# Daily Intake Study of Food Additives by Age Cohort based on the Market Basket Method

## Overview

The study was conducted as part of the Ministry of Health and Welfare's efforts in ensuring the safety of food additives.

The study group prepared a list of 246 types of food products, and calculated the average daily intake of each food type for five age categories: 1-6 year olds (younger children), 7-14 (older children), 15-19 (youths), 20-64 (adults), and over-64 (older adults). Based on the list, 9 collaborators (eight local governmental health laboratories and one university) purchased food products at 9 locations nationwide and classified them into 7 food categories (I. seasonings and beverages; II. cereals; III. potatoes, legumes and nuts; IV. fish/shellfish and meat; V. fats/oils and milk/milk products; VI. sugar and confections/savories; VII. fruits, vegetables and seaweeds). Five collaborators (non-governmental laboratories) analyzed 100 types of compounds (covering 241 food additives) in the homogenized samples for the 7 food categories by age category, and determined the concentration of each compound, then estimated the intake of each compound for each age category.

The intake of many target compounds tended to slightly increase with age. Among others, sodium saccharin was particularly noteworthy: the intake was about 10 times higher for adults and older adults than that for younger children. This result was in sharp contrast with the intake of xylitol: the intake of older adults was a tenth that of children (younger and older). Thus, this study has found that there is a difference in the daily intake of some additives between age categories. These results indicate the significance of a study by age cohort. The study group considers that continuous study by age cohort is necessary to obtain more realistic information on food additive intake.

In general, there were no findings that raise safety concerns about of food additives. In comparison between the estimated intakes and the corresponding acceptable daily intakes (ADIs), the estimated intakes of all substances but nitrate were below the corresponding ADIs. For nitrate, most of its intake is derived from natural nitrate contained in vegetables, and therefore a very small part is considered to be derived from additives. Considering several factors, such as the benefits of vegetables as food, our historical eating habits, and the international recognition as given in JECFA's assessment, the study group determined that nitrate intake does not pose any problems with safety at the present stage.

**Objective**

The study group conducted this study to identify the intake of food additives of the Japanese by age category. It is very important to estimate more accurate intakes to ensure food safety and protect public's health. Japan has extensively conducted intake studies since the 1980s, using several methods,[1-3] including the market basket method. However, the previous intakes have been estimated as averages for the Japanese public and the studies have hardly considered age categories.

The Ministry of Health and Welfare evaluates the safety of food additives for the purpose of safety assurance of additives. Safety evaluations are basically, based on toxicity data, mainly from animal experiments. The daily intake of food additives and the acceptable daily intake (ADI) are at the core of theses safety evaluations. It is necessary to confirm whether the daily intake of each in everyday life is less than its ADI, which is established for each substance. Japan usually adopts ADIs established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA)[4] or it establishes the ADIs on its own. Thus, it is necessary to estimate the accurate intake of food additives as one pillar of safety evaluations.

After 1965, Japanese dietary habits changed a lot and also diversified. This is due greatly to increased imported foods and diversified processed foods. These factors, changes in dietary habits and diversified foods, can greatly affect food additive intake. Hence, it is necessary to identify the current additive intake for safety evaluation.

In this study, the study group first decided the types of food products, and estimated the consumptions of these products by age category to obtain basic data for the market-basket based study. Then, based on the obtained consumption data, they estimated food additive intakes by age category for 100 compounds covering 241 food additives, which were regarded to be identifiable.

## Method

Prior to the implementation of the study, the study group prepared two types of guidelines and distributed them to the collaborating organizations of this study. These guidelines are those for purchasing products, etc. and those for preparing samples and conducting analysis.

### 1. Target Food Additives

Table 1 shows the names of 100 compounds targeted at analysis and the names of 241 individual food additives covered by these compounds. The 241 additives consisted of 199 designated food additives and 42 existing food additives. Some compounds were analyzed twice per chemical. Calcium citrate, for example, was measured both on citric acid and calcium. The number of additives has slightly changed since some additives have been withdrawn from the designated additives after the study finished.

### 2. Food Consumption Survey by Age Cohort

The study group used the data from the National Nutrition Survey to estimate the food consumption for the five age categories. The National Nutrition Survey is annually conducted in November, targeting some 15,000 individuals age of 1 or older taken from approximately 6,000 randomly-selected households nationwide[5]. In 1995, the diet study method was revised, and consequently, the study requires the individual-based food consumptions[6]. The study group used data up to 1997 (n=41, 548) from 1995, which were available from the computerized database.

The National Nutrition Survey is based on a unique food numbering system, in which respective food numbers are assigned to a total of 1,194 types of food products[6]. Out of these, the four types of foods—"processed food," "ready-to-eat prepared food," "restaurant food," and "school lunch"—are categorized as "mixed dish," and are treated as a combination of other "single-item food products" (970 types of food products appearing in the Standard Table of Food Compositions, including "eggplant" and "soy sauce"). In other words, they are broken down into "single food items," and the number and the weight (g) of each food consumed by an individual per day are stored in the database in the form of a "single-item food consumption card." [7]

Using a "single-item food consumption card," the study group estimated food consumption on a particular weekday in November. The information obtained includes the proportion of people who consumed each of the 970 types of products, the average consumption by all target people including non-eaters, as well as the average consumption excluding non-eaters. The study group prepared a list of 246 types of food products representing the 970 types of products to purchase them in a more practical manner. In preparing the list, nutritionists chose a certain product out of multiple similar products, considering actual conditions of consumption (frequency and level of consumption), ways of processing, and use standards of food additives. These 246 were then divided into 7 categories (I. seasonings and beverages; II. cereals; III. potatoes, legumes, and nuts; IV. fish/shellfish and meat; V, oils/fats and milk/milk products; VI. sugar and confections/savories; VII. fruits, vegetables and seaweeds)[8]. The study group calculated the average daily consumption for the 246 types of products for 5 age categories; 1-6 year olds (younger children: n= 2,620), 7-14 (older children: n= 4,175), 15-19 (youths: n= 2,715), 20-64 (adults; n= 25,281), and over-64 (older adults; n= 6,757) (Table 2). The average body weight was 15.9 kg for 1-6 year olds, 37.1 kg for 7-14, 56.3 kg for 15-19, 58.7 kg for 20-64, and 53.2 kg for over-64.

## 3. Purchase of Sample Products, Sample Preparation, Analysis and Report of Study Results

The purchase of foods, sample preparation and analysis were based on the guidelines given in section "Method," above.

### 1) Purchase of Sample Products

The 9 organizations (eight local governmental health laboratories and one university), given in Table 3, purchased products within the areas in which the corresponding organizations are located, according to Table 2 (Food Consumption Table). These products were purchased between January 18, 2000 and January 21, 2000. Thereafter, they were given minimal treatments, such as the removal of soil and fish guts. The products were numbered serially, marked with colored tapes for category identification, packed according to category, and sent in a frozen state to the Tama Research Institute of the Japan Food Research Laboratory.

**2) Sample Preparation**

The sample preparation was based on the guidelines given above. The Tama Research Institute checked the products received from the nine organizations for food categories, crushed them separately, and then took the required quantities of samples from the individual products for each age category, according to the Food Consumption Table. The collected samples falling under the same category were put all together and homogenized with an adequate amount of water added (5 age groups x 7 categories = 35 samples). Each homogenized sample was divided into five parts. They are separately packed in antioxidant-free polyethylene bottles, and frozen. The samples, excluding the parts for the Japan Food Research Laboratory, were sent to four of the five laboratories, which were responsible for analysis, by frozen-parcel delivery service. The samples taken for adults were twice as large as those for the other age categories, since they were also to be used for food additives recovery tests.

**3) Analytical Method**

Unless there was any particular problem, analysis was based on the Analytical Methods for Food Additives in Food (2000) published by the MHW[9)] and the Guidance for Food Safety Testing－Analytical Methods for Food Additives in Food[10)]. Methods were modified as necessary. Table 4 gives the organizations which were responsible for testing and the analytical methods used. These organizations are all designated by the Minister of Health, Labour and Welfare (designated laboratories) as testing laboratories. The test data were stored in a computer disk according to the guidelines for purchasing food products, etc. and sent to the Japan Food Additives Association, by which the data were refined and compiled. The items reported by the laboratories include the contents of compounds, the daily intakes of additives, the limits of determination, the limits of detection, the amounts of compounds added in food additives recovery tests, and recovery rates by age and food categories.

## Results and Discussion

### 1. Study Results and Estimated Intake

Table 5 shows the estimated daily intakes of food additives by age category. Table 6 shows the ratios of the estimated intakes of individual compounds (only those for which the ADIs have been set) to the corresponding ADIs (percent of ADI). Table 7 compares the estimated intakes of adults (20-64 year olds) obtained in this study with those obtained in other studies (as average intake of the Japanese population).

The intakes estimated in this study were based on the contents of target compounds in food. Hence, for some substances which naturally occur in the natural environment such as nitrate and phosphoric acid, the amount determined includes not only that used as an additive, but also that naturally included in foods (amount derived from the natural environment) such as vegetables, fruits and meat. Therefore, the estimated intake are also the sum of the both.

### 1) Intake by Age Group

The results show that there were few differences in intake between age categories for many compounds. However, the intake tended to slightly increase with age, as shown in Table 5. This study group considered that this trend was attributable to an increase in food consumption with age.

Notable differences in intake between age categories were observed for some compounds. The intake of sodium saccharin roughly increased with age and was nearly 10 times higher for adults and older adults than that for younger children. The sources of this substance were categories IV (fish/shellfish and meat) and VII (fruits, vegetables and seaweeds). Young people tended to consume the substance more from category IV than from category VII, and adults and older adults from category VII. The study group considered that the notable difference between age categories was probably attributable to the fact that adults and older adults consume a larger quantity of pickled vegetables. Contrary to saccharin sodium, the daily intake of xylitol was significantly high for younger children and older children, and it gradually decreased with age. The intake of older adults was approximately 1/10 that of children (younger and older). The major source of xylitol was category VI (sugar, savories/confections) for children and category I (seasonings and beverages) for older adults. Xylitol is a sweetener with refreshing sweetness and is used in chewing gums and candies, which probably resulted in the notable difference in the intake level of xylitol between age categories.

The daily intake of lactic acid was the highest among the targeted compounds for all age categories, at 1.5 g for younger children, 2.0 g for older children, 2.2 g for youths, and 2.6 g for adults and older adults each. The intakes of the following compounds were also higher than other compounds: citric acid (2.1 g in adults), phosphoric acid (2.1 g in adults), and malic acid (1.7 g in adults). The intakes of these compounds tended to be lower in the younger age categories.

Table 5 shows the estimated intakes based on the determined levels. If the concentration of an additive was below the limit of determination, it was regarded to be zero in calculation. No corrections using the corresponding recovery rates were applied to the determined levels, which means that the estimated daily intakes may be a slight underestimate. Table 8 shows the estimated maximum intakes calculated based on Table 5. In calculation, the corresponding limits of detection were added for compounds which were not detected, or the corresponding limits of determination were added for compounds which were detected but not measurable. Compounds whose values were different from the corresponding values in Table 5 mean that their contents were below the corresponding limits of detection. There was no substantial difference between the estimated maximum intake in Table 8 and the estimated intake in Table 5. It should be noted that in this study, fresh foods were not prepared/cooked and losses through preparation processes such as cooking were not taken into account. For fresh foods which are usually washed or cooked, concentrations of additives or natural ingredients in foods are considered to be reduced through preparation processes. Hence, actual intakes can be lower than those obtained in this study.

### 2) Ratio of Intake to ADI

Nitrate was the only compound whose estimated intake exceeded the ADI. The intakes of all other substances were below the corresponding ADIs, as shown in Table 6.

The intake of nitrate exceeded the ADI for each age category, and the intake for younger children was estimated at about twice the ADI. The intake for younger children was less than half that for adults, but the body weight of the younger children was roughly a quarter that of the adults. This helps raise the ratio of nitrate intake to ADI for young children. According to surveys based on production[2] and official food inspections[3], the use amount of nitrate as food additives was 1mg or less, and the nitrate intake derived from the food additives used is reportedly less than 1% of the ADI. On the other hand, according to the intake surveys using the market basket method under the Health

Science Research Program[1], the intake of nitrate is 232mg, or 125% of the ADI, out of which more than 80% was derived from fresh foods. In this study by age cohort, all age groups ingested more than 96% of nitrate from category VII (fruits, vegetables, and seaweed). In short, this study confirmed that nitrate is mostly derived from natural nitrate contained in vegetables and a limited amount is derived from food additives. The intake of nitrate has also been assessed by the JECFA. The JECFA mentions in the WHO Technical Report Series No. 859 [11] "…. vegetables are an important potential source of intake of nitrate. However, in view of the well-known benefits of vegetables and the lack of data on the possible effects of vegetable matrices on the bioavailability of nitrate, the Committee considered it inappropriate to compare exposure to nitrate from vegetables directly with the ADI and hence to derive limits for nitrate in vegetables directly from it." Hence, considering the benefits of vegetables as food and historical Japanese eating habits, nitrate intake does not pose any problems with safety at this stage. Also, this study did not take account of preparation processes of foods such as washing and cooking. When vegetables are handled normally, the content of nitrate could be reduced through such processes and the actual intake would be less than the intake estimated in this study. Continued study is necessary for more accurate intake estimation.

The intakes of all other compounds did not exceed the corresponding ADIs for any age category. The ratios of intakes of individual compounds to the corresponding ADIs were generally high for young people, and tended to decrease with age. This is because the intake does not increase greatly with age while the body weight is lower for young people. For sodium saccharin and adipic acid, an inverse tendency in the ratio to the ADI was observed. Sodium saccharin intake accounted for 0.1% of the ADI for the younger groups (younger children, older children and youths) and 0.3% of the ADI for the adults groups (adults and older adult); adipic acid intake accounted for 0.3% of the ADI for younger children and, thereafter gradually increased with age up to 0.7% for older adults.

The compounds for which the ratio to the corresponding ADI exceeded 10% were D-α-tocopherol (17.5%), nitrite (11.5%), riboflavin (15.1%), tartaric acid (29.6%), phosphoric acid (38.4%), aluminum (32.5%), and iron (45.1%) for younger children; and phosphoric acid (16.1%), aluminum (13.1%), and iron (20.1%) for adults.

Among the compounds targeted by this study, those having recommended dietary allowances established by the MHW[12] are β-carotene (as vitamin A), D-tocopherols (as vitamin E), L-ascorbic acids (as vitamin C), thiamin (as vitamin $B_1$), riboflavin (as vitamin $B_2$) calcium, phosphoric acid (as phosphorus), iron and magnesium. For the compounds for which the ratio of intake to ADI exceeded 10%, as stated above, comparison was made between the intake and the corresponding recommended dietary allowance. The intake of D-tocopherols (α, β, γ, and δ) calculated in terms of D-α-tocopherol was roughly the same as the recommended dietary allowance of vitamin E in all age categories. On the other hand, the intake of riboflavin was about twice the recommended dietary allowance for the younger groups (1-6 year olds, 7-14 year-olds). (Note: The tolerable upper intake limit is not established for riboflavin.) Each intake of iron and phosphoric acid (as phosphorus) tended to be slightly lower than the corresponding dietary allowance. Neither exceeded the tolerable upper intake limit.

Table 9 indicates the ratios of the estimated maximum intakes, based on Table 8, to the corresponding ADIs. Few compounds were affected with respect to the ratio of intake to ADI, except that the ratio was a little over 20% for nitrite and 3-7% for sulfite.

### 3) Comparison with Estimated Intake by Other Methods

Previous intake studies for additives in Japan have been based on three methods: the market basket method[1]; the method based on production[2]; and the method based on official inspections which is used for a limited number of additives[3]. These study results have been reported as average intake levels for the Japanese population, while this study has determined intake levels by age category. Table 7 compares the estimated intakes in adults (20-64 year olds) obtained from this study with the estimated intakes (averages for the Japanese population) from the three study methods mentioned above.

The results from this study were very close to those from the market-basket study conducted from 1995 to 1996 [1]. The study group determined that this was because the same market basket method was used, despite differences in the time of study and age category used. When compared with the results from the three methods for use categories, Table 7 shows that results from this study were almost the same for seasonings and dietary supplements, slightly higher for acidifiers, and slightly lower for preservatives. When compared with the production method[2], results from this study were slightly higher for additives naturally occurring in food (additives in category B), but lower for additives not naturally occurring in food (additives in category A). When compared with the official-inspection method[3], the results from this study were generally lower. The study group assumed that this trend was based on the following reasons: the official-inspection method targeted mainly food products in which additives are permitted, and sample products were separately analyzed by product and it was easier to determine levels.

In this study, the following additives were targeted for the first time: nordihydroguaiaretic acid, naringin, hesperidine, kojic acid, asparagine, glutamine, cystine, and hydroxyproline. No ADIs have been established for these food additives. The intake of glutamine was the highest among these substances, and nordihydroguaiaretic acid, naringin, and kojic acid were not detected.

## 2. Basic Data for Food Additive Analysis

As basic data, Tables 10-1 through 10-5 show the additive intakes for individual food categories by age category. Table 5 shows compiled data based on Table 10. Tables 11-1 through 11-5 indicate the concentrations of food additives in the consumed food products for individual food categories by age category. The intake levels given in Table 10 were obtained by multiplying the concentrations given in Tables 11-1 through 11-5 by the consumptions of the corresponding food products by food category. Table 12 gives the limits of detection confirmed using food products for adults (20-60 year olds), Table 13 the limits of determination, Tables 14-1 through 14-5 the contents of food additives in food products calculated using the corresponding limits of detection or the corresponding limits of determination, and Table 15 recovery ratios. The recovery ratios were slightly lower for some food categories. This is probably based on the following reasons: Microanalysis was required, unlike food additive analysis which is generally conducted according to food product, and recovery tests were conducted on samples of a considerably low concentration. No corrections were made to the determined levels of additives in the samples.

## 3. Comparison of Determined Values by Collaborative Study

In this program, a confirmation study was conducted by the Tokyo Metropolitan Research Laboratory of Public Health (hereafter referred to as the Tokyo laboratory), on additives which were regarded to be consumed in considerably large quantities. The target additives were saccharine, sorbic acid, propylene glycol and 17 amino acids. The data were compared with those reported from the corresponding laboratories. Table 16 shows the values reported by the Tokyo laboratory and the corresponding laboratories. Determination was basically conducted on samples for adults (20-60 year olds) of certain food categories. Food categories IV and VII were used for saccharine, categories IV and VI for sorbic acid, categories I and II for propylene glycol. For category II intended for propylene glycol, samples for older adults (over-64 year olds) were used. For amino acids, category IV (viscous food group) and category III (non-viscous food group) were used.

In general, there was no significant difference in value between the Tokyo laboratory and the corresponding laboratories, with some exceptions. The differences observed for some samples were considered to be attributable to viscosity of the samples.

1. For saccharin in categories IV and VII and sorbic acid in categories IV and VI, similar results were obtained from the Tokyo laboratory and the corresponding laboratory.

2. For propylene glycol in category I for adults, similar results were obtained from two laboratories. For category II for older adults, however, the level obtained from the Tokyo laboratory was 17μg/g, whereas that obtained from the other laboratory was 46μg/g. This is considered to be attributable to the lack of uniformity in samples due to viscosity. Even though the samples may have appeared to be uniform, the study group assumed that they were nonuniform.

3. For amino acids in category IV (viscous samples) and category III (non-viscous samples), the Tokyo laboratory and the corresponding laboratory exchanged samples and determined the quantities. No significant differences were observed in their results for glutamic acid and glycine, which are considered to be most frequently used among food additives.

Judging from the above findings, the results from the Tokyo laboratory and the corresponding laboratories were almost the same. However, there was the difference in value which was assumed to be attributable to viscosity. More caution is required in sample preparation to ensure uniformity for viscous samples.

## 4. Conclusion

The study group estimated the intakes of 100 compounds, covering 241 additives, based on the market basket method. This study was characterized by the intake estimation of food additives by age cohort (5 categories), based on food consumption by age cohort.

There were no findings that raise safety concerns about the intake of food additives. However, the study has confirmed that there are the clear differences in the consumption of food between age categories. The study group considers that the differences in food consumption can give rise to differences in the intake of food additives. It is not appropriate to make conclusions based on the study alone, since no other intake studies have been conducted by age cohort. However, it is still significant to have first confirmed that additive intake differs by age category, in considering food safety in the future. Given that the differences in dietary patterns between age categories may be growing the need to consider the difference in the intake of food additives between age categories is likely to heighten. Therefore, it is necessary to continuously conduct intake studies by age cohort in order to collect information on the presence or absence of additive residues and annual changes in additive intake. Future studies should focus on the intake of nitrate and additives whose intakes are extremely high in certain age groups. The study group hopes that continued studies can help to more accurately identify the current situation regarding Japanese additive intakes, and thereby contribute to safety assurance for food additives by providing adequate grounds for establishing additive standards.

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