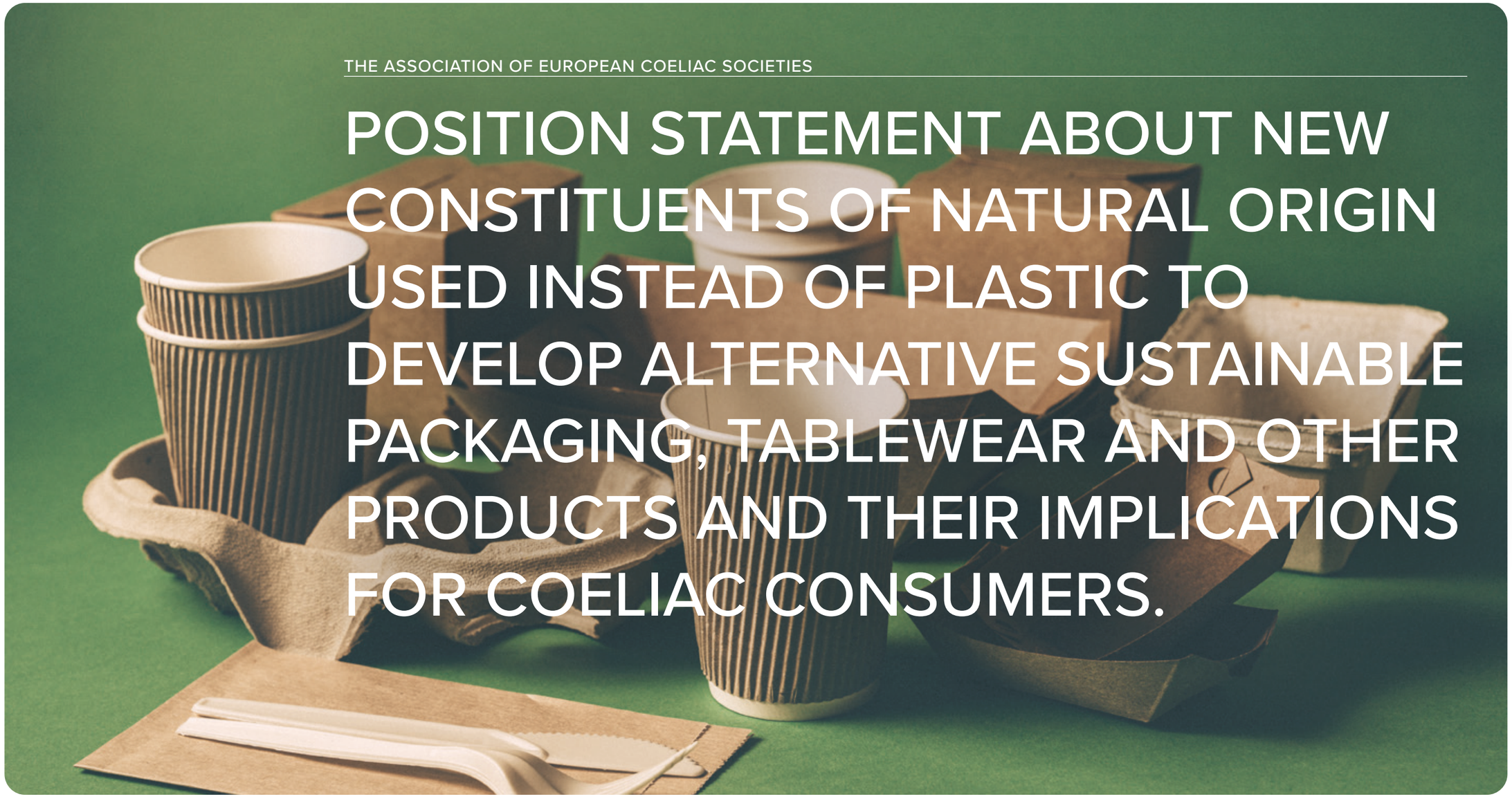


THE ASSOCIATION OF EUROPEAN COELIAC SOCIETIES

POSITION STATEMENT ABOUT NEW CONSTITUENTS OF NATURAL ORIGIN USED INSTEAD OF PLASTIC TO DEVELOP ALTERNATIVE SUSTAINABLE PACKAGING, TABLEWEAR AND OTHER PRODUCTS AND THEIR IMPLICATIONS FOR COELIAC CONSUMERS.

AOECS
Association of European Coeliac Societies

POSITION PAPER

INTRODUCTION

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 few cereals such as wheat, barley and rye.

Coeliac disease may affect about 1,4% of the population. If it remains undiagnosed, coeliac disease can result in symptoms ranging from minor discomfort to life-threatening conditions like severe anaemia and dangerous nutritional deficiencies, and even some forms of cancer such as intestinal lymphoma.

Today, the only known effective treatment for coeliac disease is a strict life-long gluten-free diet.

The Association of European Coeliac Societies (AOECS) is a non-profit umbrella organisation made of national coeliac societies in Europe and beyond.

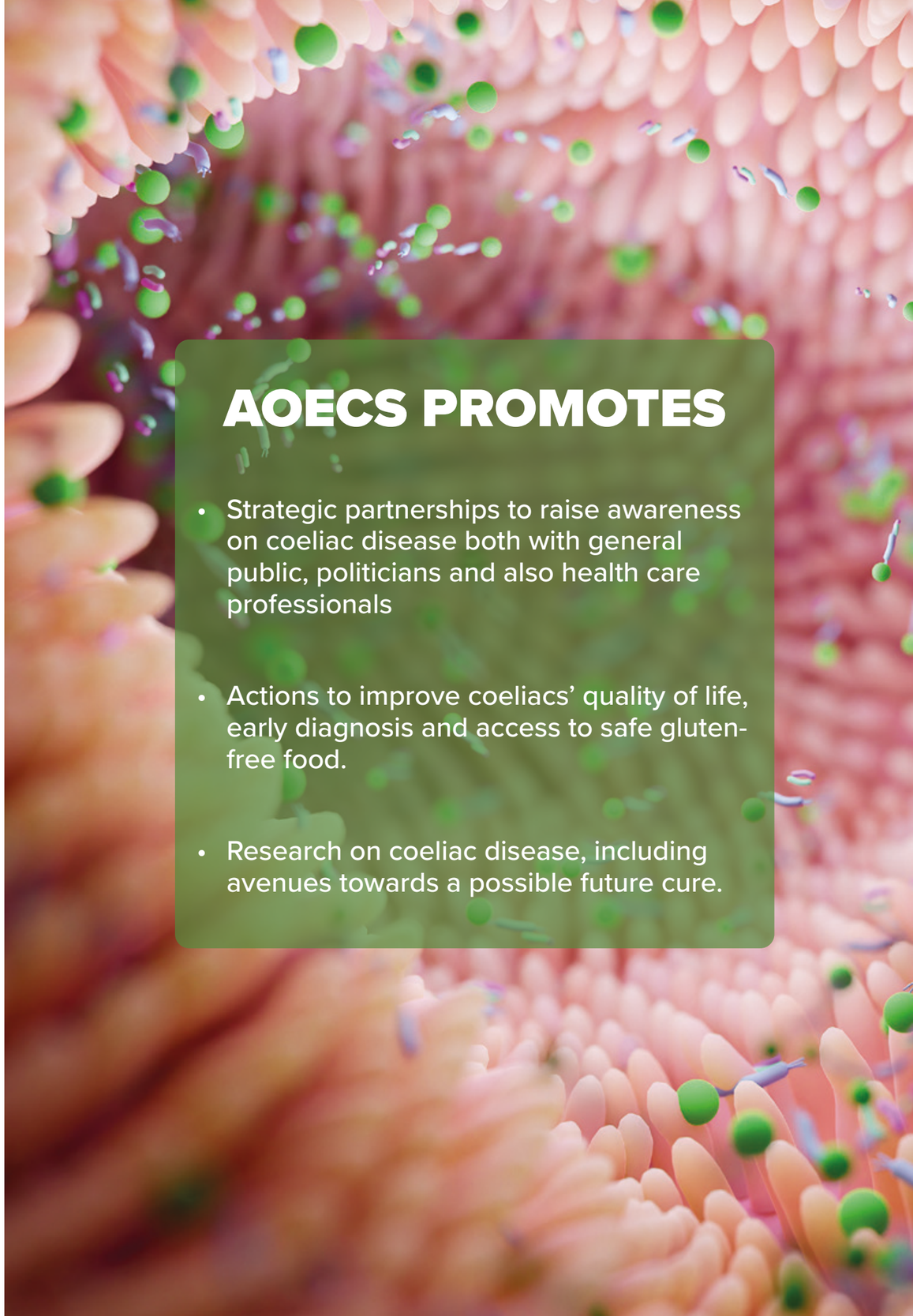
Together with its members, AOECS represents the voice of coeliac patients and their families in over 40 countries.

The AOECS owns the AOECS Standard for pre-packaged food products and the Crossed Grain Registered Trade Mark Licencing System, which is managed by its National Coeliac Societies in their respective countries.

As a result, thousands of safe gluten-free food products are available in the market and easily recognisable by any consumer.

AOECS Standards fully adheres to the Codex Alimentarius, which is the collection of standards and guidelines jointly established by FAO and WHO to protect consumers' health.

AOECS is an observer member of the CODEX Commission, to advocate for coeliacs and ensure their specific concerns are taken into consideration.



THE ASSOCIATION OF EUROPEAN COELIAC SOCIETIES

SITUATION OVERVIEW

Reduction of the use of plastics and microplastics is a topic on the worldwide agenda for the following years and part of the Goals to Transform Our World.

The European Union's commitment to sustainability, understood as a call for action to promote and protect the planet, has led to a significant shift from traditional plastics to bio-based and biodegradable alternatives in food contact materials (FCMs).

That is why plastics are being replaced by alternative materials of vegetal/ animal source, which are coming up and becoming more and more common.

The majority of the new materials used are biobased raw materials derived mostly from corn and cellulose pulp, mixed or not, with other components that could be (or not) from vegetal origin, including sugar cane, seaweed, or cereals like wheat bran, barley, or rye.

Moreover, in the current market, there are some proposals made with wheat pasta or cookie paste.

While this transition aligns with environmental objectives, it inadvertently introduces new health risks, particularly for individuals with coeliac disease and food allergies.

Recent scientific research highlights the migration of gluten from certain bio-based FCMs into food, posing potential health hazards.

This position paper underscores the urgent need for regulatory measures to ensure consumer safety without compromising environmental goals.

DEFINING FOOD CONTACT MATERIALS

Food Contact Materials (FCMs) encompass all materials and articles intended to come into contact with food during production, processing, storage, or consumption. These include packaging materials, containers, tableware, and utensils. The safety of FCMs is paramount, as their constituents can migrate into food, potentially affecting its safety and quality.

According to the European Food Safety Authority (EFSA), FCMs must be manufactured in compliance with good manufacturing practices to ensure that any migration of substances into food does not pose a risk to human health, alter the food's composition in an unacceptable way, or deteriorate its organoleptic properties under normal or foreseeable conditions of use.

Sometimes, components that come from waste products such as gluten, whey (from milk and lactose) or kitosan (from crustaceans proteins) are used to produce FCMs. These kind of materials are each time more accessible and are being used to develop not only compostable or even biodegradable packaging, but also edible packaging, improving shelf-life and environmental sustainability of food supply chains.

Biomaterials alternative to plastic can be used:

a) (mostly) as-disposable tableware and cutlery

b) as packaging (even edible, in some cases)

c) but also, toothbrushes, toys and many other things, some of them in direct contact with food and people.

If cereals containing gluten or just gluten itself is used in the production of alternative biomaterials, it can pose a problem for celiacs and people allergic to wheat.

Since 2018, when these FCMs became popular, some AOECS member societies have been doing a follow up about this topic and have developed some small studies with tableware (straws, cutlery and plates) available in their national markets. Also, some university research groups developed structured and longer research about this topic.

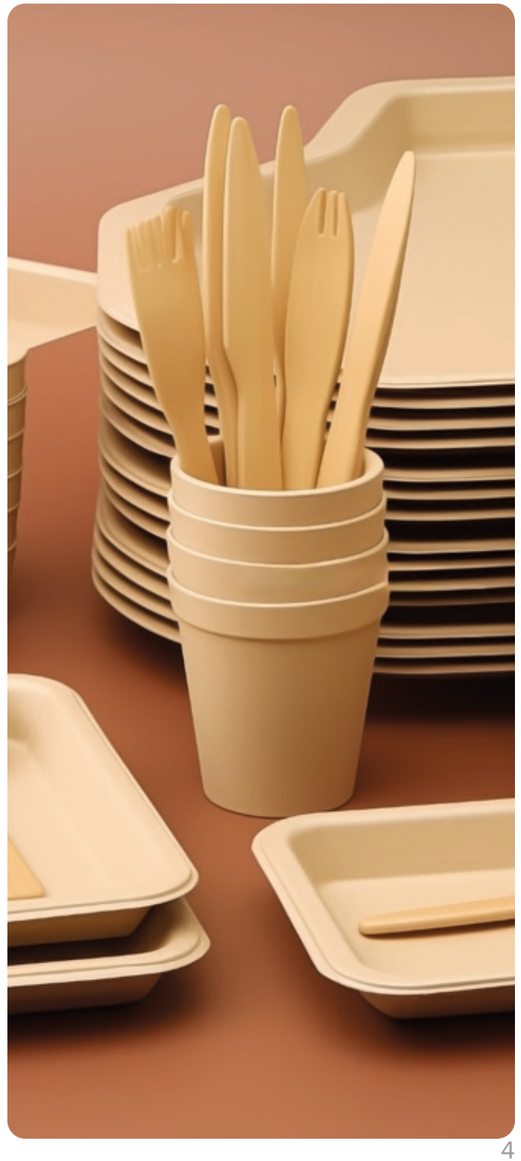
All studies conducted show that when gluten-containing cereals are used as components of FCMs, gluten can migrate into food. Although the amount of gluten migration depends on the type of food and its temperature, in all cases the measured concentrations were very high and well above the 20 ppm (mg/kg) threshold, which is the limit for food to be considered safe for people with coeliac disease.

Framework European Regulation 1935/2004 plus good manufacturing Practice (EC) 2023/2006 regulate all the materials in contact with food used by the industry and migration is included: FCMs must not transfer their constituents to food in quantities that could endanger human health.

Nevertheless, European legislation does not regulate explicitly the information on allergens in FCMs. Plus, quality requirements for disposable utensils made of biobased materials or re-usable materials are not regulated and clear (e.g. not keeping their original consistency and structure as glass or plastic ones).

Many European countries are currently planning to require companies that frequently use single-use drink cups or takeaway food containers to switch to reusable alternatives. These cups and containers must be washed and reused; however, it is currently unclear how they should be cleaned or what their expected safe lifespan is.

Furthermore, there is a lack of clarity on how bars and restaurants will manage this in practice, which may introduce an additional risk for coeliac consumers.



We need to have the scope in two main points: (1) scientific evidence about gluten migration from bio-based FCMs to food, and (2) the different regulatory gaps and challenges of using bio-based FCMs. These two points are important because:

- **Migration is a reality**. Many studies point out significant gluten migration, particularly from wheat bran-based plates. Contamination by transfer can be produced just due to contact, but quantities migrating can vary based on the temperature and the food matrix. So those products that contain gluten can be very unsafe for the coeliac community, especially considering that there is no obligation to inform consumers about the constituents of FCMs.
- **Gluten is being used** as a raw material to develop coatings and films and also for disposable tablewear, even their use is still limited, knowing how those products are primarily produced needs to take into account consumers with gluten related problems. Products are already on the market without any warning for coeliacs (or allergic people).
- **FCMs are not food**, so there is no specific legislation for allergen management; there is no obligation to label allergens present in FCMs, leaving consumers unaware of potential risks.
- **Regulation for FCMs defines some substances to be controlled** in the composition of those products and their migration. Raw materials containing gluten are not included on that list.
- **There is no evidence that the official method of analysis to quantify gluten is useful in non-food matrices**. Existing methods for detecting allergens are designed for food products, not FCMs, making it challenging to assess gluten contamination accurately. This needs to be studied.
- **There are no standardised analytical methods to extract or find gluten in materials other than food.** We don't know if gluten proteins can change when mixed with different materials. Might be harder to detect gluten, and it's not sure if it will it still be dangerous or not.
- **There is no information about the production process of the different food contact materials** or if cross-contact is controlled during the production process. Currently, there are no specific safety schemes to regulate the production of these products.
- **Unclear guidelines for reusable FCMs:** With the push towards reusable packaging, there is a lack of clarity on cleaning protocols and the lifespan of such products, especially those made from bio-based materials. If the reusable cups and containers are made from, or contain allergens, as well as dangerous chemicals, the people using and washing them need to be aware of all risks.
- **EU Recommendation 2019/794 does not specifically include biobased raw materials** (including gluten-containing cereals) now used in packaging and for products in contact with food that must be sampled to test overall migration. How to test it properly still needs to be defined because, as mentioned before, there is no standard available.
- **The stability of the final products is still uncertain.** Can a cup made from plastics, gluten and other materials withstand the same temperatures and the corrosive dishwashing detergent that can be used safely on ceramics, plastics, metal and glass? The producer has to provide detailed instructions on use and cleaning for the specific item, and indicate if there are any restrictions on what can come into contact with the cup or container.
- **Industry is** at this point **focused on the assimilation with the use of more new bio-based materials** (on its own or mixed with other plastics), but has to understand that with these new materials comes a risk in use for vulnerable consumers who need to be protected.

Currently, EFSA has not published any opinion or benchmark study. AOECS is working on this topic, with the results of the studies done by its member societies. A letter was sent to the European Commission and EFSA in 2021 asking about this matter, and a response has not yet been received.

In 2023, two Italian Members of the European Parliament submitted a parliamentary question[1] to the European Commission. The Commission replied[2] that it is aware of changes in the materials used in contact with food as a result of EU environmental objectives and that, at present, it is carrying out preparatory work towards a revision of EU rules on food contact materials (FCMs).

As part of this revision, the European Commission aims to improve consumer information requirements, including the labelling of FCMs, and to introduce more specific rules on the migration of substances into food.

In support of this work, the European Food Safety Authority (EFSA) is preparing a technical report on the safety assessment of the use of mixtures of natural origin in the manufacture of FCMs, which will also address allergenicity.

[1] https://www.europarl.europa.eu/doceo/document/E-9-2023-002998_EN.html

[2] https://www.europarl.europa.eu/doceo/document/E-9-2023-002998-ASW_EN.html

RECOMMENDATIONS FOR EU POLICYMAKERS

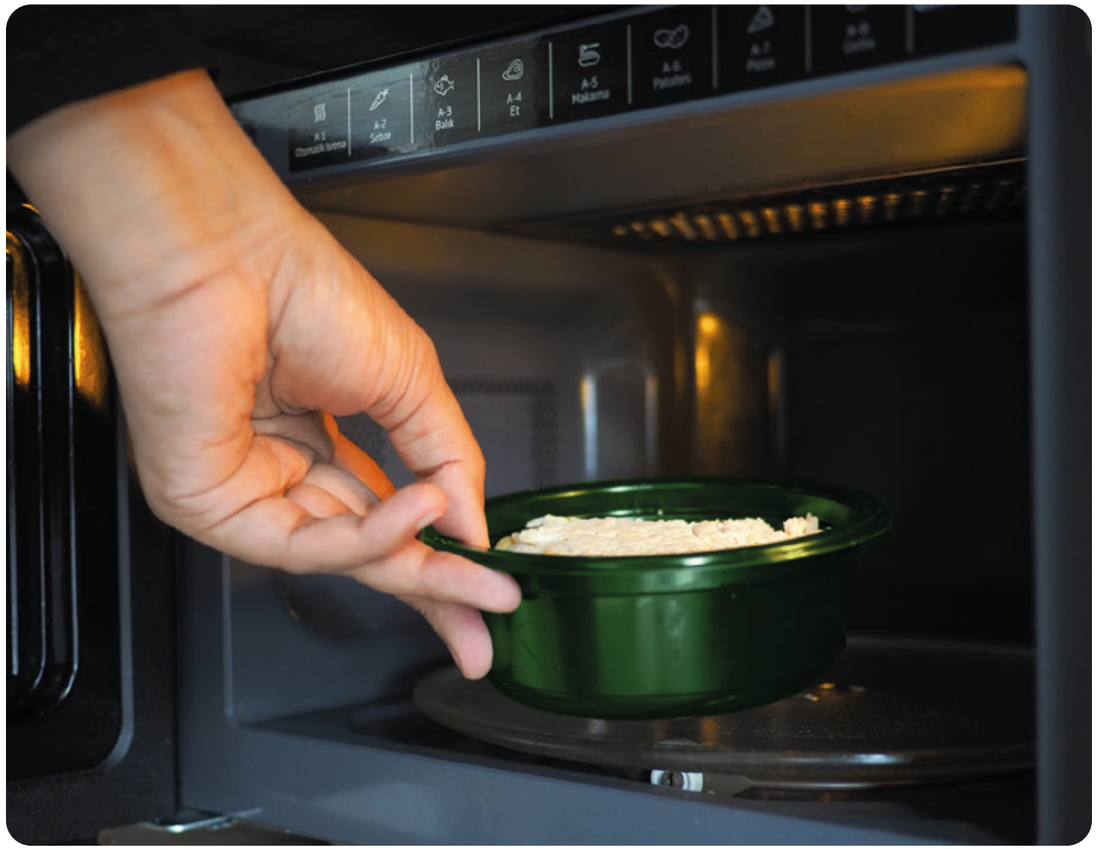
To safeguard public health while advancing environmental objectives, the following actions are recommended for FCMs:

1. **Mandatory Allergen Labelling:** Implement regulations requiring clear labelling of all allergens present in FCMs, enabling consumers to make informed choices.
2. **Development of Analytical Methods:** Invest in research to develop and validate analytical methods specifically designed to detect allergen migration from FCMs to food.
3. **Standardized Testing Protocols:** Establish standardized procedures for assessing the migration of allergens from FCMs into various food types under different conditions.
4. **Guidelines for Reusable FCMs:** Develop comprehensive guidelines outlining the safe use, cleaning, and lifespan of reusable bio-based FCMs, considering their potential to harbour allergens.
5. **Stakeholder Collaboration:** Foster collaboration among industry stakeholders, healthcare professionals, and consumer advocacy groups to raise awareness and develop best practices for the safe use of bio-based FCMs.
6. **Review and Update Legislation:** Reassess existing FCMs regulations to incorporate considerations for allergen migration, ensuring comprehensive consumer protection

CONCLUSIONS

WITH THE CURRENT INFORMATION AVAILABLE

- Awareness of the potential risks posed by allergens in FCMs and other materials is essential for coeliac patients, allergic patients, manufacturing companies, food business operators (both prepacked food producers and caterers), food safety authorities, legislators, scientists and politicians
- Collaboration among all stakeholders to increase knowledge of these potential risks is fundamental and also represents an opportunity to promote safe use.
- The development of appropriate testing protocols and methods is needed. In particular, the extraction and analysis of gluten and other proteins in these new products require further study.
- It is important for people with coeliac disease to be cautious when using these products and to avoid those made from cereals or from ingredients of unknown origin, instead choosing products made from gluten-free raw materials. This is particularly challenging when eating outside the home, as many caterers may not be aware of this potential risk
- Regulatory changes are currently under way; AOECS is working to advocate for and protect people with coeliac disease, and to encourage legislators to classify food allergens as risk ingredients in these products.
- People with coeliac disease need to be able to distinguish between different types of products (for example, straws made from plant stems versus products made from whole grains) in order to make informed choices.



REFERENCES

- Directive (EU) 2019/904 of the European Parliament and of the Council.
- Commission Implementing Regulation (EU) 2020/2151.
- EU Regulation Number: 1935/2004 (article 3).
- EU Regulation Number: 178/2002 (article 14).
- Recomendation CE nº 2019/794.
- Glutenvrij Magazine, The Dutch Celiac Society, NCV.
- Food contact materials https://www.efsa.europa.eu/en/topics/topic/food-contact-materials.
- Chen, H., Wang, J., Cheng, Y., Wang, C., Liu, H., Bian, H., Pan, Y., Sun, J., & Han, W. (2019). Application of Protein-Based Films and Coatings for Food Packaging: A Review. Polymers, 11(12), 2039. https://doi.org/10.3390/polym11122039.
- van der Hofstadt Rovira, M, De Abreu, C., Sousa, C.,Comino I., Segura, V. Potencial contaminación de gluten en alimentos con productos biodegradables de menaje elaborados a partir de cereales no aptos para el colectivo celiaco. Revista Mazorca, 2020;59:16.18.
- FSA Review of bio-based food contact materials: https://www.food.gov.uk/news-alerts/news/review-of-bio-based-food-contact-materials-published.
- Fritjof Nilsson, Optimal Plasticisers for New Biobased Plastics Through a Combined Experimental and Molecular Simulations Approach, 2021: https://www.kth.se/fpt/polymeric-materials/research/optimal-plasticisers-for-new-biobased-plastics-through-a-combined-experimental-and-molecular-simulations-approach-1.763288.
- Tomy J. Gutiérrez, Julieta R. Mendieta, Rodrigo Ortega-Toro, In-depth study from gluten/PCL-based food packaging films obtained under reactive extrusion conditions using chrome octanoate as a potential food grade catalyst, Food Hydrocolloids, Volume 111, 2021, 106255, ISSN 0268-005X, https://doi.org/10.1016/j.foodhyd.2020.106255.
- Biodegradable vegetable materials in contact with food, are there any risks for coeliacs? The results of an Italian study, Associazione Italiana Celiachia, 2022.
- What consumers say about safe and sustainable food packaging; Findings of an eleven-country consumer survey, The European Consumer Organisation, BEUC, 2023.
- Xu, J., & Li, Y. (2023). Wheat gluten-based coatings and films: Preparation, properties, and applications. Journal of food science, 88(2), 582–594. https://doi.org/10.1111/1750-3841.16454.
- Mossburger, J., Scherf, K.A. Gluten migration from biodegradable food contact materials poses a risk to celiac disease patients. Eur Food Res Technol (2024). https://doi.org/10.1007/s00217-024-04570-4.
- Can biodegradeable food packages contaminate gluten free food? https://www.aoecs.org/news/can-biodegradeable-food-packages-contaminate-gluten-free-food/.
- Does bio-based food packaging pose a health risk to Coeliacs?, Baking Europe Journal, Summer 2024, 40-43. https://bakingeurope.com/Portals/0/online-publications/Summer2024/index.html#p=40.
- C. Sousa et al. (2025). Potential Transfer of Toxic Gluten from Biodegradable Tableware to Gluten-Free Foods: Implications for Individuals with Gluten-Related Disorders. Journal of Agricultural and Food Chemistry DOI: https://pubs.acs.org/action/showCitFormats?doi=10.1021/acs.jafc.5c07516&ref=pdf

ABOUT AOECS

AOECS is an independent, non-profit organisation. Since 1988, we have been dedicated to improving the lives of people affected by coeliac disease. AOECS represents 41 European national coeliac societies and six affiliated organisations, five from outside Europe and one from Bosnia and Herzegovina.

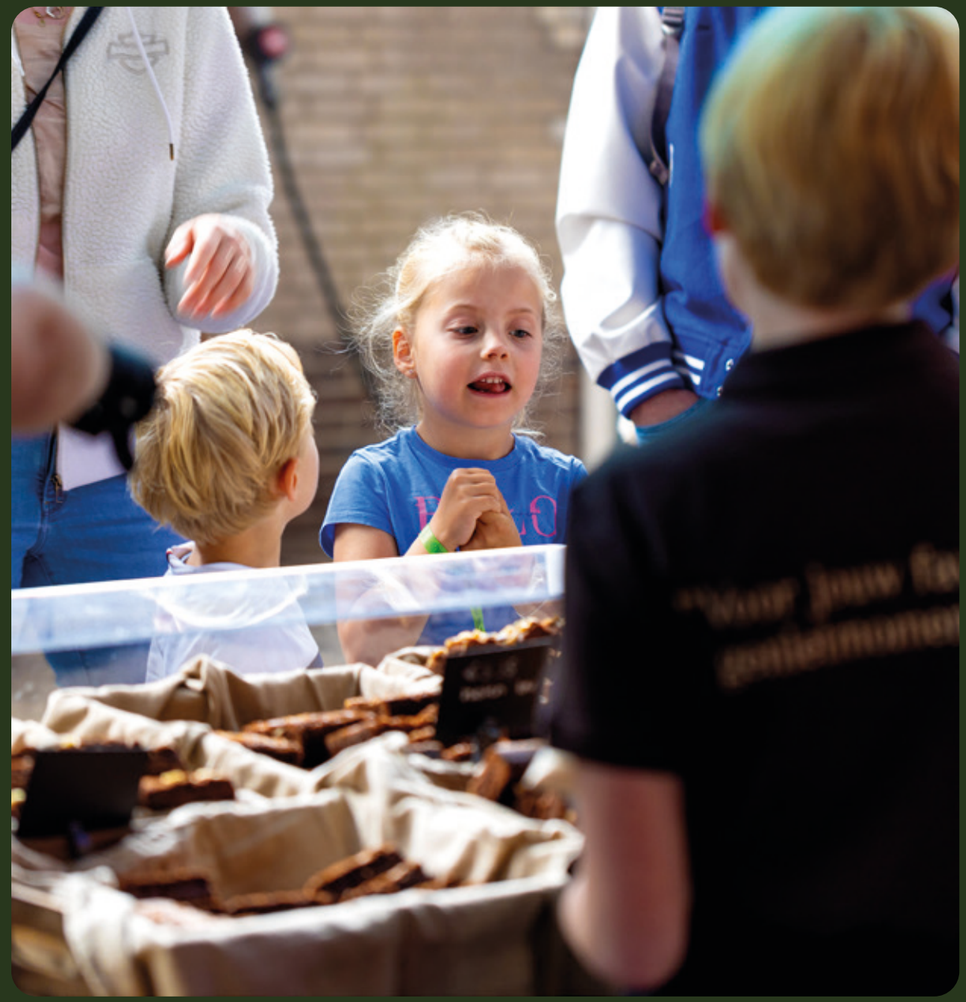
Coeliac disease (also spelled celiac disease) is an autoimmune disorder in which cereals containing gluten trigger an inflammatory reaction in the small intestine.

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.