammonium sulfate in those food categories were considered to be unnecessary. The use of aluminum potassium sulfate and aluminum ammonium sulfate in batters and fried wheat flour products was irreplaceable and the maximum use level in current standards was valid; therefore, these provisions were suggested to be maintained.

Aquatic Products GB 2760-2011 approvedthe use of aluminum potassium sulfate and aluminum ammonium sulfate in all kinds of aquatic products (including fish, crustaceans, shellfish, mollusks, and echinoderms, and their processed products)[2]. However, the survey showed that only the processing of jellyfish needed aluminum potassium sulfate and aluminum ammonium sulfate, while other aquatic products barely used them. Thus, the application range of aluminum potassium sulfate and aluminum ammonium sulfate were narrowed to 09.03.02 *Pickled fish and fish products (only used for jellyfish)*.

Several aquatic products associations and enterprises pointed out that the maximum aluminum residual level of 100 mg/kg (in dry samples, expressed as aluminum) cannot meet the demand for jellyfish products, and suggested to modify the residual level of aluminum-containing food additives in jellyfish to be 1000 mg/kg (in ready-to-eat jellyfish products, expressed as aluminum), which significantly exceeds the limit value in GB 2760-2011[2].

However, the Ministry of Agriculture (MoA) randomly inspected 531 jellyfish samples in 2013. The detection results showed that the aluminum contents in fresh jellyfish were all less than 10 mg/kg; 84.7% of salted jellyfish had an aluminum content within 500-1500 mg/kg, and the average value was 819.0 mg/kg; 94.5% of ready-to-eat jellyfish's aluminum content was less than 800 mg/kg, while 73.5% of ready-to-eat jellyfish had an aluminum content within 300-800 mg/kg, with a mean value of 473.1 mg/kg. Therefore, the MoA proposed 500 mg/kg (in ready-to-eat jellyfish products, expressed as aluminum) as the maximum aluminum residue level in jellyfish according to the results.

According to the risk assessment, if the aluminum residue limit in ready-to-eat jellyfish was raised to 1000 mg/kg, it would bring health risks to high-consumption consumers[3]. Thus, it was imperative to conduct laboratory tests in ready-to-eat jellyfish products and field research of jellyfish production enterprises to see the actual situation of jellyfish production. Graph 1 showed the aluminum content of 30 ready to eat samples from jellyfish production enterprises. For the products with stable water and salt content, the concentration of aluminum varied from 94.3 mg/kg to 1027.7 mg/kg, with a mean value of 379.0 mg/kg; most samples (86.7%) had an aluminum content lower than 500 mg/kg.

Taking into account the risk assessment results as well as the laboratory data on aluminum content in ready-to-eat jellyfish products, it was appropriate to set the maximum residual level of aluminum at 500 mg/kg (in ready-to-eat jellyfish product, expressed as aluminum). This limit could provide adequate health protection to all jellyfish consumers. Meanwhile, it would guarantee that most jellyfish products on the market would meet the regulatory requirements for aluminum. However, in order to further standardize the salted jellyfish production process, it was recommended to specify the cleaning method, monthly consumption frequency and other information to maximize the health protection of consumers.

The application range and restrictions of aluminum potassium sulfate and aluminum ammonium sulfate before and after revision are listed in Table 2. After revision, the application range was narrowed as the use in some food categories was revoked. Moreover, the aluminum residual of aluminum potassium sulfate and aluminum ammonium sulfate in jellyfish was revised to 500 mg/kg to meet the requirements of both the jellyfish industry and the protection of human health.

Aluminum Lakes

Most colorants are water soluble and must be dissolved in water to stain. For fatty food and dry food with no water, such as chocolates, cocoa products, cream products and puffed food, aluminum lakes are widely used due to their excellent dispersibility. Aluminum lakes are generated by the reaction of pigment substances with aluminum oxide in aqueous solution and they have low solubility in water or organic solvents. There are nine aluminum lakes permitted for use as food additives in GB 2760-2011, which include erythrosine aluminum lake, tartrazine aluminum lake, sunset yellow aluminum lake, allura red aluminum lake, brilliant blue aluminum lake, ponceau 4R aluminum lake, new red aluminum lake, indigotine aluminum lake, and amaranth aluminum lake[2].

According to GB 2760-2011, the maximum usage level of colors with aluminum lakes is 0.01-0.5 g/kg in different food categories[2]. Aluminum oxide in synthetic colorant aluminum lakes are used as a carrier, and its quality fraction usually ranged from 15% to 17%. The aluminum residuals in food from aluminum lakes is no more than 45 mg/kg in the worst case, which was much lower than that from other aluminum-containing food additives.

The contribution rate of aluminum dietary intake in China from all kinds of food was described in the aluminum risk assessment report. Based on the report, wheat powder (44%), steamed bread (24%), fried bread stick (10%), and noodles (7%) contributed most to the aluminum dietary intake, while these foods were not allowed to use aluminum lakes[3]. Therefore, the reducing of aluminum intake would be very limited by restricting the use of aluminum lakes.

The USA permitsthe use of FD&C Red #40 - Aluminum Lake and carmine, which is the aluminum or calcium-aluminum lake with chiefly carminic acid, under GMP. The European Union authorized the use of aluminum lakes prepared from the colors listed in COMMISSION REGULATION (EU) No 1129/2011 with no specific restriction[9]. Taking into account the

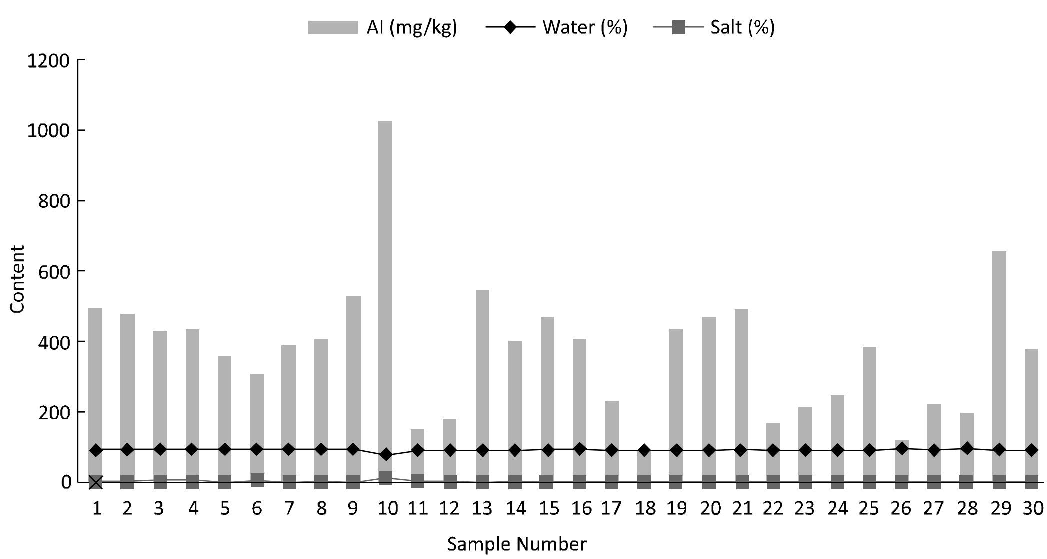

Figure 1. Aluminum Content in Ready-to-eat Jellyfish Products.

regulations of other countriesand organizations, as well as combiningthe actual usage situation of aluminum lakes, it was suggested to maintain the use of synthetic colorant aluminum lakes in GB 2760-2011.

Aluminum-containing Food Additives Used in Puffed Food

According to the aluminum dietary exposure risk assessment report, the average intake of aluminum through aluminum-containing food additives among children aged 7-14 years has exceeded the PTWI (account for 105.2%-126.7% of PTWI). Puffed food contributed the most to the intake of aluminum among children aged 7 to 14, and the contribution rates were 29% (7-10, years old), 21% (11-14-year-old boys), and 23% (11-14-year-old girls), which were significantly higher than those of other age groups[3]. To protect the health of these children, it was not recommended that aluminum-containing food additives be usedin puffed food.

Given the risk assessment results and public opinions, it was suggested that all aluminum-containing food additives (including synthetic colorant aluminum lakes) in puffed food be revoked, while the use of synthetic colorants in puffed food were maintained. Therefore, after the revision, the use of aluminum potassium sulfate and aluminum ammonium sulfate in puffed food was revoked, and the application range of seven synthetic colorants: erythrosine and its aluminum lake, indigotine and its aluminum lake, brilliant blue and its aluminum lake, tartrazine and its aluminum lake, sunset yellow and its aluminum lake, ponceau 4R and its aluminum lake, and allura and its aluminum lake, were narrowed by adding notes for use in puffed food: 'For erythrosine only', 'For indigotine only', 'For brilliant blue only', 'For tartrazine only', 'For sunset yellow only', 'For ponceau 4R only', and 'For allura only'.

Sodium Aluminum Phosphate, Sodium Aluminosilicate, and Starch Aluminum Octenylsuccinate

Sodium aluminum phosphate was permitted for use in wheat flour and its products, bakery products, fish and fish products and puffed foods as aleavening agent in GB 2760-2011, and the residual levels of aluminum in these products should be less than

Table 2. The Comparison of Application Regulations of Aluminum Potassium Sulfate and Aluminum Ammonium Sulfate Before and After Revision

Before Revision				After Revision			
Food Category No.	Food Category	Maximum Usage Level	Aluminum Residual (mg/kg)	Food Category No.	Food Category	Maximum Usage Level	Aluminum Residual (mg/kg)
04.04	Bean products	GMP	≤100[a]	04.04	Bean products	GMP	≤100[a]
06.03	Wheat flour and its products	GMP	≤100[a]	06.03.02.04	Batters (e.g., for breading or batters for fish or poultry)	GMP	≤100[a]
		GMP	≤100[a]	06.03.02.05	Fried flour products	GMP	≤100[a]
06.05.02.02	Shrimp-flavored starch flakes	GMP	≤100[a]	06.05.02.02	Shrimp-flavored starch flakes	GMP	≤100[a]
07.0	Bakery wares	GMP	≤100[a]	07.0	Bakery wares	GMP	≤100[a]
09.0	Aquatic products (including fish, crustaceans, shellfish, mollusks, and echinoderms, and their processed products)	GMP	≤100[a]	09.03.02	Pickled fish and fish products (only used for jellyfish)	GMP	≤500[b]
16.06	Puffed food	GMP	≤100[a]	—	—	—	—

Note. [a]In dry samples, expressed as aluminum. [b]In ready to eat jellyfish products, expressed as aluminum.

100 mg/kg[2]. Sodium aluminosilicate, as an anticaking agent, was used in milk flour, cheese, cocoa products, starch, sugar, table sweetener, edible salt and its substitute, and powdered drinks at GMP levels[2]. Starch aluminum octenylsuccinate, which functions as a thickener, anticaking agent and emulsifier, is used in cocoa products, batters, instant rice and noodles, powdered seasonings, and powdered drinks at GMP levels[2]. These three additives were reported to be replaceable by other food additives that have the same function, such as calcium silicate and silicon dioxide. In order torestrict the usage of aluminum-containing food additives and to reduce the aluminum intake of the total population, it was suggested that these three aluminum-containing food additives be repealed.

CONCLUSIONS

According to the brief assessment, the average weekly aluminum dietary intake of the population in northern China can be reduced from 3.028 mg/kg bw to 0.416 mg/kg bw. In the total population, the level can be reduced from 1.795 mg/kg bw to 0.258 mg/kg bw. For children aged 7-14 years old, there vocation of aluminum-containing food additives in puffed foodwasemployed to ensuretheirhealth.The average weekly aluminum dietary intake of these children can be reduced to 0.365 mg/kg bw for 7-10-year-old children, 0.311 mg/kg bw for 11-14-year-old boys and 0.295 mg/kg bw for 11-14-year-old girls. Generally, the dietary intake of aluminum would be much lower than the PTWI of 2 mg/kg bw after this revision, which indicates effective protection for human health.

Proper implementation of safety standardsis the foundation to lower the aluminum dietary intake. Therefore, widespread publicity of the revised provisions needs to be strengthened. This would be very helpful to increase public awareness. Also, strict supervision is also vital to prevent abuse and misuse of aluminum-containing food additives.

Considering the special situation of China, the industry status and the consumption pattern of the Chinese population varies when compared with other countries. Therefore, it is essential that the relevant associations and enterprises participate in the formulation of food safety standards to provide product-related information and industrial opinions. Thus, the food safety provisions generated from these data would reflect the actual situation in China and carry on effective risk management.

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