

EUROPEAN SPICE ASSOCIATION (ESA)

**ALLERGEN RISK ASSESSMENT MODEL FOR
DRIED HERBS AND SPICES**

ESA guidance on allergen risk assessment for dried herbs and spices

ESA Secretariat

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Foreword

ESA would like to thank our colleagues in the UK Seasoning and Spice Association (SSA) for their innovative work in the risk assessment of allergen cross-contamination in the herb and spice supply chain and their willingness to share their expertise and guidance with ESA.

1) ESA Approach to Food Safety and Supply Chain

The European Spice Association (ESA) supports the production of safe and wholesome foods and takes all matters relating to food safety very seriously. To ensure the quality and integrity of their products, ESA members and National Associations (NA's) have in place a series of fully implemented process controls. These controls are based on well-established good manufacturing practices (GMPs) and sound food safety management systems (FSMS).

Furthermore, ESA members and NA's are committed to purchase all their products from approved suppliers in order to ensure full traceability at all stages of production, processing and distribution.

This document relates to ESA members'/NAs' products that are placed for sale within the EU and if members'/NA's products are to be exported to third countries they are advised to check the legal position in the destination country.

2) Objective of This Guide

There are a limited number of herbs and spices which are regulatory allergens, such as mustard and celery. However, like other agricultural products herbs and spices may be subject to unintentional contamination with allergenic material. The objective of this guidance is to provide members with a systematic way of assessing the need for precautionary allergen labelling in herbs and spices based mainly on the VITAL[®] Reference Doses^{1, 2, 3, 4, 5, 6}, ***once an issue has been identified; or following a positive test result.***

Members need to give consideration to the potential for multiple steps in the supply chain in order that each step can be risk assessed and that consideration should also be given to other potential sources of allergens in composite food products.

The VITAL[®] Program⁵ (Voluntary Incidental Trace Allergen Labelling) is an initiative of the Allergen Bureau in Australia, <http://allergenbureau.net/vital/>. VITAL 2.0 is the second iteration of the program and identifies action levels for labelling based on comparisons with reference doses for individual allergens. The Allergen Bureau site provides a downloadable guide "Food Industry Guide to the Voluntary Incidental Trace Allergen Labelling (VITAL) Program Version 2.0" which can be found at: <http://allergenbureau.net/wp-content/uploads/2013/11/VITAL-Guidance-document-15-May-2012.pdf>

Disclaimer: This Guidance has been produced by the European Spice Association with the aim of providing informal, non-statutory advice and should be read in conjunction with the relevant legislation. It is not exhaustive. The Guidance should not be taken as an authoritative interpretation of the law. It is the responsibility of individual food business operator to ensure their compliance with the law. You may wish to seek advice from your Primary Authority.

3) The Regulatory Position on Allergens

The General Food Law Regulation (EC) No.178/2002 is directly applicable EU legislation and provides the general principles of food safety which include the requirement on food businesses to place safe food on the market, for traceability of food, for presentation of food, for the withdrawal or recall of unsafe food placed on the market and that food and feed imported into, and exported from, the EU shall comply with food law.

In particular Article 14 sets out food safety requirements, whereby:

- Food shall not be placed on the market if it is unsafe.
- Food shall be deemed to be unsafe if it is considered to be:
 - (a) injurious to health;
 - (b) unfit for human consumption.
- In determining whether any food is unsafe, regard shall be had:
 - (a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and
 - (b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.

The EU Food Information for Consumers Regulation No. 1169/2011 details the responsibilities of food business operators (FBO's) for providing information to consumers (Article 8). It applies to all foods intended for the final consumer, including foods delivered by mass caterers, and foods intended for supply to mass caterers" (Article 1.3).

The list of allergens requiring labelling is as follows:

- Cereals containing gluten [i.e. wheat (such as spelt and Khorasan wheat), rye, barley, oats, and their hybridised strains]
- Crustaceans (e.g. crab, prawn, lobster) and products thereof
- Eggs and products thereof
- Fish and products thereof
- Peanuts and products thereof
- Soybeans and products thereof
- Milk (including lactose) and products thereof
- Nuts (i.e. almond, hazelnut, walnut, cashew, pecan, Brazil, pistachio, macadamia and Queensland nuts)
- Celery (this includes celeriac) and products thereof
- Mustard and products thereof
- Sesame Seed and products thereof
- Sulphur dioxide and sulphites at concentrations of more than 10mg/kg or mg/l
- Lupin and products thereof
- Molluscs and products thereof

Where allergenic ingredients are deliberately used, members or National Associations can refer to the following documents as to how these should be labelled, or consult their own national guidelines (if available):

„COMMISSION NOTICE of 13.7.2017 relating to the provision of information on substances or products causing allergies or intolerances as listed in Annex II of Regulation (EU) No 1169/2011 on the provision of food information to consumers (Brussels, 13.7.2017 C(2017) 4864 final)“.

„Guidelines relating to the provision of information on substances or products causing allergies or intolerances as listed in Annex II of *Regulation (EU) No 1169/2011 on the provision of food information to consumers*“.

It must be stressed that general food law (EU Regulation 178/2002) is contravened when the product sold is not of the nature or substance as demanded by the consumer due to either deliberate adulteration or contamination with significant levels of allergen which is not declared on the label.

This ESA guidance on herbs and spices intends to address the unintentional presence of allergens in herbs and spices by linking to the VITAL[®] Reference Doses^{1, 2, 3}.

N.B. Fish, molluscs and celery do not have VITAL[®] Reference Doses^{1, 2, 3}. Therefore, in this guidance fish and molluscs are assigned a threshold of zero⁶ to ensure they are considered, whilst the celery reference dose is based on the EuroPrevall 2015 study: <http://www.ncbi.nlm.nih.gov/pubmed/25640688>

Regulation seeks to ensure that consumers are advised when any allergen containing ingredients are used deliberately in foods. Further, it is clear that the regulation is contravened when products are intentionally adulterated with allergenic compounds for economic advantage.

Despite all the supply chain controls and good manufacturing practices to control allergenic cross-contamination a situation may arise where low level cross-contamination (LLC) is detected. In these situations, members/NA's are advised to follow the ESA's risk assessment model which is based on the UK FSA's approach to allergen risk assessment.

⁶ For the purposes of the Calculator (Annex I) fish and molluscs have been assigned a value of zero. Whilst this is lower than the current, most appropriate and sensitive methods Limits of Detection (LOD) or Quantification (LOQ), for numeric purposes this ensures that they are not omitted.

4) Sampling, Allergen Cross-Reactivity and False Positives

As with all testing regimes, the sampling of the material for allergen testing should be done on a statistical basis and allow for possible non-homogeneity in the sample. ESA recommends that its members use the Square Root Sampling Plan⁷ .

The type of material being tested (the matrix) can have a considerable effect on the ability to accurately detect and, where applicable, quantify the substance of interest. Refer to Annex II detailing questions to consider when selecting a test methodology.

A test may also indicate that a substance is present when it is not, due to cross-reactivity with another related species. Some allergens have been shown to cross react with other members of the same botanical genus (e.g. mustard with *Brassicaceae* family; almond with mahaleb).

Herbs and spices are potentially one of the most complex and challenging matrices to analyse. There will be cases where suitable and accurate testing methods are not currently available for the matrix of interest.

Therefore, when interpreting test results due consideration should be given to type of material being tested, how the sample was selected, the availability of SEN or ISO17025 accredited test methods and their limitations.

Members/NA's are advised to consider the Measurement of Uncertainty (MU) when interpreting the test result.

⁷ Spices and condiments – Sampling EN ISO 948 – 2009

5) ESA's risk assessment model for allergens in spices

Using the spreadsheet as detailed in Annex I work through the following steps in Table 1. to arrive at your recommended action given in Table 2

Step 1. Identify the ingredient(s) you are examining in the first column of Table 1

Step 2. Select the allergen of concern from drop down list in the 2nd column of Table 1.

Step 3. Insert your test result (allergen protein content) in the 3rd column of Table 1 in mg/kg (ppm);

Step 4. Enter the usage of the spice for a typical recipe/meal in the 4th column of Table 1

BEST PRACTICE IS TO IDENTIFY THE WORST CASE SCENARIO USAGE FOR THE SPICE CONTAMINATED WITH THE ALLERGEN IN QUESTION

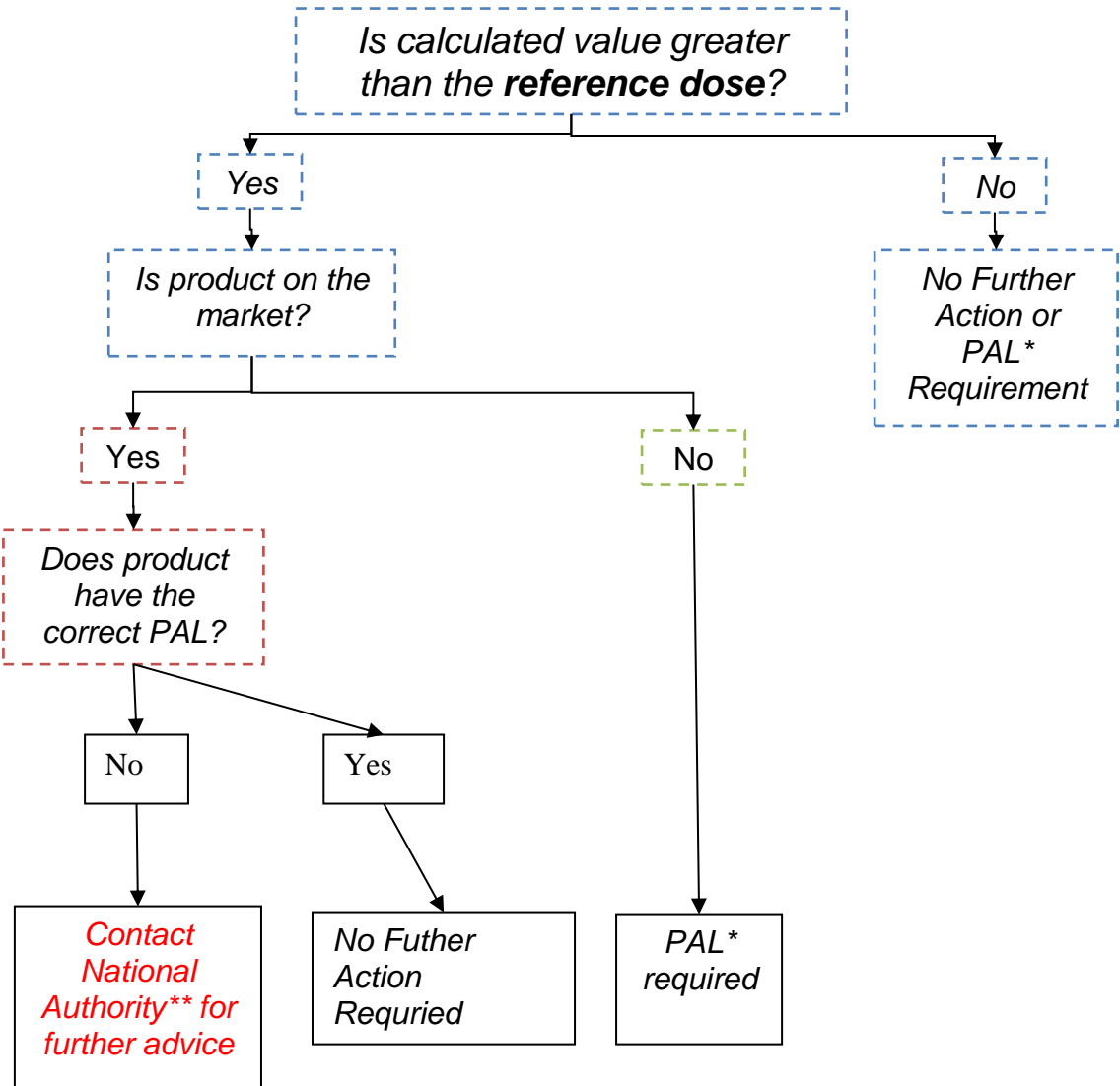
Members are advised to use their own company recipe data on herb and spice usage, or in the absence of company data to refer to the attached Typical Usage of Herbs and Spices in Recipes document at Annex III

Step 5. Enter the number of portions that the typical recipe/meal selected will generate into in the 5th column of Table 1

THE SPREADSHEET WILL NOW AUTOMATICALLY CALCULATE THE QUANTITY OF ALLERGEN PROTEIN CONSUMED ("the calculated value") AND COMPARE IT TO THE REFERENCE DOSE – RECOMMENDING WHETHER OR NOT ACTION IS REQUIRED

Step 6. Use the decision tree below to determine the next steps which you need to consider.

6) Risk Assessment Decision Tree



Key

*PAL – Precautionary Allergen Labelling

** Member is advised to contact their National Competent Authority for advice

Advice to Members/National Associations

Following a **positive allergen** detection that produces a calculated value **greater** than the **reference dose**, members or National Associations (NA's) are advised to **immediately** contact their local National Authority, to advise them of the situation and seek their recommendations.

Annex I

Allergen Risk Assessment Model Calculator - ESA Allergen Risk Assessment Model Calculator – see separate file

Annex II

Summary: Questions for Laboratories

To address the above points, you may wish to ask the laboratory you are using the following specific questions:

Do they hold BS EN ISO/IEC 17025 accreditation or other external independent validation and is allergen testing within the scope of that accreditation or, at least, are they experienced and proficient in the use of the methods they are offering?

Which test(s) would they propose using to meet your identified objective (ie ELISA and / or PCR)?

Can they demonstrate the method validation has been done for the specific matrix to be tested?

As part of method validation, has cross-reactivity been identified?

Have they established the sensitivity of the method [Limit of Detection (LOD) and, Limit of Quantification (LOQ)] for the matrix you wish to test and not just for the kit being used?

How will the result be expressed:

- in relation to the LOD and, where applicable, the LOQ;
- in the case of quantitative results, what units of measurement will be used for reporting the results (ie “ppm nut protein” or “ppm whole nut”)?
- if required, can they express quantitative results as “ppm total protein” (including documenting and applying the appropriate conversion factors provided by the kit manufacturer where necessary)?
- what is the measurement of uncertainty for the test?

Annex III

Typical Usage of Dried Herbs and Spices in Recipes

Source - UK market recipe data (if applicable, members can use their own data)

Product	Common Recipes Used In	Average Measurement Used (per recipe for 4 servings)	Average Measurement Used (per serving)	Equivalent Weight (g)
ALLSPICE (PIMENTO) GROUND	Walnut Dip	½ tsp (8 servings)	0.25 tsp	0.2g
ASAFOETIDA	Lamb Curry	¼ tsp	0.1 tsp	0.1g
BASIL	Spaghetti Bolognese (and other Italian Pasta Dishes)	1 tsp	0.25 tsp	0.2g
	Soups (any type)	2 tbs	1.5 tsp	1.5g
	Tomato Salads or Dressings	1 tsp	0.25 tsp	0.2g
BAY LEAVES	Rice Pudding	3 bays	1	0.1g
	Braised Red Cabbage	2 bays	1	0.1g
BOUQUET GARNI	Vegetable Soup, Beef Bourginion	1 sachet	1 sachet	0.2g
CARAWAY SEED	Carrots, Sausage Casserole	1 tsp	0.25 tsp	0.8g
CARDAMOM WHOLE	Fruit Salad	5 pods (8 servings)	1 pod	0.2g
	Spiced Hot Chocolate	2 pods (4 servings)	1 pod	0.2g
CAYENNE PEPPER	Basque Style Cod	¼ tsp	0.1 tsp	0.1g
CELERY SALT	Prawn Cocktail	¼ tsp	1/8 tsp	0.2g
CHILLIES	Spicy Pickled Onions	1 chilli	0.25g	0.25g
CHILLIES BIRDS EYE	Pickled Pumpkin & Prawn Salad	1 chilli	0.25	0.2g
CHILI POWDER HOT	Lamb Curry	1 tsp	0.25 tsp	0.8g
CHILI POWDER MILD	Mexican Casserole	2 tsp	0.5 tsp	1.5g
CHILLIES CRUSHED	Rogan Josh	½ tsp	0.12 tsp	0.1g
CINNAMON GROUND	Minced Pies	1 tbs (12 servings)	0.25 tsp	0.7g
	Spiced Parsnips	1 tsp	0.25 tsp	0.7g
CINNAMON STICKS	Egg Nog	4 sticks (infused)	1 stick	4.2g
CHIVES	Cheesey Baked Potato	2 tbs	1.5 tsp	0.6g
CLOVES WHOLE	Bread Sauce	4 cloves (6 servings)	1 clove	1.0g
CLOVES GROUND	Cranberry Sauce	pinch	pinch	0.1g
CORIANDER LEAF	Tomato Couscous Salsa	2 tsp	0.5 tsp	0.3g
CORIANDER GROUND	Lamb Curry	4 tsp	1 tsp	3g

CUMIN GROUND	Chilli con Carne (and other Mexican dishes)	2 tsp	0.5 tsp	1.1g
	Indian Curries (any type)	1½ tsp	0.4 tsp	1g
	Moroccan Tagines (and other Moroccan dishes)	½ tsp	0.12 tsp	0.4g
CUMIN SEED	Chick Pea Curry	1 tbs	0.75 tsp	2.7g
CURRY POWDER HOT	Chicken Madras	2 tbs	1½ tsp	4.5g
CURRY POWDER MEDIUM	Left Over Turkey Curry	2 tbs	1½ tsp	4.5g
CURRY POWDER MILD	Mild Chicken Curry	2 tbs	1½ tsp	4.5g
CURRY SPICE KORMA	Indian Curries (Any type)	2 tbs	1.5 tsp	4.5g
CURRY SPICE MADRAS	Indian Curries (Any type)	2 tbs	1.5 tsp	4.5g
CURRY SPICE TIKKA	Indian Curries (Any type)	2 tbs	1.5 tsp	4.5g
DILL WEED	Beetroot & Dill soup	2 tbs	1.5 tsp	1.5g
FENNEL SEED	Spanish Tortilla	½ tsp	0.12 tsp	0.1g
	Saffron Rice	1 tsp	0.25 tsp	0.2g
FENUGREEK GROUND	Curry Puffs	¼ tsp	0.1 tsp	0.1g
GARAM MASALA	Chicken Kashmir Curry	1 tbs	0.75 tsp	1.8g
GARLIC GRANULES	Spaghetti Bolognese (and other Italian Pasta Dishes)	1 tsp	0.25 tsp	1g
	Indian Curries (Any type)	1 tsp	0.25 tsp	1g
	Chilli con Carne (and other Mexican Dishes)	1 tsp	0.25 tsp	1g
GARLIC MINCED	Spaghetti Bolognese (and other Italian Pasta Dishes)	1 tsp	0.25 tsp	1g
	Indian Curries (Any type)	1 tsp	0.25 tsp	1g
	Chilli con Carne (and other Mexican Dishes)	1 tsp	0.25 tsp	1g
GARLIC PEPPER	Mediterranean Salad	½ tsp	0.12 tsp	0.08g
GARLIC SALT	Garlic Potatoes	1 tsp	0.25 tsp	1.75g
GINGER GROUND	Ginger Bread Cake	2 tsp (8 servings)	0.5 tsp	1g
	Paprika & Ginger Chicken Thighs	¼ tsp	0.1 tsp	0.4g
HARISSA	Spatchcock Grilled Chicken	1 tbs	0.75 tsp	2g
HERBES DE PROVENCE	Vegetable Provençale	1 tbs	0.75 tsp	1.0g
ITALIAN HERB SEASONING	Pasta Mixed Veg Bake, Tomato Based Pasta Sauces	1 tbs	0.75 tsp	1.0g
JUNIPER BERRIES	Braised Red Cabbage	6 Berries (8 servings)	1 berry	1g
KAFFIR LIME LEAVES	Thai Green Curry	2 Leaves	1 leaf	0.2g
MACE GROUND	Halloween Biscuits	½ tsp	0.12 tsp	0.3g
MARJORAM	Beef & Ale Stew, Pan Fried Brussels	2 tsp	0.5 tsp	0.5g
MINT	Koftas	1 tbs	0.75 tsp	0.5g
	Lamb with Cranberry Sauce	1 tsp	0.25 tsp	0.1g
MIXED HERBS	Spaghetti Bolognese (and other Italian Pasta Dishes)	2 tbs	1.5 tsp	1.5g
	Cottage Pie	1 tbs	0.75 tsp	0.75g

	Soups (Any type)	1 tsp	0.25 tsp	0.4g
MIXED SPICE	Chocolate Bites with Caramel	1 tsp (8 servings)	0.12 tsp	0.3g
MULLED CIDER	Mulled Cider	2 sachet	½ sachet	1g
MULLED WINE	Mulled Wine	2 sachet	½ sachet	1g
MUSTARD SEED	Mustard Mash	2 tsp (8 servings)	0.25 tsp	0.7g
NUTMEG GROUND	Ginger & Nutmeg Porridge	pinch	pinch	0.1g
NUTMEG WHOLE	Ginger & Nutmeg Porridge	pinch	pinch	0.1g
ONION BLACK SEED (NIGELLA/KALONJI)	Chick Pea Curry	½ tsp	0.12 tsp	0.2g
ONION SALT	Ribs	1 tsp	0.25 tsp	1.80g
OREGANO	Spaghetti Bolognese (and other Italian Pasta Dishes)	1 tbs	0.75 tsp	0.75g
	Bruschetta	1 tsp	0.25 tsp	0.25 g
PAPRIKA	Chilli con Carne (and other Mexican dishes)	2 tbs	1½ tsp	5.4g
	Goulash (and other Hungarian dishes)	2 tbs	1½ tsp	5.4g
	Soups (Any type)	2 tsp	0.5 tsp	3g
PAPRIKA HOT	Beef Goulash	1 tbs	0.75 tsp	2.7g
PAPRIKA SMOKED	Hummous	½ tsp (8 servings)	0.1 tsp	0.1g
PARSLEY	Spanish Tortilla	1 tbs	0.75 tsp	0.4g
PEPPER BLACK COARSE GROUND	Multipurpose table seasoning	1 tsp	0.25 tsp	0.88g
PEPPER BLACK GROUND	Multipurpose table seasoning	1tsp	0.25 tsp	0.88g
PEPPER WHITE GROUND	Leek & Potato Soup	½ tsp	0.12 tsp	0.4g
PEPPER SZECHUAN	Crispy Duck Breast	1 tsp	0.25tsp	0.5g
PEPPER BLACK & RED	Glazed Carrots, Cranberry Bean Soup	½ tsp	0.12 tsp	1g
PEPPER LEMON	Tray-Bake Piri Piri Chicken	1 tsp	0.25 tsp	0.8g
	Roast Chicken	2 tsp	0.5 tsp	1.75g
PEPPERCORNS BLACK	Multipurpose table seasoning	1tsp	0.25 tsp	0.88g
PEPPERCORNS MIXED WITH SPICE	Peppered Steak	2 tsp	0.5 tsp	2.2g
PICKLING SPICE	Pickled Onions	1 tbs (8 servings)	0.4 tsp	0.2g
PIMENTON	Garlic Prawns	1½ tsp	0.4 tsp	0.2g
POPPY SEED	Lemon & Poppy Drizzle Cake	1 tbs (8 servings)	0.4 tsp	1g
ROSEMARY	Rosemary Roasted Potatoes	2 tsp	0.5 tsp	1g
SAFFRON	Saffron Mashed Potatoes	pinch	pinch	0.1g
SAGE RUBBED	Sausage Sweet Pickle Plait	1 tsp	0.25 tsp	0.4g
SESAME SEED	Tasty Root Vegetables	1 tbs	0.75 tsp	2.7g
STAR ANISE	Crispy Duck Breast	2	0.5	1g
TARRAGON	Salmon & Broccoli Quiche	1 tsp	0.25 tsp	0.2g
THYME	Brussels Sprouts, Stuffing	2 tsp	0.5 tsp	0.6g
TURMERIC	Prawn Curry	¼ tsp	0.1 tsp	0.1g
VANILLA POD	Real Vanilla Custard	1 pod (8 servings)	0.2g	0.2g

Additional References

¹ Taylor *et al* (2014) Establishment of reference doses for residues of allergenic foods: report of the vital expert panel, food and chemical toxicology. Food Chem Toxicol 63: 9–17.

² Allen *et al* (2014) Allergen Reference Doses for precautionary labeling (VITAL 2.0): clinical implications J Allergy Clin Immunol. 2014 Jan 133(1):156-64.

³ Allergen Bureau, summary of the VITAL scientific expert panel recommendations 2011

⁴ Allergen Bureau, VITAL® Science - <http://allergenbureau.net/vital/vital-science/> - date sourced 13 NOV 2017

⁵ Allergen Bureau, The VITAL® Program - <http://allergenbureau.net/vital/vital-science/> - date sourced 13 NOV 2017

⁶ Food Allergy Research and Resource Program (FARRP) – University of Nebraska-Lincoln Institute of Agriculture and Natural Resources.
<https://farrp.unl.edu/thresholds-for-allergenic-foods>