

CALL TO ACTION

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# **GLUTEN MUST BE INCLUDED IN THE CCFL PAL GUIDELINES TO ADDRESS SAFETY CONCERNS FOR COELIACS**



# MAKE SURE TO PROTECT MILLIONS OF CONSUMERS

It would be detrimental to millions of consumers not to include all cereals containing gluten (and products thereof) from the CCFL PAL Guidelines due to a 'lack of evidence' for gluten toxicity or the absence of a reference dose for gluten.

Codex has had a Standard for foods for special dietary use for persons intolerant to gluten (CXS 118-1979) and a safe threshold of no more than 20 mg/kg for many years. Hence there is an established reference concentration for gluten anchored in a Codex Standard.

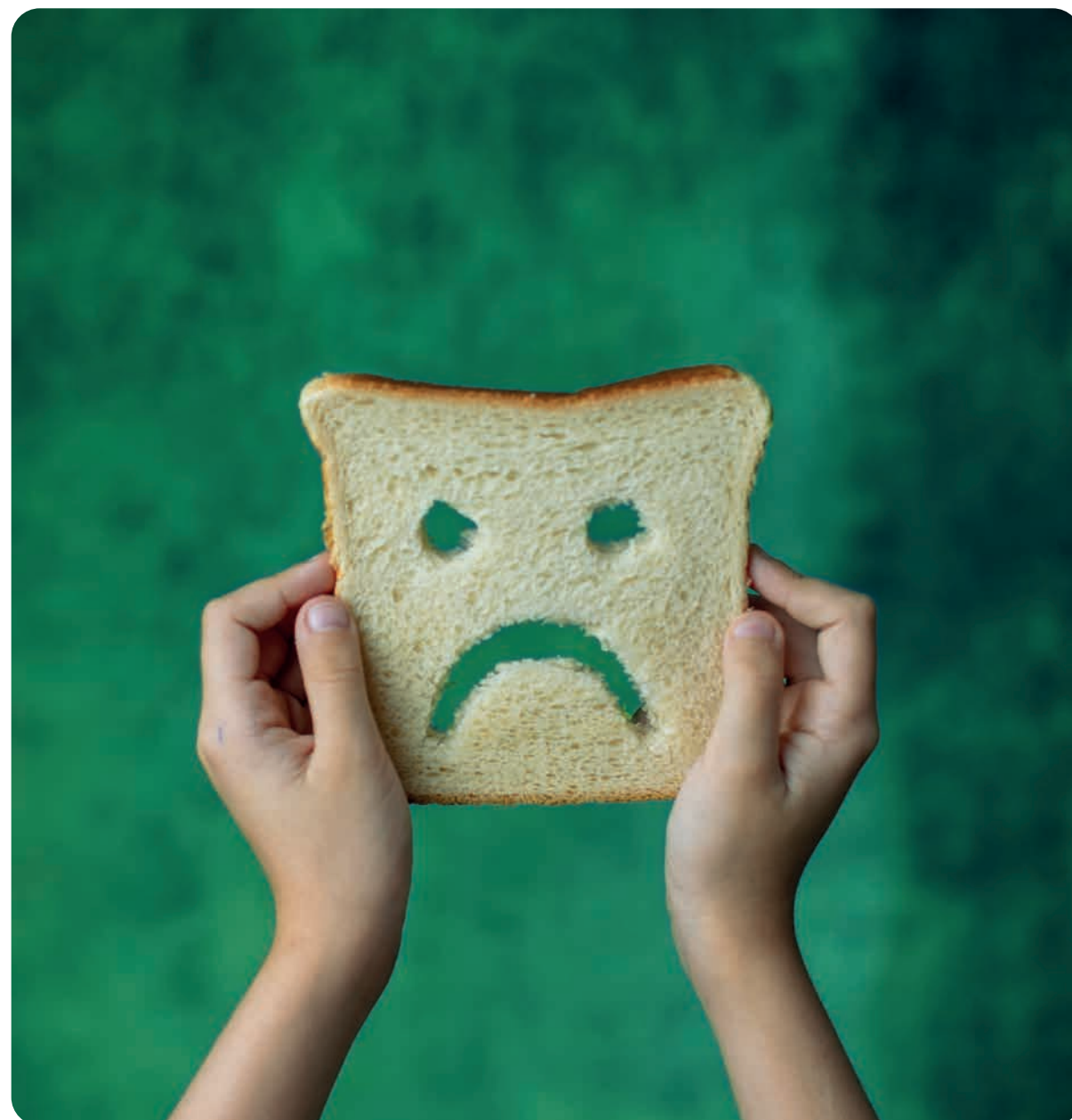
We welcome the Electronic Working Group acknowledging coeliac disease in the latest revised guidelines on the use of precautionary allergen labelling under the *Purpose* section; we now urge CCFL to consider all cereals containing gluten and the existing gluten threshold.

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We urgently request that the level of gluten not exceeding 20 mg/kg in total and the needs of the coeliac community are considered alongside the needs of people with IgE-mediated allergies; and that all cereals containing gluten be included in the proposed draft guidelines.







## THE ASSOCIATION OF EUROPEAN COELIAC SOCIETIES

# FACTS

- The **gluten** found in the cereals wheat (i.e. all Triticum species, such as durum wheat, spelt, and khorasan wheat), barley and rye (collectively referred to as cereals containing gluten) **triggers an autoimmune reaction** in people with coeliac disease.
- **Proteins** in wheat can cause, in some people, IgE-mediated **allergic reactions** (wheat allergy).
- In the case of Unintended Allergen Presence (UAP) and any Precautionary Allergen Labelling (PAL), people with coeliac disease rely on a **concentration of gluten (i.e. portion independent)**; for people with an IgE mediated food allergy the proposal suggests an **action level/reference dose (per portion)**. This causes a discrepancy that can be visualised in the next two pages.
- People with coeliac disease and people with IgE mediated allergies both rely on the correct labelling of foods — including PAL — to make safe food choices.

# WHAT ARE THE ISSUES

## SAFETY

For smaller food portions (< 200 g), the presence of wheat protein at 5 mg or less is unlikely to trigger the presence of PAL for wheat; however, there is a risk of high concentrations of gluten, above the 20 mg/kg threshold, posing a risk for people with coeliac disease (please refer to table below and the annex). Potentially harmful concentrations of other cereals containing gluten such as spelt, barley and rye would be ignored altogether.

## CHOICE

For bigger portions (> 200 g), a presence of wheat protein at 5 mg or above, is likely to trigger PAL for wheat (as RfD is based on serving size); however, the concentration of gluten is likely to be very low and therefore not cause a problem for people with coeliac disease. A PAL for wheat would deter people with coeliac disease to consume these foods although they are safe for them and therefore reduce choice. (Please refer to table below and the annex).

## REGULATORY

The existing Standard for foods for special dietary use for persons intolerant to gluten (CXS 118-1979) – where the gluten concentration in foods must not exceed 20 mg/kg (20 ppm) – has not been considered in the CODEX draft proposal for PAL. This creates a discrepancy and it's unclear how the proposal and the standard can sit alongside each other. The standard is based on a concentration, the proposal to use a RfD, is based on a serving size.

### SAFETY

*NO PAL FOR WHEAT as wheat unintended presence is <5 mg, however, gluten concentration is ≥20 mg/kg (20 ppm) — i.e. a risk for people with coeliac disease.*

| Gluten concentration (mg/kg) depending on quantity of wheat protein in portion size |              |  |                     |                   |                     |   |                     |                   |
|---|--------------|--|---------------------|-------------------|---------------------|---|---------------------|-------------------|
|   |              | NO PAL FOR WHEAT<br>UAP wheat protein < RfD of 5mg |                     |                   |                     | PAL FOR WHEAT<br>UAP wheat protein ≥5mg |                     |                   |
|   |              | 3mg wheat protein                                  | 3.5mg wheat protein | 4mg wheat protein | 4.5mg wheat protein | 5mg wheat protein                       | 5.5mg wheat protein | 6mg wheat protein |
|   |              | [2.4mg gluten]                                     | [2.8mg gluten]      | [3.2mg gluten]    | [3.6mg gluten]      | [4mg gluten]                            | [4.4mg gluten]      | [4.8mg gluten]    |
| Portion (g)   | Portion (kg) |  |                     |                   |                     |   |                     |                   |
| 25  | 0,025        | 96   | 112                 | 128               | 144                 | 160                                     | 176                 | 192               |
| 50  | 0,05         | 48   | 56                  | 64                | 72                  | 80                                      | 88                  | 96                |
| 100   | 0,1          | 24   | 28                  | 32                | 36                  | 40                                      | 44                  | 48                |
| 150   | 0,15         | 16   | 18,7                | 21                | 24                  | 26,7                                    | 29,3                | 32                |
| 200   | 0,2          | 12   | 14                  | 16                | 18                  | 20                                      | 22                  | 24                |
| 250   | 0,25         | 9,6  | 11,2                | 12,8              | 14,4                | 16,0                                    | 17,6                | 19,2              |
| 300   | 0,3          | 8  | 9,3                 | 10,7              | 12,0                | 13,3                                    | 14,7                | 16,0              |
| 350   | 0,35         | 6,9  | 8                   | 9,1               | 10,3                | 11,4                                    | 12,6                | 13,7              |
| 400   | 0,4          | 6  | 7                   | 8                 | 9                   | 10                                      | 11                  | 12                |
| 450   | 0,45         | 5,3  | 6,2                 | 7,1               | 8                   | 8,9                                     | 9,8                 | 10,7              |
| 500   | 0,5          | <5   | 5,6                 | 6,4               | 7,2                 | 8,0                                     | 8,8                 | 9,6               |
| 550   | 0,55         | <5   | 5,1                 | 5,8               | 6,5                 | 7,3                                     | 8,0                 | 8,7               |
| 600   | 0,6          | <5   | <5                  | 5,3               | 6,0                 | 6,7                                     | 7,3                 | 8,0               |
| 650   | 0,65         | <5   | <5                  | <5                | 5,5                 | 6,2                                     | 6,8                 | 7,4               |
| 700   | 0,7          | <5   | <5                  | <5                | 5,1                 | 5,7                                     | 6,3                 | 6,9               |
| 750   | 0,75         | <5   | <5                  | <5                | <5                  | 5,3                                     | 5,9                 | 6,4               |
| 800   | 0,8          | <5   | <5                  | <5                | <5                  | 5,0                                     | 5,5                 | 6,0               |
| 850   | 0,85         | <5   | <5                  | <5                | <5                  | <5                                      | 5,2                 | 5,6               |
| 900   | 0,9          | <5   | <5                  | <5                | <5                  | <5                                      | <5                  | 5,3               |
| 950   | 0,95         | <5   | <5                  | <5                | <5                  | <5                                      | <5                  | 5,1               |
| 1000  | 1            | <5   | <5                  | <5                | <5                  | <5                                      | <5                  | <5                |

*Products in this area are both ≥ 5 mg wheat protein (RfD for wheat) AND ≥ 20 mg/kg gluten*

### CHOICE

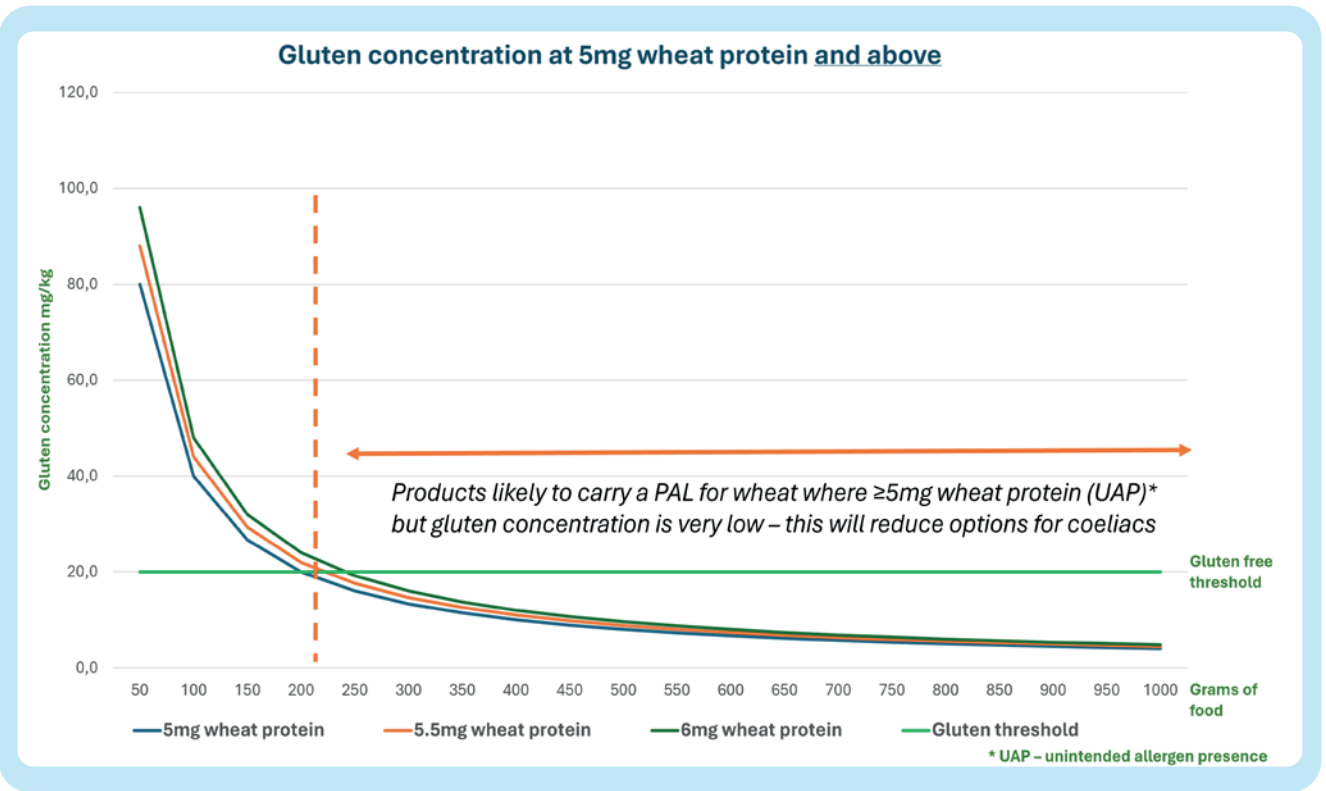
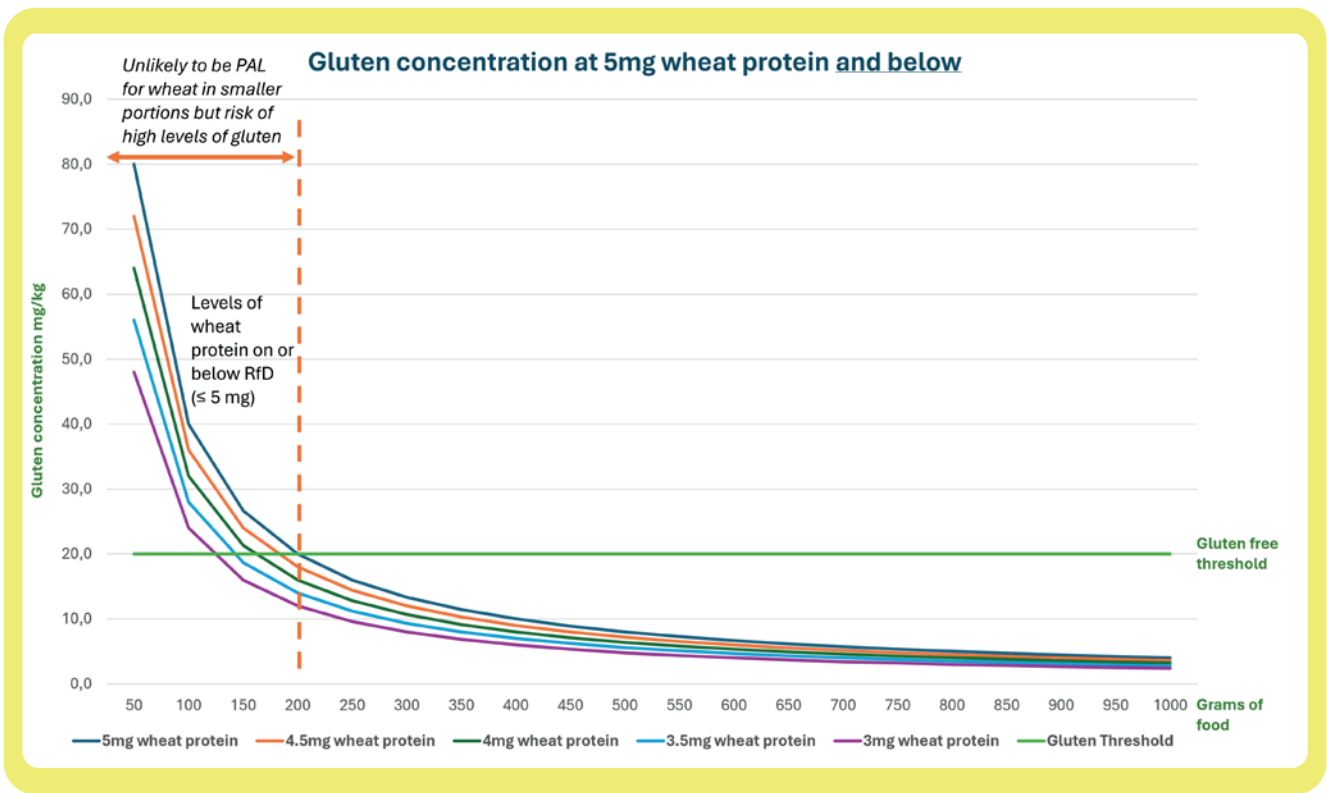
*PAL FOR WHEAT as wheat unintended presence is ≥5mg, however, gluten concentration is ≤20 mg/kg (20ppm); for portions >200g the concentration of gluten is very low — i.e. suitable for people with coeliac disease but not for people with IgE-mediated food allergy to the cereal.*

1) Only about 80% of wheat protein is gluten therefore, 1 mg wheat protein has 0.8 mg gluten. 2) The LOQ for gluten with the current available methodology is 5 mg/kg (i.e. 5 ppm). Therefore, all levels <5 ppm would not be quantified. 3) Calculation example — on the top line of the table to the left: 144 mg/kg is the gluten concentration in 0.025 kg food when there is an Unintended Allergen Presence of 4.5 mg wheat protein. We know that only 80% of wheat protein is gluten, therefore 4.5 mg x 80 / 100 = 3.6 mg gluten in 4.5 mg wheat protein. To calculate the concentration of gluten (i.e. in 1 kg of food) we do: 3.6 mg gluten x 1kg / 0.025kg = 144 mg/kg. This means that whilst the UAP of wheat protein in the portion is "just" 4.5 mg (and will not trigger a PAL), the gluten concentration is well above the established 20 mg/kg threshold.

# ANNEX

## SAFETY

For smaller food portions (< 200 g), the presence of wheat protein at 5 mg or less is unlikely to trigger the presence of PAL for wheat; *however*, there is a risk of high concentrations of gluten, above the 20 mg/kg threshold, posing a risk for people with coeliac disease.



## CHOICE

For bigger portions (> 200 g), a presence of wheat protein at 5 mg or above, is likely to trigger PAL for wheat (as the RfD is based on the serving size); *however*, the concentration of gluten is likely to be very low and therefore not cause a problem for people with coeliac disease. A PAL for wheat would deter people with coeliac disease to consume these foods although they may potentially be safe for them to consume (reducing choice).



# 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 39 European national coeliac member societies and five 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.

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Read more on [www.aoecs.org](http://www.aoecs.org)



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