กฎระเบียบอาหารก่อภูมิแพ้ของประเทศญี่ปุ่น (ใหม่)

กระทรวงสาธารณสุขแรงงาน และสวัสดิการญี่ปุ่น (MHLW) ได้มีการปรับปรุงกฎระเบียบเรื่องอาหารก่อภูมิแพ้ในอาหาร ซึ่งบังคับให้มีการติดฉลากอาหารในอาหารก่อภูมิแพ้จำนวน 7 รายการ (เดิม 5 รายการ) และแนะนำให้ติดฉลากอาหารจำนวน 18 รายการ (เดิม 19 รายการ)

ทั้งนี้ MHLW ได้มีการประกาศให้มีการบังคับใช้กฎระเบียบดังกล่าวตั้งแต่วันที่ 3 มิถุนายน 2551 และผ่อนผันได้จนถึงวันที่ 3 มิถุนายน 2553

- บังคับให้ติดฉลาก 7 รายการ ได้แก่

1. ข้าวสาลี (wheat)
2. โซบะ (buckwheat)
3. ไข่ (egg)
4. นม (milk)
5. ถั่วลิสง (peanut)
6. **กุ้ง (shrimp/prawn/lobster)**
7. **ปู (crab)**

- แนะนำให้ติดฉลาก 18 รายการ ได้แก่

1. ปลาหมึก (squid)
2. ไข่ปลา ikura (salmon roe)
3. เนื้อวัว (beef)
4. ถั่วเหลือง (soybeans)
5. วอลนัท (walnuts)
6. วุ้นเจลาติน (gelatin)
7. ลูกพีช (peaches)
8. มันแกว (yams)
9. ส้ม (oranges)
10. เนื้อหมู (pork)
11. เนื้อไก่ (chicken)
12. ปลาแซลมอน (salmon)
13. ปลาซาบะ (mackerel)
14. หอยเป๋าฮื้อ (abalone)
15. กีวี (kiwifruit)
16 แอปเปิ้ล (apples)
17. เห็ดโคนญี่ปุ่น (masutake)
18. กล้วย

<Annex 2>

FAQs on Labeling System for Foods Containing Allergens

Standards and Evaluation Division, Department of Food Sanitation,
Pharmaceutical and Medical Safety Bureau, Ministry of Health, Labour and Welfare

A. The need for mandatory labeling

A-1
What is "allergy" by food intake?

Reactions that cause an impediment to the living body due to food intake and immunological reactions against food antigens are referred to as food allergies. These immunological reactions function to protect our bodies from the intrusion of a foreign substance (antigen). They indicate that antibodies are being created. When antibodies become effective against the intrusion of an antigen thereafter, immune response is able to prevent disorders. However, individuals with allergies show sensitive reactions against certain antigens. The various allergic symptoms may include a drop in blood pressure, respiratory distress, or loss of consciousness. Antigens that cause such allergies are referred to as allergens.

Reactions to food that cause impediments to the living body include intolerable ailments caused by poisoning by toxins and defects in digestive enzymes. Distinctions must be made between food allergies and these latter two ailments.

A-2
What sorts of foods contain allergens?

The Ministry of Health, Labour and Welfare is now pursuing studies to elucidate the actual circumstances of food allergies and potential allergens under its Scientific Research Projects. Based on the results of studies up until now, from case examples which revealed a drop in blood pressure, respiratory distress, loss of consciousness, etc. at a certain frequency in the past, the Ministry has designated "Specified ingredients" as ingredients containing allergens clearly identified by foods taken by such patients concerned at the time. Specified ingredients recently designated include 25 items: shrimp/prawns, crab, wheat, buckwheat, eggs, peanuts, abalone, squid, salmon roe, oranges, kiwifruit, beef, walnuts, salmon, mackerel, soybeans, chicken, bananas, pork, *matsutake* mushrooms, peaches, yams, apples, and gelatin.

It is vital that information be provided so that an allergic patient can make informed choices of what food does or does not contain allergens to which he/she reacts. Therefore, when making available information concerning specified ingredients, etc. contained in foods based on "Ingredient labeling for

foods containing allergens" (hereinafter referred to as "allergen labeling"), due to the fact that actual cases of allergies and their frequencies differ, such ingredients are now being separated into two categories. One is for "mandatory labeling" by Ministerial Ordinance, the other "labeling recommended" by Notice.

The former category, designated mandatory by Ministerial Ordinance, consists of seven items: shrimp/prawns, crab, wheat, buckwheat, eggs, milk, and peanuts (hereinafter referred to as "Specified ingredients"). The latter lists 18 items: abalone, squid, salmon roe, oranges, kiwifruit, beef, walnuts, salmon, mackerel, soybeans, chicken, bananas, pork, "*matsutake*" mushrooms, peaches, yams, apples, and gelatin (hereinafter referred to as "items corresponding to specified ingredients") as items recommended for labeling.

Because it is considered that substances causing food allergies may change with the times, the "Food Allergy Study Group under the Research Project by MHLW " (hereinafter referred to as "Food Allergy Study Group") will perform further studies of circumstances and scientific research and, from such knowledge and reports that become available, the specified ingredients, etc. will be reconsidered and reexamined as appropriate.

A-3
Why did foods containing allergens become subject to mandatory labeling?

Because there were a large number of health hazards caused by food containing allergens, there was an increasing need to provide information to consumers by labeling in order to prevent such hazards. However, the labeling system that was effective until fiscal 2000 did not impose mandatory labeling, and therefore did not sufficiently inform consumers to enable them to know whether the food contained an allergen or not. In consequence, the Special Subcommittee on Labeling, Food Sanitation Investigation council held on 5 March 1999, in its "Study Report on Food Labeling (fiscal 1998)" concluded that mandatory labeling should be required for allergens in food. On 13 July 2000 the Special Subcommittee on Labeling published its report entitled "Labeling of genetically modified foods and foods containing allergens." This report, on the level and frequency of past health hazards, came up with a method of "labeling by name of specified ingredients, etc." for ingredients having actually caused serious allergic symptoms. It suggested 24 specified ingredients, etc. based on a survey of actual conditions.

Furthermore, a June 1999 Session of a Joint FAO/WHO Codex Alimentarius Commission agreed that labeling of foods containing eight kinds of ingredients known as allergens must indicate that the food contains such substances. Member nations are now in the course of investigating labeling methods suitable for their respective systems.

Based on such international movements, it was felt that the Food Sanitation Act (Act No. 233 of 1947) should be amended, and that foods containing allergens be labeled to the effect that they contain such substances was necessary from the viewpoint of preventing health hazards to consumers.

A-4

How should labeling under the Food Sanitation Act be viewed?

Article 19 of the Food Sanitation Act stipulates that necessary standards can be prescribed from the viewpoint of public health. Proper food labeling will provide accurate information to consumers and those in businesses concerned and contribute to reasonable awareness and informed selection. It will concurrently be indispensable for prompt and effective administrative control. Arrangements for food labeling can be summarized as follows:

○Functions to convey information to the consumer

(1) Labeling when a potential health hazard exists if attention is not paid to declared facts such as "Use-by date" and "How to store . . ."

(2) Labeling to make the contents of food understandable to the consumer, to enable informed choices from the viewpoint of public health. (Example: additives)

○Functions to convey information to distributors

(1) Presents facts to which attention should be directed for marketing/selling purposes, such as "Use-by date" and "How to store"

(2) Functions to enable seller to easily furnish information to the consumer by the label affixed by the manufacturer.

○Functions to promote observation of standards

(1) Psychological effect of labeling on traders. (For example, declaring all food additives used would prove to impede use of non-standard additives.)

(2) Information used by administrative authorities when confirming observance of specifications and/or standards. (For example, testing the amount of the additive used to confirm compatibility with specifications and/or standards.)

A-5

How should labeling be done to meet mandatory requirements prescribed by law to prevent inconsistency?

There is labeling under the Food Sanitation Act and labeling required by the Act concerning standardization and Proper Quality Labeling of Agricultural and Forestry Products (hereinafter referred to as "JAS Act"). Whereas the latter is labeling to enable informed choices by consumers, the former is labeling from the viewpoint of public health (viz. labeling indicating the danger of a potential heath hazard if attention is not paid to labeled facts; labeling to make contents of the food understood by consumers and to enable selection from the viewpoint of public health). What the two types of labeling aim at differs. Therefore, as it is not a matter of which has or should be given priority, labeling is a matter which should be observed in accordance with each of the laws and ordinances.

Aside from the above-mentioned, there is an Act for the Prevention of Improper Premiums (gifts) and Unlawful Labeling ("Premium Labeling Act"). This law controls improper, false, or exaggerated

labeling, but as declaring very small quantities is required in connection with allergen labeling, care must be taken so as not to mislead consumers. (Refer to C-3)

A-6

What are the opinions of the Allergy Labeling Investigation Council under the Food Labeling Study Group on the necessity of allergy labeling?

The purpose of the Food Sanitation Act is "to prevent sanitation hazards resulting from eating and drinking and to contribute in the improvement and enhancement of public health." It was decided that the labeling of foods containing allergenic substances should be made mandatory with an aim to prevent the induction of serious allergic symptoms based on such a principle. The items were reviewed thereafter, and under the current Ministerial Ordinance, it was decided that labeling is mandatory for seven specified ingredients with a high necessity of labeling, and that labeling is recommended for 18 items corresponding to specified ingredients, considering the number and seriousness of cases.

The Allergy Labeling Investigation Council defined the purpose of allergy labeling as "to make it possible for food allergy patients to avoid foods that may induce serious allergy symptoms and as a result make it possible for them to select products they can ingest."
Under this concept, by improving the method of allergy labeling based on the currently established legal framework, it is expected that accurate information on allergenic substances will become available when selecting processed foods.

In specific, there were strong opinions that the induction of allergic symptoms is prevented as result of allergy labeling, and also that it is desirable to implement labeling that allows allergy patients to select foods they can intake. The Council believes that labeling in such manner is desirable.

B. Items subject to allergen labeling

B-1

What is the scope of items subject to allergen labeling?

The scope of items subject to mandatory allergen labeling extends to foods and food additives offered for sale prescribed by Table 3 of the Food Sanitation Act Enforcement Regulations and based on Article 19 (Labeling standards) of the Food Sanitation Act. To be specific, the scope includes processed foods and additives coming in containers and packages. However, labeling on containers used for transportation (Refer to B-2) and packaged items of which the (exterior) space is less than 30 square centimeters may be omitted.

B-2

How should existence of specified ingredients be confirmed and labeled for products in the distribution (wholesale) stage?

When a container/package containing ingredient B at time of purchase is labeled to the effect that it contains specified ingredient A is used to manufacture processed food C, the processed food C shall also be allergen labeled to the effect that it contains specified ingredient A.

In the above-mentioned instance, items sold by the manufacturer of ingredient B as is through wholesalers and retailers to the manufacturer and seller of a processed food inclusive of the commodity shall require labeling. But when the wholesaler or retailer takes back the exterior container (such as a returnable delivery box, etc.) used for transporting or conveying merchandise on each such occasion, labeling may be omitted. Similarly, when food is manufactured and processed and sold directly to consumers, labeling shall not be required. In this context, processed foods sold by measure, placed in a box or wrapped for every sale for the sake of convenience or prepackaged or prewrapped foods to be sold during the day in expectation of a crowd are simply considered containers for transportation and labeling may be omitted. When items are boxed (whether in temporary or regular boxes) or wrapped by the seller at the request of the purchaser, labeling may likewise be omitted.

However, to also be able to provide information to consumers when using ingredients for which labeling is omitted, it would be useful to ask the supplier (wholesaler) whether or not an item contains specified ingredients, or to confirm the availability of details concerning ingredients together with the invoice or statement of delivery, and then to retain such information as manufacturing records for accurate labeling of the final product. Various means should be used to collect information, do accurate labeling, and to provide ample information to consumers.

B-3

How are the specified ingredients determined?

To prevent health hazards by foods containing allergens and as the cry for information through labeling became intensified as well as from other causes, research and studies were conducted by the Welfare Scientific Study Project to identify what allergens seriously affected health-caused anaphylaxis for example. In fiscal 1996 and 1997, a nation-wide food allergy frequency survey (on food allergies causing immediate reaction) by age was conducted. Then in fiscal 1998 and 1999, surveys on actual conditions were carried out through medical institutions throughout the nation on patients affected by immediate allergies. Physicians who directly performed food allergy diagnoses were consulted.

Any food can cause an allergy, such surveys indicated the study of foods that would be labeled because resultant symptoms were serious and there was a particular need to provide information. Based on study results and from case examples in which serious health hazards such as drop in blood pressure, respiratory distress, loss of consciousness, etc. occurred at certain frequencies in the past, 24 ingredients were designated as specified ingredients. This was done because they evidently could cause

allergies when ingested.

Since then, items have been reviewed based on the results of studies of actual circumstances implemented from fiscal 2001 to 2002 and in fiscal 2005, and there are currently 25 specified ingredients.

In addition, as it is felt that substances causing food allergies are bound to change with the times, further surveys of actual conditions and scientific studies will be performed by the Food Allergy Study Group and others, and reexamination of the situation will take place as appropriate, as new knowledge is acquired and reports become available.

* Revision of specified ingredients, etc. so far
  Fiscal 2004: "Banana" was added to items corresponding to specified ingredients
  Fiscal 2008: "Shrimp/prawns" and "crab" were added to specified ingredients

B-4
What is the difference between labeling of specified ingredients pursuant to Ministerial Ordinance and Notice?

As there was a difference in the actual number of allergy cases and the seriousness of the cases among the 25 specified ingredients, mandatory labeling by law and/or ordinance and recommended labeling by Notice, in other words, separate stipulations, were considered practical. The classifications are as described hereinafter.

(1) With the introduction of the labeling system, seven items-shrimp/prawns, crab, wheat, buckwheat, eggs, milk and peanuts-among the 25 items that were found to be the cause of the largest number of allergic cases and particularly serious, are designated to be subject to Ministerial Ordinance and mandatory labeling imposed by law.

(2) For 18 items among the 25, including gelatin, known to contain allergens but for which reported allergy cases are either small in number or serious cases are infrequent or, scientific knowledge is not always sufficient for the moment, labeling is recommended by Notice as being items corresponding to specified ingredients.

(3) As for "gelatin," its origin is largely beef and pork and as they are both items corresponding to specified ingredients, gelatin should be, originally, labeled accordingly. However, from the fact that allergies are caused by gelatin itself and as public comment strongly called for separate labeling (labeled "gelatin"), it was established as an independent item. (Refer to F-16 and F-19)

Because it is possible that substances causing food allergies may change with the times, the Food Allergy Study Group will carry on with its surveys of actual conditions and scientific research to revise the above decisions on specified ingredients, etc. accordingly, based on new knowledge and reports that become available.

<Regulations by Ministerial Ordinance/Notice>

Regulation concerned	Specified ingredients, etc.	Reason
Ministerial Ordinance	Egg, milk, wheat, shrimp/prawns, crab	Numerous cases reported.
	Buckwheat, peanuts	As cases are serious and could turn to be a matter of life-and-death, special attention is required.
Notice	Abalone, squid, salmon roe, oranges, kiwifruit, beef, walnuts, salmon, mackerel, soybeans, chicken, banana, pork, "*matsutake*" mushroom, peaches, yams, apples	Cases are few and will require further surveys for prescription by Ministerial Ordinance
	Gelatin	Its origin in many cases is either beef or pork which are items corresponding to specified ingredients and already require labeling as "beef" or "pork." However, as public comment was strong for separate "gelatin" labeling and also from opinions raised by experts, an independent item was established.

B-5-(1)
Is labeling required even if only an extremely small amount of the specified ingredient is present?

Food allergies can be caused by an extremely small amount of an allergen. Anaphylactic symptoms may be induced in some people by a mere lick of the food concerned. Therefore, foods that always contain allergens require labeling to the effect that such ingredients are present regardless of the intent of use as an ingredient.

B-5-(2)
When an extremely small amount of the specified ingredient is contained in the food, to what extent should it be labeled as an ingredient?

From the perspective of preventing health hazards, it was decided that the amount of substances inducing food allergy should be considered by focusing on the amount of total protein such as

specified ingredients within the processed food, rather than the amount of antigens such as specified ingredients (particular protein).

As for the amount of antigen inducing allergic symptoms, the consensus was reached that when the amount of total protein is at the mg/ml concentration (weight within ml of solution in the food load test) level, the symptoms almost always appear in general, while when it is at the few μg/ml level, whether the symptoms appear or not varies between individuals, and at the ng/ml level, the symptoms almost never appear.

Therefore, it is considered that foods containing more than a few μg/ml concentration level or a few μg/g content level of specified ingredients in terms of the amount of total protein need labeling. On the other hand, when the amount of the total protein of specified ingredients contained in the food is less than a few μg/ml concentration level or a few μg/g content level, there is no need to label them.

Furthermore, as for the judgment of the necessity of indicating ingredients of an extremely small amount, it is technically difficult to make a decision at a certain point in the production stage. Also, if it is judged at that certain point in the production stage, the amount of specified ingredients left in the end products could vary largely. Therefore, it is considered as appropriate that the judgment be made based on the amount of specified ingredients left in the end product.

If a new method to detect allergenic substances left in the food is developed in the future and it becomes possible to detect the protein amount of specified ingredients included in processed food at a few μg/ml concentration level or a few μg/g content level or less, it is considered that such methods should be sufficient to decide whether labeling is necessary or not.

* Note: mg (milligram) = 10^{-3}g, μg (microgram) = 10^{-6}g, ng (nanogram) = 10^{-9}g

B-5-(3)

Are allergic symptoms not caused if the specified ingredients contained is less than the μg/g content level?

In the Interim Report by the Allergy Labeling Investigation Council under the Food Labeling Study Group, the consensus was reached that the content of allergenic substances that may cause food allergies is the level of a few μg/ml at the largest, and that it is considered that it should hardly cause any allergic reactions in general at the ng/ml level or less.

Because the data accumulation concerning the amount inducing allergy is still limited, the Ministry of Health, Labour and Welfare will be engaged in research in the future as well.

B-6-(1)

If a specified ingredient is unintentionally mixed into a product (an occurrence of contamination) in the manufacturing stage even though it is not used as an ingredient, would labeling to that effect be required?

When food “B” is manufactured on a production line (with machinery, equipment, etc.) using a certain specified ingredient “A,” and thereafter another food “C” that does not use specified ingredient “A” is manufactured, specified ingredient “A” will, at times, get mixed into “C” despite washing and cleaning of the production line. In such a case, even if possible mixing cannot be totally denied, if the commingled substance can be judged to not be an ingredient, “A” will not be regarded as an ingredient of food “C,” and labeling will not be mandatory.

Nevertheless, food allergies can be caused by even a very small quantity of an allergen, so thorough washing and cleaning of the production line to prevent occurrence of contamination is important.

Control of production lines to keep track of what foods are being manufactured using what ingredients and providing relevant information to consumers as required is desirable. (Refer to B-7)

If the specified ingredient “A” always gets mixed, food “C” can be expected to contain “A” and therefore labeling must indicate this.

B-6-(2)

When an egg protein is detected in a chicken product that does not use eggs as an ingredient, how should it be labeled?

As for chicken products, it is reported that there are cases where egg protein is detected due to incorporation at the stage of processing chicken even though it is not used as an ingredient.

Even if the possibility of incorporation cannot be denied completely, if it is judged that egg does not constitute a part of the ingredients for the end product, the labeling is not mandatory.

B-6-(3)

Even if shrimp/prawns or crab are not used as ingredients, if there is a possibility for the end product to be contaminated by shrimp/prawns or crab, which are specified ingredients, due to reasons such as bycatch, fish that are used as an ingredient having preyed on shrimp/prawns or crab, the processing method of ingredients, etc., would labeling to that effect be required?

If shrimp/prawns or crab is always commingled in the end product, it is considered that shrimp/prawns or crab constitute a part of the ingredients, so labeling is necessary.

On the other hand, even if the possibility of incorporation cannot be denied completely, if it is judged that shrimp/prawns or crab does not constitute a part of the ingredients, labeling is not mandatory.

It is possible that products such as minced fish are contaminated with shrimp/prawns and crab at

various stages. However, in such a case, if the frequency of the unintentional incorporation of shrimp/prawns or crab is low or the amount commingled is small, it is considered that there is no need to call attention to it, because a warning notice may excessively limit the food choice of patients (refer to B-6-(4) and B-7).

(Reference)

For some minced fish using fish such as whitebait, baby sardines or those for which it is difficult to remove the gastrointestinal tract because of their shape, the incorporation test implemented by the Ministry of Health, Labour and Welfare confirmed that shellfish including shrimp/prawns and crab, which are the specified ingredients, are commingled in these foods.

* Results of incorporation test → http://www.nihs.go.jp/dnfi/manuscripts/konkaku.pdf

B-6-(4)

Is it necessary to call attention when cereals imported from abroad are contaminated by specified ingredients at the stage when they are used as ingredients?

There may be rare occasions when cereals imported from abroad are contaminated because of the use of common silos and transportation facilities (e.g. soybean and wheat). In such cases, if the frequency of the unintentional incorporation of cereals is low or the amount commingled is small, and there are very few alleged cases of food allergy caused by such incorporation, it is considered that there is no need to call attention to it, because a warning notice may excessively limit the food choice of patients.

B-7

How should attention be called to contamination?

If there is a risk of contamination, it is desirable to call attention to the possibility thereof in an area outside the ingredients column.

However, even outside the ingredients column, because “possibility labeling” such as “May contain (name of specified ingredients)” is not permitted (refer to C-1), it should clearly call attention when it is expected that specified ingredients may occasionally be commingled due to reasons such as the use of the same production line or the method of gathering.

(Examples of calling attention)

○ Contamination through the use of a common production line

- “The plant manufacturing this product produces products containing xxx (name of the specified ingredient).”
- “This product is manufactured at facilities that used X X (name of the specified ingredient).” etc.

○ Contamination through the method of gathering the ingredients

- Whitebait used in this product is gathered in a fishing method where crabs (name of the specified

ingredient) may be intermingled."

○ Contamination due to the shrimp/prawns or crab being preyed upon
- "The golden threadfin bream used in this product (*kamaboko*) preys on shrimp/prawns (name of the specified ingredient)."

B-8
Are there ways and means to prevent contamination at the time of manufacturing?

It is fundamentally undesirable for an allergen used for some other product to contaminate a certain product on the production line when manufacturing the product. Countermeasures should be taken to prevent occurrence of this. When a production line is used jointly to turn out several products, one way to prevent contamination is to start manufacturing products that do not contain specified ingredients after thorough washing and cleaning of the line. Of course, using dedicated tools as much as possible would also be effective.

B-9
Is labeling required for foods that go through a refining process such as distillation?

Processed foods in general go through various manufacturing/refining processes such as heating, concentration, filtration, distillation, etc. and become final products. During such processes, there is a possibility that allergens decrease their antigenicity or lose it entirely by denaturation of allergens.

However, all allergens have by no means been identified at present and as knowledge regarding what part of a substance has antigenicity is not sufficient, it is unknown what manufacturing or processing process would do away with the danger of allergens. It cannot be assumed that antigenicity has been eliminated from foods that have gone through various processes.

Consequently, it is difficult to judge whether labeling is required or not from the manufacturing process of processing specified ingredients, and unless either antigenicity cannot be noticed in the processed food or corresponds to substances, etc. of low antigenicity as per the report of the Food Allergy Study Group, labeling shall, in principle, be required. Further surveys will have to be conducted on individual foods to study the presence of antigenicity in a scientific manner. By doing so, processed foods (whey, soy oils, etc.) known to be allergenic from past cases should be made distinguishable through labeling.

B-10

Mandatory labeling for genetically modified foods is limited to only those destined for general consumers, but for what allergies does mandatory labeling apply to business use and processed food ingredients?

Allergen labeling is mandatory even if the item concerned is for business use or an ingredient is used for a processed food. Please ensure that mandatory labeling is performed.

B-11

How should labeling be done for products whose contents are not visible such as noodles in plastic cups, instant noodles, confectionaries (in Christmas stockings or special gift boxes or tins, etc.)?

The principle is that labeling must appear on the outside of the box, bag or container as practiced up till now. However, if labeling of the content is possible on the bag so much the better.

B-12

When pectinase is used as an additive and an allergen such as wheat, etc. is mixed to culture an enzyme, should even such a product become subject to labeling as it contains an allergen?

Labeling will not be required only if the enzyme is collected. But when the medium itself is to be mixed, it becomes subject to labeling as food containing an allergen.

C. Examples of forbidden labeling

C-1

Are there any regulations for possibility labeling such as “May contain (specified substance),” “Concern of possible contamination (by specified ingredients),” etc.?

“Possibility labeling” is not allowed.
If such labeling were to be recognized, some manufacturers may choose the easy way out to escape liability as provided in the Product Liability Act or as a means to avoid shouldering the responsibility

and resultant expenses for ingredient investigation. If easy-going "possibility labeling" were allowed, it is feared that even for merchandise that do not reveal allergic symptoms to allergic patients would tend to bear "possibility labeling" thus all the more narrowing options for patients.

C-2

Are there labeling methods that could substitute for indication of specified ingredients? What substitute declarations are forbidden?

The principle is to declare the name of specified ingredients (refer to Specified Ingredients Substitute Declaration List) in accordance with and as prescribed by Ministerial Ordinance and Notice. Complex or combined means of declaring specified ingredients such as described hereunder are not recognized.

<Examples of forbidden use of major classification/category names>

Correct labeling	Forbidden general or combined labeling
"Cereals (wheat, soybean) or "Wheat, soybeans"	"Cereals"
"Beef, pork, chicken"	"Meat," "animal X X"
"Apple, kiwifruit, peaches"	"Fruits," "fruit juice"

Note: This by no means forbids labeling of even "Cereals" and so on that do not contain allergens.

However, due to reasons related to manufacturing processes and others, this is limited to the undermentioned foods only. In such cases labeling may be as follows:

Exceptionally prescribed labeling	Reason
"Protein hydrolytic substance (fishes and shellfishes)" "Fish sauce (fish and shellfish)" "Minced fish (fish and shellfish)" "Fish oil (fish and shellfish)" "Fish extract (fish and shellfish)"	As netted catch is used as ingredients on the spot, what sort of fishes and shellfishes go into the product cannot be identified

C-3

As concerns processed foods that contain only a very small quantity of high-grade (expensive) ingredients (such as abalone, salmon roe, "*matsutake*" mushroom, etc.), allergen labeling could give the impression that such are contained in large quantities, etc. and may mislead consumers. Do regulations in such respects exist?

There is concern that labeling that would give the impression that expensive ingredients (abalone,

salmon roe, "*matsutake*" mushroom) among specified ingredients are contained in large quantities although only a very small amount is contained, and that this would mislead consumers. Therefore, a declaration regarding their contents and a form such as "contains X X essence," etc. is recommended. As labeling is supposed to provide accurate information to consumers, labeling should not cause the misunderstanding that these are the main ingredients.

<Labeling examples>

Specified ingredients	Labeling examples
Abalone	"Powdered abalone" when a small amount of abalone in powder form is used
"*Matsutake*" mushroom	"*Matsutake*" mushroom extract" if essence extracted from "*matsutake*" mushroom is used

C-4
What sort of measures are taken when allergen labeling is not done properly?

According to the provisions of Article 19, Paragraph 2 of the Food Sanitation Act, foods, additives, utensils, containers/packages for which labeling standards have been prescribed by the Minister of Health, Labour and Welfare shall not be sold, displayed for sale or used for business purposes unless relevant labeling conforms to standards. In case where the trader violated such provisions, prefectural governors may:

(1) indicate mandatory labeling requirements to the trader, and instruct the trader to observe regulations.

(2) when the trader violates a. above, revoke the trader's business license, prohibit all or port of the business, or suspend all or part of the business for a certain period.

Any person who does not obey such an order shall be punished by penal servitude of not more than 2 years or by a fine of not more than 2 million yen (100 million yen in the case of a corporate body).

C-5
Is labeling indicating "Contains some ingredients of xx origin" permissible?

In connection with the JAS Act, two types of labeling, i.e. "Some ingredients contain x x" and "Also contains ingredients of x x origin" were allowed in the past. However, because an increasing number of consumers now want to know what food contains what allergen, such as for each side dish in a box lunch, it was decided to add and allow "△△ (contains ○○,○○)" type labeling, which indicates individual specified ingredients in parentheses directly after individual ingredients. Please have labeling

in accordance with one of the three.

Combined use of more than one of these labels are not allowed.

<Example of Labeling>

Food	Example of labeling
Sauce for grilled meat	Shoyu (contains wheat), sugar, onion, tomato, garlic, sesame oil, red pepper, black pepper, monosodium glutamate, preservative (sodium benzoate)
Potato salad	Potato, carrot, ham (includes pork), mayonnaise (contains soybean oil), protein hydrolysate, seasoning (amino acid), color fixative (nitrous acid Na), sodium phosphate

* Labeling within ( ) in protein hydrolysate (including pork) of potato salad is declared in ham and thus labeling is not required.

C-6

When allergen labeling is declared separately and outside the comprehensive label of the product concerned, can ingredient labeling be omitted?

Even if allergen labeling is performed in a separate space, allergen labeling may not be omitted from ingredient labeling.

D. Allergen labeling of food additives

D-1

When a “food additive” manufactured from specified ingredients is used to manufacture a food, is similar labeling required?

Ingredients other than those in which antigenicity has not been recognized among food additives require labeling to identify specified ingredients used. Method of labeling is as follows:

(1) In principle, declaration should be “Name of substance (X X origin).”

(2) When food additives are usually referred to by a general name such as emulsifier, flavoring (seasoning), etc., declaration may use such a general name (X X origin).”

(3) In the case of food additives referred to together with their use, such as sweetener, this should

be labeled as “Name of use (Name of substance: X X origin)” or “Name of use (Name of substance (X X origin)). However, in terms of ease to read, using “:” is more desirable than using double parentheses.

Also, as for food additives that are made of two or more specified ingredients, this should be labeled as Name of use (Name of substance: X X/△△ origin, name of substance: ●●/▲▲ origin).

(4) In the case of food additives that are recognized by a substitute or a simplified name as to mean “eggs,” “soybeans,” “milk,” etc., labeling may be omitted by the mention of such names.

The way to look at it is to not change contents declared and method of food additives practiced in the past. For those that cannot be taken to be of specified ingredients, origin from past declaration methods, (X X origin) is to be mentioned.

See Annex 1: Labeling examples for food additives of specified ingredients origin.

D-2

It is said that allergen labeling is exempt at times even if a food additive used is manufactured from specified ingredients. In what sort of case is it exempt?

Even if it is food additive of a specified ingredient origin, when it is determined that antigenicity cannot be recognized from antigenicity tests, mandatory labeling shall be exempt.

The antigenicity test referred to here is based on “Guidelines for Amendments to Designation of Food Additives and Standards for Use “ presently used to examine food additives. When the existence of antigenicity is unclear labeling shall be required.

In the event the Food Allergy Study Group reports that antigenicity is low, labeling shall also be exempt. Therefore, antigenicity of calcinated eggshell calcium is unknown, and as for additives in that the existence of other substances cannot be recognized from only pure specific ingredients extracted such as tocopherol, etc. extracted from soybeans labeling relative to specified ingredients shall be exempt.

Whether allergen or not, whether allergenicity is high or low, etc. are matters in which studies are far from being complete, case examples as well the mechanisms that cause allergies will have to be inspected, and including the way low molecule substances present antigenicity are subjects that will have to be studied.

D-3

Do traces of food additives remaining such as processing aids, carry-over, etc. require labeling?

Carry-over (*1) and processing aids (*2), etc. are commonly exempt from food additive labeling, but food additives of specified ingredients origin shall require labeling as follows:

(1) Regarding the seven items (by Ordinance) for which mandatory labeling is required, carry-over and processing aids shall be identified in final product labels.

(2) Regarding the 18 items (by Notice) for which labeling is recommended, please undertake to perform labeling as much as possible.

Furthermore, because excessive labeling would limit the choice of consumers, the labeling method in the case when an extremely small amount of the specified ingredient is contained should follow B-5-(2).

*1 Carry-over	: This is with reference to a substance used in food ingredient manufacturing or processing but not used in manufacturing and processing of the food concerned, and the contents of which are less than the quantity by which it can demonstrate its effect in such food.
*2: Processing aid	: This is with reference to a substance added at time of processing, eliminated prior to completion of the food concerned, originates from the ingredient of the food concerned, converted to a constituent identical to the ingredient normally contained and although it does not clearly increase the volume of such a constituent or the volume contained in the food concerned, it is small, and the constituent does not affect the food concerned.

D-4

When a food manufactured from specified ingredients is used to stabilize food additives, is labeling of specified ingredients required?

When a food manufactured from the specified ingredients is used for stabilization of a food additive (Example: Dilution by soy oil to stabilize food additive extracted tocopherol), labeling such as “Tocopherol (contains in part soybeans as an ingredient)” is required so that the use of the specified ingredients can be known.

Use of secondary agents in conjunction with flavorings shall be labeled likewise.

D-5

As regards casein that is “An item commonly provided as food and used as a food additive (common food and drink additive),” does it have to be labeled “milk origin” as with food additive labeling?

Although it may be used as an ingredient (when it itself is used) and not as a food additive, labeling

“Casein (milk origin)” is permissible.

For details of specified ingredient labeling of milk, please refer to Query group H.

	Labeling in the past	Specified ingredient labeling
Food	Casein	Casein (milk origin)
Common additive for eatables and drinkables	Casein	Casein (milk origin)
Food additive	Sodium caseinate	Sodium caseinate (milk origin)

D-6

The answer to D-2 above mentions “Only pure specific ingredient is extracted, and what is recognized as being free of any other substances is exempt from required labeling of specified ingredients.” But if the final product is 100% L-leucine of which “soybean protein hydrolytic substances” is the initial ingredient, would it come under the same category?

For L-leucine, there are no reported cases of allergies from simplex amino acid so if the specified constituent of the final product is 100% it would correspond to this.

E. Allergen labeling of flavorings, alcohols, etc.

E-1

Specified ingredients are at times used as ingredients for flavoring. Are they subject to such labeling?

Knowledge as to flavorings actually being the cause of allergic diseases is limited, and therefore specified ingredient labeling is not a requisite at present. However, in consideration of the fact that even a very small quantity could cause allergic symptoms, further surveys and studies are required. When a secondary agent manufactured from one of the 25 specified ingredients is used aside from an aromatic constituent, labeling becomes necessary. Again, when specified ingredients are used as a secondary agent for flavorings, labeling such as “Flavoring (contains X X in part as ingredient)” is required.

E-2
Alcohol and the like sometimes use wheat and fruit as ingredients. Are these also subject to labeling?

Knowledge as to flavorings actually being the cause of allergic diseases is limited, and therefore specified ingredient labeling is not a requisite at present. However, in consideration of the fact that even a very small quantity could cause allergic symptoms, further surveys and studies are required. When a secondary agent manufactured from one of the 24 specified ingredients is used aside from an aromatic constituent, labeling becomes necessary. Again, when specified ingredients are used as a secondary agent for flavorings, labeling such as "Flavoring (contains X X in part as ingredient)" is required.

E-3
In the manufacture of fermented foods, specified ingredients are at times used as a constituent used to culture the starter for lactic acid bacteria used to initiate fermentation. In such cases, would specified ingredients be subject to labeling?

Among culture media of starters used for fermented products, detected specified ingredients used as constituents that finally remain in the food is regarded as an ingredient. However, if remains are not detected and also not treated as an ingredient, labeling is not required.

E-4
The answer to E-2 mentions "Industrial alcohol manufactured from drinking alcohol and skimmed milk is not subject to mandatory labeling at present," but when industrial alcohol manufactured from skimmed milk is used for food, what would be the consequences?

As industrial alcohol manufactured from drinkable alcohol and skimmed milk whey is not subject to mandatory labeling at present, industrial alcohol manufactured from drinkable alcohol and skimmed milk also does not require labeling.

F. Scope of specified ingredients

* The scope of specified ingredients pertains to, in principle, the scope designated by numbers of Annex 2, Japan Standard Commodity Classification. Refer to Appendix 2: Scope of specified

ingredients (Source: Japan Standard Commodity Classification), Notice No.79 of 15 March 2001. Refer to Appendix 2.

F-1
What is the scope of the specified ingredient “eggs?”

Whether chicken eggs only or eggs of other birds should be included is a difficult judgment to make, but as cross reactions are recognized (those who are allergic to chicken eggs are, at times, also allergic to eggs of other birds), labeling is not limited to chicken eggs and includes eggs of all commonly edible birds such as those of ducks, quail, etc. However, eggs of other living things such as fish, reptiles, or insects are not included in this category.

The requirement is not limited to whole eggs. If yolks or whites are separated, labeling indicating this is required. It goes without saying that the use of raw eggs requires labeling, but don't forget that the use of liquid eggs, powdered eggs, frozen eggs, etc. also require labeling to the effect that “eggs” are used.

F-2
What is the scope of the specified ingredient “wheat?”

Wheat flour is representative of wheat. Wheat is classified as common wheat, semi-strong wheat, strong wheat, durum wheat, etc. from the difference in gluten content. They are all subject to wheat labeling. It is the same with wheat flour classified as strong flour, semi-strong flour, soft flour, durum semolina, special flour, etc.

Wheat is very frequently used as part of a food ingredient. Most often a mere glance at the final food product will not tell you whether wheat is used or not. Allergies caused by wheat are serious, and Westernization of eating habits in this country has led to an increase of wheat allergy patients, and wheat has become one of the main ingredients causing an immediate type of allergy. By no means should labeling be forgotten.

Labeling to indicate barley or rye is not mandatory.

F-3
What is the scope of the specified ingredient “milk?”

The requirement for “milk” among specified ingredients covers any food prepared or manufactured from cow's milk. Milk other than that of cows (goat milk, sheep milk, etc.) is not subject to labeling at

present.

"Milk" is as referred to in "Ministerial Ordinance (Ordinance No.52 of 1951 of the Ministry of Health and Welfare) on constituent standards, etc. for milk and Milk products," hereinafter referred to as "Milk, etc. Ministerial Ordinance" and items corresponding thereto. Excluding milk other than cow's, this ordinance applies to "raw milk, normal liquid milk, certified milk, modified milk, low-fat milk, fat-free milk and processed milk." "Milk products" would refer to "cream, butter, butter oil, cheese, concentrated whey, ice cream products, concentrated milk, concentrated skim milk, evaporated milk, evaporated skim milk, sweetened skim milk, sweetened condensed skim milk, whole milk powder, skim milk powder, cream powder, whey powder, protein concentrated whey powder, butter milk powder, sweetened milk powder, formulated milk powder, fermented milks, lactic acid bacteria drinks, milk drinks."

All such items are individually defined and items that do not come under those definitions cannot be labeled by names corresponding to them. Therefore, although milk may be the main ingredient, foods that do not fall under this definition are classified "Foods in which the main ingredient is milk or a milk product."

Now subject to labeling are milk, milk products and food products in which milk or a milk product are used as a main ingredient, and other products in which milk ingredients are used (even if only in a small quantity).

F-4

What is the scope of the specified ingredient "buckwheat?"

Buckwheat has long been widely known as an allergen causing serious symptoms in Japan. Some patients show serious symptoms even if an extremely small amount of buckwheat is mixed.

As a specified ingredient "buckwheat" is used in flour form in such foods as noodles, buckwheat cookies, buckwheat steamed buns, and buckwheat cakes, labeling is required for all.

Buckwheat, at times, is used as a seasoning (Chomiryo) in pepper, etc. so processed items should be minutely checked and ingredients confirmed to ensure accurate labeling.

F-5

What is the scope of the specified ingredient "peanuts?"

Peanuts are widely used in various cuisines. As peanut oil, peanut butter, etc. they become an allergen so careful attention must be paid.

Cases of peanut allergies were extremely rare in Japan in the past, but patients are on the increase, and the tendency is forecasted to continue. Small-sized peanuts rich in oil are generally used to extract oil and large-sized peanuts rich in protein are eaten as food. They are both subject to labeling.

F-9

What is the scope of the specified ingredient “shrimp/prawns?”

“Shrimp/prawns” is “shrimp/prawns” as classified by Japan Standard Commodity Classification No. 7133 (excluding the Japanese spiny lobster, and crawfish and its sort), as well as the Japanese spiny lobster, fan lobster, and crawfish shrimp and its sort as classified by Japan Standard Commodity Classification No. 7134. In specific, Japanese tiger prawns and its sort (kuruma prawns, taisho prawns, etc.), shiba shrimp and its sort, sergestid shrimp and its sort, river prawn and its sort, small shrimp and its sort (hokkai shrimp, snapping shrimp, sweet shrimp, etc.), and other shrimp/prawns, as well as Japanese spiny lobster and its sort, fan lobster and its sort, and crawfish and its sort (lobster, etc.) are subject to labeling.

Although Japanese lobster, fan lobster, and crawfish and its sort had been excluded from the scope of “shrimp/prawns” for the sake of allergy labeling in the past, they were newly added to the scope of “shrimp/prawns” as a specified ingredient according to the results of a study by the Food Allergy Study Group.

F-7

What is the scope of the specified ingredient “crab?”

“Crab” is “crab” as classified by Japan Standard Commodity Classification. “Golden king” crab and its sort (king crab, “Hanasaki” crab, “Abura” crab), spider crab and its sort (snow crab, “takaashi” crab), “watari” crab and its sort (swimming crab, “ishi” crab, “hiratsume” crab, etc.), “kuri” crab and its sort (horsehair crab, “kuri” crab) and other crabs and their sort are subject to labeling.

F-8

What is the scope of “abalone,” an item corresponding to specified ingredient?

Abalone and its sort mainly refer to “abalone” and “Japanese abalone,” but only “abalone” is subject to labeling at this time. The outward appearance of Japanese abalone closely resembles abalone, but it can be distinguished by its 7-8 breathing apertures, compared to 4-5 for abalone.

Japanese abalone is currently not subject to labeling as its antigenicity cross reaction has not been confirmed. This is a matter requiring further study to define its scope. “Abalone” referred to here is “abalone” as classified by Japan Standard Commodity Classification and covers everything being distributed as “abalone,” whether of domestic origin or imported.

F-9

What is the scope of "squid," an item corresponding to specified ingredients?

Every kind of squid is subject to labeling. To be more precise, it includes firefly squid and its sort, Japanese common squid and its sort, arrow squid and its sort, cuttlefish and its sort and other squid and its sort (mimika bobtail, pygmy squid, boreal clubhook squid, etc.).

F-10

What is the scope of "Ikura" (salmon roe), an item corresponding to specified ingredients?

"Ikura" refers to roe of salmon, trout, etc. in granular form after removing the ovarian membrane and salted. "Sujiko" refers to the salted whole ovary of such fishes without removing the membrane. Therefore, it falls within the category of an item corresponding to a specified ingredient, considered identical to salmon roe and is to be labeled likewise.

F-11

What is the scope of "oranges", an item corresponding to specified ingredients?

According to the Japan Standard Commodity Classification, oranges are a citrus fruit. The scope of "oranges" for allergen labeling refers to navel oranges, Valencia oranges, etc., all commonly called oranges. In consequence, Satsuma mandarins (tangerines), citrus natsudaidai (summer oranges), "Hassaku" oranges, grapefruits, lemons, etc. are not subject to labeling.

F-12

What is the scope of "beef," "pork" and "chicken," items corresponding to specified ingredients?

Meat itself is subject to labeling, but internal organs classified separately from meat according to the Japan Standard Commodity Classification when they include the derma of the ear, nose, skin, etc., in particular, are subject to labeling. Animal fat (lard, tallow) also require labeling. However, internal organs (including casing materials), skin (limited to those which do not include derma) and bones (limited to those from which meat has been removed) among the aforesaid do not require labeling for the time being.

F-13

What is the scope of “salmon” an item corresponding to specified ingredients?

“Salmon” now subject to labeling refers to salmonid, including the salmon and salmo genera. It does not include landlocked salmon. To be specific, they are of an anadromous salmon and trout family such as chum salmon, sockeye salmon, silver salmon, king salmon, masu salmon, and pink salmon.

Salmon is the generic name with reference to salmon, sockeye salmon, silver salmon, king salmon, etc. Landlocked rainbow trout, Kokanee, etc. are generally referred to as trout, but as there is no scientific classification for trout and its sort they are all referred to and classified as salmon and its sort.

Current labeling requirements are for fishes generally sold as “salmon.” Landlocked rainbow trout, charr, and “masu” trout, etc. are excluded.

F-14

What is the scope of “soybeans” an item corresponding to specified ingredients?

The scope of “soybeans” for labeling purposes includes unripe green soybeans, soybean sprouts, etc., and those which have germinated.

There are various kinds of soybeans classified according to color, size, and shape. Yellow colored soybeans are used to make “miso,” soy sauce, “natto” (fermented soybeans) and tofu. The specification as applies to green colored soybeans (referred to as green peas, confectionary soybeans) used to make soybean flour, confectionary and its sort and black-colored (black soybean) for cooking.

All are subject to allergen labeling.

F-15

What is the scope of “yams,” an item corresponding to specified ingredients?

“Yams” covers “yamanoimo” under the Japan Standard Commodity Classification, which includes Japanese yams, Chinese yams, Tsukune yams, “gingko” yams, and Yamato yams.

Popular yam foods are “tororo” (grated yam), “yamakake,” and “tororo soup.”

F-16

What is the scope of “gelatin,” an item corresponding to specified ingredients?

The main ingredients which go into the making of “gelatin” are beef and pork. Gelatin is used as an ingredient in a great number of processed items.

There is no clear classification for “gelatin” according to the Japan Standard Commodity Classification, but any product used as an ingredient marketed as “gelatin” is subject to allergen labeling.

F-17

Is animal blood, gall or blood plasma subject to labeling?

Labeling is not required for animal blood, gall or blood plasma in isolation. However, if bits of meat are mixed labeling becomes necessary.

F-18

Note 2 of Table 2 giving examples of “Food additives of specified ingredient origin” mentions “Collagen (beef or pork). Isn't “Origin X X” type labeling required?

“Origin X X” type labeling is required if collagen is used as an additive, but if collagen itself is to be taken as is, it is not required.

F-19

When gelatin is used as an ingredient, should labeling be such as “gelatin (cow origin)”, “contains gelatin,” etc?

Labeling gelatin alone as an ingredient will suffice. Notations such as “origin X X” or “contains X X” are not required.

F-20

Is labeling required for landlocked salmon or anadromous rainbow trout but are raised at sea?

Salmon and trout are considered to be the same kind of fish. As it was decided that anything caught at sea would be subject to labeling, fishes raised at sea are subject to labeling. Salmon and trout should be labeled “salmon,” etc.

G. Substitute declaration and specified processed food

G-1

Does labeling of specified ingredients always have to be in accordance with prescribed methods?

There are space and other limitations when it comes to actual labeling. Some believe that if the certain common declaration is suggestive of a specified ingredient it should be allowed, but if, for example, it turns out to be a difficult Chinese character, etc. which an average consumer would find difficult to understand such a declaration would be useless. Responses to questionnaires passed out to allergy patients (children, their guardians, adults) have been studied. The results led to the decision to recognize the substitute declarations of the type described below as being basically understandable, even by children with allergies who buy snacks themselves.

Substitute declarations listed below can be used (see *1). Indications of specified processed foods (see *2) can be used along with other means. Such methods will be reexamined and reconsidered as required.

-> Appendix 3: Substitute Declaration List for Specified Ingredients, etc.

If a name identifying a specified ingredient, etc. and a declaration prescribed by the Substitute list is in the name of the ingredient, that will serve the purpose of declaration as regards specified ingredients.

-> Deep fried spring chicken, fried prawn, soybean oil, wheat starch, etc.

*1 Substitute declaration: Declaration by which it can be understood to be identical to specified ingredients, although means of declaration or language differs from specified ingredients. (Refer to Query H for “Milk”)

1) Eggs:

Any phonetically identical declaration will be accepted as use of the specified ingredient “egg” can be understood. Substitute declaration will be expanded and items such as “thick fried egg loaf,” “ham and eggs,” “egg yolk,” “egg white” considered as to be readily understandable that egg is used are recognized as declarations relative to this specified ingredient.

2) Salmon:

Any phonetically identical declaration will be recognized as a substitute declaration as it can be understood that “salmon” is used. But, “trout” cannot be taken to indicate “salmon” and it is not recognized as a substitute declaration. (Refer to F-13 for definition of salmon and trout)

Expanding Substitute declaration and declarations such as “salmon flakes” and “smoked salmon” will serve the purpose of specified ingredient declaration.

3) Soybeans:

Any phonetically identical word will be recognized as a substitute declaration, but “edamame (green soybeans),” “bean sprouts,” “kuromame (black soybeans)” will not be recognized as it is generally difficult to tie such to soybeans. Therefore, labeling should be declared “edamame (soybeans),” “soybean sprouts,” etc. As expanded substitute declarations, “soy oil,” defatted soybeans” can serve as a declaration corresponding to specified ingredients.

*2 Specified processed food: Processed food which can be understood that specified ingredients, etc. are contained as an ingredient without declaration as it is generally known that such are made from specified ingredients, etc.

1) Squid:

It is generally known that the ingredient of "surume (dried cuttlefish)" is "squid" so "surume" will serve as specified ingredients, etc. declaration.

2) Wheat:

It can be generally understood that "wheat" is an ingredient which goes into the making of "bread" and "noodles." For confectionary, however, in which milk products are used in addition to wheat, "wheat" may be omitted from labeling but "milk products" can not.

For specified processed foods, when "wheat," "milk," "cream," etc., are used as ingredients for making "rolls," declaring "bread" as concerns "wheat" may be omitted but labeling should include "milk and eggs." Therefore, labeling such as "rolls (contains milk and eggs in part as ingredients)" is required.

Declarations for items such as "spaghetti," "Chinese noodles," "flour paste," etc. cannot be generally understood to mean that "wheat" is an ingredient. For these items declaring to the effect that "wheat" is an ingredient is necessary.

3) Soybeans:

It can be understood that an ingredient of "shoyu (soy sauce)" is the soybean. However, when soybeans and wheat are used as ingredients for shoyu, declaring to the effect that wheat is used is required. In other words, even though "soybeans" may be omitted, wheat requires declaring by means such as "shoyu (wheat, salt, etc.)" or "shoyu (contains wheat in part as ingredient)"is required. Other examples of specified processed foods include "tofu, "miso," etc.

Furthermore, declarations which cannot be recognized as specified processed foods (generally cannot be understood to be so) are "okara (bean curd lees)", "kinako (soybean flour),"etc.

G-2

If all specified ingredients used for a processed food were to be minutely declared, labeling space is far from sufficient. What should be done?

In case of duplicated use of the 25 specified ingredients, omission may take place as follows:

(1) For compound cooked and processed foods which use compound ingredients (food ingredients consisting of two or more kinds of ingredients, e.g. flour paste as per Example 1.) containing specified ingredients, all ingredients (including ingredients of compound ingredients) may be labeled in descending order by weight, but not to the extent not to mislead consumers.

<Example 1> In case declared without parentheses

Compound cooked and processed food	Ingredient	Examples of declaration in which omission is possible

Cream puff	Flour paste (wheat flour◎), corn starch, sugar, soybean oil●, etc.), eggs★, cow's milk▲, sugar, wheat flour◎, starch (wheat flour◎), salt	Egg★, cow's milk▲, sugar, wheat flour◎, starch, soybean oil●, salt

* ★, ▲, ◎, ●, Those marks are inserted for easy recognition and are not required for actual labeling.

(2) For foods in which ingredients are generally mixed (potato salad, biscuit, etc.) or eaten together with other items (individual dishes), use of specified ingredients, etc. in processed foods may be labeled by declaring to the effect that specified ingredients are used by indicating in parentheses (contains in part soybeans, wheat, ..., ... as ingredients) at the end of ingredients labeling after labeling according to the JAS Act.

As for labeling of specified ingredients, there is no need to repeat labeling of ingredients. (In Example 2., regarding "whole milk powder," "whey powder (milk product)," "casein Ca (milk origin)," and "casein Na (milk origin)" in biscuits, as "whole milk powder" is a substitute declaration for "milk" and as the specified ingredient labeling relative to other "milk" has already been declared it may be omitted.

<Example 2> Declarations

Compound cooked and processed food	Ingredient	Examples of declaration in which omission is possible
Potato salad	Potato, carrot, ham (pork*, salt, sugar, etc.), mayonnaise (egg★, soybean oil●, fermented vinegar, etc.), protein hydrolysate (pork*), seasoning (amino acid, etc.), color fixative (nitrous acid Na), phosphoric acid Na	Potato, carrot, ham, mayonnaise★, protein hydrolysate, seasoning (amino acid), color fixative (nitrous acid Na), phosphoric acid Na (ingredients in part contain pork* and soybean oil●)
Mixed vegetables with beans	Soybean●, carrot, lotus root, dried mushroom, burdock, sugar, shoyu (soybean●, wheat◎, salt, etc.), sake, sweet sake, soybean oil●, salt, seasoning (amino acid), emulsifier (soybean● origin)	Soybean●, carrot, lotus root, dried mushroom, burdock, sugar, shoyu, sake, sweet sake, soybean oil●, salt, seasoning (amino acid), emulsifier (ingredients in part contain wheat)
Noodle sauce	Shoyu (soybean●, wheat◎, salt, etc.), dried bonito, kelp, amino acid fluid (wheat◎ origin), sugar, salt	Shoyu●, dried bonito, kelp, amino acid fluid, sugar, salt (ingredients in part contain wheat ◎)
Biscuit	Wheat flour◎, sugar, egg★, whole milk powder▲, whey powder (milk product▲), casein Ca (milk▲ origin), casein Na (milk▲ origin)	Wheat◎, sugar, egg★, whole milk powder▲, whey powder, casein Ca, casein Na

* ★, *, ◎, ●, ▲: Those marks are inserted for easy recognition and are not required for actual labeling.

(3) Items or matters which require labeling for foods in which several compound cooked-processed foods are packed together (including boxed lunches) have become numerous, and there is concern that it would be rather difficult for consumers to understand what they are about to buy.
It is also impossible to actually have allergen labeling practiced for each and every compound cooked-processed food item. In such cases, the solution is to declare, in parentheses, between ingredient labeling and additive labeling, "also includes xx, xx of xx origin." What is required is to make it possible to grasp and control information regarding what sort of specified ingredient is in what compound processed food to enable quick and pertinent responses. (Refer to query I-7 for how to provide information)

<Example 3> Declarations for packed compound cooked-processed foods

Packed foods	Names of ingredients	Examples of declarations that may be omitted
Packed cuisine	Deep fried spring chicken (chicken◇, starch, corn starch, wheat◎, soybean oil●, shoyu (soybean●, wheat flour◎, etc.), curry croquette (potato, soybean oil●, wheat flour◎, bread crumb◎, hen's egg★, onion, carrot, pork*, sugar, salt, curry powder), salami sausage (meat (pork*, beef○), binding agent(wheat flour◎, soybean protein●), salt, sugar, etc.), prawn broiled with salt (prawn☆, salt), edamame (soybean●, salt), fried potato (potato, vegetable oil, salt, spice), processed cheese▲, tomato, color fixative (nitrous acid Na), preservative (sorbic acid K), seasoning (amino acid), phosphoric acid Na	Deep fried spring chicken◇, curry croquette, salami sausage, prawn broiled with salts☆, edamame, fried potato, processed cheese▲, tomato, (also includes wheat◎ egg★, soybeans●, beef○, pork* origin ingredients), color fixative (nitrous acid Na), preservative (sorbic acid K), seasoning (amino acid), phosphoric acid Na

Variety lunch box	Rice, vegetable fritters (onion, carrot, burdock, wheat flour◎, vegetable oil, starch, garland chrysanthemum, powdered albumen★), deep fried spring chicken (chicken◇, starch, corn starch, wheat flour◎, soybean oil●),cooked vegetables (taro, carrot, burdock, lotus root, sugar, dried bonito soup stock, kelp soup stock, spice, shoyu (soybeans●, wheat◎, salt, etc.), grilled salmon (salmon◆, salt), spaghetti (wheat flour◎, egg★, vegetable oil, salt), fried prawn (prawn☆, wheat flour◎, bread crumb◎, vegetable oil, starch, powdered albumen★), potato salad (potato, carrot, onion, mayonnaise (egg★, vegetable oil, fermented vinegar, etc.), salt, fried cake of minced meat (beef○, powdered vegetable protein (soybean●), onion, tomato, soybean oil●, wheat flour◎, bread crumb, starch hen's egg★, beef extract○), pickled sliced radish (radish, kelp, salt, sugar, fermented vinegar, shoyu (soybeans●, wheat◎, salt, etc.), garnish, seasoning (amino acid, etc.), acidity regulator, glycine, color (caramel, carotenoid, red #102, red #106, safflower yellow), flavorings, raising agent, sweetener (licorice), preservative (sorbic acid K)	Rice, vegetable fritters, deep fried spring chicken◇, cooked vegetables (taro, carrot, burdock, lotus root, etc.), grilled salmon◆, spaghetti, fried prawn☆, potato salad, fried cake of minced meat, pickled sliced radish, garnish, (also includes wheat◎, egg★, soybeans●, beef○ origin ingredients), seasoning (amino acid), acidity regulator, glycine, color (caramel, carotenoid, red#102, red #106, safflower yellow), flavorings, raising agent, sweetener (licorice), preservative (sorbic acid K)

* ★, ☆, ◎, ●, ○, ▲, ◆, ◇: Those marks are inserted for easy recognition and are not required for actual labeling.

G-3

The answer (3) to Query G-2 mentions “declaration also includes other ingredients of x x origin” between ingredient and additive labeling.” Is there no exception as to where the declaration should be placed?

It does not necessarily have to be between the two as mentioned. It could be stated all together at the very end. However, please try to have it as near as possible to the ingredients for which labeling is required.

G-4

Are there items for which omissions in labeling are difficult under JAS Act?

For example, should there be edible fats and oils in which lard (40%), beef tallow (30%), palm oil (20%) and soybean oil (10%) are mixed, labeling would be "Edible fats and oils (lard, beef tallow, palm oil, soybean oil)" in case all ingredients were to be mentioned. Only palm oil does not correspond to specified ingredients among all ingredients. However, if palm oil were to omitted and soybean oil which is less in content were to be declared, consumers might be given the wrong idea, so it is not accepted. So, in this cases, do not omit palm oil. Declare "○○, △△, edible fats and oils, x x, (some ingredients contain pork, beef, soybeans)."

It would mislead consumers all the more if only specified ingredients were to be identified in parentheses and other ingredients omitted.

It is essential to confirm that no omission takes place and to follow all regulations under the Food Sanitation Act and JAS Act as just described.

G-5

In consideration of the volume of labeling contents, would it be permissible to provide information by attaching a sheet giving minute particulars?

The Food Sanitation Act Enforcement Regulations and Milk, etc. Ministerial Ordinance require that labeling should appear on the container or package where it can be easily seen without being opened. Therefore, only providing an attached document with information to the effect that the food contains an allergen will not be considered labeling. However, providing additional information by means of an attached document after performing accurate labeling is allowed.

G-5

Would just allergen labeling suffice when only a trace of genetically modified "soybeans" is contained in the food concerned?

Genetically modified (GM) food labeling is limited to ingredients which are among the top three ranked by weight and which account for 5% or more of the food. Therefore, anything under that is subject to only allergen labeling.

H. Specified ingredient "milk"

H-1

Labeling means separate from those for foods in general have already been prescribed for the numerous kinds of “milk” available, but how should allergen labeling and any related declaration be done?

Labeling of foods in which milk is the ingredient in the specified ingredients shall be performed in accordance with the Milk, etc. Ministerial Ordinance. Special remarks will be required for ingredients that most consumers do not understand contain milk. Such remarks as “milk product” or “contains milk as a constituent” would be required.

As concerns “Milk, etc.,” definitions stipulated by the Milk, etc. Ministerial Ordinance and described hereunder shall be used and substitute declarations (declaration by classification) shall serve the purpose of specified ingredient declaration. “Milk” quoted in the Milk, etc. Ministerial Ordinance refers to raw milk, normal liquid milk, certified milk, raw goat milk, pasteurized goat milk, raw sheep milk, partly skimmed milk, skimmed milk and processed milk. Presently, milk other than cow's milk (goat milk and sheep milk) is no longer subject to labeling. As cross-reaction has not been confirmed in goat milk and sheep milk further studies will continue hereafter.

<29 items covered by Milk, etc. Ministerial Ordinance>

Substitute declaration	Definition of labeling
“Raw milk”	Cow's milk in as milked state
“Normal liquid milk”	Cow's milk sold for the purpose of direct intake
“Certified milk”	Normal liquid milk sold as certified milk
“Modified milk”	Product obtained by removal of part of the milkfat or other constituents from raw milk
“Low-fat milk”	Modified milk from which milkfat is removed
“Fat-free milk”	Modified milk from which milkfat is almost entirely removed
“Processed milk”	Food obtained by processing raw milk, normal liquid milk or certified milk, or foods manufactured using these milks as ingredients, which are sold for the purpose of direct intake (excludes partly skimmed milk, skimmed milk, fermented milk and lactic acid bacteria drinks)
“Cream (milk product)”	Product obtained by removal of all constituents other than milkfat from raw milk, normal liquid milk or certified milk
“Butter”	Product made by churning and working fat globules obtained from raw milk, normal liquid milk or certified milk
“Butter oil”	Product obtained by removal of almost all constituents other than milkfat from butter or cream
“Cheese”	Natural cheese and processed cheese
“Concentrated whey (milk product)”	Product obtained by concentration to solidification of the whey obtained either by fermenting milk with lactic acid bacteria, or by the addition of the enzymes or acid to milk
“Ice cream products”	Products obtained by processing, or using as principal ingredients, then freezing raw milk, normal liquid milk, or certified milk or foods manufactured using these as ingredients, which contains not less than 3.0% of milk solids (excluding fermented milks)

“Concentrated milk”	Product obtained by concentrating raw milk, normal liquid milk, or certified milk
“Concentrated skimmed milk”	Product obtained by removing the milkfat from raw milk, normal liquid milk, or certified milk, then concentrating
“Evaporated milk”	Concentrated milk sold for the purpose of direct intake
“Evaporated skimmed milk”	Concentrated skimmed milk sold for the purpose of direct intake
“Sweetened condensed milk”	Product obtained by concentrating raw milk, normal liquid milk or certified milk after the addition of sucrose
“Sweetened condensed skimmed milk”	Product obtained by concentrating raw milk, normal liquid milk or certified milk after removal of the milkfat and the addition of sucrose
“Whole milk powder”	Product obtained by removing almost all the water from raw milk, normal liquid milk or certified milk, then reducing to powder
“Skimmed milk powder”	Product obtained by removing milkfat from raw milk, normal liquid milk or certified milk, then removing almost all the water and reducing to powder
“Cream powder (milk product)”	Product obtained by removing all the other constituents than milkfat of raw milk, normal liquid milk or certified milk, then removing almost all the water and reducing to powder
“Whey powder (milk product)”	Product obtained by fermenting milk with lactic acid bacteria, or by the addition of the enzymes or acid to milk, then removing almost all the water from the whey obtained and reducing to powder
“Protein concentrated whey powder (milk product)”	Product obtained by fermenting milk with lactic acid bacteria, or by the addition of the enzymes or acid to milk, then removing lactose from the whey obtained and then removing almost all the water and reducing to powder
“Buttermilk powder”	Product obtained by removing almost all the water from buttermilk and then reducing to powder
“Sweetened milk powder”	Either the product which is obtained by removing almost all the water from raw milk, normal liquid milk or certified milk after the addition of sucrose, then reducing to powder, or the product which is obtained by adding sucrose to whole milk powder
“Formulated milk powder”	Product obtained by processing or using as principal ingredients raw milk, normal liquid milk or certified milk, or the product manufactured by use of these as raw material, then adding the necessary nutrients for infants and reducing to powder
“Fermented milks”	Product obtained by fermenting milk, or milk, etc. containing an equal or greater amount of non-fat milk solids, with lactic acid bacteria or yeast, and forming a paste or liquid, or the frozen product of the same
“Lactic acid bacteria drinks”	Drinks (excluding fermented milks) which are obtained by fermenting milk, etc. with lactic acid bacteria or yeast, then processing or using it as the principal ingredient
“Milk drinks”	Drinks obtained by using as principal ingredients raw milk, normal liquid milk or certified milk, or foods manufactured using these as ingredients, excluding “raw milk,” “normal liquid milk,” “certified milk,” “partly skimmed milk,” “skimmed milk.” “processed milk” and items listed in “milk products.”

H-2

How should specified ingredients labeling of food products containing milk be done?

When it comes to labeling indicating “milk,” as an ingredient, because of the need to adhere to the Milk, etc. Ministerial Ordinance, the process turns out to be complex. As referred to in H-1 above, if the definition of an item does not correspond to that of an item indicated in the Milk, etc, Ministerial Ordinance, the name of the item cannot be used in any substitute declaration.

As for foods containing “milk” which now require specified ingredients labeling, in addition to “milk,” “milk products” and “foods in which milk or a milk product is the main ingredient,” foods containing (even if a very small amount) milk as defined by the Milk, etc. Ministerial Ordinance become subject to labeling. A specified ingredient declaration that enables the average consumer to determine that the product contains “milk” shall be required for each and every item.

H-3

How should specified ingredients labeling be done when “milk” prescribed by the Milk, etc., Ministerial Ordinance is used as an ingredient?

Labeling of processed foods in which “milk” as prescribed by the Milk, etc. Ministerial Ordinance is an ingredient shall indicate that (1) “milk” is an ingredient, (2) a milk constituent is an ingredient, or (3) the type of milk shall be declared. However, ingredients for “milk products” prescribed by the Milk, etc. Ministerial Ordinance shall be milk and indicated by substitute declaration in accordance with H-1. Labeling shall indicate specified ingredients according to type (some shall require “milk product” labeling).

- Only “cow's milk sold for the purpose of direct intake” as prescribed by the Milk, etc. Ministerial Ordinance shall be allowed to use substitute declaration of “normal liquid milk” as specified ingredients labeling.
- For processed food in which milk is an ingredient and more than one sort of milk such as normal liquid milk, skimmed milk, etc. are used, declaring only one sort, “normal liquid milk,” shall suffice.

H-4

How should specified ingredients labeling be handled when “milk products” as prescribed by the Milk, etc. Ministerial Ordinance are ingredients?

Declarations of specified ingredients in “milk products” as prescribed by the Milk, etc. Ministerial Ordinance or in processed food shall be required to indicate (1) that “milk products” are ingredients, (2)

that milk is an ingredient or, (3) declare a milk product classification (some shall require “milk product” labeling).

- When whole milk powder is an ingredient for chocolate, labeling should declare “chocolate (sugar, whole milk powder, cocoa butter,...).”
- When processed foods contain “milk products” and, for example, a number of milk products such as normal liquid milk, modified milk, etc. are used, declaring one or only “whole milk powder” shall suffice.

H-5

When “food in which the main ingredient is milk or a milk product” is an ingredient, what should specified ingredients labeling look like?

Although it does not precisely match the definition of “milk” and “dairy products” under the Milk, etc., Ministerial Ordinance, when labeling a food item in which the main ingredient is either milk or a milk product, and, when it can be judged by name or the name of the item that only the specified milk is used as an ingredient, declaration of the name or name of the item will serve the purpose of specified ingredients labeling.

- For example “Cheese food,” can be considered a permissible expansion of a substitute declaration (The use of the word “cheese” as a substitute enables the reader to understand that milk is an ingredient. (Refer to Query G-1 for details.)

On the other hand, when it cannot be judged only from the name or name of the item that milk is an ingredient, the following can be considered:

- For “foods in which either milk or a milk product is a main ingredient” labeling must indicate (1) that it contains milk or a milk product as an ingredient, (2) that it contains milk constituents, or (3) that milk is one of the main ingredients.
- In case a food in which either milk or a milk product is used as a main ingredient,” a compound ingredient cannot be simply labeled “milk” or “milk product.” The reason is that the Milk, etc. Ministerial Ordinance does not permit labeling as if the product is “milk” or the “milk product” itself. In such cases, the ingredient declaration should be “Food in which milk or a milk product is a main ingredient” or, as omission labeling it could be “Ingredients in part contain milk constituents,” between the ingredients labeling and additives labeling.

H-6

What should labeling actually indicate when a food product contains a specified ingredient “milk” as a compound ingredient?

The declaration to be used when a food product containing the specified ingredient milk as compound ingredient is an indication to the effect that the product also contains an ingredient of milk origin or an ingredient contains milk as a constituent.

- When vanilla cream is used in a Western-style confectionary and ingredients of vanilla cream happen to be "vegetable oil, starch syrup, milk product, albumen and sugar," this would mean that a milk constituent is being used. Declaring merely "vanilla cream" cannot always be understood that it contains milk constituent. So by declaring that it does contain a milk constituent as the "Western confectionery, wheat, egg, vanilla cream, ...,(some ingredients contain milk constituent)" would serve the specified ingredient declaration purpose. However, declaring that the ingredient is contained with reference to the use of specified ingredients is limited to "milk" among specified ingredients.

<Examples> Labeling to indicate that a product has a milk constituent

Item	Ingredients	Examples of declarations where omission possible
Cookies	Wheat flour◎, sugar, shortening, white chocolate (sugar, whole milk powder▲, cocoa butter, etc.), egg★, starch (wheat◎), whole-fat soybean flour●, salt, emulsifier, flavorings, caramel color, raising agent	Wheat flour◎, sugar, shortening, white chocolate, egg★, starch, whole-fat soybean flour▲, salt, (contains other ingredients of milk origin▲), emulsifier, flavorings, caramel color, raising agent
Western confection ary	Custard cream (normal liquid milk▲, egg★, sugar, wheat flour◎, etc.) wheat flour◎, saccharide, shortening, egg★, yeast, salt, emulsifier, yeast food, seasonings (amino acid, etc.), food acids, viscosity augmenting polysaccharide, sodium caseinate (milk origin), color (carotene), flavorings	Custard cream, wheat flour◎, saccharide, shortening, egg★, yeast, salt, (contains other ingredients of milk▲ origin), emulsifier, yeast nutrient, flavorings (amino acid, etc.), food acids, viscosity augmenting polysaccharide, sodium caseinate, color (carotene), flavorings

* Labeling for ingredients in the ingredient labeling column may use only "milk" for specified ingredients. Other specified ingredients, etc. may not be used.

H-7

For ingredient and allergen labeling of bread using approximately 3% "food in which either milk or a milk product is used as a main ingredient," is it permissible to have the product simply labeled "milk product" or "skimmed milk powder product?"

As "food in which either milk or a milk product is used as a main ingredient" itself, is an independent name, labeling this type of bread or similar product as a "milk product" or "skimmed milk powder product" would be considered misleading.

H-8

What is the view of the Ministry of Health, Labour and Welfare regarding the labeling of milk sugar?

There were several different phases before the labeling of milk sugar was decided in its present form.

1. The report by the study group on elucidating the actual circumstances of food allergies and potential allergens, "Labeling of Foods Containing Allergic Substances" dated November 30, 2000 stated, "As for milk sugar, it is basically considered not to cause allergic reactions if it is completely refined and there are no proteins left, so it should not be necessary to label this as including a milk constituent if it is labeled as milk sugar. However, if any new knowledge or cases of proteins remaining are found out through studies in the future, this should be reexamined." Based on this report, the Standing Committee of the Food Sanitation Investigation Council provided its opinion to the Minister of Health, Labour and Welfare on December 26, 2000. It was stated in this opinion that "As for milk sugar with no protein left, it should not be necessary to label this as including a milk constituent if it is labeled as milk sugar."
2. In accordance with the partial revision of the Food Sanitation Act Enforcement Regulations, it was stated in the Q&A in Policy Planning Division Announcement No. 4, Inspection and Safety Division Announcement No.48 dated March 21, 2001 as: B-9 "As for milk sugar, there is knowledge that it is non-antigenic if it is completely refined and there are no proteins remaining. Therefore, labeling as a specified ingredient is unnecessary.
   However, if any new knowledge becomes available, the decision should be reexamined." As stated here, allergy labeling for milk sugar with complete refinement and no protein remaining is unnecessary.
3. The addition for Q&A through Clerical Notice dated June 15, 2001 states as: "Because labeling is unnecessary for completely refined milk sugar, the antigenicity of the food will be unclear in this case even if the word "milk" is used. Therefore, (milk origin) for casein sodium cannot be omitted." That is, for milk sugar, it should be indicated that it is not a substitute declaration for "milk," and should be declared as "milk sugar (milk origin)" for milk sugar with proteins left.
4. Since August 29, 2001, the minimum amount of protein inducing an allergic reaction was being considered in the Allergy Labeling Investigation Council. An interim report from the Council dated October 29, 2001 was issued, and based on the result of such a report, additions were made to Q&A through a Clerical Notice dated December 28, 2001. The addition included B-14 "The consensus was met that the content of allergic substances that may cause food allergies is at the level of a few μg/g, and allergic reaction is rarely induced at the ng/g level in general…" Therefore, criteria for the minimum amount of protein that requires allergy labeling was provided, and it was decided that this criteria will also apply to milk sugar.
5. As for the degree of the refinement of milk sugar, data were provided from several companies with relevant experience in milk sugar, and the following facts became clear:

(1) Proteins are left even in “highly refined milk sugar,” which had been considered as not causing allergic reactions.
(2) About 0.3% of protein remains even in “highly refined milk sugar” that is available on the market.

Furthermore, the Allergy Labeling Investigation Council showed the following views:

(3) It is necessary to apply the definition of the extremely small amount shown in the interim report to milk sugar as well.
(4) Because milk sugar includes the word “milk,” it is reasonable to recognize it as substitute declaration for “milk.”

However, considering the fact that there is a delay in taking action because “milk sugar” was not being recognized as an allergenic substance, the necessity of setting the period for provisional measure is also being pointed out.

H-9

How should milk sugar labeled in specific?

Based on the background as explained in H-8 and following the results of consideration at the Allergy Labeling Investigation Council, the Ministry of Health, Labour and Welfare have decided:

1. Because protein is found to also remain in “highly refined milk sugar,” the necessity of labeling should be decided based on the amount of protein left.

2. Because milk sugar includes the word “milk,” it should be added as substitute declaration for “milk.”

I. Measurers to be taken by administration, etc.

I-1

Would the 25 specified ingredients, etc. ever be reexamined and changed?

Because it is possible that substances causing food allergies may change with the times, organizations such as the Food Allergy Study Group will carry on with their studies of actual conditions and scientific research to revise decisions accordingly, based on new knowledge and reports that become available. Due to the necessity of revision, the specified ingredients, etc. are scheduled to be reexamined on a regular basis.

I-2

For the sake of securing safety, shouldn't administration conduct inspection by monitoring (random sampling)?

Monitoring is implemented at health centers of municipalities, health institutes, etc., by using the testing methods to measure specific ingredients contained in food that are developed, in order to monitor the appropriateness of the labeling of specified ingredients. This monitoring is implemented in a comprehensive manner through scientific tests and the confirmation of manufacturing records.

I-3

Is it possible to perform tests for specified ingredients?

In order to confirm whether allergy labeling is implemented appropriately or not, a method to detect specified ingredients is necessary. Methods to detect specified ingredients in food that are currently available are as follows:

(1) To test certain proteins included in specified ingredients through Sandwich ELISA and Western Blotting.

(2) To test certain genes included in specified ingredients through genetic amplification (PCR)

(3) As a simple measuring method, to test quickly and simply through immunochromatography method.

These detecting methods are used for monitoring by the government.

However, in some cases it is difficult to prove the use of specified ingredients only by tests using these scientific detecting methods. Therefore, labeling is also confirmed through confirmation based on manufacturing records.

I-4

What sort of research is being conducted by the sate to search for foods which may contain new allergenic substances?

The Ministry of Health, Labour and Welfare has been conducting studies and researches under its Immunity & Allergy Research Project to elucidate actual conditions of allergy and substances of its cause since 1996 from growing demand for information by labeling to prevent health hazards caused by allergenic substances before they occur.

Hereafter, studies will be conducted by the Food Allergy Study Group set up in fiscal 2000 for the various problems which are bound to occur as a consequence of mandatory labeling actually being

enforced. The currently specified 25 items will be revised with changes of the times, the Food Allergy Study Group will survey conditions as they are as well as undertake scientific research and reexamine the situation as appropriate based on new information, knowledge and reports as they become available.

I-5
What is the situation regarding regulations in other countries?

The June 1999 session of joint FAO/WHO Codex Alimentarius Commission agreed to the effect that food containing the 8 undermentioned types of ingredients known to be allergenic substances should be labeled. Each member nation is now studying means of labeling which suit their respective systems.

(1) Cereals containing gluten and products thereof
(2) Crustacea and products thereof
(3) Eggs and egg products
(4) Fish and fish products
(5) Peanuts, soybeans and products thereof
(6) Milk and milk products (including lactose)
(7) Tree nuts and nut products; and
(8) Foods which contain more than 10mg/kg sulphite

Codex's items subject to labeling are what may be referred to as a classification concept and believed not to be contradictory even if ingredients were to be labeled individually and the “specified ingredients, etc.” correspond to ingredients (1) through (7) subject to labeling by Codex.

As regards item (8) above, the ample research necessary will be conducted in the days and years to come.

I-6
By what means should manufacturers or those in the business make information available to others?

It is desirable that manufacturers and those in the business disseminate not only information relative to specified ingredients and items corresponding to specified ingredients required for allergy labeling but also those regarding other ingredients, respond to phone enquires and through the Internet as well.

It is important that individual manufacturers and those in the business receive detailed information on products from their suppliers when the products are purchased, sort out such information, and try to establish a system allowing them to respond expeditiously to inquiries from consumers.

(1) Contents of ingredients which went into the food concerned should be detailed as much as possible and for the 7 items prescribed by Ministerial Ordinance, it is desirable that, for example, a special information box is established to arouse the attention of consumers.

a. Presentation should be made in the place designated, individually and in an easily understandable way and ensure that the reference can be taken to concern a certain item among many similar merchandise on the market.
b. In case the method of labeling adopted is according to omission stipulations and specified processed foods (refers to specified processed food stipulated in Article 5, Paragraph 13 of the Regulations) for actual food due to space limitations, information should be provided separately stating all specified ingredients accurately.
c. No matter how small the contents may be, specified ingredients and any ingredient corresponding thereto should be grasped as much as possible and such information provided.
d. In case information is provided by Internet website, be sure to insert the name of the staff/department in charge who/which can respond, address, telephone number, E-mail address, etc. on each page in a clearly visible location.
e. Even if such should concern a business secret, labeling to the effect that it contains specified ingredients shall be required. However, in case information concerning details of other ingredients cannot be provided, mentioning that it contains ingredients other than those labeled and giving particulars of the party to contact for allergy problems would serve the purpose.

(2) In case there should be enquiries concerning specified ingredients and other ingredients which went into the item, it is desirable to establish a system to respond expeditiously and make it operational.

(3) Additionally, considering that raising society's awareness towards food allergies should further increase the effectiveness of allergy labeling in the future, the Allergy Labeling Investigation Council is scheduling to prepare pamphlets targeted to consumers, manufacturers, and those in the business. Please refer to these pamphlets as well.

I-7
Some imported marine products come in cartons with only English labeling, but shouldn't they also be labeled in Japanese? If such is a requirement, would seals or stamps serve the purpose?

Seals and/or stamps will suffice so please see to it that labeling in Japanese are affixed.

I-8
Please elaborate on food manufacturers' labeling of the fact that specified ingredients are not used in a product.

Currently, it is not mandatory to label items corresponding to specified ingredients. However, it is being pointed out that this is limiting the choice of foods for the patients of allergic diseases, because when such items are not labeled, the patients cannot determine precisely whether said food "does not use items corresponding to specified ingredients" or "does use items corresponding to specified

ingredients but they are not labeled." To this end, for food that the patients of allergic diseases recognize as "possibly including an item corresponding to specified ingredients" according to social convention, if such food was manufactured without using such an item corresponding to specified ingredients, it is desirable to declare the fact that it does not use such an item corresponding to specified ingredients considering the spirit of the system. Thus, from fiscal 2004, the provision of information regarding the use of items corresponding to specified ingredients has been promoted.

In specific, in cases where a food that consumers generally regard as using a specified ingredient is manufactured without using said specified ingredient, and if that fact is appropriately confirmed with manufacturing records and by other means, it is recommended to declare the fact that it does not use said specified ingredient in an area outside the comprehensive label.

For example, although "mixed fruit juices" generally use "apples (an item corresponding to specified ingredients)," if it is appropriately confirmed that "mixed fruit juices" were manufactured *without using* "apples," it is recommended to declare "this product does not use apples."

In addition, in the case of a food consumers generally regard as not using a specified ingredient, for instance mineral water not using soybeans, the above cases do not mean that it is recommended to declare that "this product does not use soybeans (specified ingredients)."

I-9

Does the labeling "does not use specified ingredients" mean that the food does not contain specified ingredients?

A label declaring "does not use" does not necessarily mean that it "does not contain." This labeling means that the declarer appropriately confirmed with manufacturing records and by other means whether it does or does not use the specified ingredients, etc.

For example, "cakes" generally use "wheat (specified ingredient)." However, if a "cake" is manufactured without using "wheat," and if such fact is appropriately confirmed with manufacturing records and others, it can be declared as "this product does not use wheat." However, this declaration shall not deny the possibility that the product might contain wheat.

I-10

Should food manufacturers also provide information on the scope of labeling for items corresponding to specified ingredients for which labeling is not mandatory?

Because information regarding items corresponding to specified ingredients is not currently being provided, it is hard to tell whether said food actually does contain items corresponding to specified ingredients but they are not labeled, or if the food really does not contain items corresponding to specified ingredients.

Therefore, it is considered that clearly stating which allergenic substances are included in the scope of labeling in an area outside the comprehensive label is a highly effective method to help the patients of allergic diseases make choices about foods.

For example, in the case when (1) all items corresponding to specified ingredients are included in the scope of labeling, it is recommended that they be declared as "the scope of labeling for this product includes all items corresponding to specified ingredients provided in the Food Sanitation Act (abalone, squid,…(an omission)… banana)." In the case when (2) only chicken and beef among items corresponding to specified ingredients are included in the scope of labeling, it is recommended that they be declared as "the scope of labeling for this product includes chicken and beef among items corresponding to specified ingredients provided in the Food Sanitation Act (ingredients recommended to be labeled when included in food)."

It should also be useful to provide information to consumers using websites, etc.

I-11

Is it allowed to change the color, size, etc., of letters so that the label will be easier to understand for consumers, and especially food allergy patients?

As one of the measures to improve the visibility of ingredients labeling related to specified ingredients and items corresponding to specified ingredients, and to let patients of allergic diseases make adequate decisions, it is possible to change the color, size, etc., of letters used for the labeling of specified ingredients, etc.

In specific, it is possible to make the letters larger than other labeling (within approximately 1.5 times larger than other letters), or to use colors for letters different to other labeling in consideration of the background colors of packages. It is also possible to change the fonts of the letters, to use bold letters, to underline, to use hatching, or to use shaded letters, outlined letters, embossed letters, or raised letters. However, when labeling more than one specified ingredients, use uniformed color and size for all specified ingredients so that it may not constitute misleading representation about quality*.

Also, when specified processed foods for which the labeling of specified ingredients, etc. can be omitted (processed foods generally known to contain specified ingredients, etc. as an ingredient: bread (using wheat) and miso (using soybean), etc.) are used as ingredients, it is possible to change the color and size of letters for specified processed food labeled as an ingredient, similarly to the case of specified ingredients, etc.

* Misleading representation about quality: Representation by which the product is shown to general consumers as being much better than it actually is.

I-12

What kind of measures should be taken to provide information to the patients of allergic diseases in the cases of face-to-face selling and sales by measures at storefronts, or at eating and drinking establishments such as restaurants?

Labeling, including allergy labeling, is not mandatory under the Food Sanitation Act for foods for face-to-face selling, foods sold by measures at storefronts or foods sold at eating and drinking establishments. However, in order to prevent health damages, it is desirable to improve the quality of information provided for the patients of food allergy diseases even at face-to-face selling or at eating and drinking facilities.

In specific, it is important to keep records so that information necessary for the patients of food allergy diseases can be presented accurately, and to take voluntary approaches such as improving the quality of information provided through menus, etc.

When providing information through menus, etc., it is desirable to clearly state the scope of allergy substances of which information is provided, such as by stating: “The menu at our restaurant labels eggs, milk, wheat, shrimp/prawns, crab, buckwheat, and peanuts, which are mandatory items under the Food Sanitation Act (specified ingredients), and abalone, squid,…(an omission)… banana, which are items for which allergy labeling is recommended (items corresponding to specified ingredients).”

I-13

Where can I get more information or advice concerning?

Public Health Centers, etc. accept inquiries and are available for consultation. Again, the Labeling Survey Group, Standards and Evaluation Division, Department of Food Sanitation, Pharmaceutical and Medical Bureau, Ministry of Health, Labour and Welfare are also prepared to answer questions.