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Food allergens and its management as per international and national requirements

Dr. Laly.S.J
Senior Scientist
Quality Assurance and Management Division
ICAR-Central Institute of Fisheries Technology, Cochin

Introduction

Two important aspects related to food processing are food safety and food quality. Food safety hazards like biological hazards (bacteria, viruses, parasites, protozoan, and prions etc.) and chemical hazards (pesticides, heavy metals, natural biological toxins, adulterants etc.) have already received attention both from food safety researchers and regulators. Over the last two decades, food allergens have been recognized as a food hazard. Food allergies are emerged as a major public and personal health burden which is growing in nature. Food allergens are a serious threat to sensitive individuals, showing an increasing tendency. It also has gained importance due to the increase in food allergy incidences in many countries especially in US, Canada, Europe, Australia, New Zealand, UK, and Japan where the regulations on food allergens are very stringent. All the developed countries have their own set of guidelines to deal with the food allergens but are not well documented in developing countries. Food allergies affect more than 1 to 2 % of general population but within a maximum of 10% with increased prevalence in children and adults. Even though it affects a comparatively lower population in the world, the allergic reactions can be severe or potentially fatal. Risks due to challenges in health, regulatory requirements and business plans make food allergy as an important concern in food industry. Including of an Allergen Control Plan in the food processing industries is a critical component for ensuring product safety.

Adverse reactions to food can be broadly classified into food intolerance and food allergy/hypersensitivity. Food allergy is regarded as a public health problem that must be considered seriously. Even the intake of minute amounts of food allergens can cause allergic reactions in sensitized individuals. Among the adverse reactions to food, there are immune-mediated and non-immune-mediated reactions. An allergy is a hypersensitivity reaction where symptoms appear rapidly following exposure to macromolecules or proteins. They are commonly

mediated by a specific class of antibody, known as immunoglobulin E (IgE), which is normally generated as part of immune reactions or other immunological pathways. Symptoms range from mild hives to severe gastrointestinal and respiratory symptoms, such as nausea, vomiting, throat swelling, asthma, and the most serious food allergic reaction of anaphylactic shock.

In contrast, food intolerances are reproducible non-immune-mediated reactions whose symptoms can sometimes take days to manifest themselves. They do not necessarily have an immunological basis although coeliac disease, is one of the best-defined food intolerances. Food intolerances comprise non-immune-mediated responses that are dependent on enzyme deficiencies, pharmacological reactions, or, as is true in the majority of cases, arise by unknown mechanisms. It includes intolerances secondary to metabolic disorders (e.g., lactose intolerance), reactions to toxic contaminants (e.g. histamine in scombroid fishes), or pharmacologically active food components (e.g. caffeine in coffee causing jitteriness, tyramine in aged cheeses triggering migraine). It is important to distinguish food allergy from other non-immune mediated adverse reactions to foods, particularly since more than 20% of adults and children alter their diets due to perceived food allergy.

Types of food allergies

The antigens which stimulate the production of IgE antibody are called as allergens. There are four different types of allergic reactions. In case of IgE mediated food allergy the symptoms appear within minutes to 2 hours and are known as type I or immediate hypersensitivity which are also called as 'true' food allergies. IgG or IgM mediated cytotoxic hypersensitivity comes under type II which can lead to issues like autoimmune haemolytic anaemia. Hence testing of food antigen specific IgG for diagnosing food allergy is not recommended. Type III comprises immune complex of antigen and antibody mediated hypersensitivity. The associated

manifestations are localized arthus reaction, serum thickness, systemic lupus erythematosus. Type IV hypersensitivity comprises food antigen-specific T-cell responses affecting the gut mucosa, associated with disorders like celiac disease. Celiac disease is a hypersensitivity reaction against the wheat gluten fraction containing alcohol soluble gliadins and acid-, alkali-soluble glutenins, accompanied by an autoimmune component.

Shellfish and fish allergens

Seafood is a significant contributor in human nutrition and health and generally comprises fishes (chordates) and shellfishes (crustaceans and mollusks). The leading drivers of seafood consumption are nutrition, taste and convenience, and the main barriers include price, availability, and concern about quality. Fish and shellfish are

Order	Fish	Allergen Protein Identity
Clupeiformes	<i>Clupea harengus</i> (Atlantic herring)	Parvalbumin
	<i>Sardinops sagax</i> (Pacific pilchard)	Parvalbumin
Cypriniformes	<i>Cyprinus carpio</i> (common carp)	Parvalbumin
Gadiformes	<i>Gadus callarias</i> (Baltic cod)	Parvalbumin
	<i>Gadus morhua</i> (Atlantic cod)	Parvalbumin Enolase Aldolase
Perciformes	<i>Lates calcarifer</i> (barramundi)	Parvalbumin
	<i>Oreochromis mossambicus</i> (tilapia)	Tropomyosin
	<i>Thunnus albacares</i> (yellowfin tuna)	Parvalbumin Enolase Aldolase
		Parvalbumin
Pleuronectiformes	<i>Lepidorhombus whiffiagonis</i> (megrim)	Parvalbumin
Salmoniformes	<i>Oncorhynchus keta</i> (Pacific salmon)	Vitellogenin
	<i>Oncorhynchus mykiss</i> (rainbow trout)	Parvalbumin
	<i>Salmo salar</i> (Atlantic salmon)	Parvalbumin Enolase Aldolase
		Parvalbumin
Scorpaeniformes	<i>Sebastes marinus</i> (redfish)	Parvalbumin
Shellfish		
Crustacean	Crab	
	Northern sea shrimp	
	American lobster	Tropomyosin
	White leg shrimp	Arginine kinase
	Shrimp	Myosin light chain
	Spiny lobster	Sarcoplasmic binding protein
	Black tiger shrimp	
	Narrow-clawed crayfish	
Brine shrimp		
Mollusca	Pacific oyster	
	Abalone	
	Brown garden snail	Tropomyosin
	Scallop	
	Tropical green mussel	
	squid	

important causative of severe acute hypersensitivity reactions like fatal anaphylaxis. Many major and minor allergens were identified and reported both in the case of fish and shellfishes (Table 1). Seafood allergy is a type of food allergy which is most regular and it included both fish and shellfish, part of “big eight” food allergens. Crustaceans mainly shrimps are the 3rd major source of food induced anaphylaxis in the world after peanut and tree nut and are reported to affect >2% of population. Many of the allergens are having the potential for cross reactivity. IgE mediated reactions can result nausea, vomiting, abdominal pain and diarrhea which can be triggered within minutes of ingestion.

Code of Practice on Food Allergen Management (CXC 80-2020)

The scope of this CoP focus on allergen management starting from primary production to manufacturing, and retail food service. This CoP is to manage allergies mediated through IgE and non IgE. Globally the eight major allergens are causing majority of allergies. Other than this, other recognized allergens are also need to be considered while exporting. This CoP does not cover non-immune mediated intolerances such as lactose intolerance and sulphite sensitivity. This code has to applied in conjunction with the General Standard for Labelling of Prepackaged Foods (CXS 1-1985) and Code of Hygienic Practice for the Transport of Food in Bulk and Semi packed Food (CXC 47-2001). It outlines the principles of food allergen management for different sections.

Primary production

Principle - ‘Where the introduction of an allergen may adversely affect the allergen profile of food at later stages of the food chain, primary production should be managed in a way that reduces the likelihood of introducing such allergens.

The code says that care has to be taken to reduce the

likelihood of allergen cross contact via equipment’s used for harvest, storage areas, storage bags and transportation vehicle.

Establishment: design and facilities

Principle - ‘Establishment design should prevent or minimise the potential for allergen cross-contact with respect to delimitation and isolation of areas, location of equipment, process flow, personnel movement and ventilation systems’.

Facilities commonly handle multiple allergens using the same equipment. Use of dedicated processing lines for food with specific allergen profiles is ideal. Adequate separation between lines can prevent or minimize allergen cross-contact when foods with different allergen profiles are processed at the same time.

Control of operation

Principle - ‘The unintentional presence of allergens in food is prevented or minimised by taking preventive measures through GHPs and HACCP-based controls at appropriate stages in the operation.

A structured assessment of the likelihood of allergen cross-contact resulting in a risk to the consumer with a food allergy and taking control measures is important. Equipment and preparation areas should be adequately cleaned between manufacturing foods with different allergen profiles to prevent or minimise the potential for allergen cross-contact.

Establishment: maintenance and sanitation

Principle - ‘The effective management of food allergens is facilitated by establishing effective maintenance and cleaning programs that prevent or minimise the potential for allergen cross-contact’.

Establishment: personal hygiene

Principle - 'Personal hygiene practices should prevent or minimize the potential for food handlers to contribute to allergen cross-contact'.

Transportation

Principle - 'Foods containing allergens should be managed during transportation so that allergen cross-contact is prevented'.

Product information and consumer awareness

Principle - 'Consumers should have access to adequate and correct information on the allergenic nature of a food.

It should be ensured that those with allergies can avoid allergenic foods and ingredients'.

Training

Principle - Personnel engaged in food operations should have sufficient training in food allergen management to implement measures to prevent or minimise allergen cross-contact and ensure the correct label with appropriate allergen information is applied to food.

US Food Allergen Labeling and Consumer Protection Act (FALCPA)

The eight major allergens identified are milk, egg, fish, shellfish, tree nut, peanut, wheat and soybean and these accounts for 90% of food allergic reactions. As per the International Codex Alimentarius guidelines and the US Food Allergen Labeling and Consumer Protection Act (FALCPA) food manufacturers has to label specifically the allergen source and any product with an ingredient or

food protein derived from any of these food allergens (USFDA 2004). Under the FASTER (Food Allergy Safety, Treatment, Education, and Research) Act of 2021, sesame is being added as the 9th major food allergen effective from January 1, 2023.

The law requires that the customer can use the food labels to identify the food source of all major food allergens. Identity of the allergen should be written in the name of common or usual name of an ingredient and it must be declared at least once on the food label. The name of the food source has to be given in parentheses following the name of the ingredient (E.g. lecithin (soy)). A "contains" statement of the allergen source has to be given immediately after or next to the list of ingredients (E.g. Contains wheat soy).

In addition to the major food allergens, FDA also monitors other allergens, food ingredients, or food additives that are causing a significant health risk. This is to evaluate emerging evidence about non-listed food allergens in a consistent and transparent manner. Non-listed food allergens are identified based on evidence of IgE mediation in food allergy, its prevalence, severity and potency. More than 160 foods are identified as causative of IgE-mediated food allergic reactions of varying severity and lower prevalence rates.

How to prevent allergen cross contact?

Allergen cross-contact happens through the accidental entry of allergens into foods that are not declared on the labels. Allergen control plan is a written document showing effective control measures to minimize allergen cross-contamination.

Prevent misbranding, controlling through separation by time and space between allergen and non-allergen containing products, or between comprising diverse allergens is important and which can be introduced at all steps in processing. Seafood processors must meet the requirements of 21 CFR 117.4. Seafood processors must ensure that their employees have

LNSK GREEN HOUSE AGRO PRODUCTS LLP

(Formerly known as Green House Agro Products)

SURVEY NOS.173 A,B,C & 174/A,B

NORTH RAJUPALEM VILLAGE & POST 524366.,

KODAVALURU MANDAL SPSR NELLORE DIST

ANDHRA PRADESH, INDIA

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PEELED AND DEVEINED TAIL ON SHRIMPS

MANAGING DIRECTOR: O.SANTOSH KUMAR REDDY

MOBILE NO:7893077664, MAIL ID:santhosh.ghap@gmail.com

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been trained in the controls necessary to prevent allergen cross-contact. FDA has identified the following recommendations to assist allergen cross-contact control program.

- **Receiving** – Comparing the labels of ingredients against product specifications with the list of declared allergens and segregate. Damaged packages has to be segregated to prevent the allergen cross contact. A color-code system to identify the specific allergen hazard can be utilized. Need to ensure the integrity of ingredients received by transportation system.
- **Storage** – Adequate storage precautions can be taken to prevent allergen cross contact. Dedicated storage areas to ensure physical separation of allergen and non-allergen containing products is useful. Make clear procedures for storing allergen and non-allergen containing products when dedicated storage area is not available. Dedicated colour coding for major allergens in the storage area. Ensure procedures to prevent mixing of allergen and non-allergen containing products and disposal of damaged packaging materials.
- **Processing** – Adequate designing of the facility, equipment and processes to prevent allergen cross-contact has to be ensured. Lay out design to minimize allergen cross contact, unidirectional traffic flow of employees with an allergen free buffer zone, air flow control, partitioned areas, facility and process design upgradation, physical barriers with sufficient spacing to protect during spillage, dedicated sections for processing the product, dedicated and color coded equipment's, utensils and employee apparel, change of work clothing when employees move from an allergen to a non-allergen area, movement of materials through closed lines, waste disposal procedure, control of aerosolized allergenic material. The production process can be scheduled in such a way to prevent the cross contact of allergen and non allergen containing products including effective allergen cleaning and sanitation procedures.

- **Rework and work-in-progress (WIP)** – Entry of finished or partially finished products can increase the risk of introduction of allergens. Hence the separation of such materials should be under control by means of colour coding, separate storage area and proper labelling.

The FDA's "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" rule (CGMP & PC rule, 21 CFR part 117) gives the requirements for manufacture, process, pack, or hold human food. The CGMP & PC rule provides requirements for allergen preventive controls to prevent allergen cross-contact in manufacturing and packaging and to prevent undeclared allergens. The FDA monitors food allergic reactions based on the complaints received from the consumers and take regulatory action(s) to improve product safety and protect the public health. Analytical testing methods to verify the food labeling based on immunoglobulin antibodies by enzyme-linked immunosorbent assay (ELISA), immunoblotting, DNA-based polymerase chain reaction and mass spectrometry are followed.

Food allergen labelling and information requirements - EU Regulation No. 1169/2011

An Allergen Control Plan is a critical component in product safety. Allergen provisions for prepacked, prepacked for direct sale and non-prepacked foods can be found in the EU Food Information for Consumers Regulation (No. 1169/2011) (EU FIC) and Commission Delegated Regulation (EU) No. 78/2014. The allergen rules came into effect in the UK and the EU on 13 December 2014. This guidance provides allergen provisions for prepacked, prepacked for direct sale and non-prepacked foods. These guidance notes are intended to help producers, manufacturers, packers, importers, distributors, wholesalers, retailers, caterers and also for enforcement officers responsible for enforcing relevant measures.

It provides informal and non-binding technical guidance on the interpretation and practical application of EU FIC's specific requirements on allergen labelling and information. Penalties are outlined in the Food Information Regulations 2014 (SI 2014/1855). It emphasizes any of the 14 specific allergens in the ingredients list of prepacked food. The 14 allergens listed are cereals containing gluten (wheat, rye, barley, oats and their hybridised strains), crustaceans and products, egg and products, fish and products, peanuts and products, soybeans and products, milk and products, nuts, celery and products, mustard and products, sesame seeds and products and sulphur dioxide and/ or sulphites (greater than 10 mg/Kg). In case of non-prepacked food, such as retailers, restaurants, takeaways, bakeries and institutional caterers the EU FIC requirement was to provide information on allergenic ingredients in writing and/or orally. Failure to meet the allergen requirements is a criminal offence due to the impact of non-compliance on public health.

Crustaceans

- The rule covers all including for example lobster, crab, prawns.
- Labelling of crustaceans and products made from them need to have a clear reference such as 'prawns (crustaceans)', 'crayfish (crustaceans)', 'lobster (crustaceans)', shrimp paste (crustaceans)

Fish

- The rules do not name any species of fish because 'fish' means all species of fish and fish products. The generic terms provisions allow the generic name 'fish' to be used in an ingredient list only where there is no specific reference to a common fish species name on the label.
- Labelling of fish ingredients or products need to have a clear reference to the food; for example, 'cod (fish)', 'salmon (fish)', 'tilapia (fish)'

Sulphur dioxide

- The labelling rules apply to sulphur dioxide and/ or sulphites that have been deliberately added in the preparation of the food or have been added to an ingredient used in a preparation of the food.
- The rules require sulphur dioxide and/ or sulphites to be labelled when present above 10mg/kg or 10mg/litre

All written mandatory allergenic information should be easily visible. Precautionary allergen labelling is to be used to indicate the unintentional presence of allergen.

Food Safety and Standards (Labelling and Display) Regulations, 2020

Food labelling is considered as an important element in order to improve the consumer safety. Food Safety and Standards (Labelling and Display) Regulations, 2020 requires inclusion of mandatory declaration of allergen information and the regulation. Declaration on food allergen separately as 'Contains..... (Name of allergy causing ingredients)' is required for following foods and ingredients namely

- (I) Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these (To be declared as name of the cereal);
- (ii) Crustacean and their products (To be declared as Crustacean);
- (iii) Milk & Milk products (To be declared as Milk);
- (iv) Eggs and egg products (To be declared as Egg);
- (v) Fish and fish products (To be declared as Fish);
- (vi) Peanuts, tree nuts (e.g. almonds, walnuts, pistachio, cashew nuts) and their products (To be declared as Nut);

(vii) Soybeans and their products (To be declared as Soy);

(viii) Sulphite in concentrations of 10mg/kg or more (To be declared as sulphite)

Provided that in case presence of ingredients due to cross-contamination which are known to cause allergy may be declared separately as 'May Contains..... (Name of allergy causing ingredients)'. This declaration is not required in the case of oils derived from these ingredients. Raw agricultural commodities are exempted from the allergen labelling requirements. In case of prepared food served for immediate consumption such as in hotels or by food service vendors or caterers or halwais or hospitals or at religious gathering or food served in airline/railways/passenger vehicle or any mobile unit shall accompany or display the information relating to allergen. Food Service Establishments shall also mention the information relating to food allergens on the menu cards or boards.

Summary

An allergic reaction can be produced by a tiny amount of food containing allergen in

immunologically sensitive individuals. Symptoms range from mild to severe and also can be worse situations like anaphylaxis. Food compounds involved in the allergic immune responses are mostly represented by proteins intentionally added or unintentionally incorporated into food by cross-contamination. As there is no cure for food allergy, it is of highly important to provide clear and accurate information about allergenic ingredients. The big eight major allergens are given higher priority by USFDA while EU emphasizes information of 14 specific allergens in the labels. As per the codex code of practice, food allergen management starts from primary production to manufacturing, and retail food service. FDA enforces regulations requiring companies to list ingredients on packaged foods with specific labeling requirements for major allergens. Providing specific allergen information as per Food Safety and Standards (Labelling and Display) Regulations, 2020 of India is aligning with the European and US standards of labelling. Compliance of precautionary allergen labelling to indicate the unintentional presence of allergen or accurate information on allergen along with effective methods to prevent allergen cross contact can prevent triggering of allergic reactions in sensitive individuals and ensures safety.

