THE ASSOCIATION OF EUROPEAN COELIAC SOCIETIES

INFORMATION FOR COELIAC CONSUMERS ABOUT THE SAFETY AND LIMITATIONS OF GLUTEN-FREE BEER ANALYSIS METHODS

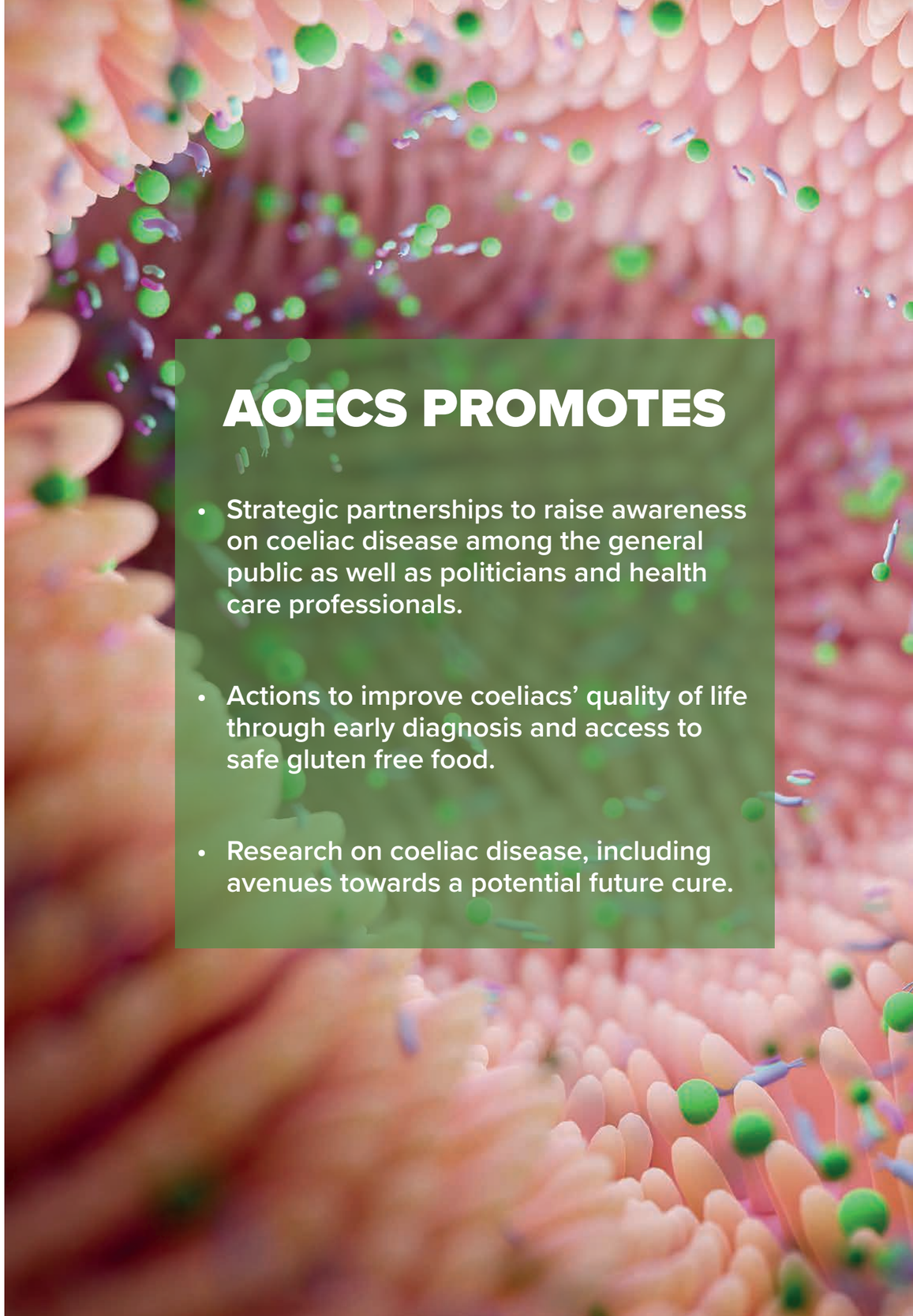
AOECS
Association of European Coeliac Societies

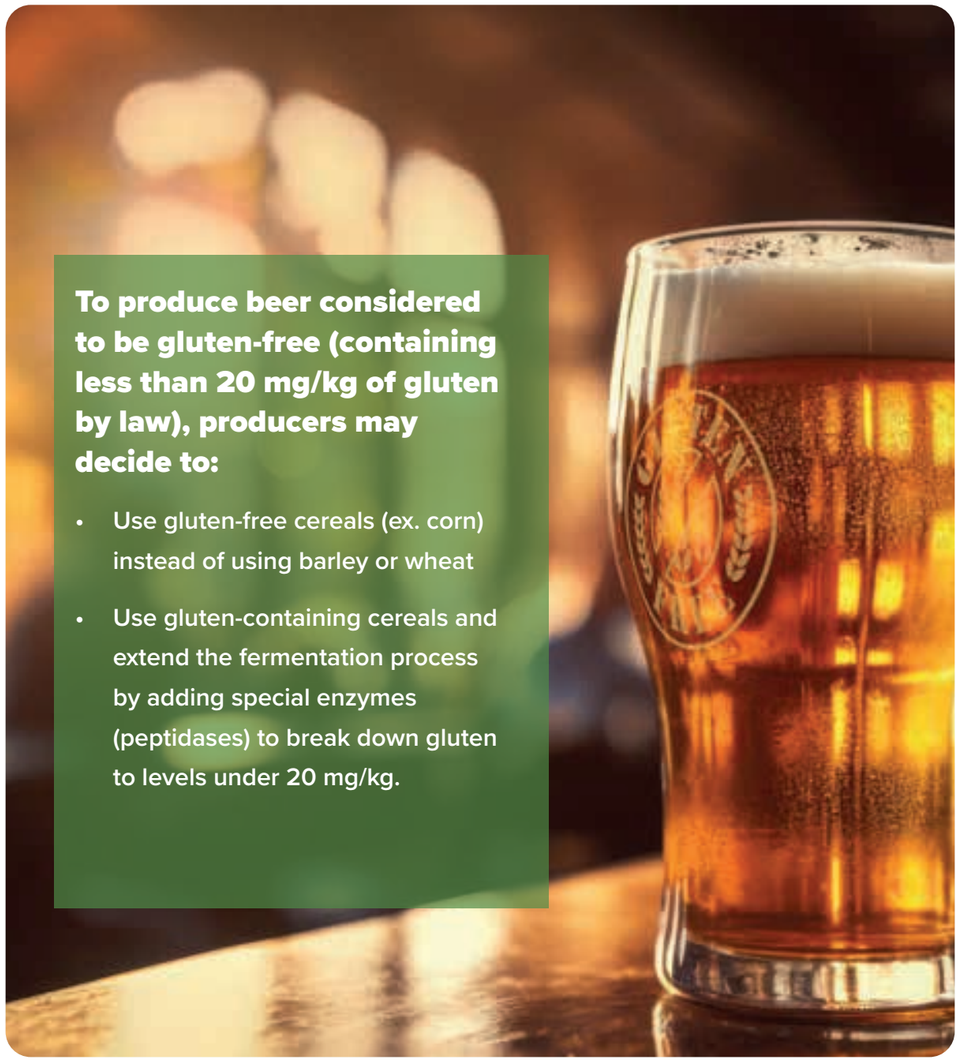
CONSUMER INFORMATION

INTRODUCTION AND CONTEXT

Coeliac disease is an autoimmune disease caused by the ingestion of food containing gluten, which is a type of protein that can be found in cereals such as wheat, barley and rye. Coeliac disease may affect up to 1-3% of the population. Today, the only known effective treatment is a strict, life-long, gluten-free diet.

The Association of European Coeliac Societies (AOECS) is a non-profit umbrella organisation comprising of national coeliac societies in Europe and worldwide. Together with its members, AOECS represents the voice of coeliac patients and their families in over 40 countries.





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ABOUT BEER

Beer is generally produced from barley, a raw material that contains gluten. By definition, beer is an alcoholic beverage made by extracting raw materials with water, boiling, and fermenting—resulting in a hydrolysed product. This means that the proteins in the raw materials have already been partially broken down.

During hydrolysis, gluten prolamin molecules are broken down into smaller peptides through the addition of yeast and enzymes that break molecular bonds. This process also makes gluten more difficult to detect.

With the second option, the hydrolysis process is further enhanced, and the enzymes break down the gluten protein into smaller peptides, making the final product safe for people with coeliac disease to consume.

In the European Union, a legislative framework outlines the special features of hydrolysed products and the implications of their production and safety. This framework enables beer producers to make informed production decisions and allows coeliac patients to make safer consumption choices.

Current scientific evidence and EU law support the licensing and labelling of beers made from barley or other cereals as gluten-free products (EU Regulation 1169/2011, EU Regulation 828/2014). Furthermore, the Codex Commission (Codex Standard 118-1979) considers hydrolysed gluten-free products safe for consumption by people with coeliac disease.

However, it should be noted that legislative frameworks differ worldwide, and patients and producers may encounter different situations outside the European Union.

IMPLICATIONS REGARDING THE ANALYTICAL METHOD

Beer producers cannot fully control hydrolysis, and thus the resulting broken-down fragments of gluten generated during the process may vary from one batch to another (H.G. Watson et al., 2018). The accurate analysis of gluten in beer is problematic, and brewers who wish to market gluten-free beers made from gluten-containing cereals such as barley or wheat must ensure that their products have been rigorously tested to comply with legislation.

It is important to bear in mind that food analytical methods are designed to determine whether the amount of a compound—in this case, gluten—is present below or above a threshold set by legislation in the final product (as noted above, products labelled 'gluten-free' in the EU must contain less than 20 mg/kg of gluten by law).

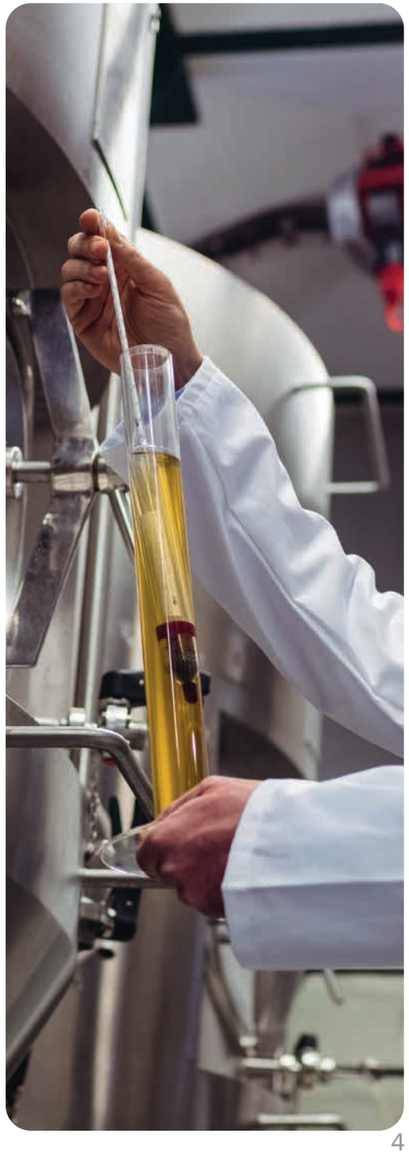
There are various methods for detecting gluten, including the R5 competitive ELISA method, the sandwich ELISA method, and other alternatives that have not yet been validated for reliability. Current scientific evidence shows that hydrolysed gluten can be detected with the R5 competitive ELISA method, as recommended by the Codex Commission. However, gluten molecules that are degraded into small peptide fragments during the fermentation or hydrolysis process are not detected by the sandwich ELISA method. Therefore, for fermented or hydrolysed products such as beer, syrup, baby food, or soy sauce, the Codex Committee recommends the use of the R5 competitive ELISA method, which can detect the altered version of the protein.

In recent years, approaches and studies regarding the limitations and sensitivity of analytical methods for testing gluten in hydrolysed products have been published (K.A. Scherf et al., 2018; H.G. Watson et al., 2019; Fernández-Gil MdP, 2021), and novel proposals and methods to analyse gluten have been developed as alternatives to ELISA (A. Cebolla et al., 2018).

Most of these publications focus on beer as the main product of study, and some support the idea of potential limitations of the R5 competitive ELISA for the analysis of hydrolysed products. To this end, they explore the use of analytical methods that show greater sensitivity, such as Liquid Chromatography-Mass Spectrometry (LC-MS) or LFIA, to quantify the number of immunogenic peptides in the final product with more precision (Liao Y.S. et al., 2017; Ja Myun Yu et al., 2021; V. Segura et al., 2023). Although these studies suggest that the methods are effective, they are not yet validated for quantifying gluten in hydrolysed products (AOAC Official Methods of Analysis: 22nd Edition, 2023).

It is also important to note that studies are limited by the reference materials used when testing hydrolysed gluten-free foods. The AOECS is advocating for researchers to define proper calibration standards for different fermentation processes, which can help avoid false negative results for gluten in final products (Panda R. et al., 2019).

That said, all methods currently under study have limitations and uncertainties. This is supported by the Prolamin Working Group (PWG), a multidisciplinary group of experts founded in 1985 to coordinate research on gluten analysis in food and its clinical implications for coeliac patients and those with other gluten-related disorders. The PWG published a 2021 position paper stating, "More scientific studies are needed to better understand MS detection of residual gluten in beer and other fermented foods and also to ensure that the R5 competitive ELISA picks up each peptide fragment it should."



CONSUMER INFORMATION

IMPLICATIONS FOR COELIACS' HEALTH

The consumption of any alcoholic drink must always be in moderation, even if it is gluten-free.

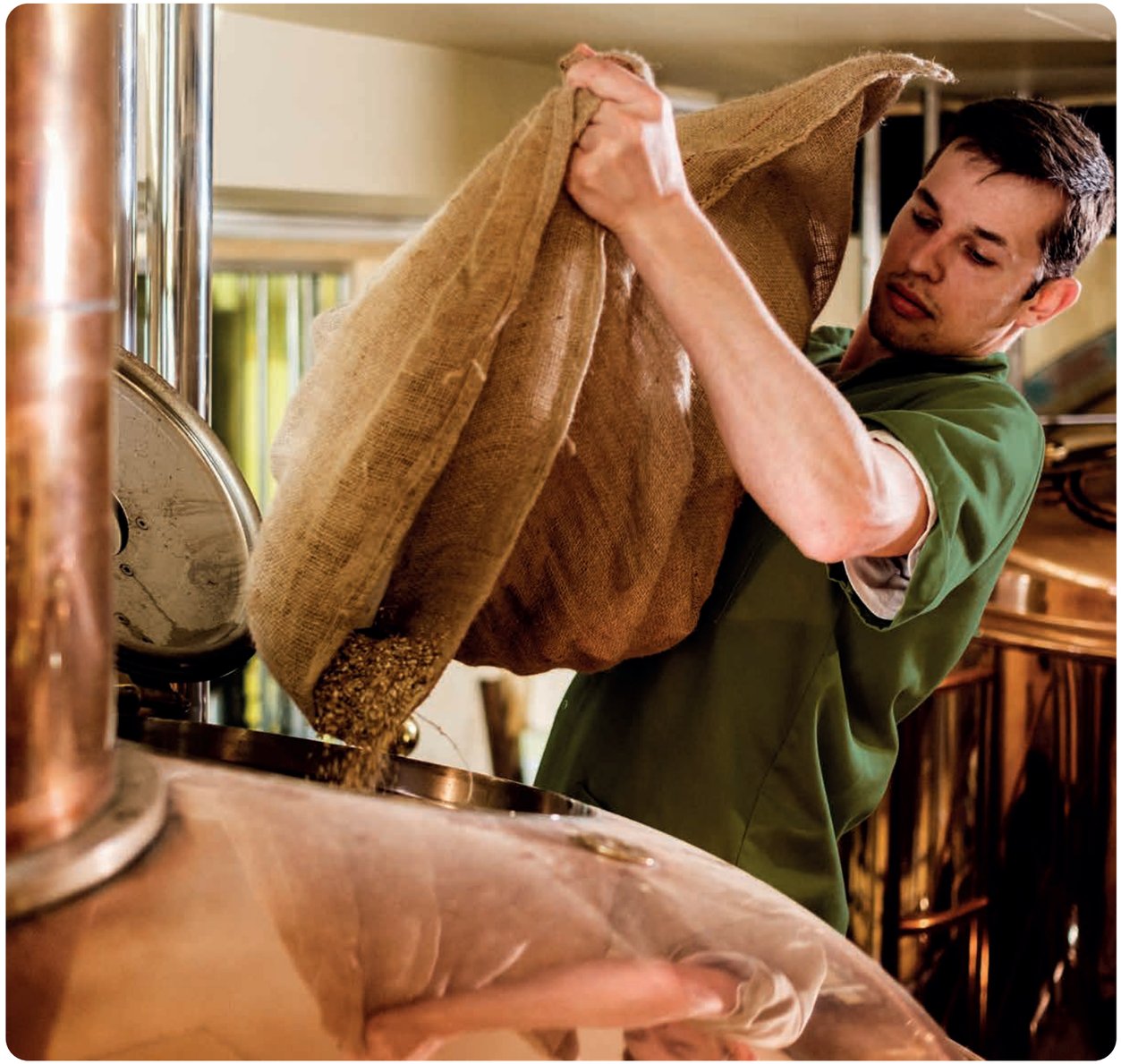
Even well-managed coeliac disease, with strict adherence to a gluten-free diet, can still result in inadvertent exposure to gluten. This uncontrolled exposure to small amounts of gluten can trigger an autoimmune response, making it necessary to study the immunogenicity (i.e., the ability to trigger an immune response) of residual peptides (Syage et al., 2018).

The immunogenicity of gluten-derived peptides can only be evaluated through clinical studies, and current research does not provide sufficient evidence to clearly define the clinical effects caused by the consumption of residual peptides in coeliac patients.

Any future studies must be designed with great care to address potential ethical concerns, as participation could be harmful to the patients involved. AOECS supports clinical studies from a "non-consumption approach" to align with the ethical principle of "do no harm" in clinical trials involving humans.

CONCLUSIONS

- Beers are usually brewed from a cereal that is a source of gluten and which, according to EU law, may contain detectable traces of gluten below the 20 mg/kg limit that allows it to be labelled as gluten-free.
- The potential immunogenicity and inflammatory effects of the detected fragments can only be evaluated by clinical studies.
- New methods for the analysis of hydrolysed products must be studied. The exploration of alternative analysis methods is important for food safety.
- Although new methods are more sensitive than the R5 competitive ELISA, they are not yet validated to reliably quantify the amount of gluten in beer.
- AOECS encourages researchers to set up a clinical study from a non-consumption/elimination approach.
- AOECS Member Societies build competence among coeliac patients to manage risk, which is critical in many aspects of coeliac disease, with the goal of helping patients make informed decisions.
- AOECS supports Member Societies to continue licensing Gluten Free beer following the AOECS Standard and analysing the product with R5 competitive ELISA until new methods that can better detect trace gluten are recognised by CODEX.



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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.

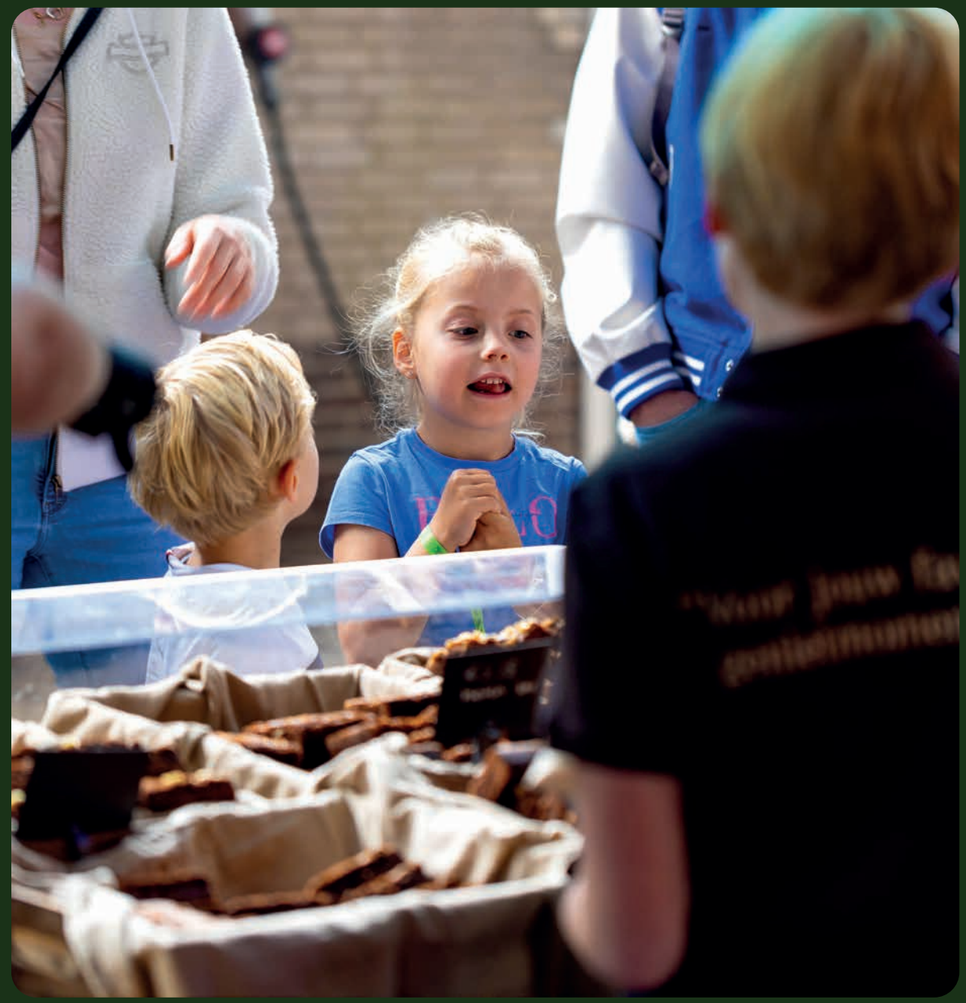
Coeliac disease (also spelled celiac disease) is an autoimmune disorder in which cereals containing gluten trigger an inflammatory reaction in the small intestine.

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.

Read more on www.aoecs.org



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

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