



EUROFINS TECHNOLOGIES

Allergens & Legislations

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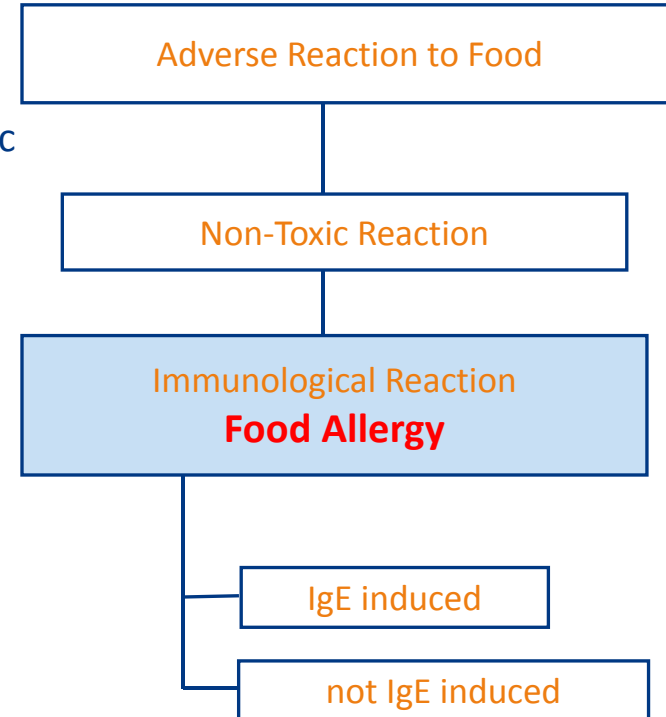




Allergens

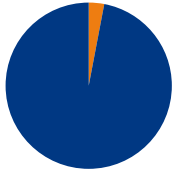
Food Allergy

- Allergens in food cause an adverse reaction in the immune system of allergic people
- Only a repeated exposure to the allergen will lead to an allergic reaction
- Almost all allergens are proteins (10-70kDa)
- Allergic reactions are caused by the presence of IgE antibodies against the allergen (epitope)





- 25% of the population believe that they have a food allergy



- 2 – 3% of adults have a food allergy



- 5 – 8% of children have a food allergy

**ALLERGY IS NOT
INTOLERANCE**



1) Skin

- itching, flush, urticarial, angioedema, atopic eczema, stomatitis, glossitis, contact dermatitis, phototoxic reactions, exanthema

2) Eyes and respiratory tract

- rhinoconjunctivitis, larynx edema, asthma bronchiale

3) Gastrointestinal tract

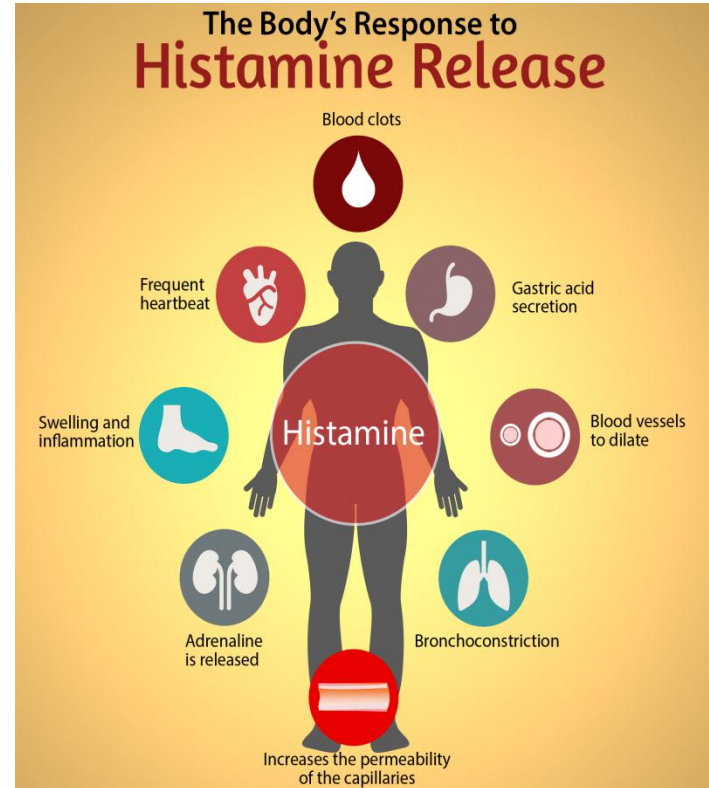
- vomiting, meteorismus, acute gastroenteritis, diarrhea

4) Cardiovascular system

- anaphylaxis

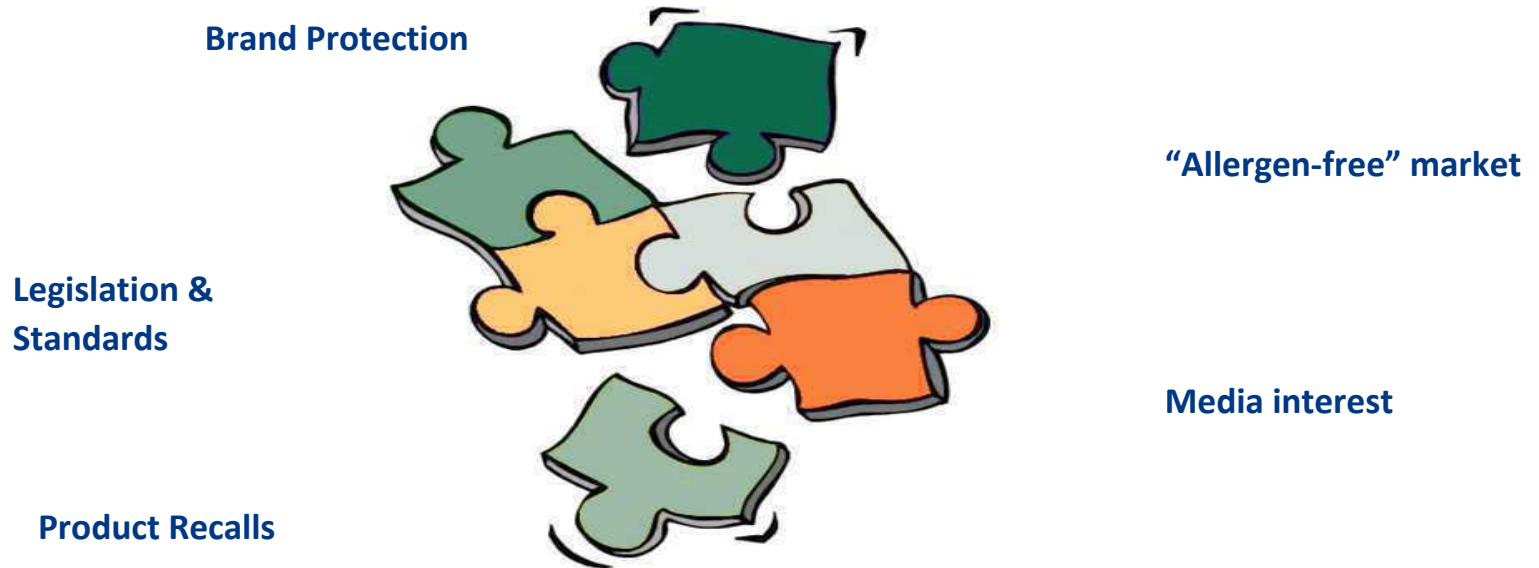


- Important neurotransmitter
 - Tells stomach to produce acid
 - Regulate sleep-wake cycle
- Too much leads to allergic reactions
- Your body exaggerates the immune response



Why testing for Allergens?

Food Allergens = Food Safety Risk





Considerations

What the analysts have to deal with...

- 1) Sampling
- 2) Units and definitions
- 3) Validations and approvals
- 4) Threshold levels
- 5) Test Kits
- 6) Calibration



Testing is a minimum duty of care

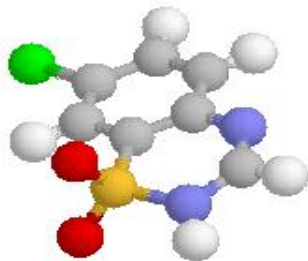
The Limit of detection of any test will vary depending on the sample matrix to be tested

- Every food factory is different
- Validate each food to be tested



Allergen protein

e.g. Peanut protein



Allergen content

e.g. Peanut content



Others

- Casein content
- dry skimmed milk powder
- whole milk

- No Reference Methods available
- No Certified Reference Materials available
- Kit calibration differs between suppliers
- Results are not necessarily comparable between different test systems



How do allergens come into products?

1) Recipe

- Ingredients
- Pre-mixing ingredients
- Rework etc.

2) Cross-contaminations

- Storage ingredients
- Production (weighing, mixing, production line, inappropriate cleaning, ...)
- Carry-over – cleaning
- Staff

Uneven distribution of Allergens !

Cross Contamination

- People
- Shared equipment
- Re-work
- Processing aids
- Raw material handling
- Air articles in manufacturing
- Packaging
- Cleaning
- Supply chain
- Storage
- Transport

Source: UK Food Standards Agency, 2006



Your Solution



Allergen Control Plans

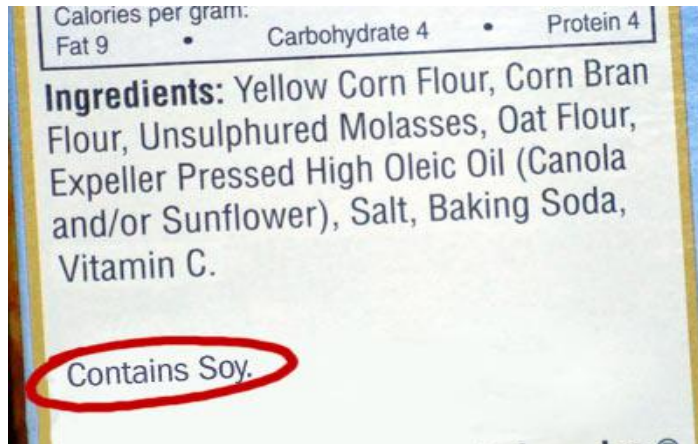
Risk Analysis

HACCP and Prerequisite
controls

Allergen Control Plans
are an integral part of an
existing quality system
and are not stand alone
plans

Abstinence

Food labels



INGREDIENTS
Water, Carrots, Onions, Red Lentils (4.5%) Potatoes, Cauliflower, Leeks, Peas, Cornflower, Wheat flour, Cream (milk), Yeast Extract, Concentrated Tomato Paste, Garlic, Sugar, Celery Seed, Sunflower Oil, Herb and Spice, White Pepper, Parsley
ALLERGY ADVICE
For allergens, see ingredients in bold

Global Allergen Product Labelling Regulations

- Disclose allergenic ingredients in commonly understood terms

- Option 1: Common Names

Wheat flour, milk, egg yolk

- Option 2: Parentheses

Lecithin (soy), casein (milk), whey (milk)

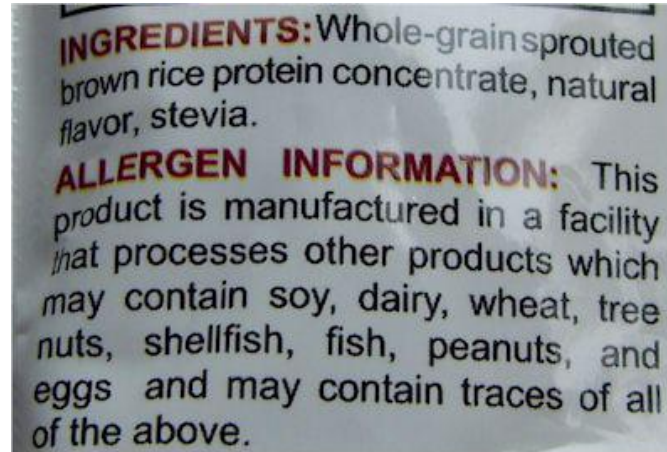
- Option 3: Separate declaration

Contains wheat, milk, and soy



Primary, secondary or tertiary precautionary labelling

1. May contain <allergen>
2. Made on same equipment as <allergen>
3. Manufactured in the same facility as <allergen>





Legislations



Food Allergen Labeling & Consumer Protection Act of 2004

Milk, egg, fish, crustacean, shellfish, tree nuts, peanut, wheat, soybean



Regulation (EU) No. 1169/2011

Milk, egg, fish, crustacean, nuts, peanut, cereals containing gluten, soybean, celery, mustard, sesame, sulphite, molluscs, lupins



Ordinance No.74 of 2010 of the Ministry of Health, Labour and Welfare

Wheat, buckwheat, egg, milk, shrimp, crab and peanut



Joint Australian New Zealand Food Standards Code (Standard: 1.2.3)

Milk, egg, fish, crustacean, nuts, peanut, cereals containing gluten, soybean, sesame, sulphite, royal jelly, bee pollen, propolis

Labeling Regulations

Allergens	EU	USA	Canada	Australia/NZ	Japan
Buckwheat					✓
Wheat/Gluten	>20 mg/kg	>20 mg/kg	✓	✓	✓
Crustacean	✓	✓	✓	✓	✓
Egg	✓	✓	✓	✓	✓
Fish	✓	✓	✓	✓	
Peanut	✓	✓	✓	✓	✓
Soybean	✓	✓	✓	✓	
Milk	✓	✓	✓	✓	✓
Tree Nuts	✓	✓	✓	✓	
Cellery	✓				
Mustard	✓		✓		
Sesame	✓		✓	✓	
Sulphite	>10 mg/kg		>10 mg/kg	>10 mg/kg	
Lupine	✓				
Shellfish	✓		✓		
Royal jelly				✓	

United States of America



Food Allergen Labeling and Consumer Protection Act of 2004 (Title II of Public Law 108-282)

1. Eight major foods or food groups – milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans – account for 90 percent of food allergies;
2. At present, there is no cure for food allergies; and
3. A food allergic consumer must avoid the food to which the consumer is allergic;



List of Allergens, Labeling Exceptions

FALCPA

1. Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.
2. A food ingredient that contains protein derived from a food specified in paragraph (1), except the following:
 - A. Any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil.
 - B. A food ingredient that is exempt under paragraph (6) or (7) of section 403(w).



“The Big 8”



Tree Nuts



Soy Bean



Peanut



Gluten



Milk



Eggs



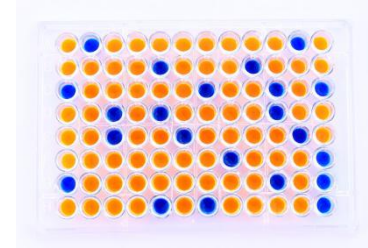
Fish



Crustaceans

The Center for Food Safety and Applied Nutrition (FDA) Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food, 2006

The report identifies 4 approaches that could be used to establish thresholds:



1. Analytical methods-based-thresholds are determined by the sensitivity of the analytical method(s) used to verify compliance.
2. Safety assessment-based-a “safe” level is calculated using the No Observed Adverse Effect Level (NOAEL) from human challenge studies and an appropriate Uncertainty Factor (UF) applied to account for knowledge gaps.
3. Risk assessment-based-examines known or potential adverse health effects resulting from human exposure to a hazard; quantifies the levels of risk associated with specific exposures and the degree of uncertainty inherent in the risk estimate.
4. Statutorily-derived-uses an exemption articulated in an applicable law and extrapolates from that to other potentially similar situations.

Europe



Directive 2003/89/EC of the European Parliament and the Council of 10 November 2003 amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs

- 1) The Scientific Committee on Food ... has stated that the incidence of food allergies is such as to affect the life of many people, causing conditions ranging from very mild to potentially fatal.
- 2) The said Committee has acknowledged that common food allergens include cow's milk, fruits, legumes (especially peanuts and soybeans), eggs, crustaceans, tree nuts, fish, vegetables (celery and other foods of the Umbelliferae family), wheat and other cereals.



ANNEX II Regulation (EU) No 1169/2011

- Cereals containing gluten (*i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains*) and products thereof
- Crustaceans and products thereof
- Eggs and products thereof
- Fish and products thereof
- Peanuts and products thereof
- Milk and products thereof (*including lactose*)
- Molluscs and products thereof
- Lupin and products thereof
- Nuts (*i.e. Almond, Hazelnut, Walnut, Cashew, Pecan nut, Brazil nut, Pistachio nut, Macadamia nut and Queensland nut*) and products thereof
- Celery and products thereof
- Mustard and products thereof
- Sesame seeds and products thereof
- Soybeans and products thereof
- Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/liter expressed as SO₂



“Big 14” (Regulation (EU) No. 1169/2011)

Cereals containing gluten



Mustard



Crustaceans



Eggs



Molluscs



Milk



Fish



Soy



Nuts



Lupin



Peanuts



Celery



Sesame



Sulphur dioxide & sulphites

ANNEX II Regulation (EU) No 1169/2011

1. Cereals containing gluten – Wheat-based glucose syrups including dextrose, Wheat based maltodextrins, Glucose syrups based on barley, Cereals used in distillates for spirits
2. Fish – Fish gelatin used as carrier for vitamins and flavors, Fish gelatin or Isinglass used as fining agent in beer and wine
3. Soybean – Fully refined soybean oil and fat , Natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources, Vegetable oils derived phytosterols and phytosterol esters from soybean sources, Plant stanol ester produced from vegetable oil sterols from soybean sources
4. Milk – whey used for alcoholic distillates incl. ethyl alcohol of agricultural origin; Lactitol
5. Nuts – Nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin



Japan



Food Labeling Amendment of the Law concerning Standardization and Proper Quality Labeling of Agricultural and Forestry Products (Law No. 175 of 1950)

- 1) Foods which require labeling
 - Considering the extent and frequency of past health hazards, etc., in cases in which the food concerned contains a specified ingredient that actually caused serious allergic symptoms in the past, the ingredient shall be identified in a label.
- 2) Ingredients which require labeling (Specified ingredients, etc.)
Labeling shall be divided into the two stages, mandatory and recommended, according to the number of cases of actual illness and degree of seriousness.



List of Allergens

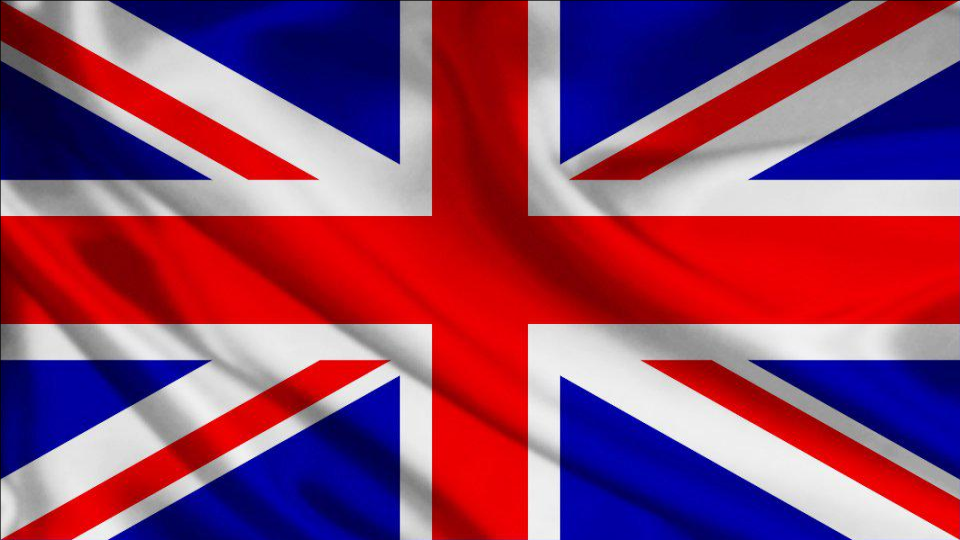
Mandatory by ministerial ordinance

Eggs
Milk
Wheat
Buckwheat
Peanuts
Shrimp
Crab



Recommended by notice

Abalone	Apples
Squid	Beef
Salmon roe	Salmon
Oranges	Gelatin
Kiwifruit	Walnut
Banana	Cashew
Mackerel	Yams
Soybeans	Sesame
Chicken (poultry)	Matsutake mushrooms
Pork	
Peaches	



Australia

- In Australia, the Allergen Bureau, proposes the so called “VITAL System” (Voluntary Incidental Trace Allergen Labelling)
- VITAL allows food producers to assess the impact of allergen cross contact and provide appropriate precautionary allergen labelling on their products.
- VITAL was developed to make a single simple standardised precautionary statement available to assist food producers in presenting allergen advice consistently for allergic consumers.
- VITAL not only assists food producers in assessing the potential impact of allergen cross contact in each of their products but also specifies a particular precautionary allergen statement to be used according to the level of cross contact identified.
- VITAL ALSO provides for ongoing monitoring and verification of the risk assessment process to ensure any changes to the level of risk are acted upon without delay



Gluten Regulation

A top-down view of a person's hands, wearing brown long-sleeved shirts, rolling out a piece of yellow dough on a wooden surface. The surface is covered with a layer of white flour. A wooden rolling pin is being used to flatten the dough. The text "Gluten Regulation" is overlaid in the center of the image.



COMMISSION *REGULATION* (EC) No 41/2009

- Gluten-free (<20 ppm gluten) - Very low gluten (<100 ppm gluten)
- No method(s) specified

Standards & Codes of Practise

- Codex Standard 118-1979 (<20 ppm gluten)

Gluten-Free Labeling of Foods

- Proposed rule for gluten-free labeling

Health Canada

- Food Allergen Labeling Regulations in Canada Gazette, Part II

Australia/New Zealand

- Food Standards Code: gluten-free = “no detectable gluten” by the most sensitive universally accepted test method

Antibodies for Gluten Testing

Antibody	G12	R5	Skerrit
Specificity	QPQLPY (wheat gliadin)	QQPFP (rye secalin)	HMW (high molecular weight) glutenins and ω -gliadin (wheat)
Detects also...	rye, barley	wheat, barley	rye, barley

CODEX Alimentarius Recommended Method

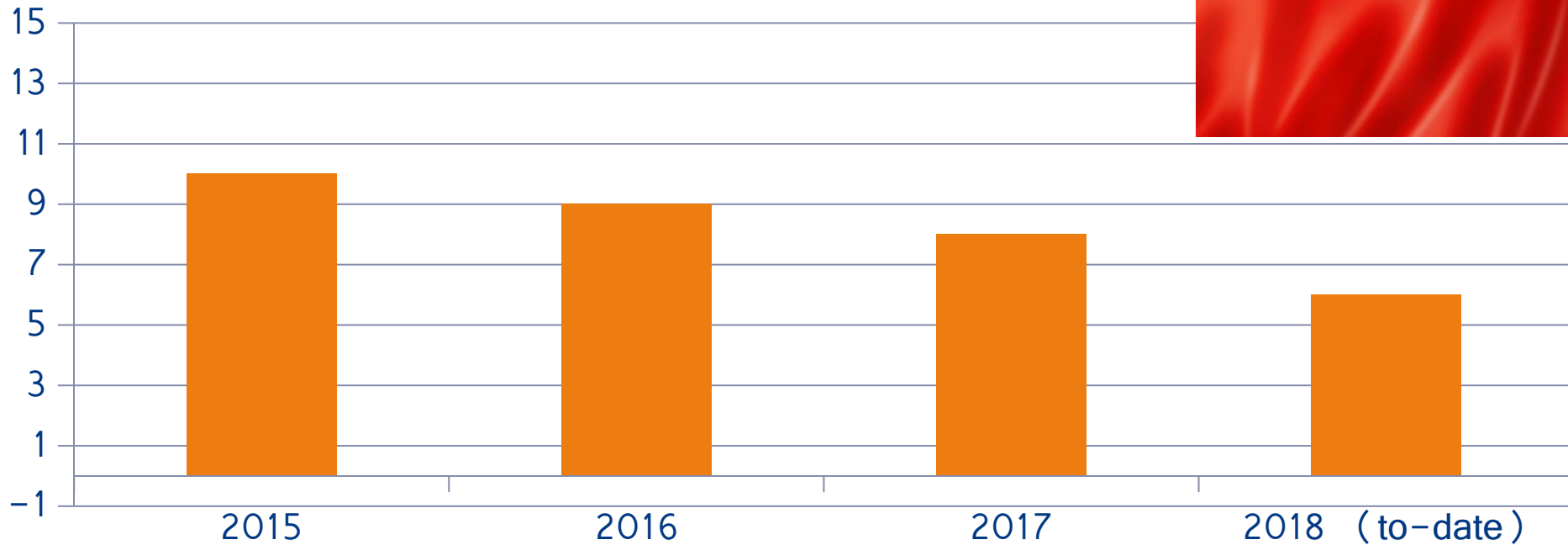
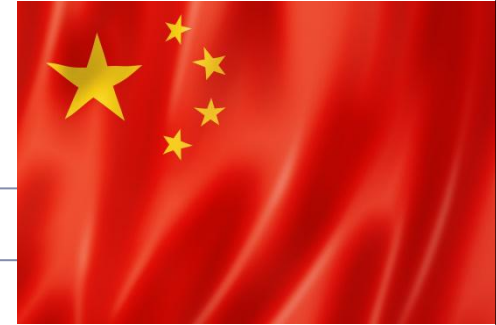


RASFF Notifications



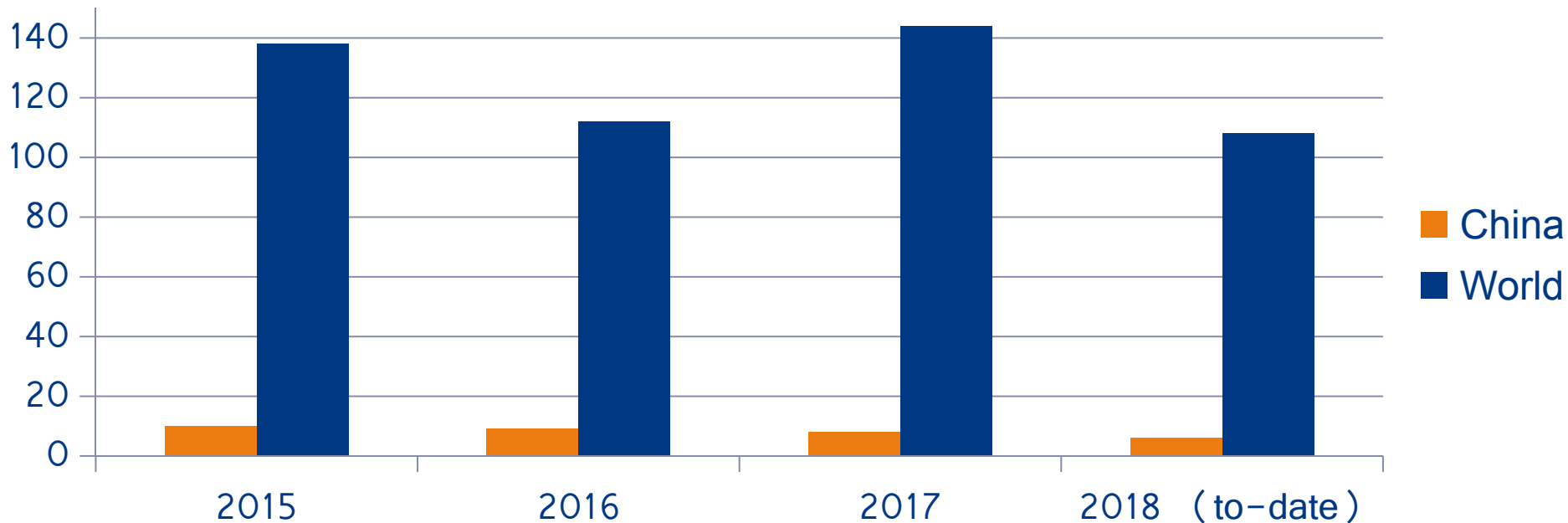
Allergen Notifications

**Imports from China rejected
due to Allergen contamination**



Allergen Notifications (CN vs World)

Rejected Imports due to Allergen Contamination



Summary & Conclusion



- An allergy is **not an intolerance**
- Allergens can get into your product via the **recipe or cross-contamination**
- An **allergy quality control program** is essential for **brand protection**
- “**May contain**” labels are **not safe** for the consumer
- **Different allergen labeling legislations** exist in different countries
- There are **no maximum levels** for allergens other than for gluten

Understand your production process and your target country's allergen requirements for a safe export of food

