



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEx COMMITTEE ON FOOD HYGIENE

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Proposed consequential amendments to the *Code of practice on food allergen management for food business operators* (CXC 80-2020)

Prepared by Codex Secretariat

BACKGROUND

1. At its 48th Session (CCFL48, 2024)¹, CCFL agreed to forward the draft revision of allergen labelling provisions in *General Standard for the labelling of pre-packaged foods* (CXS 1-1985) to CAC47 for adoption at Step 8. CAC47 subsequently adopted the revision.
2. CCFL48 also agreed to inform CCFH of:
 - the completion of the revisions, in particular the updated definitions and the new list of foods or ingredients that should be declared on a label, to ensure consistency with the *Code of practice on food allergen management for food business operators* (CXC 80-2020); and
 - the ongoing work on the development of *Guidelines on the Use of Precautionary Allergen Labelling*.
3. As noted in CX/FH 25/55/2, paragraph 26(ii)(a), CCFH55 is invited to take note that the list of allergens in CXC 80-2020 requires updating to ensure alignment with the recent revision of CXS 1-1985.

PROPOSAL

4. The recent revision to CXS 1-1985 included updating the list of allergens recognized on a global level following scientific advice from FAO and WHO. CXS 1-1985 also now recognizes that there are a range of other allergens that are more regional or country specific as identified by the FAO/WHO expert meetings. In light of this, the lists identified in CXC 80-2020 are no longer consistent with the latest CXS 1-1985, hence the need for alignment.
5. The Codex Secretariat is of the view that consequential amendments to CXC 80-2020 could be undertaken at this stage and having reviewed both texts, has developed corresponding proposals to ensure consistency between CXC 80-2020 and the provisions on food allergens in CXS 1-1985 and to avoid any conflicts. The proposed consequential amendments are described below and are presented in Appendix I to this CRD.
 - Noting that the number of food and ingredient that may cause an adverse immune reaction has been expanded in the revision of Section 4.2.1.4 and 4.1.2.5 of the *General Standard for the labelling of pre-packaged foods* (CXS 1-1985), it is proposed to delete the list included in the hazard characterization of CXC 80-2020 and simply replace it with a cross-reference to the relevant sections of CXS 1-1985. To avoid any misalignment between the two texts, the paragraph immediately following the list of foods and the first two sentences of the next paragraph should also be deleted.
 - In the second paragraph of the scope, the reference to eight food groups should also be replaced with a cross-reference to CXS 1-1985 to ensure consistency.

¹ REP24/FL paragraphs 52(i) and (ii)

- Relevant new definitions in CXS 1-1985 i.e. “allergenic food”, “food allergen”, “food allergy” and “coeliac disease” should be included for completeness, noting that all these terms are used in CXC 80-2020.

6. Regarding ensuring consistency with the future Guidelines on the use of precautionary allergen labelling, which are currently under discussion at CCFL, this would need to be addressed at a later stage when the work on PAL has been completed by CCFL and adopted by CAC.

7. CCFH55 is invited to:

- Consider the proposed consequential amendments to CXC 80-2020 (Appendix I); and
- If appropriate, submit the text for adoption by CAC49.

Proposed consequential amendments to the *Code of practice on food allergen management for food business operators (CXC 80-2020)*

New text is in **bold/underline**. Text to be removed is indicated in ~~strike through~~.

Hazard characterisation

The allergenic nature of some foods should be identified as a food safety hazard for susceptible individuals. Food allergies are caused by an adverse immune reaction (hypersensitivity) to certain food proteins. Allergies to food can be classified by their immune mechanism:

- immunoglobulin E (IgE)-mediated (immediate hypersensitivity),
- non-IgE mediated (cell-mediated, or delayed hypersensitivity), and
- mixed IgE and non-IgE mediated.

IgE-mediated symptoms typically develop within minutes to 1-2 hours of ingesting the food. Non-IgE-mediated and mixed IgE- and non-IgE-mediated food allergies present with their symptoms several hours after the ingestion of the food. Symptoms of IgE-mediated food allergy may include itching around the mouth, hives, swelling of lips and eyes, difficulties in breathing, drop in blood pressure, diarrhoea and, in its most severe form, anaphylaxis; and may result in death.

While many different foods can cause allergic reactions in susceptible individuals, the majority of food allergies ~~on a global basis~~ are caused by a variety of proteins in **various eight foods/ food groups (and derived products) as described in Sections 4.2.1.4 and 4.1.2.5 of the General standard for the labelling of pre-packaged foods (CXS 1-1985)**. These are²

- ~~cereals containing gluten (i.e. wheat, rye, barley, oats³, spelt or their hybridized strains)~~
- ~~crustaceans;~~
- ~~eggs;~~
- ~~fish;~~
- ~~milk;~~
- ~~peanuts;~~
- ~~soybeans; and~~
- ~~tree nuts~~

~~The most common allergic reactions to tree nuts involve almonds, Brazil nuts, cashews, hazelnuts, macadamias, pecans, pistachios and walnuts. In addition, cereal grains such as wheat, barley and rye contain gluten, which can cause adverse reactions in persons with Coeliac disease⁴, as well as those with specific allergies to those cereals.~~

~~While the allergens listed above are the most common, other food allergens such as sesame seeds, buckwheat, celery, mustard, molluscs and lupin are recognised as important in many countries. The list of recognised food allergens varies among countries and there is the potential for additional major allergens to be identified in the future. The controls outlined in this Code of Practice (Code) would be similar for any other allergens, and FBOs should apply these as appropriate to their own business requirements and applicable legislation. This includes being aware of the food allergens recognised as important in countries they are exporting their product to, managing those allergens and ensuring the necessary allergen labels are applied.~~

Poor allergen management can result in the presence of varying levels of undeclared and/or unintended allergens in food, which may pose a risk if consumed by an individual with an allergy to the food. The doses that provoke reactions vary among individuals and are dependent in part on the type of allergen. The risk of

² The listed foods, with one exception (i.e. deletion of sulphites), are referred to in the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985) as the foods and ingredients known to cause hypersensitivity and that must always be declared .

³ While oats do not contain gluten, they are commonly produced in the same location as gluten-containing cereals such as wheat, resulting in allergen cross-contact.

⁴ ~~Coeliac disease is a serious lifelong illness where the body's immune system attacks its own tissues when gluten is consumed. This causes damage to the lining of the gut and results in the inability of the body to properly absorb nutrients from food.~~

allergic reactions within a larger proportion of the population suffering from food allergies increases with increasing concentration of undeclared allergen.

Allergen cross-contact can result from a number of factors in processing, preparing and handling foods, some of which pose a greater potential for allergen cross-contact than others. The control measures implemented to prevent or minimise the likelihood of allergen cross-contact should be based on risk assessment conducted by food business operators.

It is important that FBOs are able to identify the allergenic nature of the foods, including ingredients, and processing aids they handle and take steps to manage any potential presence of undeclared allergens.

SECTION II – SCOPE, USE AND DEFINITIONS

2.1 Scope

This Code covers allergen management throughout the supply chain including at primary production, during manufacturing, and at retail and food service endpoints. It complements GHP in manufacturing and food preparation practices in food service.

This Code covers IgE-mediated, non IgE-mediated food allergies and other hypersensitivities (e.g. Coeliac disease) that can be triggered by small amounts of the offending food allergen (thus requiring attention to GHPs in addition to labelling). There are **various** ~~eight~~ foods/food groups (and derived products) that cause the majority of food allergies on a global basis, ~~these are cereals containing gluten; crustaceans; eggs; fish; milk; peanuts; soybeans; and tree nuts. (see CXS 1-1985)~~. However, since the complete list of recognised food allergens varies among countries, it is important to consider which allergens are applicable when exporting food.

This Code does not cover hypersensitivities with a non-immunological aetiology such as lactose intolerance and sulphite sensitivity. Food intolerance adverse reactions usually result from a non-immune mediated reaction to food, such as a lack of an enzyme to process foods effectively (e.g. the absence or deficit of lactase in those with lactose intolerance). While intolerances are not explicitly mentioned in the following text, some of the controls described here could be applied to protect those with food intolerances.

2.3 Definitions

Refer to definitions in the *General Principles of Food Hygiene* (CXC 1-1969) and other applicable Codes. In addition, for the purpose of this Code, the following expressions have the meaning stated:

Allergen means an otherwise harmless substance capable of triggering a response that starts in the immune system and results in an allergic reaction in certain individuals. In the case of foods, it is a protein which is found in food capable of triggering a response in individuals sensitised to it.

Allergenic Food means a food (including ingredients, food additives and processing aids) that can elicit immunoglobulin class E (IgE)-mediated or other specific immune-mediated reactions in susceptible individuals.

Allergen cross-contact occurs when an allergenic food, or ingredient, is unintentionally incorporated into another food that is not intended to contain that allergenic food.

Allergen profile means the food allergens present via intentional addition as well as those inadvertently present (or the absence of any allergens) in a food.

Food allergen means the substance in an allergenic food, usually a protein or protein derivative that can elicit IgE-mediated or other specific immune-mediated reactions in susceptible individuals.

Food allergy means a reproducible adverse health effect arising from an IgE antibody or non-IgE antibody immune-mediated response following oral exposure to a food.

Food service means a food business or institution that produces, prepares and serves food for direct consumption.

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).