Food DETECTives

Quality of Life

FOR PEOPLE WITH FOOD ALLERGIES IN EUROPE: A MENU FOR IMPROVEMENT



European Federation of Allergy and Airways Diseases Patients' Associations

Thank you!



FOOD ALLERGY PATIENTS

We sincerely thank the members of the **EFA Food Allergy Working Group** for their dedicated involvement in the Food DETECTives project, and for their support in our research and the identification of food allergy patient testimonials in their countries.

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Serving Europe



INDIVIDUALS

We also thank the following individuals for their contributions:

Chiara Genua, EFA Intern from EU4EU – European Universities for the EU

Clare Mills, University of Manchester

Antonella Muraro, University of Padua

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Project leaders: Sofia Romagosa Vilarnau with Panagiotis Chaslaridis, EFA **Design**: Charles Kinney and Maximilian Kunisch, EFA

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Foreword

A RECIPE FOR SUCCESS



I will always remember the first time my son had a life-threatening reaction (anaphylaxis) to food he was allergic to because of incorrect information, ignorance and poor food allergen management in a restaurant where we had a family meal. It scared me to death, but also brought out the best in me as I took immediate action to urgently call the ambulance and to clearly explain the situation to emergency services. Thankfully, my son survived the ordeal.

I then realised more than ever before that this situation CANNOT be tolerated. I committed to support changes in labelling, and improve information and legislation on food allergens in order to have a better quality of life for my family. My family refuses to continue to live like this, scared, isolated and always on the watch as a meticulous food detective. However, this is the life of many people with food allergies and their families. The only way to truly protect against a medical emergency is to bring your own food and drink or to barricade your loved one at home.

Much has improved in the last 10 years in terms of awareness about food allergies, dietary needs, labelling and most recently, treatment, but much remains to be done. In order to best inform and to draw recommendations for regulators and all those who have an impact on the quality of life of people with food allergies, in particular those with severe reactions, EFA launched the Food DETECTives project. In this report, we highlight excellent practices across European countries as well as some of the worst to bring the food allergy story alive. EFA brings you this Food DETECTives report in order to build a safety chain for people with food allergies in Europe, to create a recipe for success and to stop discrimination and fear.

Later, when my son recovered from the anaphylaxis incident, I contacted the restaurant owner and we were invited as a family for a safe meal at that very same restaurant. After hesitation, we decided to do it. It was a healing experience for us, and a learning experience for the restaurant staff, who were then trained to take good care of their customers with food allergies.

For our project and the report at hand, we collaborated with EU regulators, the food industry, those who are developing preventative treatments for food allergy, researchers, allergologists, and most of all, our dedicated Food Allergy Working Group of members, who are listed in the acknowledgement of this much needed report.

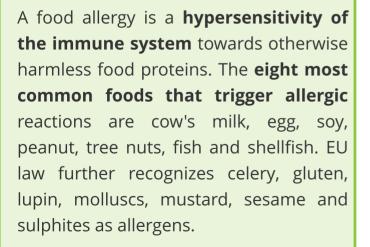
I sincerely thank all collaborative organisations and individuals, and our sustainable funder Aimmune Therapeutics, who believe in the patient perspective and gave us unrestricted grant for Food DETECTives.

Mikaela Odemyr EFA President INTRODUCTION

Starten

Food allergy is not a rare condition. 17 million Europeans suffer from food reactions, of which 3.5 million are under the age of 25. Over the last decade, the number of allergic children younger than five years of age with allergy has doubled and visits to the emergency rooms due to anaphylactic shock have increased seven-fold.¹ Sometimes people, and even policymakers, consider allergies to be a trivial disease, but they do not realise that an allergy might result in poor nutrition, impaired quality of life, fear, restrictions, social isolation and even death.

In the absence of a comprehensive implementation report for European food labelling regulations regarding allergens, this EFA analysis aims to record the food allergen labelling measures put in place across several EU countries and to report legislative gaps and the related impact on the quality of life of patients living with allergies and their families and caregivers.



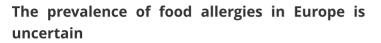
What is a food allergy?

A food allergy is a hypersensitivity of the immune system towards otherwise harmless food proteins, so-called allergens. In people with food allergies, these proteins are perceived as enemies against which the immune system defensively reacts in case of contact. This immune response ends up overreacting, causing cutaneous rash, hay fever, nasal and conjunctival discharge, and allergic gastroenteritis. It can also lead to a systemic disorder, known as anaphylaxis, in which different organs or 'systems' in our body, such as the skin, gastrointestinal, cardiovascular and respiratory systems, are activated simultaneously and can cause shock or even death.² Food allergies affect genetically predisposed people, referred to as atopic individuals. In addition, there are other factors that seem to be linked to allergies, such as environmental factors. low-food diversity, industrialised and highly manufactured food and exposure to a low diversity of microorganisms in early life.

The eight most common foods that trigger allergic reactions, especially in children, are *cow's milk, egg, wheat, soy, peanut, tree nuts, fish, and shellfish.*³ Peanut allergies are the most prevalent⁴ and also the most frequently related to episodes of allergy-related anaphylaxis and fatalities.⁵ Seafood and cow's milk are also common triggers of fatal food-allergic reactions.⁶

It is easy to confuse a food allergy with a much more common reaction known as food intolerance. While allergy is an immune-mediated reaction, intolerance is mostly caused by enzyme deficiency or the pharmacological activity of food components. This means that the immune system is not involved and, therefore, food intolerances usually do not have the same consequences as food allergies and are not as life-threatening.





The confusion between a food allergy and food intolerance is one reason why the prevalence of food allergies in Europe is uncertain. Specifically, there is a gap between the prevalence of self-reported food allergies and reports of diagnosis by a doctor based on medical history and after specific blood and skin-prick food allergy tests. When a food allergy is suspected, it is very important to have access to an allergy specialist in order to obtain a proper diagnosis. Indeed, using a test called the oral food challenge, which doctors consider to be the most definitive (highest standard) diagnostic method, the prevalence of food allergies in Europe is estimated to be between three percent and four percent in children and adults.⁷ Whereas the prevalence of self-reported perceived food allergies is estimated to be 3-35%, and possibly even higher.⁸ Nonetheless, according to a systematic review published in 2014 of all studies, food allergies affect up to 17.3% of Europeans in their lifetime.⁹

Day-to-day management of food allergies

Food allergies are a concern not only for people living with allergies, but also for their families and those involved in supplying and preparing food. Since there is no cure for food allergies, people living with the condition need to avoid eating the food that causes an allergic reaction. Avoidance is the only available preventative remedy. Accordingly, patients need to be well-informed of the ingredients in the food they buy and eat.

In practice, however, avoiding the offending food can be difficult. This is directly linked with the existing gap between patients' needs and the current regulatory framework in regards to food information that is made available to consumers.

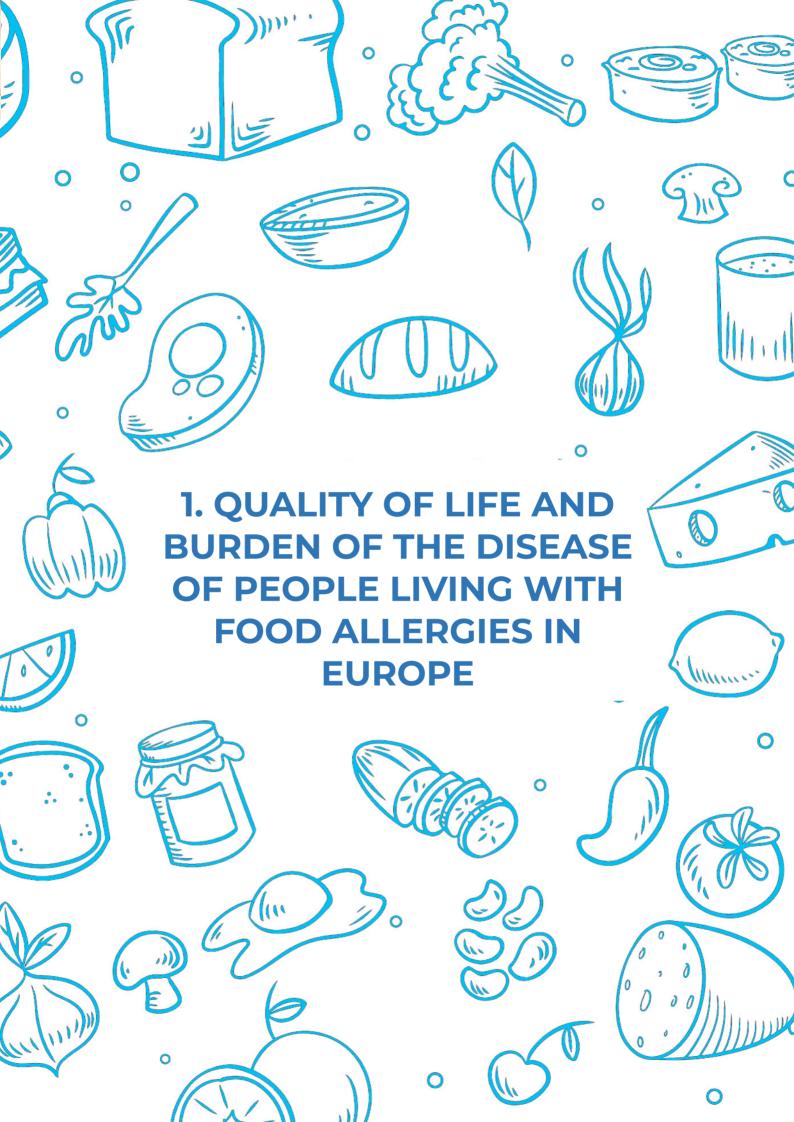


The Food DETECTives Report

Within the Food DETECTives Report, the European Federation of Allergy and Airways Diseases Patients' Associations (EFA) provides an overview on the Quality of Life (QoL) and burden of the disease of patients with food allergy in Europe, with a focus on the implementation of the EU Regulation 1169/2011 on Food Information to Consumers (FIC) and its provisions related to food allergen labelling.

Based on this information, EFA provides a set of recommendations for policymakers, public health authorities, the food industry, healthcare professionals, patient associations and food allergic patients with the aim of overcoming the legislative gaps. Ultimately, the goal is to improve the QoL for patients and their caregivers, reduce feelings of discrimination and social isolation and prevent terrifying and life-threatening events.

Moreover, EFA has collected information from existing resources and developed a to-do list on food allergen management addressed to food business operators working for prepacked and non-prepacked food providers across the food supply chain. Better management and strict control of food allergens and their traces in kitchens and throughout the manufacturing process will ensure correct and accurate communication of allergen information to consumers, who can then protect themselves against allergic reactions.



1.1 Quality of life of people with food allergies

mpanment

Food allergy is a chronic disease and has a significant daily impact on patients and their caregivers. It affects their physical, mental and social well-being¹⁰ and results in poorer Health-Related Quality of Life (HRQoL).

"Not being able to go out for dinner has a devastating impact on my quality of life."

Patient from the Netherlands

A patient's perception of the impact of food allergy on their life varies with age, gender (in adults) and cultures.¹¹ According to a 2014 study, women report a lower HRQoL than men, and the HRQoL is lower for adults than for teenagers and children. In relation to cultures, the same study shows that patients in Spain reported the highest impact on HRQoL while French patients reported the lowest.

In children, this perception is not influenced by gender or an additional allergic disease. It also does not depend on having suffered from anaphylactic shock in the past, as children typically have not fully experienced potential life-threatening consequences. The burden of the disease for children is linked with day-to-day efforts to avoid exposure to the allergen, including general food avoidance, the need for constant surveillance of allergen presence in food, and regularly informing food providers about food allergies.¹²

In addition, the type of food allergy and the type of symptoms lead to different consequences for patients.¹³ Adults with fish or milk allergies, and children with peanut and soy allergies, experience a lower HRQoL than patients with other food allergies.

Similarly, patients with skin symptoms experience a higher impact than those with respiratory or gastrointestinal symptoms. This is also due to the visibility of the symptoms,¹⁴ which makes patients feel more embarrassed, socially disadvantaged and even depressed when compared to patients with other kinds of symptoms.¹⁵

Constant surveillance of food ingredients may result in anxiety and insecurity

Managing food allergies can be challenging for people living with this disease. Dietary avoidance of the food allergen is key in the management of food allergies to prevent an allergic reaction.¹⁶ Thus, it is essential that patients are aware of the presence of an allergen in foods they eat and buy (intended ingredients and unintended allergen presence). Therefore, food labels should strive to be accurate and comprehensive.

The constant surveillance required of both patients and caregivers results in anxiety and insecurity. The unintentional ingestion of a food allergen can result in severe or fatal reactions and may make these feelings even stronger.¹⁷

"As an individual with several lifethreatening food allergies, I feel anxiety about planning for the future, in particular for dining out and travelling."

Patient from Italy

Food-allergic individuals feel that they are more at risk of death in comparison with non-allergic people, as anaphylaxis can be fatal. In addition, the administration of adrenaline may be required in an emergency, and a concern for the effectiveness of this treatment may further provoke anxiety.¹⁸



Food allergy results in emotional and social impact on patients' and their caregivers' lives

A fear of being judged and being ashamed of the condition is common among children. Some suffer episodes of bullying, teasing or harassment, or even worse, of intentional contamination. These actions pose emotional and physical risks and may lead to social isolation.¹⁹

Parents, especially mothers,²⁰ are emotionally affected as well by their child's disease. The fear of a possible allergic reaction or anaphylactic shock putting the child's life at risk can result in severe anxiety and stress. This parental fear can result in an over-interpretation of symptoms, independent of the child's experience of severe reactions.²¹ The feeling of being unable to adequately supervise and protect children from possible exposure to allergens and related health risks can also cause depression.²²

"I am on a strict diet and I do well. But I am socially handicapped. Not many people know how debilitating food allergy can be."

Patient from the Netherlands

The fear that parents face for the safety of their children may lead to overprotection. As a consequence, the social isolation that children suffer from might worsen by parents' striving to make sure children are safe.

Parents are particularly concerned for their allergic children in two specific life stages: between ages six and eleven, and during adolescence.²³ Between the ages of six and eleven, children start to spend more of their time outside the home. However, parents do not feel completely secure when leaving their child at school. This insecurity involves the lack of trust towards school or daycare staff in the management of a food allergy emergency,²⁴ given the fact that twenty percent of allergic reactions happen in schools.²⁵

The beginning of adolescence brings more independence to children, who then make their own food choices and are responsible for carrying their own medications, including the Adrenaline Auto-Injector (AAI). This new responsibility is related to higher anxiety and stress. However, the majority of allergic adolescents are more prone to risk-taking behaviours, such as deliberately eating risky food, not carrying an AAI with them or ignoring symptoms.²⁶

"At the age of 14, I missed the opportunity of a school trip to Rome. The school and hotel did not have adequate policies of food allergy management and my parents didn't trust (the authorities) to let me go."

Patient from Italy

Information on food ingredients is not always available

Information on allergies in prepacked and non-prepacked food products is not always easy to find or easy to understand, thus complicating the decision-making process for allergic consumers in order to stay safe.

Public places like restaurants, bars and bakeries are perceived by patients and parents of allergic children as unsafe and risky environments. This is due to the difficulty of getting accurate allergen information, and the potential danger of unintended ingestion of allergens due to unexpected ingredients or cross-contact.

Buying groceries can also be difficult for allergic consumers. This is linked with the overuse or confusing wording of Precautionary Allergen Labelling (PAL), such as "may contain", used by food manufacturers in prepacked food to warn consumers about the possible presence of unintended allergens in the products. In fact, according to some studies, only ten percent of food products with PAL statements actually contain the allergen to which the statement refers.²⁷ Current overuse of PAL has led to a loss of credibility among consumers.²⁸ On one hand, patients can eat the product, ignoring the real risk and accepting the possibility of potential consequences, contributing to a higher rate of accidental allergic reactions.²⁹ On the other hand, patients feel forced to avoid consuming the food for safety reasons, and risk increasing their anxiety³⁰ and restricting food choices. This is particularly worrying for people who suffer from more than one food allergy, leading in some cases to poor nutrition or malnutrition.³¹

Consequently, allergic patients and their caregivers have developed their own safety strategies. Avoiding food in public places is a common preventative measure. Allergic patients may bring their own food when eating out so they do not have to constantly ask about the ingredients in order to ensure that the food they are eating is safe. Thus, they may feel less stressed and anxious. However, this might result in a higher level of social isolation, particularly in countries where going out to eat is common.³²

"For me, it is necessary to adapt to different environments every day."

Patient from Sweden

Another concern for patients is travelling, particularly in airplanes. Anxiety is generated by the provision of allergens i.e. peanuts, or tree nuts as snacks, by many airlines, perceived risk of allergens being circulated in cabin air, and a lack of access to emergency services in the event of a reaction. Allergic patients may adopt protective behaviours, including cleaning their personal seating area, not consuming food served on board or requesting a peanut or tree-nut-free flight.³³

1.2 More education for healthcare professionals, patients, parents and the general public

Education and training are a fundamental part of managing food allergies and protecting people from the risk of allergen exposure inside and outside the home. Improved education for those at risk, their families, friends, school and food service staff about reducing the risk of allergic reactions to food can help to prevent fatalities.³⁴

Poor knowledge of anaphylaxis leads to delayed administration of adrenaline

Anaphylaxis is the true life-threatening problem in food allergy and can occur anywhere. Between 1990 and 2000 in Europe, hospital admissions due to severe allergic reactions increased sevenfold.³⁵ More recently, in **the UK**, the National Health Service (NHS) figures showed that there was a 72% increase in hospital admissions for severe allergic reactions from 2013-2014 to 2018-2019, with children under 10 years old having an even greater increase of 200%.³⁶

Most reported deaths from anaphylaxis have been associated with a delayed administration of adrenaline.³⁷ Wrongful application of adrenaline or its delayed administration by patients, caregivers or those nearby is often linked to poor knowledge of the initial symptoms of anaphylaxis, fear of needles, poor understanding of the risks and side-effects of adrenaline.^{38, 39}

Education should start with healthcare professionals: general practitioners (GPs), or family doctors, are often not well-trained to treat anaphylaxis and do not have the proper knowledge about the symptoms of an allergic reaction.⁴⁰ Consequently, patients and their caregivers are often not able to recognise the first symptoms of an allergic reaction, which thus delays the crucial administration of adrenaline.



Overestimation of food allergy knowledge among the general public

Food allergic patients feel that their disease is not taken seriously enough.⁴¹ On the contrary, the general public usually overestimates their knowledge on food allergies. Thus, their motivation to learn more about the disease is low.⁴² This represents a danger as most food allergy reactions occur outside the home.⁴³

"Often the staff thinks you are exaggerating: 'it cannot be that dangerous...' is a frequently heard reaction."

Patient from the Netherlands

Benefit of a multidisciplinary approach

The evidence shows that a multidisciplinary clinical approach,⁴⁴ and the provision of educational materials on food allergy,⁴⁵ improves knowledge of the disease and the correct use of AAI and reduces allergic reactions to food. The 2014 EAACI Food Allergy and Anaphylaxis Guidelines propose that all professionals, including GPs, school nurses, dieticians, teachers and nursery staff, should be trained. People with food allergies should be trained in proper allergen identification, and they need dietary, psychological and practical support and advice, and even technical support to be able to read labels on food products.

1.3 Personal economic burden of food allergies

Food allergies have an impact on the household and individual economy. Even though there is limited information available on the economic burden of food allergy, it is a fact that people with food allergies have a higher expenditure on food per year due to their disease. For example, the median additional costs per food allergic infant from 0-2 years in **Finland** was 3,182 euros.⁴⁶

Buying groceries is time-consuming and costly

In the UK, the Food Standards Agency, in collaboration with the patient organisation 'Anaphylaxis Campaign', undertook research on the experience of people with food allergies shopping for groceries. Shopping for groceries takes approximately fourty percent more time than for people without food allergies.⁴⁷ Allergic consumers need to thoroughly read food labels to check if a product they are not familiar with is safe to consume, or if the ingredients in products that they know have changed. Not surprisingly, it is frustrating when a product people have routinely been consuming is no longer safe to eat due to product changes *i.e.* changes in ingredients, recipe or the supply chain.⁴⁸

Moreover, groceries cost approximately eleven percent more than for people without food allergies⁴⁹ as special food products are generally more expensive.

Required training should include:

- **General knowledge** about the disease informational leaflets and access to patient organisations and scientific societies websites;
- **Correct use** of AAI informational leaflets, AAI manufacturer websites, and workshops for healthcare professionals organised by educational institutions, hospitals, patient organisations, scientific societies or charities;
- Dietary support possibility of referral to a dietitian; organised courses for healthcare professionals;
- **Psychological support** possibility of referral to a clinical psychologist, awareness about common mental health issues in food allergic patients through courses and information provided by patient organisations and scientific societies; and,
- **Practical support** phone line and available patient organisations and scientific societies information.

Costs for treatment and care

What is more burdensome for patients is the cost of emergency medications, such as AAIs. AAIs can range from 40 to 125 euros, and in some countries, such as **Poland, France and Greece**, these medications are not reimbursed.⁵⁰

Often, patients with food allergies suffer from other comorbidities, such as asthma or atopic eczema.

This results in additional costs, for example, for medical devices, medicines, visits with specialists and everyday products. Some patients and parents suffering from depression or having a high level of anxiety because of the disease may also have to cover the extra costs for related psychological care.

"We use to buy in specific places where they avoid cross-contact. That means spending more money and time but it is the only way to have safe food."

Patient from Spain

Missing work and school due to food allergies

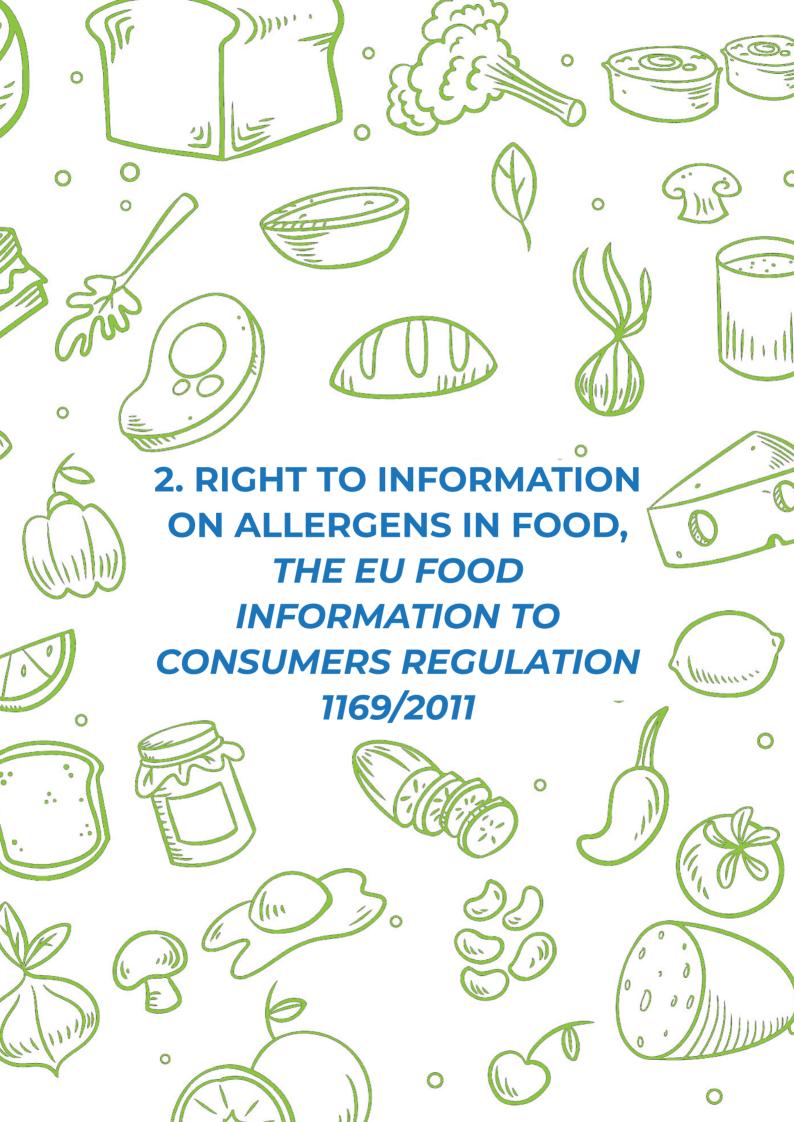
In addition to direct expenses, patients and their caregivers face indirect costs, as they are more likely to miss work or school. Time off from work and disruption of scheduled activities is sometimes judged more severely than the allergic reaction itself.⁵¹

"In high school, my fellow students would envy me, because if I wanted to go home sick, all I had to do was eat a bit of egg."

Patient from the Netherlands

Costs for Adrenaline Auto-Injectors (AAIs) can range from **40 to 125 euros**, and in some countries such as Poland, France and Greece **these medications are not reimbursed**.





The law must safeguard the ability of allergic patients and their caregivers to make informed food choices in order to reduce the burden of the disease. Effective food labelling policies are meant the risk of eating to reduce possible allergic-reaction provoking food in restaurants, bakeries, supermarkets, schools, etc., and thus improve the OoL for those affected by the disease. Food Information to Consumers (FIC) The Regulation was intended to address this need by establishing a set of requirements on food-allergen labelling in Europe. The FIC Regulation has had a large influence on allergic patients' lives.

Freat to

2.1 Background

Largely due to the food crises of the late 1990s/early 2000s (i.e. dioxins and mad cow disease), the European Union (EU) made a large-scale update to its food safety policy in order to ensure a higher level of safety across the European food chain. One major result of this process was the General Food Law (GFL) Regulation 178/2002.⁵² The GFL sets general requirements for the regulation of the EU food market, including, "Food law shall aim at the protection of the interests of consumers and shall provide a basis for consumers to make informed choices in relation to the foods they consume" (Art. 8). In addition, the GFL established the European Food Safety Authority (EFSA) as an independent agency providing scientific advice to regulators on issues related to food, including food allergens.

Most importantly, the GFL paved the way for subsequent EU decision-making on food safety, including the founding principles of Regulation 1169/2011 on Food Information to Consumers (FIC), 2008. The proposed FIC Regulation was a merger between two pre-existing laws on general food and nutrition labelling. This regulation became applicable in late 2014.

2.2. The EU food labelling law

The FIC Regulation puts forward a set of requirements for consumer food product information, including food allergens. The main goal of the Regulation was to ensure a 'high level of protection of consumers' health (Art. 1 (2)):

'This Regulation establishes the general principles, requirements and responsibilities governing food information, and in particular food labelling. It lays down the means to guarantee the right of consumers to information and procedures for the provision of food information...'

The FIC Regulation requires that product information on food labels be easily visible and clearly legible in order to help consumers make informed and safe choices about the food they buy.

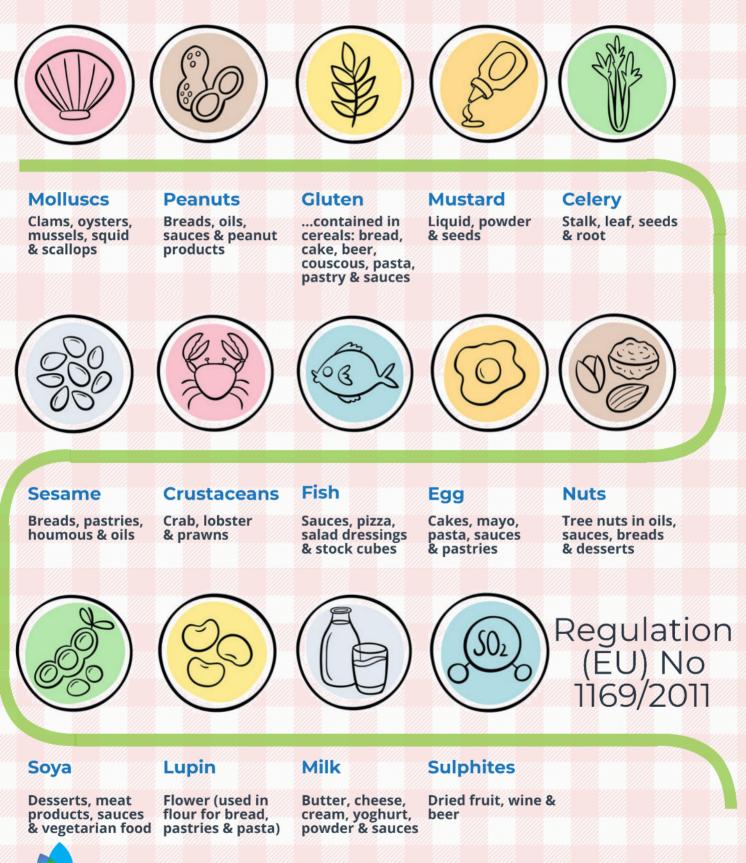
2.3 Allergen labelling requirements and the list of allergens

The FIC Regulation mandates that food business operators provide information to consumers on product labels regarding the 14 specified substances that are proven to trigger an adverse allergic or intolerance reaction in sensitive consumers.

The European Commission can re-examine and amend the list of substances in-line with the latest scientific evidence and with a view to protecting consumers' health. The FIC Regulation requires that the presence of these substances in prepacked food must be clearly listed on the label. Additionally, the ingredient list must alert consumers through the use of different font, style or colour for those substances.



ACCURACY IN EU FOOD LABELLING: FOOD ALLERGENS





#DetectiveFood efanet.org

Non-prepacked food

One of the most important innovations of the FIC Regulation is that, for the first time, there is an obligation to make information on allergens available for non-prepacked food, such as fresh fruits and vegetables. In particular, Member States are responsible to adopt a means through which information on non-prepacked food is provided to consumers. The European Commission states that this information should be available, clearly visible and understandable.

In a follow-up to the application of the FIC Regulation, the European Commission has adopted a guidance (2017 Notice) specifically related to allergen labelling. This guidance aims to assist businesses and national authorities in the implementation of allergen labelling requirements.⁵³ According to the Notice, if national governments do not specify how information on non-prepacked food is to be provided, the Regulation's prepacked food requirements would also apply to non-prepacked food.

Precautionary Allergen Labelling (PAL)

Furthermore, the FIC Regulation states that voluntary Precautionary Allergen Labelling (PAL), often worded as "may contain the following allergens", 'should not be misleading, ambiguous or confusing for the consumer', and that it should be based, where appropriate, on relevant scientific data. Typically, the notice is provided to signal a possible and unintentional presence of allergenic substances or products in food, often from the use of shared manufacturing equipment. The European Commission has not yet put forward specific measures regarding the labelling of food that possibly contains unintended allergens.

Alghough EU law is very advanced on allergen labelling, several loopholes still exist. These loopholes include a lack of common guidance on precautionary labelling, and an absence of implementation measures and standardized practices.

2

The FIC Regulation requires that product information on food labels be **easily visible and clearly legible** in order to help consumers make **informed and safe choices** about the food they buy.







Although the Food Information to Consumers (FIC) Regulation has been in force for eight years, data on its implementation at the national level is scarce. While from an institutional viewpoint the European Commission engages in considerable country-level work, its audits focus more on the control mechanisms that governments use to ensure compliance with the Regulation, rather than the actual implementation.

National implementation has two interlinked layers. On the one hand, there are measures such as guidelines and recommendations which help Member States comply with the Regulation. On the other hand, the performance of these measures, and therefore the actual impact on consumers, depends strongly on whether the measures promote factors such as training, public awareness, access to information and mandatory action.

"Think about the loss of opportunities to socialize while eating and enjoying normal conversations with friends."

Patient from Italy

Additionally, the distinction between prepacked and non-prepacked food plays a central role in this analysis, arising largely as a result of the different applicable labelling rules. Drawing from the definition of the FIC Regulation, prepacked food refers to any single item consisting of a food, either fully or partly enclosed by the packaging, that is placed on sale in a way that it cannot be altered without opening or changing the packaging. The definition does not include food packed on sale premises at the consumer's request, or foods prepacked onsite for direct sale. In the context of this definition, non-prepacked food is sold without packaging.

3.1 Allergen labelling of prepacked food

3.1.1 Implementation aspects

The FIC Regulation outlines obligations for businesses involved in the production and supply of prepacked food to indicate the presence of the 14 recognised allergens. In light of the precision of the EU legal requirements (Art. 9, 13, 18, 21), implementation at the national level has been largely successful. By all accounts, this has led to improved information by highlighting the presence of allergens in the ingredients list. Therefore, the rules for allergen labelling, including strengthening the protection of consumers, have been welcomed by consumers and generally embraced by food businesses across the EU. Also the rules have facilitated the work of national authorities in their controls for food business operators.

3.1.2 Overview of additional national measures to strengthen the implementation

The FIC Regulation automatically and uniformly affects all Member States, with no need for transposition into national law. However, in some countries the FIC Regulation has prompted the adoption of additional measures with a view to clarifying aspects of allergen labelling and/or strengthening the implementation of the Regulation.

For example, in **Spain**, relevant authorities have undertaken significant work, including regional and national implementation guidelines on how to label ingredients (2015),⁵⁴ and key provisions for food-allergen management such as guidelines for businesses to incorporate food allergen management in their self-control plans.^{55, 56} Awareness-raising publications are also available for citizens and businesses, such as those of the



Madrid Region.⁵⁷ in addition, **Spanish** authorities have encouraged the creation of a committee to develop criteria on the implementation of the FIC Regulation among regions.

In **Sweden**, in addition to the FIC Regulation, the National Food Agency has facilitated the 'Bransch Agreement' with producers and grocery store owners. The Agreement consists of an extensive guideline assisting industries in handling and labelling allergens,⁵⁸ as well as a series of guiding documents for various industry sub-sectors, such as breweries and dairy producers.⁵⁹ Although voluntary, the Bransch Agreement has made it easier for involved actors to work with allergens, and is widely respected to the extent that non-compliance bears significant reputational risks for businesses.

In **the UK** the Food Standards Agency provides comprehensive guidance for the industry on the requirements of the FIC Regulation, including prepacked food and allergen labelling.⁶⁰

The **Danish** Food Administration has published a Food Labelling Guide outlining existing rules and providing information on how the legislation should be implemented in **Denmark**.⁶¹ In particular, Section 18.2 contains basic information on what and how prepacked food should be labelled, including specific examples of wording.

Finland has adopted a Food Information Guide for food controllers and business operators (updated in April 2019) providing the mandatory general information on prepacked food and non-prepacked food and the relevant labelling requirements.⁶² The use of this guide is required, and backed by the FIC Regulation.

In **Italy**, Legislative Decree No. 231/2017⁶³ is aligned with the FIC Regulation and reiterates that prepacked food should include allergen information that is clear, readable and indelible, while including a strict disciplinary system for violations of the FIC Regulation provisions. The Ministry of Economic Development readily engages with the industry in providing information on how to implement the Regulation.

In some countries there are supplementary measures to the FIC Regulation. In the Netherlands, the non-profit Simply OK Foundation implements a certification scheme to audit the allergen management system of food business operators.⁶⁴ It provides customers an assurance of reliability for allergen information in the list of ingredients, as well as for gluten-free or lactose-free claims and in the case of cross-contact.

3.1.3 Poor practices in allergen labelling: monitoring, reporting and recalling non-compliant products

The FIC Regulation contributed significantly in drawing the attention of authorities to potential misinformation in food package labelling. To a large extent, this focus included the way food business operators label allergens, which entered increasingly into already existing official monitoring, reporting and product recall schemes at the national and EU levels. Civil society plays an increasingly important role, with various initiatives driven by consumers associations and patient groups.

"I think that in the 21st century, national and international structures should be organized to let allergic people eat easily." Patient from Italy

Since 1979, the Rapid Alert System for Food and Feed (RASFF) has been the EU's official system that allows information-sharing between Members States and the European Commission for identified health threats linked to cross-border food products.⁶⁵ Given that its legal basis is provided by the General Food Law Regulation, RASFF reports recalls of food products due to hazards linked to allergens and other issues. RASFF is based on notifications by national authorities, and has served



as a platform for collective response to food safety risks. One of the most common notified hazards is the undeclared or unintended presence of allergens in certain products, for instance, in cases of mislabelling or cross-contact. According to RASFF's 2018 annual report, there were 3,699 notifications, of which 1,118 were considered alerts (notification that requires rapid action). The alerts for allergens numbered 158, representing 14.1% of total alerts.⁶⁶

Though RASFF has allowed for faster and easier communication of potential food safety issues between authorities, there are several aspects which can be improved for the benefit of consumers. For example, there is a lack of a common definition of health risk among Member States. While the Scandinavian countries and the **UK** include the unintended presence of allergens in the definition and recall products based on the amount of allergen present in a food (regardless if it is an ingredient or it is unintendedly present), others such as Germany issue recalls and inform the public only when there is mislabelling of allergenic ingredients (not taking into account unintended presence). Therefore, RASFF criteria for product recalls are far from harmonised among Member States, which highlights the need for commonly used reference doses.

Moreover, RASFF only communicates hazard type (i.e. allergens, absence of labelling, etc.), and the product category (*i.e.* confectionery, milk products, etc.), without publishing the exact product name. In this sense, RASFF could also invest more in addressing consumers concerns and accessibility to data issues.

At the national level, most Member States have established systems to monitor food risks, communicate them to the public, and centrally enforce product recalls. In terms of recall processes, there are generally two main approaches: based on safety controls conducted by state authorities, or initiated by food companies. The ratio between the two approaches, as well as the overall effectiveness of recall systems is highly dependent on the national context, due to varying resources. Some good examples of such established systems include:

- The Sistema Coordinado de Intercambio Rápido de Información (SCIRI) in Spain, which gathers information coming from the central government, regional agencies or food operators. Also, regional agencies have their own warning platforms available in their websites, for instance, the ACSA (Catalonia). Moreover, bigger cities, like Madrid or Barcelona, have their own public health agencies which have the competency to manage alerts on food and feed, nearly always in collaboration with the state public health agency.
- The platform established by the Finnish Food Authority to provide feedback on labelling. It asks consumers to first contact the retailer/store where the food was purchased, with the logic that the food operator is responsible for the food it is producing/distributing. In severe cases, the authority asks consumers to contact local authorities on food control. The names of the local food inspectors are also readily available.
- In the UK, consumers can report cases of mislabelled products to the platform of the Food Standards Agency, or to their local trading standards office who may then open an investigation.⁶⁷

According to accounts by EFA member associations, in some countries the food product recall system is positively assessed, reflected in the time of response and risk communication (i.e. UK, Finland, Sweden, Spain, Germany). In others, there are barriers such as serious capacity restraints (the Netherlands), incomplete information (Denmark), insufficient involvement of civil society (Italy), and fragmented enforcement (Greece).



In regards to action taken by citizens and wider civil society, there are a variety of platforms and tools which aim at warning the public on potential risks due to allergens in food. For example, the 'Food Clarity' platform in **Germany**, run by a consumer organisation funded by the government, allows consumers to address guestions and file complaints. Businesses have the opportunity to react.⁶⁸ Another portal, Lebensmittelwarnung, handles food warnings and product recalls, and is attached to the Federal Office of Consumer Protection and Food Safety.⁶⁹

In short, there is a highly diverse network of monitoring schemes across the EU, which tend to widely vary in terms of ownership, resources, effectiveness, enforcement power and most importantly, how and if they protect and improve things for people with food allergies. A harmonised recall system in Europe based on a common definition of health risk, including allergens, and using allergen reference doses as a basis, would benefit allergic patients to be informed and rapidly react.

"At the grocery store when I want to buy cookies it is always written 'may contain nuts' - even if it is not in the ingredients."

Patient from Belgium

3.1.4 Voluntary Precautionary Allergen Labelling (PAL)

A less straightforward and much more contested area of allergen labelling in prepacked food concerns the unintended presence of allergens. In this case allergens may enter food as a result of cross-contact during the manufacturing, packaging or transport stage of the production cycle. As the ingredients list is only for intended ingredients, the food industry has put in place a voluntary precautionary (advisory) labelling system to alert consumers about the possible presence of unintended allergens. The notice can take different forms: 'may contain', 'may contain traces of', 'not suitable for [allergen] allergy sufferers', and 'produced in a factory that also uses', among others.

Why PAL is failing: legal gaps on implementing measures

The FIC Regulation does not lay out the requirements for the use of PAL, which means there are no commonly agreed upon scientific criteria or risk management practices on which PAL should be based.

The absence of a harmonized approach in Europe has led to a diversity in the ways manufacturers assess unintended allergens present in prepacked food and communicate it to consumers. This is further complicated by divergent enforcement approaches by national Competent Authorities. The FIC Regulation sets out in Article 36.2 the general requirements for how voluntary food information should be communicated. However, the European Commission has not vet introduced the implementation as envisaged in Article 36.3. This is essential, and in all seriousness, a matter of life and death for people with food allergies.

In practice, the current state-of-play has led to an overuse of PAL. This is largely seen by food operators as an all encompassing precautionary safety measure in case of an allergic incident, and by many allergic consumers as a way to circumvent good manufacturing practices. This overuse, coupled with the inconsistent wording of PAL, has over time undermined the trust in such labels and, therefore, their efficacy.⁷⁰ People with food allergies are thus left to be food detectives in their own right, or unnecessarily limit their food choices.

Most importantly, the widespread use of PAL ultimately shifts the burden to consumers, the self-appointed detectives, who then make personal risk assessments for their food choices that are in most cases based on insufficient information. Too often allergic consumers rely on the I ate it and didn't die method. In fact, the perception of risk is highly linked to how it is communicated: allergic consumers are more likely to buy products with written warnings like "shared facilities" than "shared equipment"⁷¹ and generally tend to avoid the purchase of products with statements like "not suitable for [allergen] allergy sufferers" and "may contain [allergens]".⁷² Nearly always, package labelling that lists ALL food allergens under a "may contain" label means it is pointless for consumers with food allergies to purchase or try it. The overuse of PAL negatively impacts both patients' quality of life and sales income for the producer.

In reality, a review of research shows that the proportion of food products with PAL statements that actually contained the warned allergen was, most of the time, 10% or less.⁷³ Still, the exposure for allergic consumers to such low risk can be enough to suffer an anaphylactic shock. Thus, food products with PAL statements leave the allergic consumer with limited choices: either they should avoid them or risk the *l ate it and didn't die* method, which is unacceptable.

How to make PAL meaningful and address current challenges

In order to provide credible trustworthy information for people with food allergies, information on risk of cross-contact should be based on a quantitative risk assessment defined by thresholds or reference doses, that are relevant to the health of consumers with food allergies.

On one hand, the use of PAL should only be possible if unintended allergen presence exceeds scientifically evaluated amounts of allergen that can be harmful to consumers with food allergies. On the other hand, a food product without PAL should not pose a risk to allergic consumers. This way, PAL becomes meaningful, while uncertainty on how to interpret PAL is reduced. This gives the opportunity to consumers with food allergies to make informed choices.

With the recently updated version of the Voluntary Incidental Trace Allergen Labelling (VITAL) 3.0 risk assessment tool,⁷⁴ reference doses have been published for 12 of the 13 allergens listed in the FIC Regulation (not taking sulphite into account, as there are already pre-defined reference doses in force in the EU). The reference doses aim at protecting 99% of food allergic consumers. The current main challenge for the scientific community is to define the risk associated with reactions at or below the reference doses and, in collaboration with other stakeholders (in particular those representing people with food allergies), develop a consensus on what level of risk is tolerable.

Understanding the minimum eliciting dose that can provoke an allergic reaction will benefit allergic consumers, healthcare professionals, regulatory authorities and the food industry. The knowledge and application of reasonable reference doses for allergens would allow European public health authorities to develop a uniform approach for performing risk assessments as a basis of PAL, which the food industry could easily follow. This would limit the current overuse of PAL and define the rules as to when and how the criteria should be used, thereby increasing consumer trust in precautionary food labelling. These factors would improve the QoL for people with food allergies considerably and would assist them in making more informed choices on food.

National binding measures for the use of 'may contain' still elusive

The use of PAL, falling under voluntary food information, is not adequately addressed in the FIC Regulation. Although legal requirements are generally not found at the Member State level, there is little shortage of initiatives at the national



level, ranging from the recommendations (non-mandatory) by food authorities promoting best practice to concrete proposals by civil society.

For example, countries such as **Denmark and** Finland acknowledge that 'may contain' labels restrict the food choices of consumers and can constitute, in principle, misleading information. Therefore, food authorities recommend avoiding such labels, unless all necessary measures have been taken by food operators in the context of self-risk assessments. Similarly, the Food Standards Agency (FSA) in the UK recommends that food manufacturers use PAL only when there is a *real* risk of cross-contact. The voluntary Guidance on Allergen Management and Consumer Information issued by the British FSA in 2006 (well before FIC), refers to the avoidance of cross-contact and using appropriate advisory labelling, and setting out a qualitative approach to risk management, as well as steps to assess whether precautionary labelling is necessary.75

"A person with food allergies is in a constant state of fear of dying and feels emotionally distressed when in contact with people who cannot understand the actual severity."

Patient from Italy

In **Spain**, inspections by food authorities are strict and driven by scientific data. This has in turn raised awareness among companies on the need to gradually reduce the use of PAL. The **Swedish** Bransch Agreement also covers PAL, so that it is not used unless traces have been found through scientific analysis conducted by the food operator. In **Italy**, the overuse of PAL by businesses who are not certain about their products has led patient organisations to suggest the use of 'contains' instead, provided that they have carried out an accurate risk assessment according to good production practices. Finally, in the absence of clear rules, the Association of Allergic and Asthma Patients in **Germany** (DAAB) recommends that consumers always ask about the background of a 'may contain' label, and that a harmonised approach in the PAL wording is highly needed.

Towards a mandatory risk assessment by industry

At any rate, this discussion is tightly linked to the extent and nature of measures used by the food industry to ensure the appropriate use of PAL. There is a need for an industrial practice that incorporates quantitative risk assessment of unintentionally present allergens. lt is а prerequisite for a fair allocation of responsibilities on risk, maximizes the protection of consumers and enables them to make more informed food choices. Here again, although no EU country has legal requirements for conducting quantitative risk assessment linked to PAL, there are significantly different approaches among Members.

For example, in **Germany**, big manufacturers have established good standards of control, which start in their facilities and extends out to their suppliers. Nevertheless, this does not always apply to small and medium enterprises, mostly due to a lack of capacity and know-how. In the UK, the FSA recently reported that in some cases, food products with no allergen declaration or PAL contained enough undeclared allergen to cause a reaction. They suggested that food businesses adopt a more transparent risk assessment procedure.⁷⁶ In **Finland**, the self-monitoring plan in the guidelines for food operators includes risk assessment. Accordingly, Spain has various guidelines on quantitative risk assessment, with one of the most important coming from the food industry association.⁷⁷ In **Denmark**, the Food Authority occasionally receives inquiries from companies that have discovered allergen traces in their products. In such cases, an individual assessment is required on the health risk. When the Danish Food Agency receives a request from a company that wants to determine whether a food contaminant is in a concentration that requires a recall of the product,



"We want restaurants to have to display clear allergen information on each individual dish on their menus. The food industry should put the safety of their customers first."

"It is simply not good enough to have a policy which relies on verbal communication between the customer and their server, which often takes places in a busy, noisy restaurant where the turnover of staff is high and many of their customers are very young."

Family of Owen Carey (Teenager who died due to food allergy in the UK)

"After anaphylactic shock, my daughter ended up at the hospital. We informed them about her allergies and according to the food assistant, she could eat safely the food they provided her. Fortunately, I checked the packaging: It contained an allergen she is allergic to... so I was able to prevent a second reaction. Luckily." Patient from the Netherlands "Not being able to go out for dinner, not being able to go on vacation, not being able to attend international conferences, has a devastating impact on my Quality of Life."

Patient from the Netherlands

"Vendors tend to minimize or give a wrong answer because they ignore the risk of an allergic shock."

Patient from Italy

the Food Authority seeks guidance from the Danish Technical University, based on VITAL reference doses. Finally, in **Greece** the practice of quantitative risk assessment is limited, and mainly performed within the HACCP control system.

The harmonisation and restriction of the use of PAL can greatly benefit all: consumers, by preserving the health and freedom of food choices; food businesses, by increasing market predictability and their credibility; and national authorities, by facilitating their control duties.

3.1.5 Voluntary Information: "Free-from" and other claims

Many food manufacturers, retailers and caterers voluntarily use "free-from" or other claims in food product labels, like lactose-free, gluten-free or vegan (contains no intended animal-derived products).

"Free-from" [allergen] means that the specified allergen is absent from a prepacked or non-prepacked product, unless a regulatory threshold or reference dose for that allergen has been established, below which adverse reactions are unlikely. Only gluten, sulphur dioxide and/or sulphites (and lactose for infant formula) thresholds have been established and transferred to a regulatory framework.⁷⁸

"I am able to find the ingredient list or the written information three out of ten times." Patient from Italy

Except for gluten-free products, no specific EU legislation covers "free-from" claims. They are regulated in accordance with the provisions of the General Food Law Regulation (EC) No 178/2002, ensuring the safety of the food, and the Food Information to Consumers Regulation (EU) No 1169/2011, ensuring accurate and clear communication of the food allergen information.

The gluten threshold is based on scientific data regarding coeliac disease treatment, which is the lifelong and strict avoidance of gluten-containing foods.⁷⁹

However, a recent study conducted by the German Allergy and Asthma Association (DAAB) on vegan products proved that such claims are not necessarily reliable. The study⁸⁰ shows that seven out of 30 vegan products (23%) analysed contained significant amounts of cow milk protein, five of which contained "may contain milk" statements. One of them had no PAL statement, and another one included a "may contain nuts" statement, but did not mention specifically milk in the statement even though milk was detected. Such statements would morally concern vegans, but could also potentially pose a serious health risk to consumers with a milk allergy. Consumers with food allergies to animal products buy and eat vegan products assuming that they are safe.

According to guidance provided by the European Vegetarian Union (EVU), the (potential) presence of unintended traces of non-vegan or non-vegetarian substances should not be an obstacle to labelling a product as vegan, as long as reasonable measures are taken to prevent cross-contact.⁸¹ Therefore, until there is a common EU definition of vegan products, consumers with allergies to food from animal sources, especially milk, must limit choices and not purchase them. At a minimum, consumers should always read labels, even when they are already familiar with the product.

Allergic consumers welcome the option of buying prepacked products with "free-from" claims. However, if the information provided in prepacked and non-prepacked products is to be accurate, "free-from" and other claims, *i.e.* vegan, must be based on rigorous quantitative risk assessments and controls to ensure their validity and avoid misleading information.



3.1.6 Prepacked food sold in bulk

One aspect of labelling for prepacked food in the FIC Regulation still remains a pitfall for allergic consumers. If a food product is sold in a multi-pack, the single packages, which are not meant for direct sale, do not need ingredient lists. Products such as chocolate bars, muesli bar, etc. are often sold this way. In practice these products are often given out separately. In this case, a consumer is unable to make an informed choice as to whether the product is safe to eat or not.

3.2. Allergen labelling in non-prepacked food

For the first time, the Regulation introduced for the requirement to provide information on allergens in non-prepacked food. Therefore, information on the presence of any of the 14 common allergenic substances used in non-prepacked food must be made available to the consumer. This affects a wide range of businesses, along with other commercial and social establishments where non-prepacked food is supplied or from which food is sold to consumers.

"Even if the operators seem confident in managing food allergies, I always check the food before eating it."

Patient from Italy

Regarding non-prepacked foods (including foods prepacked for direct sale), the FIC Regulation states that Member States may adopt national measures concerning the means through which the information is to be made available and, where appropriate, their form (oral or written) and presentation. This flexibility derives from the fact that non-prepacked food is not traded on a cross-border basis, and from the high diversity of businesses selling non-prepacked food. If national governments do not come up with national



In view of the above provisions, many Member States have developed national implementing acts and recommendations with the aim of guiding the work of businesses and public institutions on how this information is made available. Put together, they make a highly diverse set of measures (or combination of measures) with practical and technical aspects that vary from country to country and may affect consumer choice.

3.2.1 Availability, positioning and presentation of allergen information: an issue of trust Given the lack of a harmonised approach among Member States, information on allergens in non-prepackaged food can be provided in different ways across the EU, falling under two main modes of communication: written and verbal. Therefore, in a bar or restaurant, information on allergens can be given in written form on a label (near each specific food product), on the menu, via a specific allergen card, via electronic means, or by the staff verbally (including written consumer notice to consult a staff member before ordering). In some countries, the law provides for a combination of means.

Yet these communication modes are not considered by consumers as equivalent: written information is generally thought to be more authoritative than oral,⁸² provided that it is up-to-date. On the other hand, oral information is seen by allergic consumers as a useful but complementary means, as they are more likely to depend on factors such as the type and size of the business.

According to the EU database of national notifications regarding mandatory implementing acts for the Regulation, as well as a number of other external sources, EU Member States have chosen their own means of providing information on allergens in non-prepacked food to consumers. By and large, they can be divided into three main categories, based on the mandatory or



non-mandatory nature of written information:

- Both **France and Ireland** have adopted legal acts providing that food operators must have written information (either in written or in electronic form, or both) which is available and easily accessible.
- In Finland, Germany, Greece, Italy, the Netherlands, Spain and the UK verbal information is possible, but should be supported by written sources. Several differences still exist between countries, especially regarding the positioning and presentation technicalities i.e. in individual labels, on the menu, on a website, etc.
- In Belgium, Denmark, and Sweden there is flexibility as to how food information may be available to customers, and businesses can choose whether to provide it orally or in written form. Of course, information should be available on the spot, easily accessible and accurate.

Although the categorization might portray a simplified version of national approaches, the implementation of the law reveals a diverse landscape regarding the means to provide allergen information for non-prepacked food in Europe. Due mainly to factors relevant to monitoring and enforcement capacity, this fragmentation translates into different levels of protection of food allergic consumers, both among and within EU Member States. Evidence from the national level illustrates an unsettling situation:

- In Germany, the enforcement of the law is in the hands of each individual state. States tend to have diverging priorities on allergens, with some i.e. Bavaria and Baden-Württemberg, investing more in allergen controls for non-prepacked food, while others focus more on food hygiene;
- In **Italy**, even though oral information is based on mandatory written sources in retail and catering businesses, it is either inadequate or completely missing, despite

recommendations by the Ministry of Health;

- In **the UK**, the authorities have recently adopted "Natasha's Law" on prepacked food for direct sale (PPDS) *i.e.* food packed on the same premises where it is sold. From 2021, PPDS food will need to have a full ingredient list, with allergenic ingredients emphasized within.
- In Finland, businesses are obliged to demonstrate the Oiva report (a food control inspection system developed by local food safety authorities)⁸³ as a way to inform consumers about the results of official inspections on food safety and hygiene.
- Furthermore, in several countries including Sweden, Belgium, Denmark and Finland, it is mandatory for food businesses to have a sign telling customers to 'ask the staff'.

3.2.2 Voluntary information in non-prepacked food: Food allergen symbols

Another way to warn about the presence of allergens in food is the use of symbols or icons. Typically this means the use of the initial letter of the allergen in the national language or an infographic. In a setting where non-prepacked food is sold such as at a restaurant or a snack bar, symbols are frequently found on the menu or in separate signposts.

Presently, there is no single common set of symbols or icons used across the EU, and this includes both prepacked and non-prepacked food. The lack of EU-wide rules on a harmonised set of symbols is often translated into inconsistent practices at the national context. For example, in **Spain**, as well as in **Italy**, the use of symbols is based on the voluntary decision of individual businesses, which creates difficulties for consumers.

In other cases, there is even confusion between the essence of symbols and free-from claims: in **Finland,** "free-from" claims also impact non-prepacked food, as there are a few instances where restaurants and schools voluntarily use



symbols such "L" [Lactose], or "M" [Milk] to indicate that food is *free from* these allergens, while in all other countries the symbol is intended to indicate that allergens are actually present. In fact, this is a practice that predates the FIC Regulation. However, given the increasing mobility of people across Europe, such a practice may entail risks, both for non-Finnish tourists in the country but also to young **Finnish** people travelling abroad. Such barriers may be the reason why in several other countries, such as Denmark, the Netherlands and Sweden, symbols are either unpopular or absent altogether.

While symbols can help in literacy, the danger is that they may be interpreted differently by different people. That is why they can be an addition but not a replacement for other information. A harmonisation of rules and presentation of the symbols in non-prepacked food would benefit consumers by promoting uniform understanding of the allergen presence, and thus help in limiting the dissemination of misleading information.

3.2.3 The Regulation as practiced by the food service industry

Despite the efforts of some national authorities to ensure good implementation of the Regulation and the protection of allergic consumers when eating out, allergic consumers still face challenges. This is especially true in obtaining accurate allergen information from food service businesses, including restaurants, bakeries, supermarket counters, delicatessens and cafés.

How are consumers informed?

A survey by the Consumer Association of **France**, UFC-Que Choisir in 2016, revealed an association between the type of establishment and the compliance with the FIC Regulation in the country.⁸⁴ It was easier to find allergen information (provided orally or in a written form) in members of large fast-food chains (*i.e.* McDonald's) and big supermarket chains than in small and medium



enterprises (SMEs), which include small-size bars, restaurants, bakeries, and catering businesses. One of the main reasons is the availability of legal departments within the structural organisation of the businesses. When allergen management and information is poorly handled and not included in food hygiene, or there is no guidance or proper obligation to provide allergen information in non-prepacked foods, the availability of accurate information remains haphazard.

"I was not invited by my classmates to a party in a pizzeria because they thought that the restaurant was not organised for food allergies. I felt doubly discriminated against. First by the restaurant, and second by my friends who excluded me."

Patient from Belgium

In 2016, 45% of SMEs and 13% of big distribution establishments in **France** were not informing all clients about allergen information. A similar survey⁸⁵ conducted by the **Belgian** Consumer Organisation Test-Achats revealed that in 2017 in Belgium, 12% of businesses (including supermarkets, bakeries and snack bars) were not able to provide allergen information present in their products.

Low awareness

EFA discovered that at a reputable hotel in Brussels, the location of our annual general meeting, the hotel had never heard about food allergen labelling, or that they were required by law to give information on allergens in their restaurant and catering. EFA forwarded the law, and the hotel put implementation procedures in place.

While this may seem like anecdotal evidence, 80% of **French** SMEs that were not providing allergen information according to the EU Regulation in the study claimed that they were not compliant: either they were not aware of this legal obligation, or because they 'did not need to be concerned about it'. Managers working in big supermarket chains

were the most aware of the EU Regulation, but the information did not appear to be trickling down to staff. In **Germany**, a study of the University of Düsseldorf found that only 30% of restaurant staff within 15 districts of Düsseldorf could correctly name three common food allergens.⁸⁶

In fact, many vendors in **France** seem confused between the intended and unintended presence of allergens, as evidenced by one vendor's statement: *"We are a gastronomic restaurant, everything is prepared without any allergic product."*⁸⁷

Impolite vendors

One unpleasant situation that allergic patients deal with when going out for food is an unfriendly received answer when requesting allergy information. Food allergens may seem trivial, but questioning consumers are not asking with the purpose of being "difficult". When providing oral information, the consumer needs the vendor to provide the information necessary to make a safe choice. It sometimes happens that vendors become impatient and impolite. Among 232 restaurants, bakeries and caterers in France, 20% of them expressed non-cooperative attitudes: pressed or impatient staff tended to give hostile answers.⁸⁸

How the written information is presented

In France, most fast-food establishments in the study were providing allergen information next to the product through screens inside stores. Nevertheless, the allergen information was difficult to read, either because it was written in a small font size, or because the content of the screens was constantly changing with food options. 77% of big chain supermarkets were providing allergen information in a written form. However, in almost half of them, the allergen information was only available in folders where the ingredient information of all the products of the shop where listed. In **Belgium**, only seven percent of establishments (supermarkets, bakeries and snack bars) labelled allergens next to the product.⁸⁹

Another survey⁹⁰ carried out by the **Spanish**

Consumer Organisation OCU reveals that written labels next to the product are more common in supermarkets than in bakeries. However, in 96% of the establishments in the study, the information provided was quite generic and clients were almost obliged to ask for further information about the presence of allergens.

"Sometimes it is hard to bear the insensitivity of people around, who seem not to understand the implication of food allergies."

Patient from Italy

Allergic patients are generally seen to prefer written information over oral, or a combination of the two, provided that trusted and up-to-date written information is available. Information is more reliable if vendors base the given information after reading the ingredient list of a product, instead of answering on impulse. Inaccurate information leads to distrust, prevents allergic consumers from making a safe choice, and exposes them to health risks.

Oral information

Food businesses are legally obliged to use clear signposts to direct customers to where allergen information can be found.

The Food Standard Agency from **the UK** suggests the following message, "Before you order your food and drinks, please speak to our staff if you have a food allergy or intolerance."⁹¹ The signpost should be located in an obvious spot where the customer is likely to see it before ordering. Nevertheless, such messages are not always made available. In **Belgium**, it is only placed in 17.5% points of sale (supermarkets, bakeries and snack bars).

In **Spain**, 97% of vendors in bakeries, supermarkets and pre-cooked stores informed their clients orally, but only 26% of them informed the clients after reading the technical ingredient list.⁹² In **Belgium**,



93% of supermarkets, bakeries and snack bars generally informed customers orally, but only 32% consulted a written source before responding.⁹³

Cross-contact and 'may contain'

Inadequate handling practices can lead to an unintended presence of allergens in a product due to cross-contact. It is an issue that non-prepacked food producers should consider in order to correctly inform clients when buying their products.

Nonetheless, in **Spain**, 81% of handling practices done by vendors do not protect from non-intended or accidental cross-contact with allergens.⁹⁴ Alarmingly, a study⁹⁵ carried out by the Italian Consumers Organisation Altroconsumo revealed that 75% of the coffee establishments informed the client about the absence of hazelnut in the pastry bought when in reality traces of the nut were present. The same happened in seven percent of the establishments in the **Belgian** study.

The **Belgian** results reveal that vendors tend to inform clients more about the risk of cross-contact after consulting the list of ingredients (83%) rather than when orally informing without consulting it or doubting that the vendor did consult the ingredient list (27%).

Precautionary allergen statements can be found as well in establishments offering non-prepacked food that are aware of the risk of cross-contact. For example, in **France**, 60% of big distribution establishments and one in three SME mentions "traces of", "may contain" or "eventual presence of" in their notices.

"I don't want to be special, I just want to be safe."

Patient from the Netherlands

In **the UK**, the Food Standards Agency launched a campaign on anaphylaxis under the hashtag *#easytoask*.⁹⁶ The aim was to empower allergic



consumers to ask food businesses about allergens. With the campaign, establishments have the opportunity to accurately inform customers about food preparations and the risk of allergen contact, allowing clients to make an informed safe choice on what to order or buy, provided that the information is accurate and up-to-date.

Unfortunately, it is still a reality that allergic patients are challenged in finding allergen information when eating out. They need to be well-informed on food ingredients and the potential risks of cross-contact. They want to stay safe and enjoy a relaxed meal with friends or family. The difficulty in obtaining such information translates into an intensified feeling of anxiety and insecurity as it implies a higher risk of an accidental ingestion of allergens.⁹⁷ For this reason, patients might adopt preventative measures, including refusing plans with friends or family or business associates, adversely affecting their social and business life.

3.2.4 Training and educational programmes needed

In almost all EU countries for which evidence is available, the issue of training of personnel in handling allergens and dealing with an allergic incident is a key priority with regards to non-prepacked food. However, while in some, such as **Austria, Denmark, Germany, Spain and the UK**, there are extensive guidelines on the issue, training of business staff in allergen handling is not mandatory by law in most EU Member States.

Some national authorities take the initiative to training programmes develop and courses addressed specifically to the industry sector. In this respect, the Finnish food authority offers free online courses through its website. The **Dutch** authority certifies certain paid training programmes provided by expert consultants and institutes. In **Germany**, training is provided by food inspection authorities, but are more likely to be taken by large companies. The Food Standard Agency in the UK has its own training for allergen management offered to businesses. On some occasions, local councils have invited civil society organisations such as AllergyUK to training sessions. Meanwhile, AllergyUK has also developed an Allergy Aware Scheme for catering outlets to demonstrate their commitment to safeguarding those with food allergy through detailed allergen training. The food authority of **Sweden** works extensively on the training of food controllers, under the premise that good audit knowledge is easily transmitted to food business operators. Finally, Allergen management/information is part of the educational programme for chefs in **Denmark**.

On several occasions, businesses have indicated their lack of human resources, or even lack of interest in providing training. As expected, the line between big and small businesses is all the more visible, as large food chains generally have considerably greater capacity in putting in place training programmes for their staff, while it is rarely the case for SMEs. On the other hand, in some countries the interest of industry is increasing, resulting in ever tighter engagement with civil society on educational efforts. For instance, in **Sweden**, Visita (the trade association representing the hospitality sector) has developed in partnership with the **Swedish** Asthma and Allergy Association a course concerning allergens for restaurant staff.⁹⁸

"I do not trust verbal reassurances and always want to see the ingredients list." Patient from Italy

In light of this, training emerges as a highly complex issue that requires continuous commitment and investment in time and money. Yet it is tightly linked with the safety of allergic patients, as well as the preparedness of staff members to deal with an allergic incident. The quality of internal procedures and compliance with Hazard Analysis Critical Control Point (HACCP) procedures is key to an accurate and substantial credibility of the information and will help to limit cross-contact risks.

Allergen management needs to become a normal, integral part of food hygiene training, guidance and

requirements, which has been so successful in preventing food-related harm to health in Europe.

Education for the many people in contact with food production and delivery is essential. However, the level of instruction will be different depending on the work that they carry out: Low-Risk Food (waiting staff, food service bar staff) and High-Risk Food (cooks, chefs, catering supervisors, kitchen assistants).⁹⁹

Most importantly, it is crucial that staff at all levels is aware of the internal procedures put in place to be able to inform accurately customers on the composition of the foods that are sold in the business. The ultimate aim should be that customers are proactively informed of the presence of allergens and are able to trust the controls in place to prevent harm.

The Food Standards Agency in **the UK** has developed an online training¹⁰⁰ on food allergy for Food Business Operators. It is the most complete education programme that EFA has identified so far. It includes:

- Rules and legislation;
- The effects of allergies on the body;
- Considerations of allergies in the factory (guidelines for staff, dealing with allergenic ingredients, the packaging procedure, cleaning procedures, storing allergenic ingredients in the factory, processes of monitoring and review that should be in place, ways to avoid cross-contact in the production chain);
- How allergenic ingredients should be displayed on the label (ingredient list, may contain, gluten free claims); and,
- How food businesses should provide consumers with allergen information for the non-prepacked food they serve.

3.2.5 Food Allergies in public establishments where non-prepacked food is distributed

Food allergy reactions commonly occur outside the home environment.¹⁰¹ Exposure in community



settings and lack of information are factors that may put patients at risk of an allergic reaction. Therefore, it is important that stakeholders work together to protect patients against the risk of exposure to allergens and improve food allergen management for patients at places such as schools and hospitals.

Hospitals

Resolution ResAP(2003)3¹⁰² on food and nutritional care in hospitals of the Committee of Ministers of the Council of Europe recognises the need to raise the level of health protection of consumers in its widest sense, including the following:

- A food service policy should be adopted and implemented at hospital or regional level;
- Hospital management, physicians, pharmacists, nurses, dieticians and food service staff should work together in providing nutritional care;
- A continuous education programme on general nutrition and techniques of nutritional support for all staff involved in the feeding of patients should be implemented;
- The provision of meals should be flexible and individualised. Menus should be specifically targeted to different patient categories; and,
- Dishes should be described accurately so that patients have a reasonable idea of what to expect and patients should receive information regarding the nutrient composition of different foods and drinks.

Despite the existence of such a resolution, the level of awareness of its existence is low and the struggle of allergic patients in hospital care is still a reality. Additionally, different countries have their own rules and guidance for hospital catering for patients. Based on a recent study¹⁰³ from the **Dutch** Food Allergy Foundation, almost 40% of patients were not asked about food allergies upon admission. Furthermore, over half of allergic patients mentioned that a mistake had been made with their food, causing 40% to have an allergic reaction during their hospital stay.

"I have had an allergic reaction to food from food at the hospital twice - even though I had clearly indicated my allergies." Patient from the Netherlands

To avoid the problems and protect patients from harm, communication between nurses, caretakers, caterers and any food service assistants in hospitals is essential to ensure that patients receive the meal according appropriate to dietary requirements. In this context, the Food Services Specialist Group from the British Dietetic Association has produced the 'Nutrition and Hydration Digest'.¹⁰⁴ This guidance has been developed by dietitians to ensure that staff have access to training to provide patient-centred food service. As a good example of food allergen management strategy in hospitals, the Regional University Hospital of Malaga in Spain has developed an online platform¹⁰⁵ where patients, caregivers and the staff of the hospital can publicly access the nutritional description of all the dishes of the hospital, including allergen information.

Schools

Almost 20% of allergic reactions occur in school, with an estimated prevalence of food allergy in 4-7% of school-age children.¹⁰⁶ Within a school setting, food allergens may be present in virtually all situations and allergic reactions can occur at any time during lessons, meal or playtimes - effectively, at any point in a child's day. Therefore, schools should be prepared and trained to protect and integrate allergic children, and respond appropriately in case of an allergic reaction.

In reality, schools in Europe are not sufficiently prepared to deal with allergic reactions to food. The main reasons include allergy information not being communicated to the school.¹⁰⁷ Too often



emergency medication is not made available and teachers are poorly trained.¹⁰⁸ Additionally, Personalised Emergency Management Plans (PEMPs) are not consistently provided for the majority of students with food allergies.¹⁰⁹

National authorities are responsible for ensuring a safe school environment for allergic children. However, some countries are more committed than others in achieving this goal.

Many things have to be taken into account in a school to protect allergic children, however, it is not rocket science. While parents need to be proactive, integrating children in school with chronic disease should be normal practice and facilitated by the authorities and school staff. In accordance with the 2014 Food Allergy Anaphylaxis EAACI and Guidelines and the key recommendations developed by the task force on the allergic child at school (TACS),¹¹⁰ schools should develop a formal policy that guarantees a safe environment for allergic children. This includes the implementation of a system to identify food-allergic children to school staff (especially catering), and the development of personalised care plans for individual children. including Personalised Emergency Management Plans (PEMPs) in case of severe allergies. Emergency medication should be available and up-to-date at all times. School staff should also be educated on allergen avoidance, the recognition of symptoms and how to administer emergency treatment.

Despite formal school policies on food allergy management, effective implementation is very low or nonexistent. Fortunately, some national and regional authorities have taken action to protect allergic children in school. In **the UK**, since October 2017, schools can purchase emergency medication for anaphylaxis (AAIs) from a supplier without a prescription¹¹¹ making them easily available in schools. In **Italy**, the Veneto region approved a law in November 2004¹¹² recognising food allergies as a high social-impact disease and provided a programme for education and training for schools

and restaurants. The Regional Council has prepared a training plan for all school staff in the region on how to handle emergencies and problems caused by food allergies from a practical, psychological and legal/medical point of view. The Referral Food Allergy Centre, together with Food Allergy Italia, provides face-to-face training courses carried out by a multidisciplinary team (pediatric allergist, lawyer, psychologist, patient representative) which allow teachers to deal with the problem with greater confidence and competence and, at the same time, allow the student with severe food allergies a safer school life.

In **the UK**, a charity called Anaphylaxis Campaign has developed a free online anaphylaxis training course 'AllergyWise'¹¹³ for school staff to increase their awareness on the signs and symptoms of anaphylaxis. This includes how to provide emergency treatment and the implications for severely allergic children managing in an educational setting. Teachers should be well-trained on how to act in an emergency situation. In **Germany**, teachers are encouraged to take action in case of emergency by administering immediate first aid, for example, adrenaline in case of anaphylaxis. They are covered legally by the first aid law¹¹⁴ in case something goes wrong, and this is key, because people are afraid of using emergency treatment even when it is relatively simple to administer.

Education systems are different across Europe and meals are not necessarily commonly served in schools in all countries (for example, **the Netherlands**). However, those schools providing a food service, internal or external, should implement reasonable measures based on the FIC Regulation and national provisions. These include ensuring appropriate allergen information, including clear allergen labelling, and sending allergen information in advance to families or appropriate food-handling procedures to minimise the risk of cross-contact.





Food allergy is a chronic and nontrivial disease. It has an important impact on patients in their day-to-day life, affecting their physical, mental and social well-being, and resulting in an impairment of their and their caregivers' Quality of Life.

Food allergies are a concern for people living with them, their families and those involved in supplying and preparing food. Allergic patients need to be well-informed. However, in reality, public establishments cannot always guarantee a high level of food allergy and food-allergen management. While there is hope for new treatments, currently the only treatment is avoiding the allergen while carrying medication at all times in case of a severe reaction. Additionally, food allergen information is not always easy to find or understand, complicating the decision-making process for patient safety. Patients are left to be food detectives.

Allergic patients face difficulties in managing their disease outside the home (in restaurants, cafes, bakeries, supermarkets, schools, hospitals, etc.) which leads patients to feel stressed, anxious, insecure or scared, because in fact, they are not safe. A substantial part of this is due to the existing gaps between needs and the current EU Food Information to Consumers (FIC) Regulation. Therefore, patients feel limited in their eating choices, obliged to adapt their behaviour and forced to adopt their own preventative and safety strategies, directly impacting their Quality of Life.

Although the FIC Regulation represents good progress in making food allergen information available to consumers in prepacked and non-prepacked food products, there is ample room for improvement. Research has shown that grocery shopping has become more difficult and time-consuming for allergic patients. Concrete legal provisions are absent for voluntary Precautionary Allergen Labelling (PAL) for the presence of unintended allergens. The current use of such warnings by food producers is translated, on the one hand, into a loss of consumers trust by adopting risk-taking behaviour, accepting the possibility of a potential allergic reaction. On the other hand, others decide to avoid consuming products with such statements, restricting their food choices and increasing their level of anxiety. Moreover, the lack of a harmonised European approach for "free-from" claims (except for gluten) and for food-allergen symbols is creating confusion among consumers and may even be misleading.

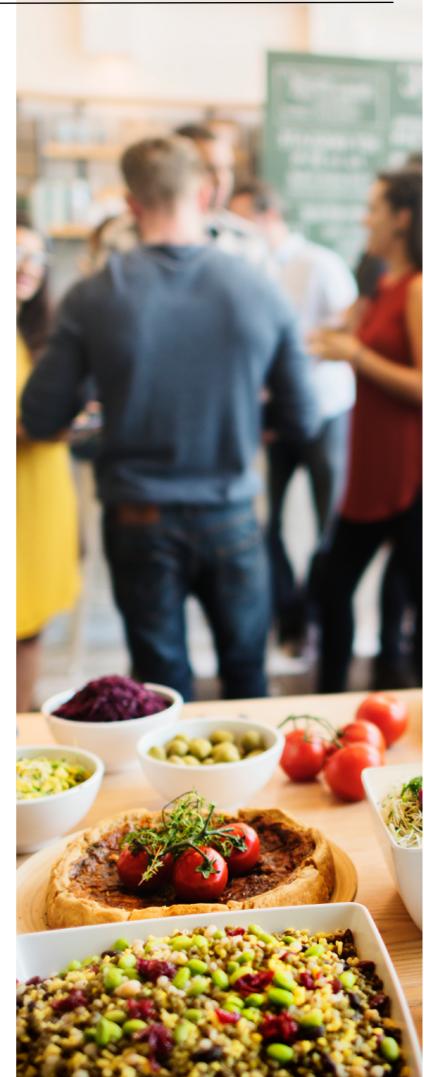
Non-compliant products are a risk for allergic patients, so monitoring and recalling schemes help them to stay safe. However, such systems are widely varied across Europe, mostly differentiated ownership, resources, effectiveness, by enforcement power and consequently, how and if they protect and improve QoL for people with food allergies. At the EU level, RASFF signals a first cross-border effort to share information on health threats linked to food, yet it suffers from a varied definition of what health risk actually is, and therefore recalls are not based on harmonised criteria across all Member States.

However, the main issue is the lack of a common definition or criteria as a basis for issuing alerts for offending products that cross borders. Information can be inaccurate, preventing countries from taking immediate action for the protection of consumer health. Food allergens may be present in nearly all situations and allergic reactions can occur at any time. Sadly, despite the efforts of national authorities for proper implementation of the FIC Regulation on non-prepacked products, in reality, accurate allergen information in many cases is difficult to obtain. Inaccurate allergen information leads to distrust and a need for constant surveillance, impacting patients socially and emotionally.

Clearly, almost all those involved in the food supply chain would benefit from mandatory education on allergen management to provide safe food. It would contribute to preventing food-related harm to health in Europe. However, such education is not mandatory across Europe.

There is an urgent requirement for effective communication healthcare between professionals, patient organizations, food industry representatives and regulators to develop a better approach to protecting consumers with food allergies. Performance and improved outcome measures care of pathways are at the core the patient-centered healthcare system.¹¹⁵

Finally, better food allergen and allergy management from food providers as well as in schools, hospitals, airplanes and other settings, will contribute to safer environments for allergic patients. Accordingly, EFA provides the following recommendations for policymakers, public health authorities, the food industry, healthcare professionals, patient associations and food-allergic patients. This will improve the QoL for patients and their caregivers, reduce feelings of discrimination and social isolation, prevent possible life-threatening events and in fact, encourage safe food for all.







FOR POLICYMAKERS

Short-term recommendations

EU authorities

- Publish a **comprehensive report on the implementation of the FIC Regulation** at the national level as it is the usual practice in other areas of EU legislative action.
- Prepacked food: **Harmonise the way PAL is communicated** to consumers and when, where and how it can be used as foreseen in Article 36 of the FIC Regulation.
- Non-prepacked: **Harmonise the way allergen information is communicated** and ensure that information is verifiable in one way or another in a written form in an establishment selling non-prepacked food, either by the customer or the staff.
- Specific issues concerning certain prepacked products:
 - Define vegan products to avoid misleading information;
 - Ensure that the allergen information is contained in **bulk products**, both in the general and individual packaging of the product.
- Food allergy management requires reinforced attention and increased research funding for the development of food allergy treatments.
- Introduce legislation to welcome people with chronic diseases, in this case those with food allergies, and provide a safe food environment in not only public establishments, especially schools, universities, hospitals, but also airlines, including storage and administering emergency medication in case of a severe food allergy reaction.

National authorities

- Non-prepacked: National public authorities should do more consistent checks to verify the proper implementation of the law and impose penalties in cases of non-compliance. In this context, national authorities should provide an overview of the European context on compliance with the FIC Regulation.
- Make sure that everyone who needs it can **afford the cost of emergency medication** for food allergies.
- Develop tailored training and educational programs for the following sectors:
 - Healthcare professionals, especially general practitioners: multidisciplinary care of food allergy, to recognise symptoms of an anaphylactic reaction and how to administer adrenaline; include food allergy in the curriculum of medicine schools/universities;
 - Food sector: develop and fund **education food management programs** where allergen management is included in food hygiene training and certification. This training should be mandatory for all relevant people working in the food supply chain, adapted to roles.

FOR POLICYMAKERS

Long-term recommendations

EU authorities

- Prepacked food:
 - Develop a harmonised approach in Europe for the use of Precautionary Allergen Labelling (PAL) statements in prepacked food which is clear and trustworthy for people with food allergies, and guide national authorities in enforcement and assessment;
 - Establish reference doses for each of the 14 food allergens listed in the FIC Regulation, below which they do not cause reactions to most food allergic patients; harmonise PAL based on an appropriate quantitative risk assessment from reference doses for safe levels of allergens;
 - Harmonise approach to risk assessment;
 - Harmonise recall system, based on a common definition of health risk.
- Prepacked and non-prepacked: **standardise the use of allergen symbols**, which would not completely replace written information.

FOR PEOPLE LIVING WITH FOOD ALLERGIES

- **Read food labels**, especially allergen information, and always carry **emergency medication if needed**, even if you are familiar with the product. Labelling **can change** at any time due to a change in the recipe or food processing which may result in allergen cross-contact. Do not take risks based on incomplete or missing information.
- **The precautionary allergen labelling** ('may contain') is not based on common rules. If you have a severe allergy you cannot trust that those products are safe.
- **Vegan products**, free from animal-origin allergens (i.e. milk or egg), cannot be guaranteed, even if the information on allergens is labelled as such. They may contain allergens above the reaction threshold for people with serious allergies. In addition, the claim 'gluten-free' means a certain level of gluten in the food based on an established threshold tolerable for coeliacs but not suitable for allergic patients.
- You should ask your doctor for a **written food allergy management plan**, digital or otherwise, including managing daily life and diet, and food allergy reactions. Do not hesitate to share it with relevant caregivers and educational work staff, as appropriate.
- You have the right to safe food: demand it!

FOR HEALTHCARE PROFESSIONALS

- Provide a personalised written management plan, including an emergency management plan and training for patients covering proper nutrition, food-avoidance strategies, interpretation of labels and warning signals. This also involves when and how to treat allergic reactions and the use of Adrenaline Auto-Injectors (AAIs), if appropriate, in addition to psycho-social aspects, as well as improving patient self-management skills.
- Healthcare professionals, especially general practitioners, need more education on the use of AAIs so that they can train patients and caregivers.

FOOD ALLERGEN M A N A G E M E N T FOR FOOD BUSINESS OPERATORS

STAFF	 Train relevant staff on allergy awareness; Ensure staff has easy access to allergen information and is informed of ingredient changes; Non-prepacked food: encourage dialogue with customers about dietary requirements through signposts or orally when ordering.
SUPPLIERS	 Identify food products or raw material from suppliers that intentionally or unintentionally contain allergens; Ask suppliers to notify changes in allergen status; do not accept delivery without full ingredient list.
STORAGE & HANDLING	Store allergic raw materials or food products containing allergens in a way that will minimise the risk of cross-contact.
PRODUCTION	 Make sure that recipes are followed and the correct ingredients are used; Keep written and up-to-date records of all foods containing allergens; Create clear procedures to minimise the risk of cross-contact. Ideally, follow 'FoodDrinkEurope Allergen Management Guideline' for more detailed and comprehensive guidance.
CONSUMER	 Prepacked food: allergens must be provided and labelled in the food packaging; Non-prepacked food producers: information may be provided written or orally. If the information is provided orally, ensure that written information is also available, clear, up-to-date and easily visible. In case of a modification of a dish, written information should be accompanied by oral communication by the staff.
FE	#DetectiveFeed

European Federation of Allergy and Airways Diseases Patients' Associations

#DetectiveFood efanet.org

GLOSSARY

- **Adrenaline Auto-Injector (AAI)**: Device designed to be used by a non-medical person to give a predefined dose of intramuscular adrenaline for treating anaphylaxis, when appropriate.¹¹⁶
- **Alert**: Within the RASFF system, an alert is a notification sent when a food or feed presenting a serious health risk is on the market and rapid action is required.
- **Anaphylaxis**: Severe, life-threatening generalised or systemic hypersensitivity reaction, characterised by being rapid in onset with life-threatening airway, breathing or circulatory problems, in which the immune system responds to otherwise harmless substances, and can result in death.¹¹⁷
- **Cross-Contact**: When there is "cross-contact" between an allergen and a residue or other trace amount of an allergenic food, unintentionally transferred into another food.¹¹⁸
- **Food Business Operator (FBO**): The natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control.¹¹⁹
- **Hazard Analysis Critical Control Point (HAACP)**: Methodology and management system used to identify, prevent and control food safety hazards.
- **Health Related Quality of Life (HRQoL)**: HRQoL is a multidimensional concept that consists of bio-psycho-social domains, including subjective reports of symptoms, side effects, functioning in multiple life domains, and general perceptions of life satisfaction and quality.¹²⁰
- **Non-prepacked food**: Foods sold without packaging; foods packed on sale premises at the consumer's request; or foods prepacked for direct sale.
- **Oral Food Challenge (OFC)**: Also called feeding test, is a medical procedure in which a food is eaten slowly, in gradually increasing amounts, under medical supervision, to accurately diagnose or rule out a true food allergy. OFCs are usually done after a careful medical history and allergy tests, such as skin and blood tests, are inconclusive. The OFC is a more definitive test because it will show whether the food ingested produces no symptoms or triggers a reaction.
- **Prepacked food**: Any food put into packaging before being placed on sale, whether such packaging encloses the food completely or only partially, in such a way that the contents cannot be altered without opening or changing the packaging and is ready for sale.
- **Precautionary Allergen Labelling (PAL)**: PAL is a voluntary statement used by food manufacturers on the unintentional presence of allergens in food products. Allergens present in food following unavoidable cross contact where the risk is real and poses a health risk statements such as "may contain" or "not suitable for" can be used to inform those with food allergies and intolerances of the risk.
- **Quality of Life (QoL)**: Individual's perception of position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.¹²¹
- **Reference doses**: The milligram protein level (total protein from an allergenic food) below which only the most sensitive of individuals in the allergic population are likely to experience an adverse reaction.¹²²

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European Federation of Allergy and Airways Diseases Patients' Associations

35 Rue du Congres, 1000 Brussels, Belgium Tel.: +32 (0)2 227 2712 E-mail: info@efanet.org efanet.org

