

THE ASSOCIATION OF EUROPEAN COELIAC SOCIETIES

THE ADOPTION OF CODEX PRECAUTIONARY ALLERGEN LABELLING (PAL) GUIDELINES FOR CEREALS CONTAINING GLUTEN

TABLE OF CONTENTS

Executive summary	3
Key concepts	4
1. Background	4
2. The AOECS perspective	5
2.1 - Support for Risk-Based Precautionary Allergen Labelling	6
2.2 - Support for Inclusion of Cereals Containing Gluten	7
2.3 - Support for the Reference Dose Approach	8
2.4 - PAL Must Remain Distinct from Gluten-Free Claims	9
2.5 - Support for Measures to Reduce PAL Overuse	10
2.6 - Clarity and Specificity of Labelling	11
2.7 - Oats	12
3. Analytical methods	14
4. Regulatory implementation	16
5. Conclusion	18
About AOECS	19

EXECUTIVE SUMMARY

The Association of European Coeliac Societies (AOECS) welcomes the agreement by the 49th Session of the Codex Committee on Food Labelling (CCFL49) of the global Guidelines on Precautionary Allergen Labelling (PAL).

The inclusion of coeliac disease and gluten within the PAL framework represents a significant milestone for people living with coeliac disease and reflects many years of scientific, technical advocacy and stakeholder engagement.

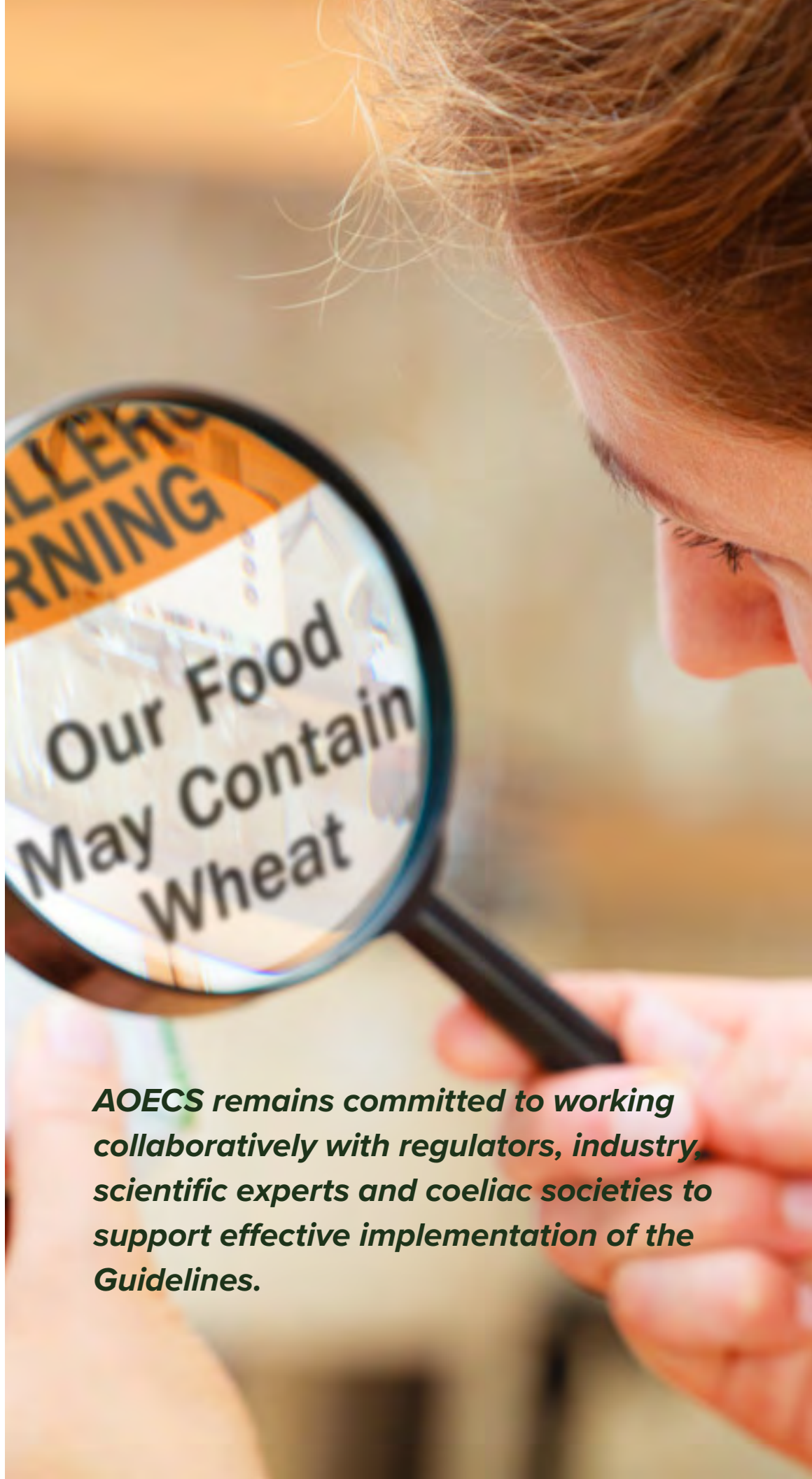
AOECS supports the principles underpinning the new Codex guidance, including:

- The use of evidence-based risk assessment to support PAL decisions
- The introduction of a reference dose for gluten (4 mg gluten)
- Measures intended to improve consistency and reduce unnecessary use of PAL
- The distinction between PAL and gluten free claims.
- The recognition that effective implementation will require education and communication for consumers, healthcare professionals, food businesses, and regulators.

At the same time, **AOECS emphasises that PAL and gluten-free claims serve fundamentally different purposes and must remain clearly separated in regulatory implementation.**

The successful inclusion of safeguards ensuring that a product carrying a PAL statement cannot simultaneously bear a gluten-free claim is therefore of critical importance.

As implementation discussions begin at national and regional level, AOECS encourages regulators and stakeholders to preserve the integrity of the agreed Codex text while supporting clear risk communication, consumer confidence and informed food choice for people living with coeliac disease.



AOECS remains committed to working collaboratively with regulators, industry, scientific experts and coeliac societies to support effective implementation of the Guidelines.

KEY CONCEPTS

Coeliac Disease:

A chronic autoimmune disease triggered by the ingestion of gluten in genetically predisposed individuals. Exposure to gluten causes damage to the small intestine and can lead to a wide range of health complications. The only effective treatment is lifelong adherence to a strict gluten-free diet.

Gluten:

A collective term for storage of proteins naturally present in wheat, rye, barley, and related cereals. Gluten triggers the autoimmune response characteristic of coeliac disease.

Cereals Containing Gluten:

Cereals that contain gluten proteins, including wheat, rye, barley and their crossbred varieties.

Cross-Contamination:

The unintended presence of an allergen or gluten in a food product as a result of shared cultivation, transport, storage, processing, manufacturing or handling practices.

Gluten-Free Claim:

A voluntary statement indicating that a food product complies with established regulatory requirements for gluten content. Under Codex standards, foods labelled “gluten-free” must contain no more than 20 mg/kg (20 ppm) gluten.

IgE-Mediated Food Allergy:

An allergic reaction involving immunoglobulin E (IgE) antibodies. Symptoms typically occur rapidly after exposure and can range from mild reactions to severe and potentially life-threatening anaphylaxis.

Precautionary Allergen Labelling (PAL):

A risk communication statement, typically expressed as “may contain”, used when a scientifically justified assessment indicates that unintended allergen or gluten cross-contamination may exceed established action levels.

Reference Dose:

The amount of an allergen or gluten that can be consumed on a single eating occasion and is considered to pose a low risk of causing adverse health effects in sensitive individuals. Reference doses are used in risk assessment to determine whether precautionary allergen labelling may be necessary. Within the Codex PAL framework, the reference dose for gluten relevant to coeliac disease is 4 mg total gluten.

Wheat Allergy:

An IgE-mediated allergic reaction to proteins found in wheat. Unlike coeliac disease, wheat allergy is not an autoimmune condition and can result in immediate allergic symptoms following exposure.

1 - THE ASSOCIATION OF EUROPEAN COELIAC SOCIETIES

BACKGROUND

Precautionary Allergen Labelling (PAL), commonly expressed through statements such as “may contain”, is intended to inform consumers about the potential unintended presence of allergens resulting from cross-contamination despite the application of appropriate control measures.

Historically, the use of PAL has been inconsistent and, in some cases, overused, leading to reduced consumer confidence and limiting food choices for individuals managing food allergies and other food-related health conditions.

When Codex began developing international guidance on PAL, the discussions focused primarily on IgE-mediated food allergies. Although cereals containing gluten were already included within the General Standard for the labelling of pre-packaged foods (CXS 1-1985), the specific needs of people with coeliac disease were not explicitly addressed within the PAL framework.

AOECS, together with international partners and scientific experts, advocated for the inclusion of coeliac disease and gluten-related considerations within the PAL discussions.

These efforts resulted in the recognition that **people with coeliac disease require clear, transparent and scientifically justified risk of communication to support informed food choices.**

Reference: FAO and WHO, 2026. General standard for the labelling of pre-packaged foods. Codex Alimentarius Standard, No. CXS 1-1985. Codex Alimentarius Commission.

2. THE AOEC'S PERSPECTIVE

2.1

SUPPORT FOR RISK-BASED PRECAUTIONARY ALLERGEN LABELLING

AOECS supports the approach set out in the Codex Guidelines that Food Business Operators (FBOs) should first work to minimize and control cross-contamination risks through appropriate Hazard Analysis and Critical Control Point (HACCP) and other preventive measures.

PAL should not be used as a substitute for good manufacturing practices.

Only where residual risk remains after mitigation measures have been applied should a precautionary statement be considered, based on a documented qualitative and, where necessary, quantitative risk assessment.

This approach promotes:

- Greater consumer confidence;
- More consistent risk communication;
- Improved industry accountability; and
- Reduction of unnecessary precautionary warnings.





2.2 SUPPORT FOR INCLUSION OF CEREALS CONTAINING GLUTEN

AOECS welcomes the inclusion of provisions relating to coeliac disease and cereals containing gluten within the Codex PAL framework.

The Guidelines include specific considerations relating to coeliac disease, including a reference dose for gluten, associated action levels and provisions relating to communication of risk from cereals containing gluten.

AOECS considers this an important advancement in international food standards. It recognises the need for people with coeliac disease to receive clear and meaningful information about potential gluten exposure due to unintended contamination.

The inclusion of coeliac disease within the PAL framework aligns risk communication more closely with the realities faced by people living with CD and helps ensure their needs are considered alongside those of people with food allergies.

2.3

SUPPORT FOR THE REFERENCE DOSE APPROACH

Based on the recommendations of the FAO/WHO expert consultation, convened by Codex, AO ECS supports the adoption of a reference dose of 4 mg total gluten for PAL risk assessment purposes.

AO ECS notes that the reference dose is:

- A risk assessment tool;
- For cereals containing gluten based on a risk analysis of repeated intakes over a day;
- Distinct from the gluten-free threshold of 20 mg/kg established under Codex standards for gluten free claims; and
- Used to derive action levels by taking into account both the amount of gluten and the quantity of food consumed.

The reference dose of 4 mg gluten should not be interpreted as a replacement for the existing gluten-free threshold of 20 mg/kg. The two values serve different regulatory purposes. The gluten-free threshold is a concentration-based standard applied to finished products, whereas the reference dose is an exposure-based risk assessment tool used to determine whether precautionary allergen labeling is required. This distinction is scientifically justified and essential for effective risk management.

AO ECS considers clear communication of these distinct purposes essential for effective implementation of the Guidelines.

- Gluten-free standards, which govern product claims and consumer assurance; and
- PAL action levels, which govern precautionary risk communication.





2.4

PAL MUST REMAIN DISTINCT FROM GLUTEN-FREE CLAIMS

AOECS considers the separation between PAL and gluten-free claims to be a fundamental principle of implementation.

A precautionary allergen statement communicates a potential health risk arising from unintended contamination. By contrast, a gluten-free claim communicates that a product complies with recognised gluten free requirements and may therefore be considered suitable for people who need to avoid gluten and, where applicable, independently certified and controlled to meet recognised gluten-free requirements.

These concepts are not interchangeable.

AOECS therefore strongly supports the Codex provision that:

A product requiring a PAL statement for cereals containing gluten shall not simultaneously carry out a gluten-free claim.

Maintaining this distinction is essential to preserve consumer confidence and avoid contradictory messaging.

2.5

SUPPORT FOR MEASURES TO REDUCE PAL OVERUSE

AOECS welcomes the provision that PAL should not be used when risk assessment demonstrates that gluten or other allergens are expected to be present at or below the established action level.

The widespread and unjustified use of PAL has historically:

- Reduced consumer trust;
- Restricted food choices;
- Encouraged defensive labelling practices; and
- Limited to the practical usefulness of precautionary statements.

AOECS supports an approach in which PAL is reserved for genuine and substantiated risks identified through risk assessment. AOECS also recognises that effective implementation of the Guidelines will require education and information for consumers, healthcare professionals, food businesses and enforcement authorities.

Furthermore, AOECS emphasises the need to educate all relevant stakeholders when the [PAL regulations](#) come into force.





2.6

CLARITY AND SPECIFICITY OF LABELLING

AOECS supports the requirement that precautionary statements use clear and consistent wording based on “may contain” declarations.

AOECS supports the Codex approach to communicating cereals containing gluten through the use of the specified names wheat, barley and rye, as set out in the General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985). The organisation also recognises the flexibility provided by the Guidelines, which allow the use of the term “gluten” in addition to the specified cereal names and, where permitted by national or regional authorities, the use of “gluten” or “cereals containing gluten” in place of barley and rye.

Specific identification improves transparency and enables consumers to make informed decisions, particularly those who may manage both coeliac disease and food allergies.

AOECS further recognises the importance of explicitly identifying wheat whenever relevant, as wheat is both a source of gluten relevant to coeliac disease and a priority allergen associated with IgE-mediated wheat allergy.

In practice, there will be many cases in which the source of gluten cross-contamination cannot be identified. Where the source of gluten cannot be verified through risk assessment, the Guidelines require the inclusion of all relevant cereals containing gluten (wheat, barley, and rye) in the PAL statement. The flexibility provided through footnote 7 should be applied in accordance with national or regional requirements.

2.7 OATS

The Guidelines include specific clarification regarding oats. AOECS notes that oats remain listed in the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985), while no specific reference dose has been established for oats within the PAL framework.

AOECS considers this clarification helpful in supporting a consistent interpretation of the PAL provisions relating to cereals containing gluten and coeliac disease.

AOECS further notes that the Guidelines recognise that individuals with coeliac disease may react to oats as a result of cross-contact with wheat, barley or rye. This clarification is important for the interpretation and implementation of the PAL provisions relating to cereals containing gluten



3. ANALYTICAL METHODS

3 - THE ASSOCIATION OF EUROPEAN COELIAC SOCIETIES

ANALYTICAL METHODS

PAL is based on qualitative and, where appropriate, quantitative risk assessment. As recognised in footnote 3 of the Guidelines, quantitative risk assessment may be informed by analytical testing and other relevant evidence. Analytical testing may therefore support risk assessment but should not be considered a substitute for effective allergen management or risk assessment.

AOECS supports the use of validated, internationally recognised analytical methods for the detection and quantification of gluten where analytical testing is used. The organisation considers it essential that any methods used for regulatory, verification, or enforcement purposes are scientifically robust, reproducible, and capable of supporting consumer protection.



4. REGULATORY IMPLEMENTATION

EXPECTATIONS FOR REGULATORY IMPLEMENTATION

AOECS recognises that agreement of the PAL Guidelines by CCFL represents a significant milestone in the development of a more consistent international approach to precautionary allergen labelling.

Following adoption by the Codex Alimentarius Commission (CAC), decisions on implementation will be made by national and regional authorities.

As countries and regions consider implementation of the Guidelines, AOECS encourages regulators to:

- Preserve the distinction between precautionary allergen labelling and gluten free claims.
- Support clear and consistent communication relating to cereals containing gluten.
- Promote education and information for consumers, healthcare professionals, food businesses, and enforcement authorities.
- Engage with patient organisations and other relevant stakeholders throughout implementation of discussions.

AOECS believes that implementation should maintain the integrity of the agreed Codex text while supporting clear risk communication, consumer confidence and informed food choice for people living with coeliac disease.

AOECS recognises that the adoption of the PAL guidelines by CCFL constitutes a major milestone but not the final step in the Codex process.

Following approval by the Codex Alimentarius Commission, implementation will depend on national and regional regulatory authorities.

AOECS calls upon regulators to ensure that:

- 1. The Codex principles are implemented consistently and harmoniously.**
- 2. PAL remains evidence-based and proportionate.**
- 3. Gluten-free claims continue to provide a high level of consumer assurance.**
- 4. Enforcement mechanisms are supported by validated analytical methods.**
- 5. Consumer organisations are involved throughout implementation of discussions.**

Encouraging European and national authorities to maintain the integrity of the Codex approach during implementation and to avoid introducing divergent interpretations that could undermine consumer confidence, create unnecessary barriers to trade, or weaken the effectiveness of risk communication.

5. CONCLUSION

CONCLUSION

AOECS welcomes the adoption of the Codex PAL Guidelines as a significant milestone for people living with coeliac disease worldwide.

The inclusion of coeliac disease and gluten within a science-based framework for precautionary allergen labelling represents an important step in international food standards and supports more consistent risk communication for consumers who need to avoid gluten.

AOECS particularly welcomes the introduction of a reference dose for gluten, the distinction between precautionary allergen labelling and gluten free claims, and the measures intended to promote more consistent and evidence-based use of PAL.

As we now move towards implementation, AOECS encourages regulators, industry, scientists and patient organisations to work together to ensure that the agreed Codex provisions are implemented in a way that supports clear communication, consumer confidence and informed food choice.

AOECS remains committed to working with stakeholders across Europe and internationally to support effective implementation of the guidelines.



ABOUT AOECS

AOECS is an independent, non-profit organization. Since 1988, we have been dedicated to improving the lives of people affected by coeliac disease. AOECS represents 40 European national coeliac member societies and seven affiliated coeliac organizations from outside of Europe.

Coeliac disease (also spelled celiac disease) is an autoimmune disorder in which cereals containing gluten trigger an inflammatory reaction in the small intestine.

It is estimated that around 100 million people worldwide suffer from coeliac disease. However, only about 25% of them have received a diagnosis; the rest are either unaware of their condition or suffer from various related ailments.

If left untreated, the disease can lead to a severely reduced quality of life and symptoms such as infertility, osteoporosis and chronic fatigue.

As of today, the only known cure for coeliac disease is a lifelong, strict gluten-free diet.

Read more on www.aoecs.org



Young girl overwhelmed by the selection at a gluten-free festival in the Netherlands.