

# Precautionary labelling The patients' perspective

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# Precautionary labelling in the regulation

- Improvements in quality and frequency of food information may be provided on a **voluntary basis** by Member States **if**
  - it does not mislead the consumer
  - it is not ambiguous or confusing
  - it is based on scientific data
- **Cross-contamination** is mentioned as a legally non-binding practice

# The patients' view – I

“May contain” labelling:

- **Reduces the choices** available to allergic consumers

- In a study from **10** European countries of over **500** types of biscuits and chocolate, “may contain” labelling for nuts is included on the packaging of **26% of biscuits and 80% of chocolate** – **regardless** of the label

Reference: Van Hengel AJ, Declaration of allergens on the label of food products purchased on the European market, Trends Food Sci Tech 2007, 18, 96-100

- It is likely that **90%** of products with “precautionary labelling” do **not contain residues of peanuts' proteins** or very small **quantities unlikely to cause a clinical reaction** – starts an **unnecessary restrictive diet**

Reference: Hefle SL, Furlong TJ, Niemann L, Lemon-Mule H, Sicherer S, Taylor SL, Consumer attitudes and risks associated with packaged foods having advisory labelling regarding the presence of peanuts, J Allergy Clin Immunol 2007, 120, 171-176

# The patients' view – II

- And therefore, results in **frustration and risk-taking behaviours** – not dependant on age, gender or the severity of the allergy
  - **Variety of the wording**: 80% of parents with children allergic to nuts would **not** let them eat products with “not suitable for” or “may contain” labelling, only 50% would do so with “cannot guarantee nut free,” “may contain traces of” labelling
  - **Distrustfulness of the message sources**: food business operators are deemed to use it to discharge any possible liability in case of adverse reactions following the ingestion of their products
  - **Implausibility of the labelling**: either when it is located on products that legitimately contain the allergen (e.g.: nuts in a packet of peanuts) or on others where it is considered impossible that they actually contain it (e.g.: nuts in a bottle of lemonade)
  - **Previous experience** and **personal preferences** **BUT**

Reference: Barnett J et al, Using “may contain” labelling to inform food choice: a qualitative study of nut allergic consumers, BMC Public Health 2011, 11, 734742



**Serious reactions, and even deaths, have been caused by foods with “may contain” labelling – 8% of people with accidental reactions may attribute it to having ignored a “precautionary labelling”**

# EFA Food Allergy Working Group position

**THEREFORE**, both for pre-packed and non pre-packed food:

- **Short-term: ultimate solution** after the implementation of best practices to avoid cross-contamination (allergen management as part of hygiene/safety manual, awareness and practical workplace training on food allergy for workers, responsibility of food business operators at each step of the distribution chain)
- **Long-term: abolish** precautionary labeling (thresholds)

# Best practices – Switzerland

**Federal law** on labelling and advertisement of food products: applying to **pre-packed** food (article 8) and **non pre-packed** products (article 36, nonbindingness of the written form)

- **Obligation to label allergens**, even when they have been **added involuntarily**, upon specified levels (1g/kg for all mandatory allergens, cereals and sulphites having their own defined thresholds)
- Under these thresholds, precautionary labelling is only authorised if the responsible food business operator can prove that **cross-contamination cannot be avoided** despite putting in place all the rules of **good practice in manufacture**

# Best practices – Voluntary measures all around the world

## Australia: Food industry guide to allergen management and labelling (Australian Food and Grocery Council, 2007)



- **HACCP (Hazard Analysis and Critical Control Point)** programme to avoid cross contamination
- **VITAL (Voluntary Incidental Trace Allergen Labelling): 3** different levels for **9** main allergens, for level 1 labelling is **not** necessary, **precautionary** labelling should be used for level 2, proper labelling of **allergen** for level 3

**USA:** precautionary labelling may **not** be used as a **substitute** for adherence to current Good Manufacturing Practices (GMP)

**Canada:** recommendations to use **only “may contain”** labels and only when they are **truthful, clear and non-ambiguous**

**Japan:** precautionary labelling allowed **BUT not** the **“may contain”** or the **“this product is manufactured at facilities that used”** labels

# Best practices – Voluntary measures in Europe

UK

**Voluntary** Guidance on Allergen Management and Consumer Information – **Food Standards Agency** (July 2006)



Best practice advises to help food producers and retailers assess the risks of cross-contamination of a food product with an allergen and to determine whether or not an advisory labelling is appropriate

## Allergen Risk Assessment, Management and Communication

- Assess risk from both **intentional** and **unintentional** presence of an allergen
- Check if the potential allergen is in the **ingredient list** or is **exempt** from mandatory labelling
- Identify the risk and the possibility to manage it
- Communicate the risk through precautionary labelling **only if it cannot be managed** (placed close to the ingredients' list in the package)



## Step 1 – Assess risk from intentional presence

Is the food manufactured from any of the allergenic foods specified in the current UK legislation or their derivatives (see Appendix I)?

YES  
(Label as necessary. Go to step 7)

NO  
(Go to step 2)

## Step 2 – Assess risk from unintentional presence

What is the likelihood, under normal operating conditions, of cross-contamination of the food by specified allergens (Appendix I)?

PROBABLE  
(Go to step 2a)

REMOTE  
(No action – Go to Step 7)

## Step 2a – Check against ingredient labelling

Is the potential cross-contaminating allergen already declared on the label as an ingredient?

YES  
(No action – Go to Step 7)

NO  
(Go to step 3)

**Step 3 – Check against exemptions list**

Is the potential cross-contaminating material exempt from mandatory labelling (see Appendix I)?

YES  
(No action – Go to Step 7)

NO  
(Go to step 4)

**Step 4 – Hazard characterisation**

Identify the physical form and the characteristics of the potential cross-contaminating allergenic material

**Step 5 – Risk management of unintentional presence**

Can the identified risk of cross-contamination be managed?

YES  
(Go to Step 7)

NO  
(Go to Step 6)

**Step 6**

Risk Communication – Include warning on label  
(Go to Step 7)

**Step 7 – Check other relevant allergens**

Have all relevant allergens been considered?

YES  
(No Action)

NO  
(Go back to Step 1)

# Best practices – Voluntary measures in Europe

**France:** How to better identify and meet the needs of people intolerant or allergic to certain foods? – National Council of Alimentation (March 2011)

→ Final objective of abolishing precautionary labelling for pre-packed food and establishing thresholds

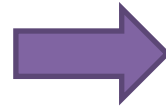
**Ireland:** Guide to Food Safety Training – Food Safety Authority of Ireland (2009)

→ HACCP systems, food safety/hygiene trainings, allergen management to avoid cross-contamination

# Best practices – Voluntary measures in Europe

## Sweden

Voluntary Swedish Food Sector Guidelines for management and labelling of food products with reference to allergy and intolerance – Swedish Food Retailers Federation and Swedish Food Federation (April 2005)



Measures to avoid cross-contamination (HACCP plans, training, recipe changes, receiving, storage and weighing of raw materials, production, premises and equipment, cleaning and controls) and advises to use precautionary labelling

“May contain” labelling as a **last resort** when the risk of cross-contamination is:

1. **Uncontrollable**: the ability to ensure the entire process is considered impossible (e.g. due to manufacturing occurring in parts of systems that cannot be properly cleaned)
2. **Sporadic**: the allergen is detected sporadically after product changes
3. **Documented** through cleaning controls, test results, or substantiated consumer reaction

# Best practices – Voluntary measures in Europe

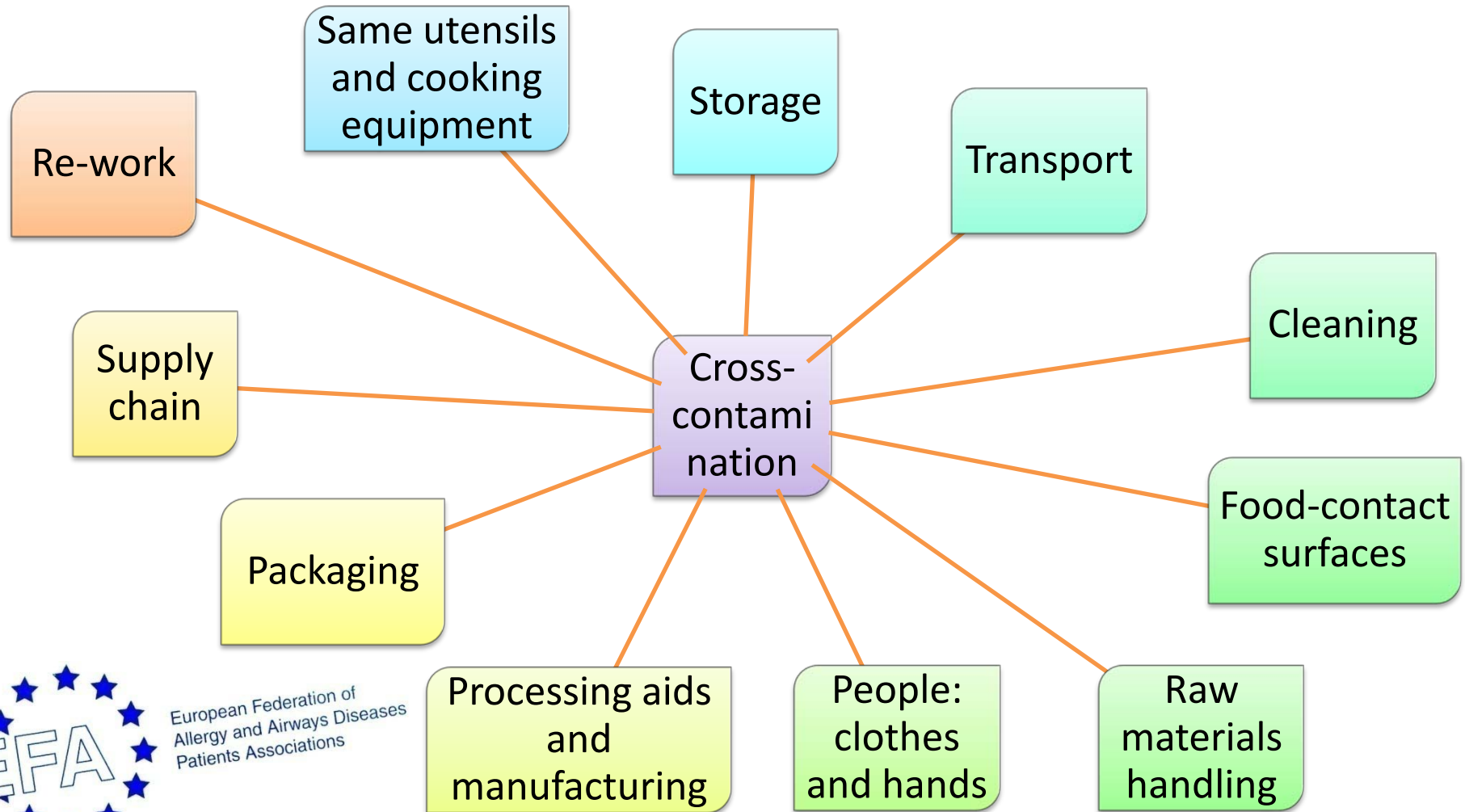
**Italy:** Italian Food Sector Guidelines on the Labelling of Allergens – FEDERALIMENTARE (November 2009)

**The Netherlands:** Guidelines on Additional Labelling Regarding the Potential Presence of Allergens Due to Cross-contamination – Dutch Food Industry Federation (2005)

**Finland:** Labelling warnings of allergen in foodstuff due to cross contamination – Finnish Food and Drink Industries (December 2005)

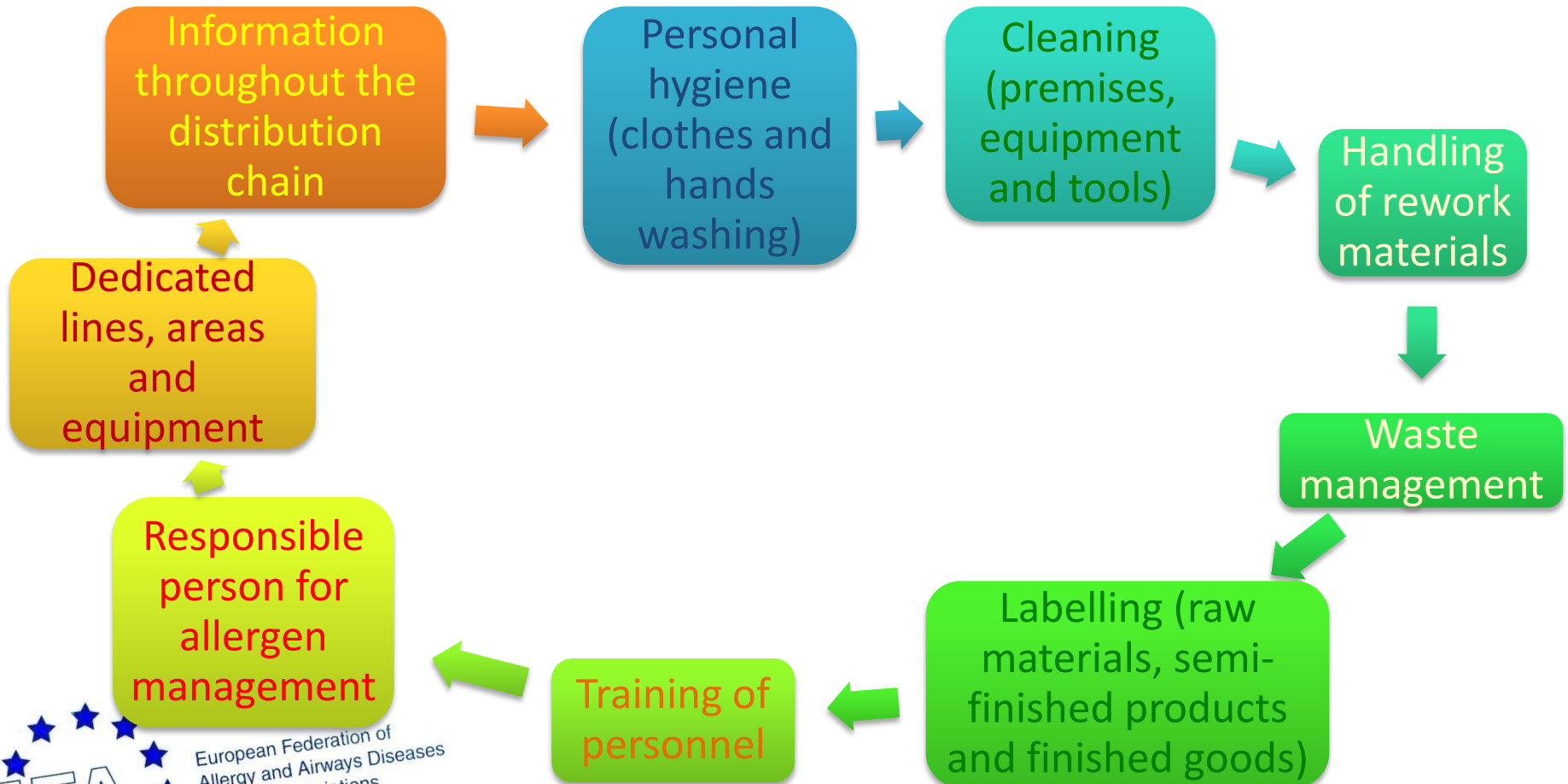
# Best practices – Voluntary measures in Europe

Main causes of cross-contamination identified by all these documents



# Best practices – Voluntary measures in Europe

## Good manufacturing practices and food allergen management



# Best practices – EFA members



ALLERGIEZENTRUM SCHWEIZ  
CENTRE D'ALLERGIE SUISSE  
CENTRO ALLERGIE SVIZZERA

## Swiss association for people with allergies “Aha!”

→ **Practical guide for managing allergens in food sold loose**: to avoid cross-contamination, to give reliable information to the allergic customers

## Swedish asthma and allergy association



→ **Hooray, an allergic guest!**: training for restaurants and catering to manage and declare allergens, certificate and endorsement from the association



**Allergy UK** (in collaboration with FSA and other organisations)

→ **Buying food when you have a food allergy or a food intolerance**: a guide to help people choose suitable food in shops and restaurants, paying attention to precautionary labelling



European Federation of  
Allergy and Airways Diseases  
Patients Associations



# Thank you!

## European Federation of Allergy and Airways Diseases Patients' Associations (EFA)



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