

# Japanese Food Allergen Labeling Regulation: An Update

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**The Japanese food allergen labeling regulation was designed to match real Japanese food allergy circumstances and also to be enforced effectively; thus, (1) regulated food allergens were selected by prevalence and seriousness according to food allergy surveys in Japan; (2) the detection criterion for ELISA monitoring, 10 µg food allergen protein/g (or mL) food, was set up as the threshold value to regulate commercial prepackaged foods; and (3) official food allergen analytical methods, which can determine the threshold value accurately, were developed. These three points are distinctive from other countries. Furthermore, as an on-going project, the regulation has been amended according to food allergy circumstances and requirements of society. This paper presents recent changes regarding the Japanese food allergen labeling regulation. To date, the Japanese food allergen labeling regulation has been enforced for more than 15 years and seems to be working effectively. Now would be an opportune time to review the regulation for its next level of development.**

In modern society, the number of individuals suffering from food allergy is increasing remarkably. Furthermore, a rise in the number of tragic fatal incidents places food allergy as one of the most significant social health issues. Due to a lack of options to cure food allergy, the practical measure to prevent food allergy risk is the avoidance of the offending food allergen by the food-allergic individual. To allow those individuals to make informed choices, food allergen labeling regulations have been enforced in many countries. These help affected individuals recognize the offending allergenic ingredient on product labels. Among the countries regulating food allergens, Japan was one of first countries to enforce its regulation (2002). The Japanese regulation has several distinctive features, which makes it different from other regulations. The perspective of the Japanese food allergen labeling regulation was already described by Akiyama et al. (1). This paper provides an update and also supplements the rationale behind the uniqueness of the Japanese regulation.

## The Origins of the Japanese Food Allergen Labeling Regulation

Table 1 shows a brief history of the Japanese food allergen labeling regulation. In the late 1990s, two driving forces moved the Japanese government to investigate the need for a food allergen labeling regulation. One driving force was the international general Codex Alimentarius standard in 1999, which recommended the labeling of eight food ingredients known as the “Big 8” (2). The second driving force was recognizing the risk of food allergy after a child allergic to buckwheat suffered a fatal reaction in 1995. In this case, the school meal, which was provided by School Lunch Program Act under the Ministry of Education, Culture, Sports, Science and Technology (MEXT) caused the fatal outcome. The school and the local Board of Education under MEXT were sentenced for violating the safe care of a school child. A subsequent MEXT survey of elementary and middle schools revealed a significant prevalence of food allergies among school children. As a consequence, the government required consideration of practical measures to prevent the recurrence of serious food allergy incidents in schools. Both international and domestic requirements strongly drove the Japanese government to establish a practical and effective regulation for food allergy.

## Food Allergens to be Controlled by the Regulation

Prior to the establishment of the food allergen labeling regulation, it was necessary to define the priority food allergens. The Japanese government had considered the reference list of food allergens included in the Codex general standard (2). However, the Codex food allergen list was based on European food allergen surveys (3). Moreover, buckwheat—which was responsible for the above-mentioned fatality and is an important food ingredient in the traditional diet of Japan, China, and Korea—is not included in the Codex standard. Thus, the Codex list could not be directly applied in Japan because it was neither suitable to local needs nor practical.

In the meantime, in 1997–1998, the Ministry of Health, Labor and Welfare (MHLW) conducted a retrospective food allergy survey focusing on immediate-type food allergies. Analysing this survey result with respect to the classification criteria of prevalence and potential to elicit anaphylaxis, five food ingredients—egg, milk, wheat, peanut, and buckwheat—were designated as priority food allergens requiring mandatory labeling. Moreover, an additional 19 ingredients were included in the recommended labeling list for food allergen. In Japan, food allergen labeling came into force in

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**Table 1. History relating to the Japanese food allergen labeling regulation**

Year	Event
1997–1998	National survey of immediate-type food allergies (retrospective)
1999	Agreement to amended Codex general standard for the labeling of prepackaged foods
2001	Announcement of the food allergen labeling regulation in the Food Sanitation Act
2001–2002	Nationwide survey of immediate-type food allergies (prospective)
2002	Enforcement of the food allergen labeling regulation
2004	Banana added as a recommended labeling ingredient based on the 2001–2002 nationwide survey
2005	Announcement of improved official food allergen ELISAs using SDS–2ME
2004–2005	Nationwide survey of immediate-type food allergies (prospective)
2006	Institution of governmental guideline for food allergen analysis method
2008	Shrimp and crab were upgraded from recommended to mandatory labeling ingredients based on the 2004–2005 survey
	Announcement of official analysis method for shrimp and crab
2007–2008	Nationwide survey of immediate-type food allergies (prospective)
2011–2012	Nationwide survey of immediate-type food allergies (prospective)
2013	Cashew nuts and sesame added as recommended labeling ingredients based on the 2011–2012 survey
2014	Amendment of official food allergen ELISAs using SDS–sulfite
2015	Enforcement of new Food Labeling Act

2002 (initial food ingredients for labeling; Table 2; 4). From the Codex list, only egg, milk, wheat (from cereals containing gluten), and peanut were incorporated into the mandatory labeling in local regulations. In addition, the Japanese list also included several specific ingredients which are typical in Japanese gastronomy, such as buckwheat (as a mandatory labeling allergen) and salmon roe and matsutake (as recommended labeling allergens), the latter being rarely eaten in Western countries. Food allergies in Japan are considered depending on food culture. Egg, milk, wheat, and peanut are part of staple diets globally; therefore, allergies to these foods are found in many countries, whereas buckwheat is eaten in Japan, Korea, and China, and, therefore, buckwheat allergy is only observed in this region. Salmon roe and matsutake are eaten in limited amounts in Japan, thus these allergies are found only in Japan. Kiwi fruit was first introduced in Japan in the 1960s (5); kiwi allergy had not existed before then. The results from the 2001–2002 nationwide food allergy survey showed that kiwi was ranked as the ninth most prevalent food allergen and, surprisingly,

it showed the highest incidence among all fruit allergies (1). A more recent survey conducted between 2011 and 2012 confirmed that kiwi fruit was the eighth most prevalent food allergen, next to shrimp, and still the top allergen in the fruit group (6). As kiwi penetrated Japanese food culture, its high popularity explains the higher prevalence of this fruit. Similarly, the recent increase in buckwheat consumption as a healthy food and wheat replacement has induced buckwheat allergy in the United Kingdom where buckwheat allergy was not known before (7). These two cases clearly illustrate how changes in dietary culture are directly linked to the dynamics of food allergy prevalence. Hence, the Japanese government conducts nationwide food allergy surveys every 3 years to monitor food allergy in a real-time fashion. The survey is designed as a fixed-point observation in order to collect prospective clinical data, which involves the collaboration of over 1000 medical doctors from all over Japan. By means of this nationwide survey, changes in allergy prevalence can be monitored efficiently, and the results are used as the basis to

**Table 2. Food ingredients for allergen labeling**

Labeling category	No. of ingredients	Food ingredient
Initial food ingredients for labeling		
Mandatory	5	Egg, milk, wheat, peanut, and buckwheat
Recommended	19	Abalone, squid, salmon roe, orange, shrimp, crab, kiwi fruit, beef, walnut, salmon, mackerel, soybean, chicken, pork, matsutake, peach, yam, apple, and gelatin
↓		
Amended food ingredients for labeling in 2017		
Mandatory	7	Egg, milk, wheat, buckwheat, peanut, shrimp, and crab <sup>a</sup>
Recommended	20	Abalone, squid, salmon roe, orange, cashew nuts, kiwi fruit, beef, walnut, sesame, salmon, mackerel, soybean, chicken, banana, pork, matsutake, peach, yam, apple, and gelatin <sup>b,c</sup>

<sup>a</sup> Shrimp and crab were upgraded from recommended to mandatory labeling ingredients in 2008 based on the 2004–2005 survey.

<sup>b</sup> Cashew nuts and sesame were designated as recommended labeling ingredients in 2013 based on the 2011–2012 survey.

<sup>c</sup> Banana was designated as a recommended labeling ingredient in 2004 based on the 2001–2002 survey.

update the food allergen labeling regulation. The surveys have resulted in the inclusion of banana on the recommended labeling ingredient list in 2004 (based on the 2001–2002 survey). Moreover, shrimp and crab were upgraded from recommended to mandatory labeling in 2008, according to the survey results of 2004–2005. After the recent 2011–2012 survey, cashew nut and sesame were included in the regulation (in 2013) as recommend ingredients. The most current version of the Japanese food allergen labeling regulation (August 2017) includes 7 mandatory and 20 recommended allergenic ingredients (Table 2). Collectively, these food allergens account for 94.9% of immediate-type food allergies in Japan (8). This periodical nationwide food allergy survey is very unique and unprecedented worldwide.

### Improvements in Analytical Methods

Since 2002, the Japanese food allergen labeling regulation mandates the declaration of mandatory food allergens when the product contains more than 10 µg soluble allergen protein/g food. Because the Japanese government recognizes protein as directly triggering food allergy, the threshold is protein-based. Both the practical regulatory rule and the government authorized official analysis methods for food allergen which support the regulation were simultaneously established in 2002 in order to enforce the regulation effectively (1, 9).

Figure 1 shows the outline of the regulatory procedure to control product compliance. If undeclared egg is suspected in a product following a consumer claim, or in the case of a regulatory investigation for an egg declaration, the first step entails examination of the product label to determine whether egg is declared or not. If egg is declared, the product complies with egg labeling rules (in the case of a consumer complaint, the consumer

might have overlooked the egg declaration in the ingredient list). If egg is not declared on the label, the next stage in the process is to carry out product verification. This process consists of three steps: (1) analytical evaluation of egg in the product by quantitative ELISA; if the egg content is more than 10 µg protein/g food, the investigator proceeds to (2) the on-site examination of manufacturing records. In this step, the enforcement and inspection authority investigates the manufacturing records at the premises of the food producer to clarify the presence of egg in the product. If it is determined from the manufacturing records that egg is incorporated as an ingredient of the raw material, the inspection authority gives the manufacturer corrective guidance. If the presence of egg cannot be explained by examining the manufacturing records, the product is subjected to (3) a scientific confirmation test in order to exclude a potential false-positive result in the first ELISA analysis. The confirmation step is conducted by PCR for wheat, peanut, buckwheat, and shrimp/crab. Western blot analysis is used for egg and milk because PCR cannot be applied to these ingredients because the test cannot distinguish egg and milk from chicken and beef meats, respectively, which are also used as food ingredients. If it is concluded that the product violates the regulation, i.e., the product contains more than 10 µg food allergen protein/g food, the regulatory administrator executes an official regulatory action according to the inspection report, which may involve corrective guidance, a product recall, business license suspension, fine, or, in some cases, even imprisonment. Because of the potential severity of the sanction, the official needs to investigate product compliance carefully before carrying out regulatory action.

With the purpose of supporting regulatory investigations, official ELISA, PCR, and Western blot analysis methods have

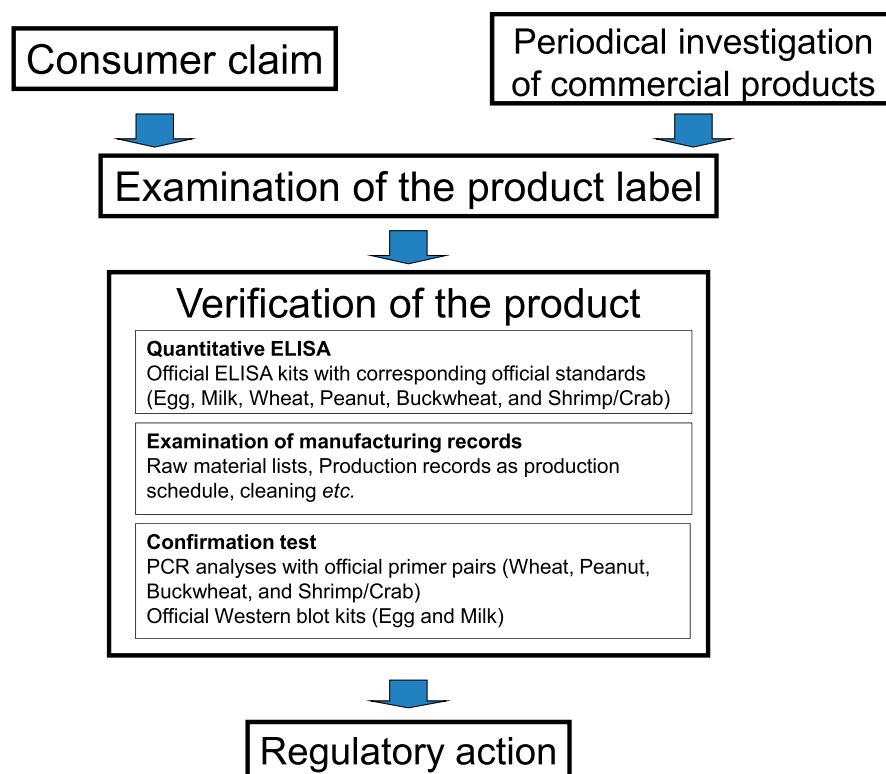


Figure 1. Outline of food allergen inspection procedure.

**Table 3. Determination of egg in commercial processed foods by conventional and SDS–2ME ELISAs**

Commercial food labeled to contain egg	ELISA with conventional solution, ppm	ELISA with SDS–2ME solution, ppm
Hamburg steak	ND <sup>a</sup>	21
Rice gruel with egg	ND	2,496
Egg sandwich	27.6	2,255
Biscuit	2,000	15,000
Bread	ND	5.6
Cookies	290	13,000
Fried noodle	ND	170

<sup>a</sup> ND = Not detected.

become some of the most important tools to monitor compliance and provide evidence of undeclared allergens in food products.

In 2002, when the Japanese food allergen labeling regulation was enforced, two ELISA kits were granted official analysis status (10). However, the use of these analytical methods revealed two problems. The first observed issue was poor allergen recovery (a lower allergen concentration than expected) in processed foods. Table 3 presents the results of an egg ELISA using a conventional sample extraction solution like water or buffered saline. The assay unexpectedly detected little or no egg in processed foods which included egg in the ingredient list. This result immediately generated questions about the reliability of the ELISA methods and, therefore, confidence in analytical results. The second problem was related to discordance between the two official ELISA results, which was, in principle, linked to the different standard materials used in each kit. The immediate consequence was difficulty in interpreting official ELISA results.

The administrative regulatory agency, National Institutes of Health Sciences Japan (NIHS), was in need of improved official ELISA methods and finally established a new, improved ELISA. The new version of the assay incorporated a unique sample extraction solution using the surfactant, sodium dodecyl sulfate (SDS), and the reducing reagent, 2-mercaptoethanol (2ME), which enhance the solubilization of target food allergen proteins from a food matrix (11). The new extraction procedure allowed the detection of egg in highly processed foods (Table 3).

NIHS also dedicated resources to improve assay comparability. This initiative allowed the development of egg, milk, wheat, peanut, and buckwheat allergen standards. Until then, no reference materials had been available for these allergenic ingredients (12). The improved ELISAs and official standards were evaluated using a food allergen-incurred processed food model (13). This evaluation criteria satisfied

AOAC INTERNATIONAL food allergen ELISA guidance requirements (14). The new ELISAs, which could efficiently detect food allergens in processed foods, were granted official analysis status in 2005 (15). Following this analytical approach, new ELISAs were developed for shrimp/crab, along with the corresponding official shrimp/crab standard (16). A confirmatory PCR analysis was also developed (17, 18). Upon evaluation, a set of shrimp/crab ELISA and PCR analyses were announced as official analysis methods in 2008 (19).

Although 2ME is a very effective reducing agent to dissociate and solubilize target allergen protein, the Globally Harmonized System of Classification and Labelling of Chemicals classifies it as a hazardous material because of its ecologically burdensome disposal, in addition to its unpleasant odor and a need for handling under a chemical hood (Table 4). Furthermore, by amendment of the Poisonous and Deleterious Substances Control Act of Japan in 2008, 2ME was designated as a poisonous substance, which requires strict handling. For this reason, any solution containing 2ME, including ELISA washing waste, is required to be collected and treated as a poisonous material. The replacement of 2ME was extremely needed to reduce the burden for the user of the official ELISA method. Once again, NIHS investigated options to solve this problem and finally established sodium sulfite as replacement for 2ME (20). The SDS–sulfite ELISA presented similar recoveries compared with those obtained by SDS–2ME ELISA (Table 5). In 2014, the optimized ELISAs were adopted as the official analysis method for all mandatory labeling food allergens (21).

The unique set of regulatory and enforcement tools, i.e., accurate official analyses OMAs (ELISA, PCR, and Western blot tests) with official standards and a regulatory decision tree (1) for result interpretation, helps inspection agencies throughout the country carry out their work and judgments in a consistent manner.

**Table 4. Chemical characteristics of 2ME and sodium sulfite**

Chemical reagent	2ME	Sodium sulfite
Smell	Unpleasant	Odorless
Handling	Handling under hood	Not requiring special equipment
GHS signal wording <sup>a</sup>	Danger	Warning
European Union classification according to Directive Nos. 67/548/EEC and 1999/45/EC	Toxic: dangerous to the environment	Not classified
Transportation	IATA 2966 6.1 poisonous material	Not restricted
Japanese poisonous and deleterious substance control law	Poisonous	Not listed

<sup>a</sup> GHS = Globally Harmonized System of Classification and Labelling of Chemicals.

**Table 5. Recovery of egg, milk, wheat, peanut, and buckwheat from model processed food incurred 10 µg food allergen protein/g food using SDS–2ME and SDS–sulfite ELISAs**

Model processed food	Egg			Milk			Wheat			Peanut			Buckwheat		
	2ME, µg/g	Sulfite, µg/g	Sulfite/2ME	2ME, µg/g	Sulfite, µg/g	Sulfite/2ME	2ME, µg/g	Sulfite, µg/g	Sulfite/2ME	2ME, µg/g	Sulfite, µg/g	Sulfite/2ME	2ME, µg/g	Sulfite, µg/g	Sulfite/2ME
Juice	9.4	9.7	1.032	9.0	10.0	1.111	9.1	9.0	0.994	10.0	10.0	1.000	14.1	11.4	0.809
Jam	8.4	9.6	1.143	9.1	9.7	1.066	—	—	—	15.0	12.6	0.840	— <sup>a</sup>	—	—
Jelly	—	—	—	—	—	—	8.6	8.9	1.035	—	—	—	—	—	—
Retort tomato stew	5.8	6.1	1.052	5.6	6.8	1.214	—	—	—	7.6	8.3	1.092	9.8	8.1	0.827
Retort vegetable soup	—	—	—	—	—	—	10.7	10.8	1.009	—	—	—	7.5	8.6	1.154

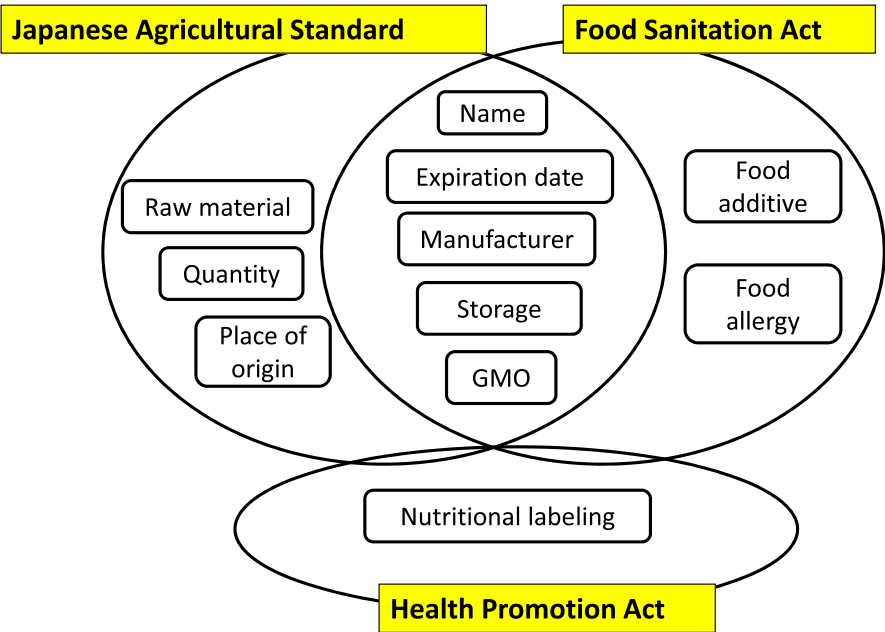
<sup>a</sup> — = Not tested.

The periodical investigation of commercial products by the inspection agency (Figure 1) has a substantial effect on food manufacturers. The inspection of food products in the market stimulates efforts by food manufacturers to comply with the food allergen labeling regulation. Regulatory actions issued by the regulatory administrator due to violations can have negative consequences for a business, including loss of the brand name (22–24). Periodical product investigations have become an invisible pressure for food manufacturers.

**New Food Labeling Act**

In 2002, the food allergen labeling regulation was issued as part of the Food Sanitation Act from the MHLW. Since then, food labeling has become more complicated year after year because of the addition of new articles and amendments due to the increased number of regulations concerning food labeling. To illustrate this point, Figure 2 shows the complexities of the

former general food product labeling, which was governed by three different acts from different viewpoints. Consequently, labeling became incomprehensible for the consumer. In order to simplify the food labeling regulatory framework and to make it more understandable, the labeling articles in the Food Sanitation Act (MHLW), Japanese Agricultural Standard (Ministry of Agriculture, Forestry and Fisheries), and Health Promotion Act (MHLW) were integrated into the newly established Food Labeling Act, which was enforced in 2015 (25) and falls under the jurisdiction of the Government of Japan, Consumer Affairs Agency. Regarding food allergen labeling, there are slight changes concerning the ingredient labeling rule, so that the food allergen is principally labeled by each ingredient individually, and designated processed foods that could originally omit allergen labeling, such as “mayonnaise,” commuting “egg” labeling, was abolished. However, major food allergen labeling regulations—such as the 7 mandatory and 20 recommended labeling foods; the 10 ppm threshold; and



**Figure 2. Laws relating to food labeling before the Food Labeling Act.**

the prohibited use of the precautionary statement, “may contain”—remain as in the former regulation. The regulatory inspection function still remains under the Food Sanitation Act of the MHLW.

## Conclusions

Japan enforced the food allergen labeling regulation in 2002. As there was neither a reference nor model country at the time that effectively regulated food allergy, Japan had to develop its own regulatory system as a national challenge. The uniqueness of Japan's food allergen labeling regulation, which is not observed in other countries, originated from this background. Japan stepped forward to set up a threshold of 10 µg soluble allergen protein/g food to regulate commercial food products accordingly. Hence, accurate food allergen analytical methods needed to be developed to provide evidence for regulatory action. The Japanese food allergen labeling regulation has already been in force for over 15 years and, in that time, it has been amended, as needed. It is notable that the 10 µg allergen protein/g food threshold has not been amended, as no inconveniences have been encountered at this value. According to the food allergy survey of 2016, carried out by the major Japanese food allergy group, ATOPICCO Network for Children of the Earth, 76% of the surveyed food-allergic individuals relied on “ingredient labeling of food products” and 68% used “allergen labeling of food product” to select suitable food (report under preparation). So food allergen labeling has surely been accepted by the food-allergic individual.

After 15 years of enforcement of the Japanese regulation, now would be a good time to scientifically review the regulation. We can recognize its advantages and disadvantages for further development, although, overall, the regulation is working effectively. It is out hope that such Japanese knowledge and experience can help other countries approach their food allergen labeling challenges.

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