

Review of the Regulatory Management of Food Allergens

Allergen Bureau Conference
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FSANZ



FSANZ is an independent statutory agency within an integrated food regulatory system involving the governments of Australia and the New Zealand Government



The map shows Australia divided into Northern Territory, Western Australia, South Australia, Queensland, New South Wales, Victoria, and Tasmania. Major cities labeled include Darwin, Broome, Alice Springs, Uluru, Adelaide, Perth, Hobart, Brisbane, Sydney, Canberra, Melbourne, and Auckland. The New Zealand flag is also shown, with major cities Wellington and Christchurch labeled. Bodies of water like the Timor Sea, Great Australian Bight, and Tasman Sea are also indicated.

Our Objectives

FSANZ's Statutory objectives, in developing or reviewing standards, are:

- protection of public health and safety;
- provision of adequate information to enable consumers to make informed choices; and
- prevention of deceptive and misleading conduct.

FSANZ must also have regard to:

- Standards to be based on risk analysis using the best available scientific evidence
- Promotion of consistency between domestic and international standards
- Desirability of efficient and internationally competitive food industry
- Promotion of fair trading in food
- Policy guidance from Ministerial Council



The Review

Presents an opportunity for FSANZ and stakeholders to:

- Evaluate a decade of experience with food allergen regulation
- Identify issues/ gaps that can be addressed
- Consider recent scientific developments/international approaches to assessment/ management of food allergen risk



The review


Elements to take into consideration in the review:

- Consumer needs/expectations**
- Industry needs/expectations**
- Availability of scientific data to underpin options**



Australia New Zealand Food Allergen Regulations

- Developed 1996-98 (expert panel convened by FSANZ)
- Major food allergens identified (the big 8 as in Codex)
- Sesame also a major allergen
- Regulation gazetted 2000
- Fully enforceable 2002



Food Allergies

Clinical information available at the time

Prevalence of food allergy in Australian children
David Hill et al. *Env Tox Pharma* 1997;4:101

Egg	3.2%
Milk	2.0%
Peanut	1.9%
Sesame	0.4%
Tree nuts	0.3%
Fish	0.07%

 FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai - Ahitereiria me Aotearoa

Australia New Zealand Food Allergen Regulations

Standard 1.2.3 Mandatory warning and advisory statements and declarations

Cereals containing gluten (except in beer and spirits)	Peanuts
Crustacea	Soybeans
Egg	Tree nuts
Fish	Sesame seeds
Milk	Added sulphites ≥ 10 mg/kg

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Australia New Zealand Food Allergen Regulations

Substances and their products must be declared when present as –

- (a) an ingredient; or
- (b) an ingredient of a compound ingredient; or
- (c) a food additive or component of a food additive; or
- (d) a processing aid or component of a processing aid.

Australia New Zealand Food Allergen Regulations

Where the food is not required to bear a label....

- (i) declared on or in connection with the display of the food; or
- (ii) declared to the purchaser upon request


Benchmark Consumer Survey

Quantitative Consumer Survey on Allergen Labelling: 2003

Purpose:

The survey sought to collect data on:

- Consumer levels of awareness and knowledge of the allergen labelling provisions for processed foods
- Consumer ability to identify foods containing relevant allergens
- Consumer behaviour towards food selection for those “at risk” of adverse reactions to food




Benchmark Consumer Survey - continued

Quantitative Consumer Survey on Allergen Labelling: 2003

Methodology

- Targeted sample recruitment was undertaken in Aus/NZ through:
 - Hospital and private allergy clinics
 - Allergy support groups
- The survey used mail-out, self-completion questionnaire



Benchmark Consumer Survey - continued

Quantitative Consumer Survey on Allergen Labelling: 2003

Results

Consumers identified a number of problems:

- Information insufficient/ terminology unclear
- Poor label format (size, contrast, location)
- Overuse of precautionary statements/ confusing

Report published on FSANZ website 2004


<http://www.foodstandards.gov.au/newsroom/publications/allergensurvey/index.cfm>



Industry Initiatives

Allergen Forum 2004/ Allergen Bureau
AFGC – Food Industry Guide to Allergen Management and Labelling – 2007 revised edition

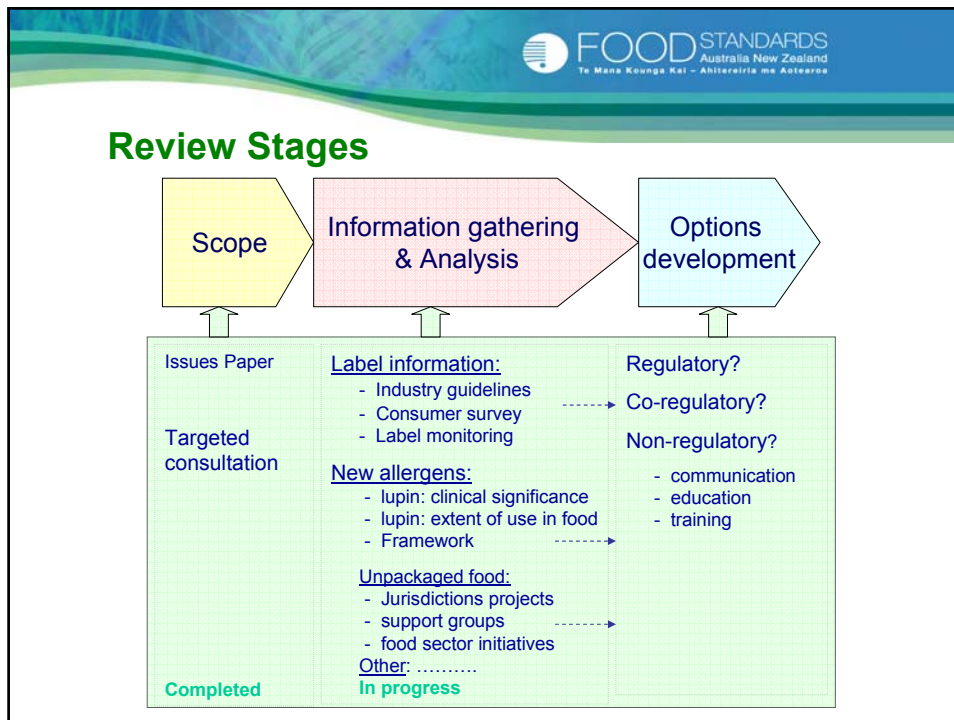
- **Recommended format:**
 - allergenic substances in **bold**
 - allergen summary statement
 - precautionary statement
- **VITAL**



Information gathering
2nd Consumer Survey

Quantitative Consumer Survey on Allergen Labelling: Follow-up Survey 2008-09

- Methodology as in benchmark survey
- Data collection Sep 08 – Jan 09
- Report finalised June 09



- Issues to be considered in the review**
- Current list of allergens**
- Terminology and definitions
- Label information**
- Presentation and clarity
- New allergens**
- Establish framework
 - consistent and transparent approach
 - Consider lupin

Issues – continued

Exemption of derivatives

- Consider non-allergenic derivatives
- Case by case
- Nature of derivative and its use
- Framework?

Allergen thresholds

- Emerging information and data gaps
- Application in food allergen risk assessment/risk management decisions

Issues – continued

Food exempt from bearing a label

- Collate information on activities undertaken by:
 - Jurisdictions
 - Food sector
 - Support groups
- Identify potential gaps regulatory/ non regulatory
- Explore ways to communicate successful approaches in Australia and New Zealand






**New allergens:
Current considerations**

Scientific framework

- To establish a transparent and consistent approach to emerging issues in food allergen regulation for:
 - Considering new major allergens
 - Lupin as a case study



**Scientific Framework
New allergen**


Criteria

- **Mechanism**
- **Incidence**
- **Severity**
- **Extent** of use and the **range** of food containing the allergen
- **Cross reactivity** with major allergen

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Lupin

- **Major crop in Western Australia**
- **Lupin allergy**
 - 3 cases reported in Australia
Smith et al., MJA 2004; 181 (4): 219-220
 - Few more reported by allergy clinicians in Australia
 - Clinical research currently underway on clinical significance including cross-reactivity with peanut
 -  ➤ Research on extent of use in food supply
 - To be considered by FSANZ in the review 

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Case Study: is Lupin a Major Allergen?

Criteria	Lupin
Mechanism:	Immune-mediated (IgE)
Incidence:	Appears to be increasing
Severity:	Severe reactions reported including anaphylaxis
Use & range of foods:	Mainly flour increasingly used in food products
Cross reactivity with a major allergen:	Peanuts




Exemption from declaration

- **FSANZ currently considering exemption for isinglass as fining agent (beer & wine):**
 - Data package provided earlier this year
 - Risk assessment
 - Risk management options
 - Take EFSA opinion/ EU exemption into account

International - Allergen Lists

		
Cereals (4 derivatives exempt) Crustaceans Eggs Fish (2 derivatives exempt) Peanuts Soybeans (4 derivatives exempt) Milk (2 derivatives exempt) Nuts -8 specified by name (1 derivative exempt) Celery Mustard Sesame seeds Sulphites >10 mg/kg Lupin Molluscs	Milk Egg Fish Crustacean shellfish Treenuts Wheat Peanuts Soybeans Exemption for highly refined oil derived from these foods Currently reviewing advisory labelling	Almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios or walnuts Peanuts Sesame seeds Wheat, kamut , spelt or triticale Eggs Milk Soybeans Crustaceans Shellfish Fish Sulphites ≥10 mg/kg Exemption for fining agents used in alcoholic beverages



Challenges in allergen regulation


Limited data on:

- Prevalence of food allergies
- Incidence and factors involved

Effective system to minimise “May contain” statements to improve consumer choice.


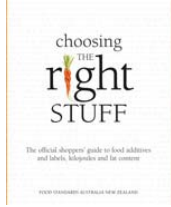
Allergen information for unpackaged food – Sector and consumer education.





Consumer education: a critical element

- **FSANZ booklet**
‘Choosing the Right Stuff’ - the official shoppers’ guide to food labelling
 - Includes section on food allergens
- **Allergy cards**
Assist allergic consumers to identify allergens/ ingredients on food labels
 - Developed by Anaphylaxis Australia (supported by FSANZ & NSWFA)



Thank You

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