Food and Agriculture Organization of the United Nations

Food allergies

Leaving no one behind

4

FOOD SAFETY

TECHNICAL TOOLKIT FOR ASIA AND THE PACIFIC

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Abstract

Food allergies may impact only parts of the world's population, but that impact can be lethal. It is, therefore, extremely important that food labels contain sufficient information to enable allergic people to avoid the risks of allergic reactions. National contexts can differ in terms of predominance of food allergies and, thus, investigation is necessary within countries to understand what foods should be labelled, and determine the allowable quantities of food allergens, including those that are considered dangerous, that may unintentionally be present in foods. International standards have been developed by the Codex Alimentarius which include a list of allergens that should always be included on the label; however, the food allergens recognized by Codex may not necessarily cover the whole list of food allergens that have an impact on different populations.

This document illustrates some examples of current practices to establish labelling regulations for food allergens, with a focus on the Japanese case, which was the first country to establish a national regulation to address the topic. The process of establishing the list of food allergens that require labelling, as well as the process to establish the maximum limits of undesired allergens tolerated in pre-packaged foods, is provided as an introductory example.

Keywords

Food allergies, immune system, Japan, food labels, survey, food regulations, threshold, limits, detection methods, food legislations, food standards, Codex Alimentarius, Food and Agriculture Organization of the United Nations (FAO), Asia and the Pacific.

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1 Introduction

Food allergies are a distinctive food safety issue that only affects parts of the world's population with the effects ranging from mild discomfort to, in the worst case, fatality (Santos, 2019). Food allergies harm only specific parts of the population sensitive for food allergens; this is a significant difference to the other common food safety issues, as microbial contamination or chemical contamination such, which impair everyone. As a minority issue, food allergy was not acknowledged significantly until recent years. Food allergies have now been recognized as the emerging problem in the limelight (Sicherer and Sampson, 2018; Taylor, 2000).

Food allergies are fairly common. At the individual level, people with food allergies can prevent allergic reactions by avoiding the particular food that causes the problem. But to do this, food labels are necessary. Prepackaged processed foods are pervasive throughout the world, but individuals with food allergies can select "safe" food by checking the product's ingredient list.

At the food industry level, the distance between manufacturers and consumers has increased significantly, due to the global food trade, and labels with food allergen information have become even more important to prevent allergic reactions from occurring (Sheridan *et al.,* 2020). Consequently, food allergen labelling regulations were enforced globally (University of Nebraska, 2020). In this document, the purpose of food allergen labelling regulations in the Asia-Pacific region are introduced.

This document aims at providing an introduction to some practices that could be used to address the increasing problem of food allergies, and provides examples of what can be done from the point of view of food safety authorities.

2 Food allergies

2.1. Background

Food allergies are the result of abnormal responses of the body's immune system to specific proteins in a food that can cause adverse reactions (Turnbull *et al.,* 2015). Due to their rapid onset and life-threatening potential, anaphylactic food allergies are regarded as the most harmful type of food reaction. It is important to specify that food allergies can sometimes be managed through natural desensitization and that, in many cases, children can simply grow out of them. However, they can develop at any stage of life.

Some individuals can be intolerant to dairy products such as lactose intolerance or to gluten: these reactions are not subject of the same abnormal immune reaction described before, and the distinction may sometimes create confusions (Turnbull *et al.,* 2015).

It is difficult to estimate the social damage caused by food allergies. In the United States of America, it is estimated that approximately two percent of adults and five percent of infants and young children suffer from food allergies (Sampson, 2003). Furthermore, also in the United States of America, each year, roughly 30 000 individuals require emergency room treatment, and 150–200 individuals die because of allergic reactions to food. (Sampson, 2003). In addition, serious food allergies often require medical treatment, and those costs must be taken into account when discussing the impact of food allergies.

A further problem with food allergies is that they are affecting an increasing number of people. In developed countries, the prevalence of food allergies is increasing, and it is recently estimated to affect ten percent of the population (Sicherer and Sampson, 2018; Savage and Johns, 2015). Also in developing countries, food allergies that were previously overlooked have now become obvious, and the number of reports on food allergies has increased markedly (Loh and Tang, 2018; Gray, 2017, Tang and Mullins, 2017). Food allergies have now become a significant global health problem.

2.2. Addressing food allergies

There is no "cure" for food allergies and, thus, the best way to prevent them is to completely avoid the offending food. Because allergic reactions differ from one person to another (e.g. some people are sensitive to peanuts, others to eggs), avoidance is the best way to self-protect against them. The allergic consumer has no idea whether an offending food is contained in commercial prepackaged food products unless all food items are listed on the product's label. Consequently, a label conveying allergen information is important, and food allergen labelling regulations should be enforced worldwide (University of Nebraska, 2020).

2.3. Concepts, principles and considerations to regulate food allergens

2.3.1. Learning from country examples

The first question for labelling regulation is, "Which foods should be labelled?" Over a hundred foods have been documented as causing allergic food reactions (Taylor, 2000). Furthermore, food allergies are related to food consumption habits. For example, kiwi fruit allergy did not exist in Japan until the 1960s, when kiwi fruit was first introduced in the country. According to recent food allergy surveys, kiwi fruit is one of the top-10 allergy-causing foods, and has the highest prevalence of allergy among fruits due to its popularity (Tables 1–9). Similarly, the recent increase of buckwheat consumption as a "health food" and wheat replacement has induced buckwheat allergy in Great Britain and Northern Ireland, where buckwheat allergy was previously unknown (Sammut *et al.,* 2011). These examples clearly indicate the change of food consumption that a population is not used to consuming can transform food allergy prevalence dynamically. Therefore, epidemiological surveys can help to identify which foods to regulate, because communities with different food habits may be more sensitive to different types of food allergens.

Table 1. Food allergens identified by surveys in Japan: survey result of the prevalence of immediate-type food allergies in Japan in 2017[1]

No.	Allergen	Percentage	No.	Allergen	Percentage
1	Egg	34.7	12	Banana	0.8
2	Milk product	22.0	13	Sesame	0.6
3	Wheat	10.6	14	Peach	0.5
4	Walnut	5.2	15	Yam	0.5
5	Peanut	5.1	16	Almond	0.4
6	Salmon roe	3.8	17	Crab	0.4
7	Shrimp	2.5	18	Macadamia	0.3
8	Buckwheat	3.8	19	Salmon	0.3
9	Cashew	1.7	20	Squid	0.3
10	Soybean	1.6	21	Apple	0.2
11	Kiwi fruit	1.6			

Sources: Nationwide survey in 2017 (CAA, 2018).

[1] In the nationwide survey, immediate-type food allergy is stipulated as an allergic reactions elicited within 60 minutes from allergen intake, and the reaction must be diagnosed by the medical institution.

Table 2. Food allergens identified by surveys in Japan: survey result of the prevalence of immediate-type food allergies in Japan in 2014

No.	Allergen	Percentage	No.	Allergen	Percentage
1	Egg	35.0	12	Banana	0.8
2	Milk product	22.3	13	Crab	0.8
3	Wheat	12.5	14	Yam	0.7
4	Peanut	5.6	15	Peach	0.6
5	Salmon row	3.9	16	Apple	0.5
6	Shrimp	2.9	17	Mackerel	0.4
7	Kiwi fruit	2.0	18	Sesame	0.4
8	Walnut	1.6	19	Salmon	0.3
9	Buckwheat	1.5	20	Almond	0.3
10	Soybean	1.2	21	Squid	0.3
11	Cashew	1.1			

Sources: Nationwide survey in 2014 (CAA, 2015).

Table 3. Food allergens identified by surveys in Japan: survey result of the prevalence of immediate-type food allergies in Japan in 2011

No.	Allergen	Percentage	No.	Allergen	Percentage
1	Egg	39.0	12	Yam	0.6
2	Milk product	21.8	13	Crab	0.6
3	Wheat	11.7	14	Cashew	0.6
4	Peanut	5.1	15	Peach	0.4
5	Salmon row	3.5	16	Sesame	0.4
6	Shrimp	2.7	17	Mackerel	0.4
7	Buckwheat	2.2	18	Salmon	0.3
8	Kiwi fruit	1.4	19	Squid	0.3
9	Walnut	1.4	20	Chicken	0.2
10	Soybean	0.9	21	Apple	0.2
11	Banana	0.6			

Sources: Nationwide survey in 2011 (CAA, 2012).

Table 4. Food allergens identified by surveys in Japan: survey result of the prevalence of immediate-type food allergies in Japan in 2001–2002

No.	Allergen	Percentage
1	Egg	38.3
2	Milk product	15.9
3	Wheat	8.0
4	Fruits	6.0
5	Buckwheat	4.6
6	Fish	4.4
7	Shrimp	4.1
8	Peanut	2.8
9	Soybean	2.0
10	Meat	1.8

Sources: Nationwide survey in 2001-2002 (Akiyama *et al.*, 2011).

Table 5. Food allergens identified by surveys in Japan: survey result of the prevalence of immediate-type food allergies in Japan in 1998–1999

No.	Allergen	Percentage
1	Egg	29.6
2	Milk product	22.8
3	Wheat	10.4
4	Buckwheat	5.8
5	Fish	5.1
6	Fruits	4.6
7	Shrimp	3.6
8	Meat	3.1
9	Peanut	2.4
10	Soybean	1.9

Sources: Government survey in 1998-1999 (Akiyama *et al.*, 2011).

Table 6. Food allergens identified by surveys in Japan: survey result of anaphylaxes cases in Japan in 2017

No.	Allergen	Percentage
1	Egg	23.9
2	Milk product	22.5
3	Wheat	16.6
4	Walnut	8.0
5	Peanut	7.3
6	Shrimp	3.4
7	Cashew	2.9
8	Buckwheat	2.7
9	Salmon roe	2.3
10	Kiwi fruit	1.5
11	Soybean	1.0
12	Cacao	0.6
13	Banana	0.4
14	Barley	0.4
15	Coconut	0.4
16	Yellowtail	0.4
17	Macadamia	0.4
18	Tuna	0.4
19	Crab	0.2

Sources: Nationwide survey in 2017 (CAA, 2018).

Table 7. Food allergens identified by surveys in Japan: survey result of anaphylaxes cases in Japan in 2014

No.	Allergen	Percentage
1	Egg	27.8
2	Milk product	25.4
3	Wheat	19.2
4	Peanut	5.5
5	Shrimp	3.1
6	Cashew	2.0
7	Salmon row	1.8
8	Kiwi fruit	1.4
9	Walnut	1.4
10	Buckwheat	1.2
11	Crab	1.0
12	Soybean	0.8
13	Almond	0.8
14	Mackerel	0.6
15	Banana	0.6
16	Peach	0.6
17	Yam	0.6
18	Pork	0.4
19	Squid	0.2

Sources: Nationwide survey in 2014 (CAA, 2015).

Table 8. Food allergens identified by surveys in Japan: survey result of anaphylaxes cases in Japan in 2011

No.	Allergen	Percentage
1	Egg	25.1
2	Milk product	21.5
3	Wheat	20.8
4	Peanut	6.5
5	Shrimp	4.8
6	Salmon roe	3.9
7	Buckwheat	3.6
8	Banana	1.6
9	Cashew	1.6
10	Walnut	1.3
11	Crab	0.7
12	Soybean	0.7
13	Kiwi fruit	0.7
14	Apple	0.7
15	Rice	0.7
16	Mackerel	0.7
17	Squid	0.7
18	Abalone	0.3
19	Bamboo shoot	0.3

Sources: Nationwide survey in 2011 (CAA, 2012).

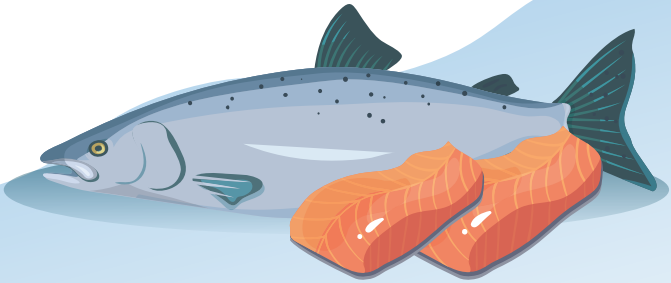
Table 9. Food allergens identified by surveys in Japan: survey result of anaphylaxes cases in Japan in 2001–2002

No.	Allergen	Percentage
1	Egg	27.6
2	Milk product	23.5
3	Wheat	17.7
4	Buckwheat	7.1
5	Peanut	4.6
6	Shrimp	3.5
7	Salmon roe	2.0
8	Peach	2.0
9	Soybean	1.8
10	Kiwi fruit	1.8
11	Banana	1.0
12	Yam	1.0

Sources: Nationwide survey in 2001-2002 (Akiyama *et al.,* 2011).

However, conducting a large-scale epidemiological survey is not easy. First, a medical professional who can correctly identify a food allergen is required. The time lag between allergen intake and the onset of an allergic reaction makes the identification of a food allergen difficult; thus, a reliable survey needs the participation of expert medical institutions. Needless to say, self-reporting by the allergic individual is often incorrect. Second, medical professionals capable of identifying food allergens need to have the same qualifications throughout the region, otherwise the survey result cannot be comparable.

The next best way is to utilize food allergy survey reports in the region, which can reflect regional food allergen characteristics. This approach is less reliable, however, than a large-scale survey, because each report would conduct the survey differently and the results would not be comparable. An alternative approach to allergen designation is to follow the international Codex standard because a food allergen labelling standard recommendations have already been adopted by Codex. This may, however, not always match the local food allergy situation, such as the case of buckwheat in Japan (Tables 1–9).



2.3.2. How much is too much?

The next consideration is how to regulate food allergens. For this, food manufacturing needs to be considered. The food manufacturer should be ready to apply food labels on the allergens used in the foods they make, for ensuring the safety of the allergic customer. However, in food manufacturing, there is a problem with unintentionally introducing a food allergen in a product through cross-contamination with, for example, shared food production equipment.

Before and after the emergence of food allergy problems, the food manufacturing practice on unintentional inclusion of foreign food materials changed completely. When a food allergy was unknown, the unintentional inclusion in the product was tolerated because the included foreign material was originally edible (i.e. safe). However, after the emergence of a food allergy problem, the material, which is not formulated but unintentionally included, is unacceptable as potential harm exists (Bucchini *et al.,* 2016).

The unintentional inclusion of food allergens may occur during the processing of multiple different products within the same facility in order to satisfy economic efficiency. Eventually, the manufacturer uses the shared production line but with preventive measures in place for cross-contamination (e.g. thorough cleaning). While it is possible to disassemble completely and clean 100 meters of a steel belt oven in every batch of biscuit production, the price of doing so would be prohibitive, and the resulting one single biscuit would cost USD 100. Total production management, such as that in the commercial biscuit example, controlling eggs and soybeans is the only practical way to prevent the unintentional inclusion of allergens, and accomplishes the balance of food safety and economic production (Shoji and Obata, 2010). A comprehensive allergen management guide for food business operators in Australia was made available in 2019 by the Australian Food and Grocery Council and Allergen Bureau, and can be found online (AFGC and Allergen Bureau, 2019).

The potential of unintentional inclusion of allergens cannot be completely avoided, however; in fact, recalls of undeclared food allergens occur (Do *et al.,* 2018). The identification and use of food allergen thresholds are tools for manufacturers to manage the unintentional inclusion of a food allergen in a product and, if necessary, to take necessary actions to protect the safety of allergic consumers (Yeung and Robert, 2018). Setting up regulatory values requires a conservative approach and accountability to society due to the life-threatening characteristics of some food allergies. Currently, there is no recognized food allergen threshold to be used as the basis of a regulatory value.

Without setting up regulatory values, allergens that are unintentionally included in food become unmanaged. One solution is to use precautionary labelling such as "May contain [name of allergen]", as this would alert the allergic consumer as they choose food products (Yeung and Robert, 2018). Of course, if precautionary labelling is abused, the food allergic individual will have a limited choice when buying foods, because food allergic consumers cannot use food with such precautionary labelling. The purpose of food allergen labelling is to help consumers avoid the risks of food allergens, and manufacturers worldwide are required to use precautionary labelling properly.

2.4. Standards of and regulations on food allergens

2.4.1. Codex standards

A list of ingredients that must be declared on products was made available in 1999 through the "Codex General Standard for the Labelling of Prepackaged Foods" (Messina and Venter, 2020). The standard was developed taking into consideration the report of a technical consultation on food allergens published by the Food and Agriculture Organization of the United Nations (FAO, 1995). The Codex General Standard requires the labelling of the so-called "Big 8" foods and ingredients that cause food allergies (Table 9) (FAO/WHO, 2018).

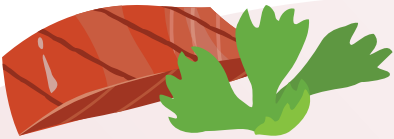
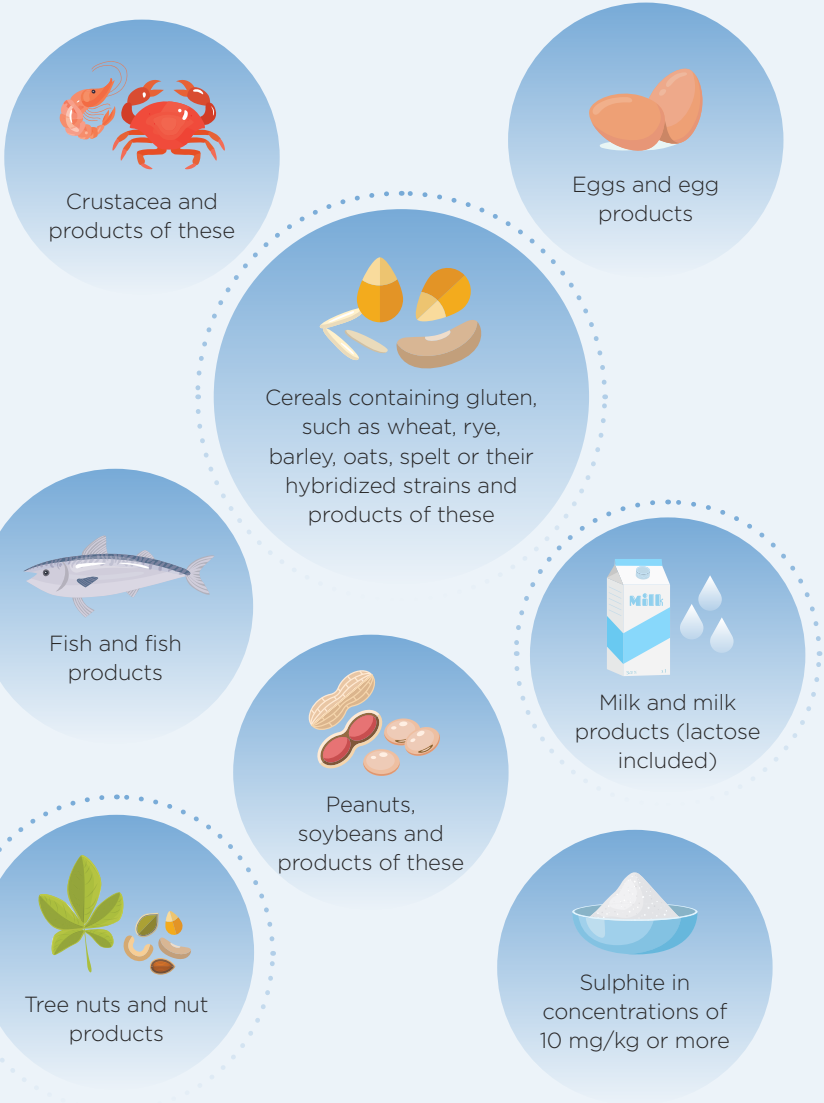


Table 10. Foods and ingredients known to cause hypersensitivity, which the Codex General Standards for the labelling of prepackaged foods indicates shall always be declared



Source: (FAO/WHO, 2018).

The Codex General Standard covers a wide range of adverse reactions to food, not only food allergies but also gluten and lactose intolerance and asthma caused by sulphites. Although the Codex General Standards is voluntary in nature, Codex standards are recognized as benchmark standards by the World Trade Organization for food traded internationally.

Codex continues to work on allergens, based on the latest scientific information and is currently in the process of updating its list of food and ingredients known to cause hypersensitivity and developing guidance on precautionary allergen labelling.

2.4.2. Case study 1: Japan

Japan first began to investigate a food allergen labelling regulation in the 1990s. As there was neither a reference nor a model country that was regulating food allergens, Japan had to develop its own regulation (Akiyama *et al.,* 2011; Shoji, 2018), and was the first country to do so. One driving force was the Codex General Standard, and another was the fatal incident (in 1995) of a child who was severely allergic to buckwheat.

These international trade requirements and substantial relief for domestic cases of food allergies keenly drove the Government of Japan to establish practical and effective regulation.

At the time when the Ministry of Health, Labor and welfare started the food allergen investigation, only recognized food allergens listed by the the Codex General Standard was used (Table 10). Codex standards are based on globally available data and need to be adapted to the national context. For example, buckwheat, which is known to generate severe allergic reactions in Japan was not included in the Codex General Standard as there was a lack of information on the prevalence of buckwheat allergy in the population in most countries. Therefore the Codex list needed to be tailored to the Japanese context.

A retrospective food allergy survey was conducted in 1998 and 1999 (Akiyama *et al.,* 2011), focusing on clinically ensured, immediate-type food allergies, which are responsible for acute, severe reactions (Table 5). Based on these surveys, labels for five ingredients – eggs, milk, wheat, peanuts, and buckwheat – were designated as mandatory on food product labels, and 19 ingredients (abalone, squid, salmon roe,

orange, shrimp, crab, kiwi fruit, beef, walnut, salmon, mackerel, soybean, chicken, pork, matsutake mushroom, peach, yam, apple, and gelatin), were selected for recommended labelling of allergens, according to prevalence and seriousness in causing anaphylaxis. The designated food ingredients included those listed in the Codex General Standard, as well as specific ingredients of Japanese custom foods such as buckwheat, salmon roe, and matsutake mushrooms.

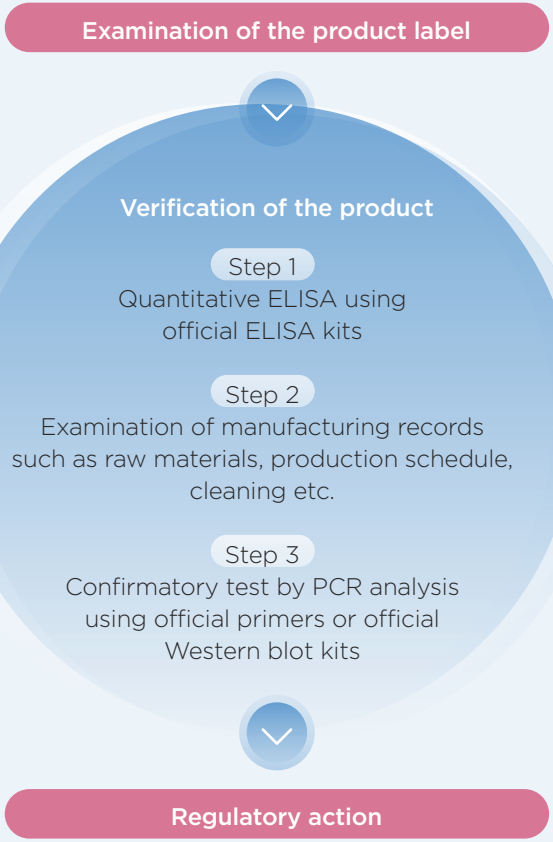
Once the full list of allergens was established, the next step consisted of identifying regulatory limits of food allergens in foods. Two study groups addressed this attempt from different viewpoints: one focused on the labelling, the other on the possible methods to easily detect food allergens in foods (Akiyama *et al.,* 2011).

A zero threshold could not be used for regulatory purposes because food manufacturers need regulatory values to manage the possible unintentional presence of food allergens; without it, allergic consumers would be at risk. The conclusion was reached that threshold values could be defined by the amount of allergen proteins on the order of a few micrograms per gram food. Detection methods such as an enzyme-linked immunosorbent assay (ELISA), a lateral-flow assay, and a polymerase chain reaction (PCR) were investigated as possible ways to provide regulators with scientific evidence. These methods led to the identification of precise limits of detections within the range of 0.1–5.0 µg of protein per gram of food.

The final labelling regulation in Japan now requires that prepackaged foods containing more than 10 µg food allergen protein in one gram of food requires mandatory labelling for food allergen. Figure 1 shows the regulatory procedure to examine product compliance in Japan.

If it is suspected that a product contains undeclared traces of egg, the first step is to examine the product's label to check whether egg is listed or not. If egg is listed, the product complies with egg labelling. If egg is not declared, a verification is needed, which consists of three steps. The first step is to test the quantity of the allergen through the method of "quantitative ELISA". If the quantity is greater than 10 µg protein/g food, the manufacturing records are examined. If egg inclusion is reported, the regulator gives the correction guidance to the manufacturer; otherwise, a confirmation test is done using different methods PCR analysis or Western blot to investigate the presence of particular DNAs or proteins.

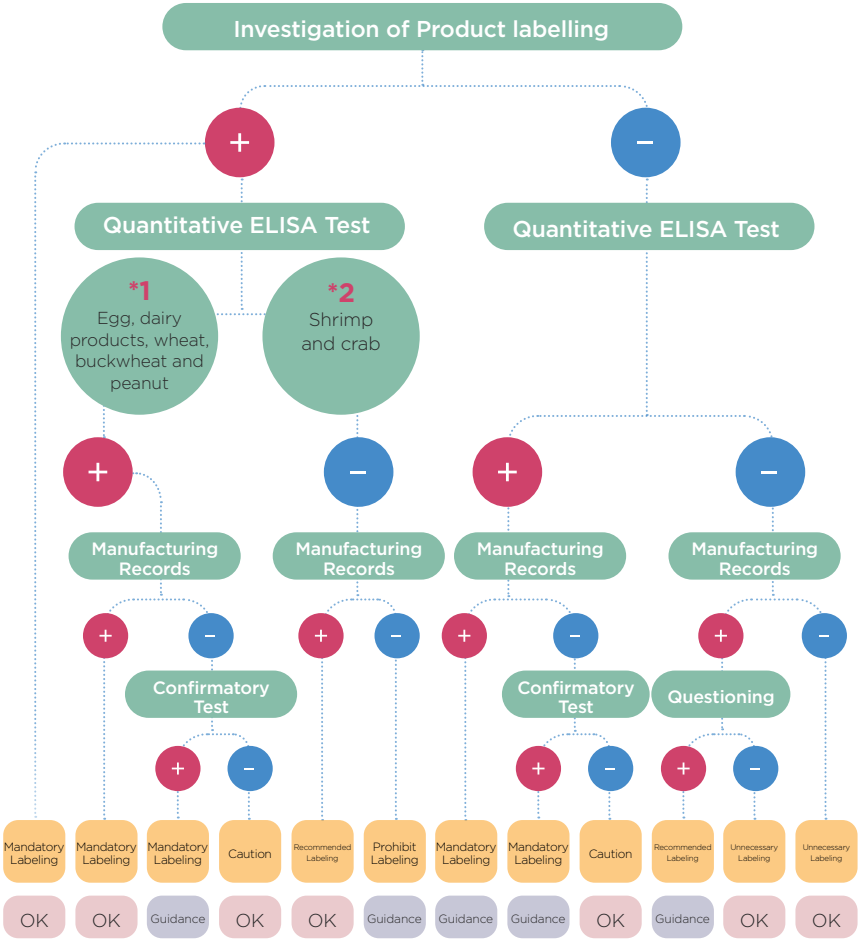
Figure 1. Regulatory procedure to assess the compliance of commercial food



If the product is concluded to violate the regulation, the regulator executes regulatory action. This procedure is illustrated as a decision tree (Figure 2), which stipulates that any local inspection agency can make a universal regulatory decision.

To back up this regulatory procedure, the official ELISA, PCR and Western blot analyses are important. The regulatory procedure is communicated to the public and relevant stakeholders. In addition, the reagents used in the procedure are readily available so that manufacturers can self-check their own products.

Figure 2. Decision tree used by regulatory authorities when investigating the compliance of commercial food



Source: Akiyama *et al.*, 2011.

The regulation prohibits the use of, “May contain [name of allergen]” labelling. However, the voluntary labelling, “This product is manufactured in a facility using [name of allergen]” is allowed, which causes occasional confusion. Some food allergic individuals are susceptible to specific allergic reactions with very small amounts of food allergens, while some people are less sensitive. The intent of voluntary labelling is to increase the food choices of less sensitive individuals because otherwise, food allergic individuals have very limited food choices. A product that does not list egg (as done in mandatory labelling) but uses the voluntary label (i.e. “This product is manufactured by a facility that uses egg”), can be interpreted as having the potential of containing a small amount of egg, but the quantity of egg does not exceed the regulatory value of 10 µg egg protein per gram of food. Accordingly, some egg-allergic individuals can eat this product.

Continuous monitoring of the regulation is done to ensure its effectiveness, because even a small defect can lead to a life-threatening incident. First, updates are made to the periodic nationwide survey (see Tables 1-4 and 6-9), which aim at capturing the real-time food allergy situation in the country. The nationwide survey was designed specifically to monitor food allergies that occur immediately after ingestion (also known as “immediate-type”), and collaboration with more than 1000 medical doctors all over Japan helped with better data collection. Thanks to these updates, presently presently seven mandatory labels and 21 recommended labels; in 2019, an update included almond for recommended labelling (Table 11) (CAA, 2019), covering 94.4 percent of the total immediate-type food allergies (CAA, 2018). The periodic nationwide survey is unique and unprecedented globally.

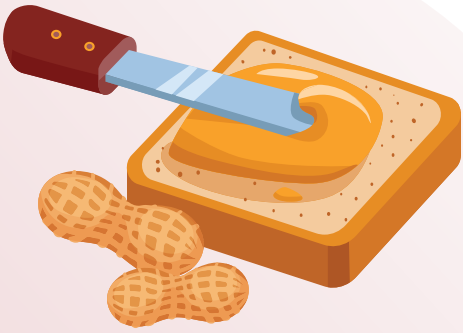


Table 11. Follow-up and update of the food allergen labelling regulation in Japan

Year	Update of the regulation	Baseline survey	Reference
2001	Enforcement of food allergen labelling regulation (5 mandatory and 19 recommended labelling ingredients)	Government survey (retrospective) in 1998–1999	Akiyama *et al.*, 2011
2004	Banana was added to recommended labelling ingredient	Nationwide survey (prospective) in 2001–2002	Akiyama *et al.*, 2011
2005	Announcement of new official analysis method using SDS/2-mercaptoethanol extraction solution	-	Akiyama *et al.*, 2011
2008	Shrimp and crab were upgraded from recommended to mandatory labeling ingredient	Nationwide survey (prospective) in 2005	Akiyama *et al.*, 2011
	(No update)	Nationwide survey (prospective) in 2005	Akiyama *et al.*, 2011
2009	Announcement of the analytical set of ELISA and confirmatory PCR for shrimp and crab	-	Akiyama *et al.*, 2011
2013	Cashew nuts and sesame were added to recommended labeling ingredient	Nationwide survey (prospective) in 2011	CAA, 2012
	(No update)	Nationwide survey (prospective) in 2014	CAA, 2015
2014	Announcement to replace SDS/sulfite instead of SDS/2-mercaptoethanol in official analysis method	-	Shoji *et al.*, 2018
2019	Almond was added to recommended labeling ingredient	Nationwide survey (prospective) in 2017	CAA, 2018

Table 12. Designated food allergens labelled as either mandatory or recommended in Japan. Foods in italics were updated by the periodical survey results conducted until 2019

Labelling requirement	Name of specified ingredients
Mandatory labelling (7 items)	*shrimp, crab,* wheat, buckwheat, egg, dairy products, and peanut
Recommended labelling (21 items)	*almond,* abalone, squid, salmon roe, orange, *cashew nut,* kiwi fruit, beef, walnut, *sesame*, salmon, mackerel, soybean, chicken, *banana*, pork, matsutake mushroom, peach, yam, and gelatin

Source: CAA, 2019.

Official analytical methods are also improved (Table 10). Techniques such as ELISA often result in poor quantification results due to the fact that food processing often leads to the denaturation of allergens (Shoji, 2011). Such poor results could lead to consumer distrust in the regulatory system. Japan's National Institute of Health Sciences finally improved the previous ELISA methodology by adding chemical substances that could avoid the problem.

So far, the Japanese regulation has proven to be effective. Notably, the regulatory value set at 10 µg/g, did not require any changes through nearly 20 years of monitoring.

2.4.3. Case study 2: Australia and New Zealand

In 2002, Australia and New Zealand adopted food allergen labelling to the Australia New Zealand Food Standards Code (FSC). FSC Standards require the declaration of allergens used intentionally in food. A review of the mandatory declaration of foods listed in the FSC Standard was recently done due to the increased use of lupin. The present mandatory declaration of foods is presented in Table 12 (FSC, 2017). This list is legally mandatory, and contraventions to it can result in the enforcement of measures by both governments. FCS specifies neither the requirement to declare unintentionally included allergens, nor the threshold to manage unintentionally included allergens.

Table 13. Mandatory declaration foods in Australia New Zealand Food Standards Code Standard 1.2.3-4

The Australian food industry is also voluntarily making efforts to prevent food allergy accidents. The Allergen Bureau supports the food industry and provides valuable resources to manage food allergens (AFGC and Allergen Bureau, 2019). Of particular note in its activities is the Voluntary Incidental Trace Allergen Labelling (VITAL®), which addresses the challenge of scientifically determining the threshold of a food allergy.[2] With this program, food manufacturers quantify unintentionally included allergens in the final food products, and verify if preventative actions are needed on the product.

2.4.4. Case study 3: United States of America

In the United States, peanuts, tree nuts, fish, and shellfish are well known to cause fatal food allergic reactions, and food allergy is a recognized health problem in the country (Sampson, 2004; Sicherer and Sampson, 2006, 2018). The estimation of food allergy harm gave a considerable impact on the society, and as a result, the Food Allergen Labeling and Consumer Protection Act (FALCPA) came into force in 2004 (FALCPA, 2004). The act requires that all packaged foods must list the eight major food allergens, consisting of five food items and three food groups (Table 13), as these food allergens are thought to account for over 90 percent of food allergies in the United State (FALCPA, 2006).

[2] At present, the VITAL® version 3.0 program is available (Allergen Bureau, 2019).

Table 14. Major food allergens in the United States that are required to be listed in food labels

1: **Fish and crustacean/shellfish:** Fish and crustaceans are listed in The United States Food and Drug Administration's seafood list (USFDA, 2020).
2: **Tree nuts:** Almond, beech nut, Brazil nut, butternut, cashew, chestnut, chinquapin, coconut, filbert/hazelnut, ginko nut, whickory nut, lichee nut, macadamia nut/bush nut, pecan, pine nut/pinon nut, pili nut/ pistachio, sheanut, walnut, heartnut.
3: **Wheat:** Common wheat, durum wheat, club wheat, spelt, semolina, Einkorn, emmer, Khorasan wheat, and triticale.

The United States Food and Drug Administration (USFDA) provides guidance for the food industry (USFDA, 2006). This guidance informs the food industry that FALCPA labelling requirements do not apply to unintentionally included food allergens from, say, the result of cross-contamination. Ultimately, FALCPA applies to only included major food allergens, and does not require food allergen threshold managing for unintentionally included allergens. Furthermore, FALCPA does not address the advisory labelling of "May contain [name of allergen]". However, the USFDA requires that advisory labelling be truthful and not misleading. USFDA routinely inspects a variety of packaged foods to ensure the correctness labeling, and this enhances the compliance of manufacturers because non-compliance with FALCPA is subjected to legal penalties.

3 Conclusions

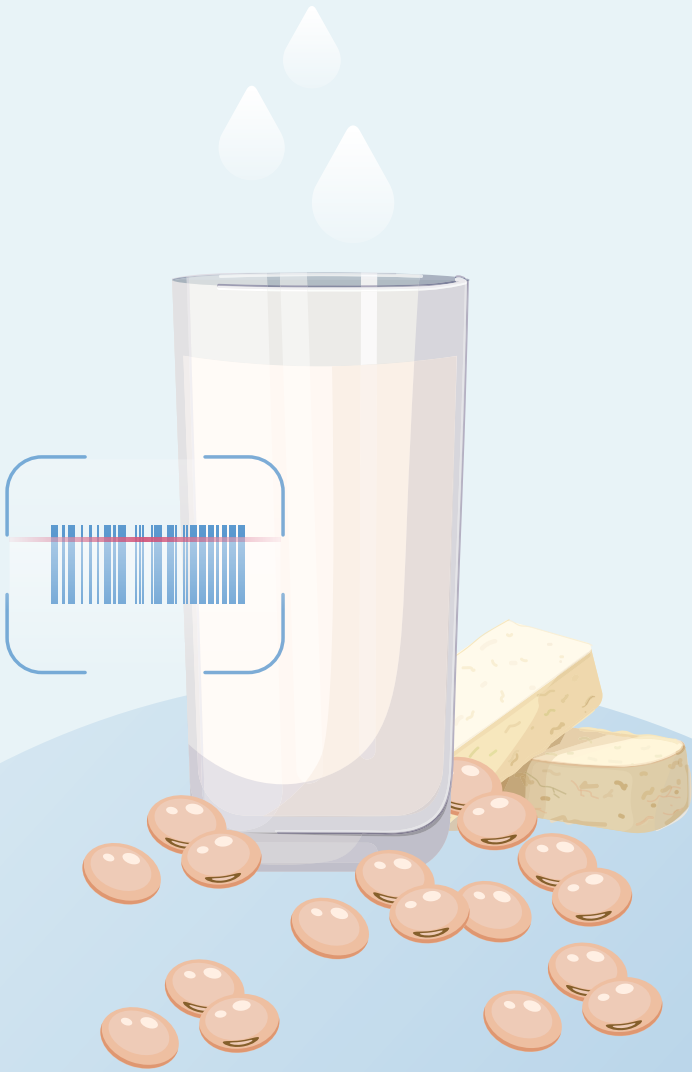
The food allergen labelling regulation is effective and provides safe commercial food products for the food-allergic individual (Surojanametakul *et al.,* 2021; Gendel and Zhu, 2013). Presently, many countries have enforced food allergen labelling regulations (University of Nebraska, 2020), and three typical regulations in the Asia-Pacific region were introduced in this document. In addition, some practices of how regulations on food allergens can be established were presented.

The approach to establishing the labelling regulation largely depends on the country and its restrictions, and so need to be tailored to the national context. Occasionally, the regulation can be initiated from the international requirement for the sake of exporting domestic food products. However, the ultimate goal must be the establishment of effective regulation that ensures the food safety of allergic individuals. The Japanese experience was fully described as a case study for establishing country-based regulations; however, this is only one example of what countries could do to achieve the food safety of allergic individuals.

4 Recommendations for food safety authorities

Below is a set of practical recommendations that national food safety competent authorities should consider:

1. Identify or develop a mechanism that regularly monitors the common food allergies in the national context.
2. Ensure clarity and readability of food labels, listing possible food allergens, and provide education on how to read them, especially to the allergic population.
3. Develop or strengthen collaborative mechanisms with the private sector, particularly with food e-commerce platforms and restaurants, to ensure that food allergens are explained to their customers, for example in menus.
4. Support research and development of diagnostic tools that could facilitate the detection of food allergies in humans.
5. Support research and development of diagnostic tools that could facilitate the detection of food allergens in foods.
6. Educate the population on the topic of food allergies through targeted communication campaigns aimed at raising awareness on the topic.
7. Contribute to global discussions, such as those at Codex Alimentarius, on food allergies by bringing national case studies and relevant data.



5 Resources

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Food allergies

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