

# Japanese Risk Analysis for Food Allergen Labeling Regulation and Prospects of the International Contribution

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**ABSTRACT**— In the Japanese allergy-labeling system, food labeling is mandated for 7 specific ingredients (egg, cow's milk, wheat, buckwheat, peanut, shrimp, and crab) and recommended for 21 food ingredients in reference to case numbers of actual illness and the degree of seriousness. To monitor the validity of the labeling system, official methods for the detection of specific ingredient proteins in processed foods were developed. The official methods consist of ELISA methods for screening, and western blot methods for egg and milk, and PCR methods for wheat, buckwheat, peanut, shrimp/prawn, and crab as confirmation tests. The official methods consist of ELISA methods for screening, and western blot methods for egg and milk, and PCR methods for wheat, buckwheat, peanut, shrimp/prawn, and crab as confirmation tests. Threshold amounts (a few mg/kg) for labeling were set based on the approach of the analytical detections. Any foods containing protein allergens should be labeled if these contain allergens at greater than 10 ppm (mg/kg). Validation protocol criteria were established to standardize the Japanese official method. Food Safety Commission of Japan conducted a risk assessment of egg as a specific ingredient and judged that current labeling system for foods containing allergens is generally appropriate for “eggs”. In the future, it is important to accumulate necessary scientific knowledge in order to carry out food health impact assessment including further refinement. The Japanese experience and knowledge of food allergy-labeling system would contribute to harmonize international labeling guidelines to protect allergic consumers globally.

**KEYWORDS:** detection, labeling, food allergy, ELISA, risk assessment

## 1. INTRODUCTION

The international Codex Alimentarius recommended the labeling of eight food ingredients (cereals containing gluten, crustaceans and products, eggs and egg products, fish and fish products, peanuts, soybeans and products, milk and milk products including lactose, tree nuts and nut products), known as the “Big 8”, in 1999 [1].

In reference to a national survey of food allergy cases from 1997 to 1998 [2], [3] in Japan, a food labeling system for allergenic ingredients was mandated under the Food Sanitation Act of the Ministry of Health, Labour and Welfare (MHLW) on April 1, 2002. In 2010, management of the food labeling policy was transferred from the MHLW to the Japanese Consumer Affairs Agency (CAA). The CAA established the Food Labeling Act, which came into effect in 2015. In this act, food allergy-labeling is divided into two levels, namely, mandatory and recommended levels, according to the case numbers of actual illness and the degree of seriousness. Currently, egg, cow's milk, wheat, buckwheat, peanuts, shrimp and crab require mandatory labeling as “specific ingredients” by Cabinet Office Ordinance. In addition, the notification recommends that foods containing ingredients such as abalone, almond, squid, salmon roe, orange, cashew nut, kiwi fruit, beef, walnut, sesame, salmon, mackerel, soybean, chicken, banana, pork, matsutake mushroom, peach, yam, apple, and gelatin be labeled as “sub-specific ingredients” (Table 1).

In 2004, the MHLW revised the recommended labeling list to include banana, as the survey from 2001 to 2002 revealed an increase in the number of allergic patients. In 2008, the MHLW revised the mandatory labeling for shrimp and crab, since crustaceans have almost unlimited uses in processed foods in Japan. According to the 2004-2005 survey, crustaceans are a frequent cause of adverse food reactions in allergic patients. In 2013, the CAA revised the recommended labeling list to include cashew nuts and sesame due to the increase in number of allergic patients and because they were a frequent cause of adverse food reactions in allergic patients according to the 2011-2014 survey. In 2019, the CAA revised the recommended labeling list to include almond due to the increase in number of patients with almond allergy and because they were a frequent cause of adverse food reactions in allergic patients according to the 2016-2017 survey. To our knowledge, Japan is one of the first countries to set up a mandatory food allergy-labeling system and regulate it under a national act.

## 2. Japanese Allergenic Ingredient Labeling System [4]

In Japan, in principle, the names of specific ingredients, etc. in the Food Labeling Standards must be used; however, alternative labels are also specified. Examples of alternative labels are eggs, chicken eggs, duck eggs, quail eggs, and alike. Meanwhile, labeling of combine specific ingredients, etc. is not allowed. For example, complex labeling such as wheat and soybean as “cereals” or beef, pork, and chicken labeled as “meat” or “animal XX” is not allowed.

However, in cases of five ingredients— (1) protein hydrolysate, (2) fish sauce, (3) ground fish meat, (4) fish oil, and (5) seafood extract— these food products consist of seafoods caught indiscriminately with fishing net. Since it is not possible to know whether specific fish and shellfish are contained in the product, complex labeling method is allowed for exception, such as display of “including seafood”. For additives derived from specific ingredients, the description “food additives” and the fact that the additives are derived from specific ingredients will be displayed. In addition, for foods containing additives derived from specific ingredients, it is indicated that the additives are contained and that these additives are derived from the specific ingredients, such as “additive name (derived from XX)”.

**Table 1.** Allergenic ingredients designated in Japan\*

Specific allergenic ingredients
Mandatory by ministerial ordinance (7 ingredients)
Shrimp, Crab, Wheat, Buckwheat, Egg, Milk(dairy products), and Peanut
Sub-specific allergenic ingredients
Recommended by ministerial notification (21 ingredients)
Abalone, Almond, Squid, Salmon roe, Orange, Cashew nut, Kiwi fruit, Beef, Walnut, Sesame, Salmon, Mackerel, Soybean, Chicken, Banana, Pork, Matsutake mushroom, Peach, Yam, Apple, and Gelatin

\*Based on Notification No.139 of March 3, 2015, from the Food Labeling Standards of Consumer Affairs Agency.

Rice, Fried vegetable (containing wheat and egg), Fried chicken (containing wheat and soybean), Spaghetti (containing wheat, egg), Fried shrimp (containing, wheat, egg) Potato salad (containing egg).....
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**Fig.1.** Example of individual allergen declaration

<p>Rice, Fried vegetable, Fried chicken, Spaghetti, Fried shrimp, Potato salad..... (Parts of Ingredients contain wheat, soybean, egg, chicken,...)</p>
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**Fig.2.** Example of collective allergen declaration

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