（資料４）
コーデックスの食品表示部会における作業状況について

コーデックスの食品表示部会における作業状況

【コーデックス委員会】(Codex Alimentarius Commission(CAC)、食品規格委員会)

- 国連食糧農業機関(FAO)と世界保健機関(WHO)によって1963年に設立された国際的な政府間プログラム
- 消費者の健康保護と公正な食品貿易の確保(品質、表示)等を目的とし、国際食品規格(コーデックス規格)の策定等を行う
- コーデックスメンバー:188加盟国(日本は1966年に加盟)、1加盟機関(EU)

※2023年5月現在

規格策定の流れ

ステップ1～5:新規作業承認 → 原案の策定開始 → 予備採択

①総会が規格作成決定

②規格原案の手配(事務局)、③原案に各国コメント、④部会にて規格原案を検討、⑤原案について各国コメント(コメント等に基づき総会が原案採択)

ステップ6～8: 案の策定 → 最終採択

⑥規格案について各国コメント、⑦部会にて規格案を検討、⑧規格案について各国コメント(コメント等に基づき総会がコーデックス規格として採択)

CCFL

食品表示部会(Codex Committee on Food Labelling: CCFL)

〈CCFL47での議題〉

議題1:包装食品の表示に関するコーデックス一般規格(GSLPF)の改訂

議題2:予防的アレルゲン表示(PAL)に関するガイドラインの新規策定

- アレルギー表示見直しについては、2019年からスタートし、議題1については現在ステップ4(④部会にて規格原案を検討)
- CCFL47(2023年5月15～19日)開催対面参加(カナダ・オタワ)

CCFLにおける改正方針について

包装食品の表示に関するコーデックス一般規格のアレルゲン表示関係部分の改正

- 「過敏症」を「食物アレルギー及びセリアック病」に改め、亜硫酸塩を食物アレルギー及びセリアック病とは別に義務表示として規定。
- 食物アレルギーに関する義務表示の規定を改正し、「木の実類」として括られていた品目を個別品目とする。

現行	修正案
4.2.1.4 以下の食品及び原材料は、過敏症の原因となることが知られており、常に明記しなければならない。	4.2.1.4 以下の食品及び原材料は、食物アレルギー及びセリアック病の原因となることが知られており、常に明記しなければならない。
・ グルテンを含む穀類（小麦、ライ麦、大麦、えん麦、スペルト小麦又はこれらの交雑種及びこれらの製品） ・ 甲殻類及びその製品 ・ 卵及び卵製品 ・ 魚類及び水産製品 ・ ピーナッツ、大豆及びその製品 ・ 乳及び乳製品（乳糖を含む） ・ 木の実類及びナッツ製品 ・ 濃度が10mg/kg以上である亜硫酸塩	・ グルテンを含む穀類（小麦、ライ麦、大麦、えん麦、スペルト小麦又はこれらの交雑種及びこれらの製品） ・ 甲殻類及びその製品 ・ 卵及び卵製品 ・ 魚類及び水産製品 ・ ピーナッツ、大豆及びその製品 ・ 乳及び乳製品（乳糖を含む） ・ 特定の木の実類 アーモンド、カシュー、ヘーゼルナッツ、ペカン、ピスタチオ、くるみ及びその製品 ・ 濃度が10mg/kg以上である亜硫酸塩については4.2.1.7に記載

⇒日本においては、従前より品目毎に指定しており、亜硫酸塩については、添加物として物質名で表示される

予防的アレルゲン表示（PAL）に関するガイドラインの新規策定

- 新たに可能性表示を行う際の規定を設け、閾値等を定める。

日本における予防的アレルゲン表示の考え方

「食品表示基準について」（平成27年3月30日消食表第139号消費者庁次長通知）より抜粋

① 食物アレルギーは、ごく微量のアレルゲンによって引き起こされることがあるため、特定原材料を含む食品にあっては、原材料としての使用の意図にかかわらず、原則、当該特定原材料を含む旨を表示する必要がある。
② 特定原材料等に関して「入っているかもしれない」等の可能性表示は認められないこと。一括表示の外であっても、同様である。

「食品表示基準Q&A」（平成27年3月 30日消食表第140号消費者庁食品表示企画課長通知）より抜粋

（H－1） 特定原材料等が「入っているかもしれません。」「入っているおそれがあります。」などの可能性表示（入っているかもしれません）について、何か規制がありますか。

（答）
「可能性表示」（入っているかもしれません。）は認められません。

「可能性表示」を認めると、PL法（製造物責任法）対策としての企業防衛、又は製造者により原材料調査の負担を回避するため、製造者によっては十分な調査を行わずに安易に「可能性表示」を実施することにもなりかねません。こうした安易な可能性表示を認めると、食物アレルギー患者にとって症状の出ない商品についても「可能性表示」によりアレルギー表示が行われ、かえって患者の選択の幅を狭めてしまうおそれがあります。

⇒日本においては、食物アレルギー患者のために、可能性表示は認めていない

包装食品の表示に関するコーデックス一般規格（GSLPF）

APPENDIX II

PROPOSED DRAFT REVISION OF THE *GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS* (CXS 1-1985) RELEVANT TO ALLERGEN LABELLING

(FOR ADOPTION AT STEP 5)

2. DEFINITION OF TERMS

"*Food allergy*" means a reproducible adverse health effect arising from an immunoglobulin class E (IgE) antibody or non-IgE antibody immune-mediated response following oral exposure to a food."

"*Food allergen*" means a food or ingredient **[**or substance or processing aid**]** used in food, usually a protein or protein derivative that can elicit IgE-mediated or other specific immune-mediated reactions in susceptible individuals.

"*Coeliac disease*" means a chronic immune-mediated intestinal disease in genetically predisposed individuals induced by exposure to dietary gluten proteins that come from wheat, rye, barley and triticale (a cross between wheat and rye).

4. MANDATORY LABELLING OF PREPACKAGED FOODS

4.2 List of ingredients

4.2.1.3 Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by a list, in brackets, of its ingredients in descending order of proportion (m/m). Where a compound ingredient (for which a name has been established in a Codex standard or in national legislation) constitutes less than 5% of the food, the ingredients need not be declared, except for the foods and ingredients listed in section 4.2.1.4, 4.2.1.7 and where applicable section 4.2.1.5 and food additives which serve a technological function in the finished product.

4.2.1.4 The following foods and ingredients are known to trigger food allergy or coeliac disease and shall always be declared using the specified name in addition to or as part of the ingredient name[1]:

FOODS AND INGREDIENTS	SPECIFIED NAME
Cereals containing gluten[2]:	
– wheat and other *Triticum* species	'wheat'
– rye and other *Secale* species	'rye'
– barley and other *Hordeum* species	'barley'
and products thereof	
Crustacea and products thereof	'crustacea'
Eggs and products thereof	'egg'
Fish and products thereof	'fish'
Peanuts and products thereof	'peanut'
Milk and products thereof	'milk'
Sesame and products thereof	'sesame'
Specific tree nuts	
– Almond	'almond'
– Cashew	'cashew'
– Hazelnut	'hazelnut'
– Pecan	'pecan'
– pistachio	'pistachio'
– walnut	'walnut'
and products thereof	

対象食品・原材料と表示事項

4.2.1.5 In addition to the foods and ingredients listed in section 4.2.1.4, the declaration of any other foods and

[1] In accordance with Section 4.1.1 of the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985), the ingredient declaration should specify the true nature of the food and be specific and not generic.

[2] Includes spelt, Khorasan, and other specific cereals containing gluten that are species or hybridized strains under the genus names of *Triticum*, *Secale* and *Hordeum*. Specified names are to be used according to the associated genus. Hybridized strains are to use specified names in conjunction from all of the parent genera (e.g. 'wheat' and 'rye' for triticale).

ingredients, including those listed below may also be required[3] using a specified name in addition to or as part of the ingredient name[4]. This shall be based on available risk assessment data for the respective population(s)[5] taking into account risk management considerations.

FOODS AND INGREDIENTS	SPECIFIED NAME
Buckwheat and products thereof	'buckwheat'
Celery and products thereof	'celery'
Oats and other *Avena* species (and their hybridized strains) and products thereof[6]	'oats'
Lupin and products thereof	'lupin'
Mustard and products thereof	'mustard'
Soybean and products thereof	'soy'
Specific tree nuts	'Brazil nut'
– Brazil nut	'macadamia'
– macadamia	'pine nut'
– pine nut	
and products thereof	

[4.2.1.6 Subject to evaluation using established criteria[7], national authorities may exempt ingredients derived from foods listed in section 4.2.1.4, and where applicable section 4.2.1.5, from being declared.**]**

4.2.1.7 When sulphite is present in a **[**ready-to-eat**]** food **[**or products as reconstituted according to the instructions of the manufacturer**]**, at a total concentration of 10 mg/kg or above, it shall always be declared using the specified name 'sulphite'.

RENUMBER existing sections 4.2.1.5 and 4.2.1.7 to 4.2.1.8 and 4.2.1.9 respectively

4.2.2 The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the foods and ingredients listed in section**s** 4.2.1.4 and where applicable 4.2.1.5 shall be declared.

When it is not possible to provide adequate information on the presence of these allergens through labelling, the food containing the allergen should not be marketed.

4.2.3 Except for those foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5, ~~A~~ a specific name shall be used for ingredients in the list of ingredients in accordance with the provisions set out in Section 4.1 (Name of the Food) except that:

4.2.3.1 Unless a general class name would be more informative, the following class names may be used. In all cases, the food and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 shall be declared using the specified names listed in those sections.

濃度が10mg/kg以上である亜硫酸塩について

4.2.4 Processing Aids and Carry-Over of Food Additives

4.2.4.2 A food additive carried over into foods at a level less than that required to achieve a technological function, and processing aids, are exempted from declaration in the list of ingredients. The exemption does

[3] These foods and ingredients are not included in 4.2.1.4 but have been recommended to be considered for risk management at the regional or national level (see FAO and WHO Risk assessment of food allergens: Part 1: Review and validation of Codex Alimentarius priority allergen list through risk assessment https://doi.org/10.4060/cb9070en.).

[4] In accordance with Section 4.1.1 of the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1- 1985), the ingredient declaration should specify the true nature of the food and be specific and not generic.

[5] The assessment of risk in the respective population(s) to be based on the evidence criteria of prevalence, potency and severity of immune mediated adverse reactions to the food or ingredient as established by FAO and WHO Risk assessment of food allergens: Part 1: Review and validation of Codex Alimentarius priority allergen list through risk assessment. https://doi.org/10.4060/cb9070en.

[6] Oats can be tolerated by most but not all people who are intolerant to gluten. Therefore, the allowance of oats that are not contaminated with wheat, rye or barley in foods covered by this standard may be determined at the national level."

[7] FAO and WHO (2022). Risk assessment of food allergens: Part 1: Review and validation of Codex Alimentarius priority allergen list through risk assessment. p15-20. https://doi.org/10.4060/cb9070en.

not apply to food additives and processing aids that contain the foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5.

6. EXEMPTIONS FROM MANDATORY LABELLING REQUIREMENTS

With the exception of spices and herbs, small units, where the largest surface area is less than 10 cm², may be exempted from the requirements of paragraphs 4.2 and 4.6 to 4.8. This exemption does not apply to the declaration of foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5.

8. PRESENTATION OF MANDATORY INFORMATION

8.3 Declaration of certain foods and ingredients

8.3.1 The foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 shall be declared so as to contrast distinctly from the surrounding text, **[**whenever possible**]**, such as through the use of font type, style or colour.

[8.3.2 When the foods and ingredients in sections 4.2.1.4, 4.2.1.6 and where applicable 4.2.1.5 are declared in the list of ingredients, they may also be declared in a separate statement, which shall be placed directly under the list of ingredients.

Bis. Foods and ingredients in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 shall be declared in the list of ingredients or in a separate statement which shall be **[**placed directly under**]** the list of ingredients or in both. The most appropriate manner to declare these foods and ingredients shall be decided by national competent authorities.

Ter. The foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 shall be declared so as to contrast distinctly from the surrounding text (such as through the use of font type, style or colour) and/or be declared in a separate statement commence with the word 'contains' (or equivalent word) directy under the list of ingredients.**]**

8.3.2.1 The statement shall commence with the word 'Contains' (or equivalent word) and must declare all the foods and ingredients which are declared in the list of ingredients as applicable in accordance with section 8.3.1.**]**

8.3.3 Where a food is exempt from declaring a list of ingredients, the foods and ingredients listed in sections 4.2.1.4, 4.2.1.6 and where applicable 4.2.1.5 shall be declared, such as in a statement made in accordance with section 8.3.2.1.

8.3.4 For single ingredient foods, section 8.3.3 does not apply where foods and ingredients listed in sections 4.2.1.4, 4.2.1.6 and where applicable 4.2.1.5 are declared as part of, or in conjunction with, the name of the food.

予防的アレルゲン表示（PAL）

APPENDIX III

PROPOSED DRAFT ANNEX TO THE GSLPF:

GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING

(FOR COMMENT AT STEP 3 THROUGH CL 2023/06/OCS-FL)

1. PURPOSE

To facilitate a consistent and harmonized approach to the effective use of precautionary allergen labelling (PAL) for communicating to consumers with food allergy about the risk from the unintended presence of allergens in food due to cross-contact.

2. SCOPE

These guidelines apply to PAL when used to indicate the risk from the unintended presence of allergens caused by cross-contact in prepackaged[1] foods.

3. DEFINITIONS

For the purpose of these guidelines:

Allergen means the foods and ingredients listed in sections 4.2.1.4 and where applicable 4.2.1.5 of the *General Standard for the Labelling of Prepackaged Foods (CXS 1-1985)*.

Precautionary allergen labelling is a statement made in the labelling of prepackaged foods to indicate a risk from the unintended presence of an allergen(s) due to cross-contact[2].

4. GENERAL PRINCIPLES

4.1 Effective management practices and controls to prevent or minimize the unintended presence of allergens caused by cross-contact shall be implemented as outlined in the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020). The use of PAL shall be restricted to those situations in which the unintended presence of an allergen(s) cannot be sufficiently controlled using these allergen management practices.

4.2 The decision to use PAL should be based on the findings of a risk assessment which shall include, but is not limited to, quantitative risk assessment.

4.3 PAL shall only be used if the presence of a protein from an allergen is equal to or above the action level[3] for this allergen, using the listed reference dose values in 4.3.1.

4.3.1 References doses

	Reference dose (RfD) (mg total protein from the allergen)
Walnut (and Pecan)	1.0
Cashew (and Pistachio)	1.0
Almond	1.0
Peanut	2.0
Egg	2.0
Milk	2.0
Sesame	2.0
Hazelnut	3.0
Wheat	5.0
Fish	5.0
Crustacea	200

[1] As defined in the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985)
[2] *Allergen cross-contact* as defined in *Code of Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020)
[3] Action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / Amount of the food (kg)

4.3.2 Where a reference dose is not established for a particular allergen by 4.3.1 above, national authorities can establish a reference dose consistent with recognized principles[4] for the purposes of determining an action level.

4.4 PAL should be accompanied by education/information programs to ensure understanding and appropriate use of PAL by consumers, health care providers and food business operators.

5. PRESENTATION OF PAL

5.1 Section 8.1.1, 8.1.2 and 8.1.3 and 8.2 of the *General Standard for the Labelling of Prepackaged Foods* (GSLPF) (CXS 1-1985) apply to PAL labelling.

5.2 PAL should appear as a separate statement in the same field of vision as the ingredient list (when present), and contrast distinctly from surrounding text, such as through the use of font type, style or colour in the same manner as Section 8.3.1 in the GSLPF.

5.2.1 A PAL statement shall commence with the words 'May contain' (or equivalent words) and include the identified allergens using the specified names as listed in sections 4.2.1.4 and where applicable 4.2.1.5 of the GSLPF.

[4] FAO and WHO (2022). Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens: Part 2: Review and establish threshold levels in foods of the priority allergens. https://doi.org/10.4060/cc2946en.

日本のCRD（Conference Room Document）

CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5 **FL/47 CRD06**

Original Language Only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING

Forty-seventh Session

Gatineau, Canada
15 – 19 May 2023

FOOD ALLERGEN LABELLING

(Comments from Burundi, Ghana, Indonesia, Japan, Nigeria, Republic of Korea, South Africa, Uganda, United Republic of Tanzania)

Burundi

Issue 1: Definition
"Food allergy" (New) means "a reproducible adverse health effect arising from an immunoglobulin class E (IgE) antibody or non-IgE antibody immune-mediated response is following oral exposure to a food."

Japan

Proposed draft revision to the *General Standard for the Labelling of Prepackaged Foods* – Provisions relevant to allergen labelling

SUMMARY
This document outlines
1. a proposal to the Committee to, as the next step, begin the discussion of how authorized detection methods for allergen(s) can be established within each country/region when new sections 4.2.1.3 and 4.2.1.4 are incorporated into its national/regional legislation.
2. Introduction of Japan's detection methods for each allergen designated to be labelled mandatorily when 'included' in prepackaged foods for consideration by member countries/regions and NGOs.

INTRODUCTION

Japan appreciates the work of Australia, the UK and the United States in guiding the draft forward to the current state. Japan's comments on the 2023 CL are summarized in CX/FL 23/47/5 Add.1 (Part A), where Japan supports the new sections 4.2.1.3 and 4.2.1.4.

For member countries/regions to promote the effectiveness of such labelling regulation, Japan thinks that it is a good idea to incorporate "authorized detection methods" (ADMs) into the legislation of each country/region, because they would make it easier for food business operators (FBOs) to comply with the regulation, while they would make it easier for national authorities to enforce the regulation. We think that, as a result, this scheme of ADMs enables food allergy patients to gain more accurate information. So, Japan proposes to the Committee, as the next step, to begin the discussion about how ADMs can be established. Japan also would like to introduce its food allergen labelling system based on such detection methods for allergen(s), hoping Japan's experience is helpful anyway to the countries/regions which are going to establish/revise their system of allergen labelling.

BACKGROUND

When Japan firstly introduced the allergen labelling system in 2001, it had already been considered that, for the proper enforcement of such a mandatory labelling regulation system, the establishment of scientific methods to detect allergens within foods is essential. Because it is a mandatory labelling regulation system, it is necessary to enable authorities to apply punishment(s) properly. Furthermore, as the production process of a food product is more and more complex, it is more and more difficult for FBOs to recognize the existence of allergen(s) within the final food product precisely (e.g. cases in which minute amount of allergen(s) is contained within a so-called "compound ingredient"). Therefore, it was also considered that, for FBOs responsible for food labelling to provide consumers with allergen information accurately, they need practical methods to check the existence of allergen(s) by themselves. Detection methods such as an enzyme-linked immunosorbent assay (ELISA) or a polymerase chain reaction (PCR) were investigated as possible ways to provide authorities with scientific evidences.

Based on such considerations, Japan's food allergen labelling regulation system was established, in which the Consumer Affairs Agency (CAA) designates and publishes quantitative and qualitative[1] "authorized detection methods" (ADMs) for each allergen item within mandatory labelling items. Test kits used in ADMs are readily available, and authorities conduct monitoring using ADMs. FBOs also check their products using ADMs by themselves. Note that, in qualitative ADMs, when the detected value of the amount of protein deriving from an

[1] Quantitative ADMs sometimes detect protein that actually derives from other items than the targeted allergen, which results in "false positive". Thus, when the value over 10 ug/g was detected by a quantitative ADM, the qualitative ADM for the targeted item is used to confirm the DNA area that is unique to that item.

allergen ingredient is over 10 ug per 1g of processed food,[2] the result is "positive". If a product is regarded as a violation of the mandatory labelling requirement, authorities apply punishment(s), but because authorities use ADMs in monitoring and inspections, this value of 10 ug/g is important when considering applying punishment(s).

MANDATORY LABELLING AND RECOMMENDED LABELLING/PERIODIC REASSESSMENT

In other words, a food allergen shall not be designated as a mandatory labelling item without the ADMs for that allergen, even if such an allergen is important in view of its frequency, severity, etc. Such allergens are designated as "recommend labelling items" to be labelled voluntarily.

For example, we recently designated 'walnut' as a mandatory labelling item. "Walnut" had been classified as a "recommended labelling" item, but based on the result of the periodic reassessment in 2021, the CAA concluded that walnut should be designated as a mandatory labelling item due to the frequency, severity, etc. of its allergen symptom. Through the necessary procedures for the revision of the "Food Labelling Standards", we took the designation of walnut as a mandatory labelling item into force on March 9, 2023, and on the same date, we published the ADMs for walnut, which was developed accompanying with this policy revision.

Mandatory Labelling Items (8 items): Shrimp, crab, wheat, buckwheat, egg, milk, peanut and walnut
Recommended Labelling Items (20 items): Almond, abalone, squid, salmon roe, orange, cashew nut, kiwi fruit, beef, sesame, salmon, mackerel, soybean, chicken, banana, pork, matsutake mushroom, peach, yam, apple, and Gelatin

The CAA has the periodic reassessment that has been conducted for approximately 20 years every 3 years in which doctors specialized in allergy monitor patients who had symptoms of immediate allergy. 6,080 cases were examined in the latest reassessment in 2021.

DETECTION METHODS

Below you can find Japan's ADMs for all mandatory labelling items (8 items)
(Sorry, only in Japanese available):
https://www.cao.go.jp/consumer/history/02/kabusoshiki/syokuhinhyouji/doc/130530_shiryou2-6-1.pdf

Shrimp and crab are distinguished from each other by name to be labelled. "Crustacean" is not used. The ADMs for shrimp and crab are also distinguished. This is not to narrow consumers' food choices too much. It is reported that over 35 per cent of patients with shrimp allergy do not have the symptom of crab allergy (2005 domestic research report).[3]

So far, the Japanese regulation system has proven to be effective. Notably, more than 20 years have passed since we set the demarcation of positive/negative in qualitative ADMs at 10ug/g, but regarding this value of 10ug/g, there are not strong opinions that a lower value should be adopted to prevent serious food allergy. Japan hopes that its experience is helpful anyway to the countries/regions which are going to establish/revise their system of allergen labelling.

FAO briefly summarizes Japan's experience below (pp.13-19);
https://www.fao.org/3/cb2868en/cb2868en.pdf

PRECAUTIONARY ALLERGEN LABELLING (relating to AGENDA 5.2)

Japan welcomes that the need to seek advice on standardized analytical methods and sampling from CCMAS are to be discussed in Agenda 5.2, wishing the information described above also contributes anyhow to the discussion of Agenda 5.2.

RECOMMENDATIONS

The Committee:

1. Begins the discussion of how ADMs for allergen(s) can be established within each country/region when new sections 4.2.1.3 and 4.2.1.4 are incorporated into its national/regional legislation.

[2] This value refers to the amount of protein deriving from an allergen ingredient within a processed food. It was set as the minimum value which (i) inspection institutes everywhere in the country can apply with sufficient reliability and accuracy, and (ii) can be detected in almost all of food products.
[3] Japanese Journal of Allergology, 55, 1536-1542 (2006)

2. Refers/Considers the experience of member countries/regions who have already implemented ADMs for allergen(s), including 20 years old Japan's case.

日本のCRD（Conference Room Document）和文

要旨

1．新たなセクション4.2.1.3及び4.2.1.4が各国/地域の国内法令に取り入れられた際に、各国/地域において、どのようにアレルゲンに関する公定検査法（authorized detection method）が確立され得るかについての議論を次のステップとして開始することについての、委員会へのご提案

2．メンバー国及びNGOのご参考のため、包装食品に「含まれる」場合に表示が義務付けられる各アレルゲンに係る日本の検査法のご紹介

はじめに

日本は、改訂案を現在の形まで導いてこられたオーストラリア、英国及び米国の作業に感謝いたします。2023年のCLに係る日本のコメントはCX/FL23/47/5 Add.1(Part A)にまとめられており、日本は新たな4.2.1.3と4.2.1.4を支持しております。

メンバー国/地域がこのような表示規制の効果を促進するためには、日本は、公定検査法（authorized detection method）を各国/地域の法制に組み込むというのはよいアイデアだと考えます。というのも、公定検査法は食品関連事業者がこのような規制を遵守することを容易にし、かつ当局が規制を執行することも容易にするからです。その結果、この公定検査法のスキームは、食物アレルギーの患者がより正確な情報を得ることを可能にすると考えます。このため、日本は本部会に対し、次のステップとして、アレルゲンに関する公定検査法がどのように確立され得るかに関する議論を開始することをご提案するものです。また、アレルゲン表示の改訂/確立に取り組む国/地域にとって日本の経験が何かしら助けとなることを期待して、そのような検査法に基づく日本の食品表示制度についてご紹介したいと思っております。

背景(Background)

2001年に日本が初めてアレルゲン表示制度を導入したときから、日本ではこうした義務表示制度の適切な執行のためには、食品中のアレルゲンの存在を検出できる科学的方法の確立が必須だと考えられていました。というのも、義務表示であることから、当局が適切にこの規制に基づき罰則の適用等を行うことを可能とすることが必要であるためです。また、食品の製造工程が複雑であればあるほど、食品関連事業者が最終製品中のアレルゲンの存在を正確に把握することは難しくなります（例えば、いわゆる複合原材料の中に微量に含まれている場合など）。このため、食品表示に責任を持つ事業者が消費者にアレルゲン情報を正確に提供するためには、彼ら自身がアレルゲンの存在をセルフチェックできる実用的な方法が必要と考えられました。ELISA試験やPCR試験といった検査法は、当局に科学的な裏付けを提供するための可能な方法として研究（investigate）されました。

このような考えに基づき制定された日本のアレルゲン表示制度では、消費者庁がアレルゲンの品目ごとに、定量的及び定性的※1な「公定検査法（authorized detection method）」を指定し公表しています。公定検査法で使用されるキットは簡単に手に入り、当局は公定検査法に基づいて監視を行っています。食品関連事業者は自身の製品についてセルフチェックしています。なお、各品目の公定検査法（定量検査法）によって陽性と判断されるのは、加工食品１グラムあたりアレルゲンとなる原材料由来のタンパク質含有量が10μg以上です※2 。もし監視の結果製品が表示義務違反だとされれば、当局は罰則の適用等を行いますが、当局は監視（monitoring）において公定検査法を用いるので、罰則の適用を考える上でもこの10μg/gという値は重要です。

義務表示及び推奨表示/定期調査(Mandatory Labelling and Recommended Labelling/Periodic Reassessment)

換言すれば、もしあるアレルゲンが頻度や深刻度等から見て重要であったとしても、公定検査法がなければ、義務表示品目として指定することはありません。そうした品目については任意の「推奨表示」品目として指定します。

例えば、「くるみ」は最近義務表示として指定しました。（かつては）くるみは推奨表示品目に分類されていましたが、2021年の定期調査結果を基に、消費者庁は、頻度、深刻度等からみて義務表示品目として指定されるべきであると結論づけました。そのため、「食品表示基準」の改正に必要な手続きを経て、義務表示品目としてのくるみの指定を2023年３月９日で施行するとともに、同日付で、この政策改訂に合わせて開発された公定検査法も公表しました。

義務表示（８品目）：えび、かに、くるみ、小麦、そば、卵、乳、落花生（ピーナッツ）

推奨表示（20品目）：アーモンド、アワビ、いか、いくら、オレンジ、カシューナッツ、キウイ、牛肉、ごま、さけ、さば、大豆、鶏肉、バナナ、豚肉、まつたけ、桃、ヤム、りんご、ゼラチン

Authorities（アレルギー専門医）約1,000名により、約20年に渡って即時型の食物アレルギー症状を呈した患者をモニタリングする定期調査を３年ごとに行っています。直近の2021年の調査では6,080症例が検討されました。

検査法（Detection Methods）

それぞれのアレルゲン（８品目）に関する日本の検査法は以下でご覧いただけます。（申し訳ありませんが、日本語のみとなっております。）

https://www.caa.go.jp/policies/policy/food_labeling/food_labeling_act/assets/food_labeling_cms201_230414_01.pdf

えびとかにはそれぞれ別々に表示されることとして区別されています。「甲殻類」は使われません。えびとかにの検査法もまた区別されています。これは消費者の食品選択を過度に狭めないためです。えびアレルギー患者のうち35%以上は、かにに関しては症状を起こさないと報告されています※3。

これまでのところ、日本の規制はうまくいっている(be effective)ことが分かっています。とりわけ、定量検査法における陽性/陰性の境界線を10μg/gとして20年以上経過しましたが、重症な食物アレルギーを予防するため、さらなる低値を設定すべきとの強い指摘はありません。日本としては、アレルゲン表示制度の確立/改訂に取り組まれる国/地域にとって日本の経験が何かしら助けとなることを望むものです。

FAOが簡単に日本の経験をまとめています。(p13-19)　https://www.fao.org/3/cb2868en/cb2868en.pdf

予防的アレルゲン表示（議題5.2関係）

日本としては、標準化された分析法及びサンプリングについて分析・サンプリング部会（CCMAS）からの助言を求める必要が議題5.2において議論されることを歓迎します。上記の情報が、議題5.2における議論において何かしら貢献することを望むものです。

推奨（Recommendations）

1．新たなセクション4.2.1.3及び4.2.1.4が各国/地域の国内法令に取り入れられた際に、各国/地域において、どのようにアレルゲンに関する公定検査法（authorized detection method）が確立され得るかについての議論を開始すること。

2．既にアレルゲンに関する公定検査法を運用(implement)しているメンバー国/地域の経験について、20年の経験を持つ日本の例も含め、参照又は考慮すること。

※1　定量検査法では、対象とする食品以外の食品に由来するたんぱく質を検知してしまい偽陽性の結果が生じることがあるので、定量検査法で10μg/g以上の結果となった場合には、定性検査法を用いて品目に特異的なDNA領域を確認している。

※2　全国どこの検査機関でも真度、精度が保たれ、大半の食品で検出できる最小値として設定しており、加工食品中のアレルゲンとなる原材料由来のタンパク質含量のこと。

※3　Japanese Journal of Allergology, 55, 1536-1542 (2006)

※英文を機械的に翻訳したものです

PROPOSED DRAFT REVISION TO THE GENERAL STANDARD FOR THE LABELLING PRE-PACKAGED FOODS – PROVISIONS RELEVANT TO ALLERGEN LABELLING (Agenda item 5)[6]

Conclusion

30. CCFL47 agreed to the text as proposed by the VWG.

4.2.1.4

31. The FAO representative explained the process of how the food allergen list was established by the FAO/WHO Expert Consultation. The experts reviewed as many foods as possible known to cause allergenic reactions, including some very rare ones. Based on the available scientific data, the experts narrowed down the list as showed in Table 17 at page 58 in the FAO/WHO Part 1 report*[10]. Based on prevalence, potency and severity data, the experts performed a sensitivity analysis and investigated prevalence. The experts ranked the food allergens and found the most appropriate point to categorize the food allergens. Both the priority food allergen list and the secondary list were established by this process.

32. CCFL47 noted general support for this section and the comment that to implement 4.2.1.4 effectively, it was important to have detection methods of analysis readily available for both the competent authority and food businesses.

アレルゲン表示の効果的な実施のために規制当局と食品事業者双方が利用できる分析方法が重要であるコメント