CURTIS

CLIENT ALERT 16 NOVEMBER 2026

New Codex Alimentarius guidelines on precautionary allergen labelling

Key developments and implications for the Food & Beverage sector

Introduction

In July 2026, the Codex Alimentarius Commission, jointly established by FAO and WHO in 1963 to develop practices aimed at protecting consumers and promoting fairness in the food market, adopted new guidelines on precautionary allergen labelling ("PAL"). These were included as an annex to the General Standard for the Labelling of Pre-packaged Foods, CXS 1-1985 (the "Guidelines").[1]

As food business operators know, PAL is defined as a "statement made in the labelling of pre-packaged foods to indicate a risk from the unintended presence of food allergens due to cross-contact with allergenic foods that has been identified by a risk assessment".

The new Guidelines therefore address warnings used to indicate the risk of unintended allergen presence resulting from "cross-contact", meaning contact between a food and other foods or ingredients capable of causing allergic reactions. An example is the statement "may contain". Although the Guidelines are not legally binding,[2] they nevertheless provide important best practices that may help to fill part of a regulatory gap at EU level. In practice, this gap has contributed to the increasingly widespread use of precautionary allergen statements which, because of their general wording, have long since lost their value as an effective source of information for consumers. Against this background, the new Guidelines seek to promote more consistent and scientifically grounded use of these statements, so that PALs can provide more reliable information.

For food and beverage businesses, the new text provides an essential reference for effective allergen management and the associated review of food labels.

---

[1] Codex Alimentarius, CXS 1-1985, 2026 edition, Annex, *Guidelines on the use of precautionary allergen labelling, Sections 1–3. FAO, press release of 7 July 2026, Global food safety standards body Codex agrees on new guidance on "may contain" allergen labels.*

[2] Codex Alimentarius, *About Codex texts*, on the voluntary nature of Codex standards and other texts and the need for their incorporation into legislation or regulations in order to become binding.

This alert therefore provides a brief overview of the main recommendations in the Guidelines and their implications for manufacturers, importers, distributors and retailers, explaining how they relate to existing EU legislation.

The main recommendations in the Guidelines

1. Preventing cross-contact and assessing risk

The Guidelines place allergen management measures at the centre of their approach, drawing on the principles of the Code of Practice on Food Allergen Management for Food Business Operators, CXC 80-2020. The central principle is that PAL must be restricted to situations in which unintended allergen presence cannot be prevented or controlled through appropriate management practices.[3]

Accordingly, precautionary measures to avoid unintended allergen presence must be effectively implemented within business processes before any assessment is made as to whether PAL is appropriate.

In all cases, PAL is justified only where a risk assessment establishes that its use is appropriate. The decision to include a warning must therefore be supported by the findings of that assessment, taking into account the characteristics of the product and the processes involved.

For businesses, this points to the need to review the basis for the statements currently used, including those reproducing warnings received from suppliers, and to retain documentation supporting their labelling decisions.

2. Reference doses and action levels

One of the main developments is the link between the use of PAL and the exceedance of specified "action levels". These are quantitative thresholds calculated from the reference doses set out in the Guidelines, taking into account the amount of food reasonably expected to be consumed on a single eating occasion. Exceeding these thresholds after the precautionary measures described above have been implemented justifies the use of PAL. Conversely, where the action levels are not exceeded, PAL should not be used.

[3] CXS 1-1985, Annex, paragraph 4.1. Codex Alimentarius, Code of Practice on Food Allergen Management for Food Business Operators, CXC 80-2020, 2026 edition, in particular Sections 5.2, 5.3, 5.7 and 6.1.

Action levels for each allergen are not expressed as absolute amounts. Instead, they are expressed in relation to the amount of food reasonably expected to be consumed on a single eating occasion. In this way, the Guidelines take account of actual allergen intake based on a reasonable portion of food. For example, a given concentration may be assessed differently for PAL purposes depending on whether the allergen is present in a sauce served with meat, typically consumed in a relatively small portion, or in a bakery product, which is expected to be consumed in larger quantities.[4]

For the time being, these criteria provide a sound basis for guiding and substantiating risk communication decisions, but they do not have the force of law.

3. The content and presentation of warnings

The Guidelines also address the wording and placement of PAL. The warning must appear as a separate statement directly below or close to the list of ingredients, where one is provided.[5]

The statement must begin with the words “may contain”, or equivalent wording determined by the competent authorities, and identify the allergenic foods using the specified names required by the Guidelines.

The statement must also be presented clearly and distinctly, for example using a font, style or colour that contrasts with the surrounding text. Where both a PAL statement and an allergen declaration are present, they must be highlighted in the same manner.

A review of food labels should therefore consider the basis for the warning alongside the accuracy of the names used, the placement of the text and its legibility.

4. Coordination with gluten statements

The Guidelines also contain specific provisions on coeliac disease. In addition to identifying a specific action level for total gluten (4 mg), paragraph 4.3.2 provides that the term “gluten-free” must not be used where PAL is necessary in relation to the presence of wheat, barley or rye.[6]

[4] CXS 1-1985, Annex, paragraph 4.3, footnote iii and Table A1. The action level is calculated by dividing the reference dose, expressed in mg of total protein from the allergenic food, by the amount of food consumed, expressed in kg. The amount to be considered is that reasonably expected to be consumed on a single eating occasion, preferably using the 50th percentile.

[5] CXS 1-1985, Annex, paragraphs 5.1–5.2.4. Paragraph 5.2.1 governs the placement of the warning where the food is exempt from declaring a list of ingredients and no list is provided. Paragraph 5.2.3 also contains a specific provision for cases where gluten exceeds the action level and its source cannot be verified through the risk assessment.

[6] CXS 1-1985, Annex, Table A2 and paragraph 4.3.2.

The Codex provisions must be considered alongside the conditions laid down in EU law. Commission Implementing Regulation (EU) No 828/2014 governs this matter and permits the use of the statement "gluten-free" in the EU where the gluten content of food as sold to the final consumer does not exceed 20 mg/kg.[7]

However, the reference dose in the Guidelines (4 mg) and the EU limit of 20 mg/kg express different quantities and cannot be compared directly. The former concerns the amount of gluten consumed in a portion of food, while the latter indicates its concentration in the food itself. Any assessment of whether the statement "gluten-free" may be used must therefore take both parameters into account.

Final remarks

The new Guidelines provide businesses with a reference for reviewing the basis for their precautionary allergen statements and their alignment with allergen management procedures.

Businesses should first map the opportunities for cross-contact throughout the production chain and ensure that they receive complete and accurate information from their suppliers. This will help them put in place appropriate precautionary measures to limit contamination with unintended allergens and follow the new approach underlying the assessment of PAL.

Labelling practices should also be reviewed in order to ensure that they meet the presentation criteria in the Guidelines which, as this brief overview has shown, are a key source of internationally recognised best practices.

[7] Commission Implementing Regulation (EU) No 828/2014, Article 3 and Annex, Part A.

****

About Curtis

Curtis, Mallet-Prevost, Colt & Mosle LLP is a leading international law firm. Headquartered in New York, Curtis has 18 offices across the United States, Latin America, Europe, the Middle East and Asia. The Firm represents a broad range of clients, including multinational corporations and financial institutions, governments and state-owned companies, investment managers, sovereign wealth funds, family-owned businesses, individuals and entrepreneurs.

For further information, please visit www.curtis.com.

Notice to clients. This material provides only a general overview of the matters discussed and does not constitute legal advice. No legal or business decision should therefore be based on its contents.

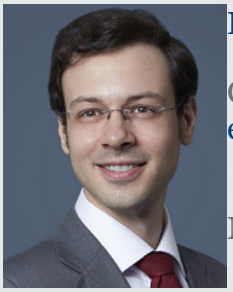
For any questions concerning this alert, please contact the lawyers listed below.



Emanuella Agostinelli

Partner
eagostinelli@curtis.com

Milan: +39 02 7623 2001



Emanuele Ballo

Counsel
eballo@curtis.com

Milan: +39 02 7623 2001