



## **Safety Assessment of Food Additives**

Food additives are substances for the technical effects (such as the maintenance or improvement of a product's quality), improve product characteristics (color, for example), and/or preserve or enhance the nutritional characteristics of a product during its manufacture, processing or preservation. Before food additives may be used in human food products, they must be assessed for safety and the absence of risks to public health must be verified.

The dietary habits of contemporary people seeking convenience have increased the opportunities of exposure of food additives to consumers compared to the past due to the development of various processed foods and increased consumption of processed foods. However, consumers who are seeking to improve the quality of life have recently developed negative perception and vague anxiety regarding various additives used in processed foods such as synthetic sweeteners, preservatives, and coloring agents.

The food additive safety assessment evaluates new risk information and intake level, and further determines the likelihood of harm to the human body in comparison with the ADI based on daily exposure estimate through intake.

The National Institute of Food and Drug Safety Evaluation (NIFDS) examines the effects of food additives on human body based on various information to eliminate the vague anxiety of consumers regarding food additives and to improve their perceptions by regularly monitoring food additives used in Korea and performing their safety assessment. The results of this safety assessment can not

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only serve as an effective communication technique to alleviate the vague anxiety of consumers regarding the food safety policy and to improve their perceptions, but can also be used as the basis for presenting scientific usage standards by providing the correct food intake level based on various food exposure pathways.

The NIFDS, according to the mid- to long-term plan, conducted a safety assessment by selecting 13 food additives (6 bleaching agents, 3 color fixatives, 1 humectant, and 3 anti-caking agents), and evaluated them according to the details described in the “Regulations on Risk Assessment Methods and Procedures” and “Risk Assessment Guideline”.

The results of internationally recognized toxicity studies and epidemiological studies were reviewed to confirm the effects on human body, and the ADIs of the 13 additives were evaluated based on the toxicological and epidemiological studies. Although most countries comply with the ADIs standards established by WHO/JECFA, the EFSA and FDA independently set and evaluate the ADI for food additives.

The NIFDS organized the Scientific Committee for Human Safety on Exposure (SCHSE) consisting of experts in medicine, toxicology, statistics and others, and assessed selected 13 food additives to determine their ADI values.

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Table 1. Acceptable daily intake (ADI) of 13 food additives

Functional class	Chemical name	ADI (mg/kg bw/day)
Bleaching agent	Sulfur dioxide	0.7 (as sulfur dioxide)
	Sodium sulfite	
	Potassium metabisulfite	
	Sodium bisulfite	
	Sodium metabisulfite	
	Sodium hydrosulfite	
Color fixative (Color fixing agent)	Sodium nitrite	0.07 (as nitrite ion)
	Sodium nitrate	
	Potassium nitrate	
Humectant	Propylene glycol	25
Anticaking agent	Sodium ferrocyanide	0.025 (Sodium ferrocyanide)
	Potassium ferrocyanide	
	Calcium ferrocyanide	

For the conduct of the exposure assessment, 6 bleaching agents, 3 color fixatives, 1 humectant, and 3 anti-caking agents were selected.

Because analytical methods for 13 food additives have been established and the ADIs for those were evaluated, the analysis data of the 13 food additives in domestically distributed products and the Korea national Health and Nutritional Examination Survey(KNHANES) data of the last three years were used to

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determine the actual food intake level according to age. After conduct of market surveys and detailed review of documents such as “Item Manufacturing reports” and and “Import Declarations” data on Sample products were compiled.

They were then purchased from department stores, large-scale discount stores, convenience stores and traditional markets located in major cities, including Seoul, Busan, Daegu, Daejeon and Gwangju, as well as from internet-based retailers. When a test result for a given analyte in a test sample was below the method detection limit, the data point was treated as a "0" and reported as not detected (ND). Relatively content ranges of 13 food additives found in products are summarized as follows.

Table 2. Concentration of sulfur dioxide in bleaching agent domestically distributed food products

Food type		Detection/ analysis (number of samples)	Detection rate (%)	Concentration (mg/kg)
Confectionaries	Biscuit	0/147	0	ND <sup>a)</sup>
	Candy	0/8	0	ND
Breads or rice cakes	Dumpling	0/48	0	ND
Cocoa products of chocolates	Chocolates	0/9	0	ND
Sugars	Other sugars	0/20	0	ND

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Bean-curd or starch	Mook(Starch-jellies) <sup>b)</sup>	0/10	0	ND
Noodles	Noodle, Naengmyeon,(Cold noodle) <sup>c)</sup> Oil-fried noodle	0/98	0	ND
Beverages	Fruit and vegetable beverages	5/115	4.3	ND~71.1
	Other beverages	0/17	0	ND
Seasonings	Vinegars	4/30	13.3	ND~57.3
	Spice products	3/30	10	ND~51.5
	Sauces	5/65	7.7	ND~97.7
Dressings	Dressing	0/17	0	ND
	Mayonnaise	0/5	0	ND
Pickles	Pickled food	13/102	12.8	ND~21.6
	Sugaring food <sup>d)</sup>	2/37	5.4	ND~15.3
Alcoholic beverages	Fruit wine	25/32	78.1	ND~102
Dried fish /shellfish fillets	Dried fish/shellfish fillet	0/14	0	ND
Other foods	Processed fruit/vegetable products	8/40	20	ND~136
	Toasted cereal flakes	0/29	0	ND
General processed foods	Processed sugar products	0/6	0	ND
	Processed potato products (include konjac powder) <sup>e)</sup>	1/11	9.1	ND~37.6
	Processed cereal products	0/7	0	ND
	Processed marine products	0/6	0	ND
Dairy products	Cheese	1/6	16.7	ND~15.3
Processed	Shrimp	3/32	9.4	ND~29.5

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marine products	Frozen crab	0/8	0	ND
Processed other products	Dried fruits	6/16	37.5	ND~380
	Dried vegetables (include dried gourd <sup>f)</sup> )	6/38	15.8	ND~164

a) Not detected.

b) A product made by processing starch, seaweeds or devil's-tongue jelly as its main material.

c) A product manufactured by using the buck wheat flour, grain flour or starch as a main material.

d) A product manufactured by the main ingredient with sugars such as honey, sugar and etc.

e) Use standard for konjac powder: less than 0.90 g/kg.

f) Dried gourd (after a gourd is scooped out, the flesh of the gourd is sliced and dried):less than 5.0g/kg.

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Table 3. Concentration of nitrite ion in color fixative domestically distributed food products.

Food type		Detection/ analysis (number of samples)	Detection rate (%)	Concentration (mg/kg)
Breads or rice cakes	Bread <sup>a)</sup>	42/67	62.7	ND <sup>b)</sup> ~ 34.5
Meat processed products	Dried meat for storage	2/61	3.3	ND ~ 1.2
	Bacon	30/40	75	ND ~ 34.9
	Ground meat	10/21	47.6	ND ~ 38.9
	Sausage	162/195	83.1	ND ~ 64.5
	Ham	125/168	74.4	ND ~ 67.6
Fish products	Fish sausage	0/16	0	ND
Dairy products	Cheese	2/91	2.2	ND ~1.10
Other foods	Ready-to-eat foods	11/23	47.8	ND ~ 6.71
Salted and fermented sea foods(Jeot)	Spiced/seasoned Jeot <sup>c)</sup>	5/50	10	ND ~ 3.29

<sup>a)</sup> bread added with sausage, ham, and bacon.

<sup>b)</sup> Not detected.

<sup>c)</sup> a liquid product manufactured by being separated from salted and fermented seafood.

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Table 4. Concentration of propylene glycol in humectant domestically distributed food products.

Food type		Detection/ analysis (number of samples)	Detection rate (%)	Concentration (mg/kg)
Confectioneries	Biscuit	166/205	81.0	ND <sup>a)</sup> ~ 4,666
	Candy	118/152	77.6	ND ~ 12,820
	Chewing gum	21/21	100	96.7 ~ 4,437
	Ice candy	12/13	92.3	ND ~ 2,278
Breads or rice cakes	Bread	81/84	96.4	ND ~ 3,626
	Rice cake	26/61	42.6	ND ~ 716
	Dumpling	9/43	20.9	ND ~ 225
Cocoa products of chocolates	Chocolates	79/85	92.9	ND ~ 5,978
Fish products	Fish cake, Fish sausage and other processed fish products	23/34	67.6	ND ~ 2,496
Noodles	Naengmyeon,, Oil-fried noodle and pasta	42/77	54.5	ND ~ 7,671
Teas	Leached tea, Liquid tea and solid tea	5/6	83.3	ND ~ 2,506
Coffee	Roasted coffee and instant coffee	7/8	87.5	ND ~ 2,143
	Liquid coffee	15/16	93.8	ND ~ 655
Beverages	Fruit and vegetable beverages	13/13	100	61.3 ~ 3,493
	Carbonated beverages	11/13	84.6	ND ~ 451
	Soymilks	5/7	71.4	ND ~ 624



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	Other beverages	21/23	91.3	ND ~ 7,795
Seasonings	Sauces, Tomato ketchup, Curry and spice products	53/68	77.9	ND ~ 1,883
Other foods	Processed peanut and nut products, Vegetable cream, Toasted cereal flakes, Ready-to-eat foods	24/45	53.3	ND ~ 1,172
Dairy products	Ice cream	38/46	82.6	ND ~ 2,890
	Processed milk, Heavy creams, Processed cheese	22/35	62.9	ND ~ 1,396
Meat processed products	Ham, sausage and ground meats	4/18	22.2	ND ~ 180

<sup>a)</sup> Not detected.

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Table 5. Concentration of sodium ferrocyanide in anti-caking agent domestically distributed food products

Food type		Detection/analysis (number of samples)	Detection rate (%)	Concentration (mg/kg)
Edible salts	Reworked salt <sup>a)</sup>	15/42	35.7	1.89
	Burnt/molten salt <sup>b)</sup>	10/175	5.7	0.29
	Refined salt <sup>c)</sup>	16/30	53.3	4.53
	Processed salt <sup>d)</sup>	30/352	8.5	0.36
	Other salt <sup>e)</sup>	0/33	0	0
	Solar salt <sup>f)</sup>	0/169	0	0

<sup>a)</sup> Salt produced by dissolving, filtering, precipitating, recrystallizing and dewatering crude salt (100%) with purified water, seawater concentrate, etc.

<sup>b)</sup> Salt obtained by transforming its original form using the methods, such as burning/melting of crude salt(100%)

<sup>c)</sup> Salt manufactured by adding brine concentrated/refined from seawater or water dissolved with crude salt(100%) to evaporation equipment.

<sup>d)</sup> Salt produced by mixing different types of edible salt together, or adding food, food additives to not less than 50% solar salt, reworked salt, burnt/molten salt, refined salt or other salts.

<sup>e)</sup> Salt are manufactured into powder or crystalline form, etc., by processing rock salt or lake salt, etc. to make it fit for human consumption.

<sup>f)</sup> Salt crystals mainly consisting of sodium chloride obtained by naturally evaporating sea water in a salt pond.

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Estimated daily intakes (EDIs) of food additives were calculated using food-consumption data for the Korean population derived from the 2010-2013 Korea National Health and Nutrition Examination Survey (KNHANES) and the quantitative results of food additives in the assayed food samples. Mean food consumption was based on matching of actual analyzed products and food consumption data for the Korean population (using 1st code from KNHANES data base).

In addition, mean body weight (kg) of all persons participated in KNHANES was used in establishing exposures on a body weight basis. For example, EDI was calculate for the total population and for high-consumption groups (by age and gender), according to the equation.

$$EDI_p \text{ (mg kg bw}^{-1} \text{ day}^{-1}) = \sum (C_i \times F_i) / W_p$$

where  $EDI_p$  is the daily intake of food additives for person  $p$ ;  $C_i$  is the mean concentration of food additives in each food class ( $\text{mg kg}^{-1}$ );  $F_i$  is the individual daily consumption of each food class ( $\text{g day}^{-1}$ ); and  $W_p$  is body weight of the general Korean population or specific consumer subgroup (kg).

The exposure scenarios were divided into total population group and high intake group, and the daily exposure estimate was calculated for each age group and gender. Because food additives are mostly consumed through processed foods, unlike contaminants, final exposure assessment was performed to determine the risk likelihood on human body based on the daily exposure estimate through food intake in comparison with ADI.

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Table 6. Exposure assessment of sulfur dioxide in bleaching agent in comparison with ADI.

Category	Average of total population		High intake group (95 percentile)	
	EDI ( $\mu\text{g}/\text{kg bw}/\text{day}$ )	Comparison with ADI* (%)	EDI ( $\mu\text{g}/\text{kg bw}/\text{day}$ )	Comparison with ADI* (%)
Total population	1.39	0.20	3.21	0.46
Male	1.55	0.22	3.20	0.46
Female	1.23	0.18	3.22	0.46
Age group				
2 years or younger	2.06	0.29	7.26	1.04
3 years to 6 years or younger	1.86	0.27	5.36	0.77
7 years to 12 years or younger	0.98	0.14	3.71	0.53
13 years to 19 years or younger	1.04	0.15	3.16	0.45
20 years to 64 years or younger	1.56	0.22	2.98	0.43
65 years or older	0.69	0.10	1.96	0.28

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Table 7. Exposure assessment of nitrite ion in color fixative in comparison with ADI.

Category	Average of total population		High intake group (95 percentile)	
	EDI ( $\mu\text{g}/\text{kg bw}/\text{day}$ )	Comparison with ADI* (%)	EDI ( $\mu\text{g}/\text{kg bw}/\text{day}$ )	Comparison with ADI* (%)
Total population	1.39	1.98	8.19	11.70
Male	1.54	2.20	9.24	13.20
Female	1.23	1.76	7.10	10.15
Age group				
2 years or younger	4.42	6.32	20.03	28.61
3 years to 6 years or younger	4.44	6.35	24.80	35.42
7 years to 12 years or younger	2.94	4.19	16.76	23.95
13 years to 19 years or younger	2.28	3.26	11.48	16.40
20 years to 64 years or younger	1.11	1.58	6.67	9.53
65 years or older	0.15	0.22	0.03	0.05

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Table 8. Exposure assessment of propylene glycol in humectant in comparison with ADI.

Category	Average of total population		High intake group (95 percentile)	
	EDI ( $\mu\text{g}/\text{kg bw}/\text{day}$ )	Comparison with ADI* (%)	EDI ( $\mu\text{g}/\text{kg bw}/\text{day}$ )	Comparison with ADI* (%)
Total population	0.52(0.517)	2.07	2.39	9.55
Male	0.52(0.523)	2.09	2.31	9.25
Female	0.51	2.04	2.47	9.90
Age group				
2 years or younger	1.54	6.16	5.69	22.77
3 years to 6 years or younger	1.48	5.93	7.11	28.43
7 years to 12 years or younger	1.13	4.53	4.61	18.45
13 years to 19 years or younger	0.72	2.87	2.93	11.73
20 years to 64 years or younger	0.41	1.63	1.95	7.78
65 years or older	0.18	0.72	0.79	3.15

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Table 9. Exposure assessment of sodium ferrocyanide in anti-caking agent in comparison with ADI.

Category	Average of total population		High intake group (95 percentile)	
	EDI (µg/kg bw/day)	Comparison with ADI* (%)	EDI (µg/kg bw/day)	Comparison with ADI* (%)
Total population	0.010	0.041	0.035	0.141
Male	0.011	0.045	0.037	0.147
Female	0.009	0.037	0.034	0.135
Age group				
2 years or younger	0.013	0.050	0.042	0.168
3 years to 6 years or younger	0.013	0.050	0.038	0.151
7 years to 12 years or younger	0.011	0.046	0.038	0.151
13 years to 19 years or younger	0.009	0.036	0.033	0.131
20 years to 64 years or younger	0.011	0.044	0.037	0.147
65 years or older	0.006	0.025	0.025	0.101

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The evaluation of risk level in comparison with ADI based on the daily exposure estimate of 13 food additives revealed that the risk level for 6 types of bleaching agents such as anhydrous sulfite was 0.2% compared with ADI, the risk level for the 3 types of color fixatives such as sodium nitrite was 2.0%, the risk level for propylene glycol used as humectant was 2.1%, and the risk level for three anti-caking agents such as sodium ferrocyanide was 0.04%. These results suggested no concern for human body through intake.

Nine types of food additives such as sulfurous acid anhydride were analyzed by the certified analysis method described in the Food Code Test Method. However, propylene glycol was analyzed by a revised test method with improved pretreatment conditions and instructional analysis conditions for use in various food types. Moreover, three food additives such as sodium ferrocyanide were analyzed by a revised test method in which the pretreatment conditions and instructional analysis conditions were improved from the ferrocyanide ion test method described in the Food Code Test Method to improve the detection sensitivity without significant effect of salt.

To calculate the accurate contents of food additives in foods, we will develop new methods or improve conventional methods for analyzing food additives in food.

Furthermore, this risk assessment report has been subjected SCHSE of the NIFDS, as well as consultation by experts, and the report will be reevaluated if new information is confirmed in future. This report can be accessed via the website of the NIFDS.