

Allergens: The 3 R's – Regulations, Realities & Recalls



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Roles of Health Canada and CFIA

- **Health Canada**
 - **Development and administration of health and safety policies and standards for foods**
 - conducts risk assessments
 - establishes regulations and guidelines
- **CFIA**
 - **Responsible for all federal food inspection programs**
 - risk management strategies
 - enforces established regulations and guidelines

Food and Drugs Act and Regulations

- Canada's primary food safety legislation
- Based on federal criminal law authorities
- Applies to all foods in Canada
- Other Trade and Commerce legislation has incorporated FDAR requirements

Section 4 of the Food and Drugs Act

- No person shall sell an article of food that
 - has in or on it any poisonous or harmful substance;
 - is adulterated; or
 - was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.

Section 5 of the Food and Drugs Act

- No person shall label or sell any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its composition or safety.

Regulation A.01.040 of the Food and Drugs Act

- No person shall import into Canada for sale a food, the sale of which in Canada would constitute a violation of the Act or these Regulations

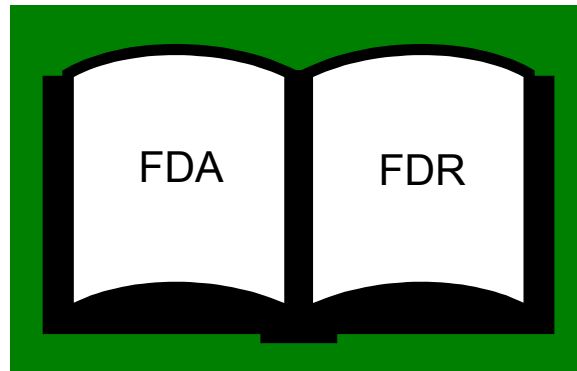
CFIA Act & Recalls

Section 19.(1)

*Where he believes that the product represents a health risk, **the Minister may, ... order that the product be recalled ...***

LABELLING

Appreciate
The Regulations Now !



Situations Requiring a Label

B.01.009 (2)[4]a

* peanut oil

**To Be
Labelled**

B.01.003 (a...f)

* all prepackaged foods

except:

- one bite confections
- fresh veggies

* meat, poultry...

* horse meat

* food additive/preparations

B.01.009 (3) components in ingredient mixtures

* salt

* MSG

* HPP

* Aspartame

* Potassium Chloride

* Ingredients effecting final food



And Now The Regulatory Exemptions

REGULATORY LABELLING GAPS

Allergens are not always declared on labels because of:

- **component exemptions for many common ingredients**
- **use of class names for seasonings, flavourings, spices etc.**
- **few specific requirements for declaring allergens**
- **most problems are from cross-over**
- **common names used may not reflect source**

Situations not Requiring an Ingredient Label

B.01.008(2) a - g prepackaged and

- bulk at retail
- with restaurant meals
- vending machines
- cooked meat, poultry at retail
- vinegars

B.01.003

- bite size confections
- fresh fruits & vegs

B.01.009(1)

- a total of 36 foods including Meat and Poultry which may contain binders, seasonings, carriers

Potential
for
Undeclared Allergens



B.01.009 (2)

- food colours, flavours, spices, *seasonings, herbs, vitamins, and minerals, rennet preparations, food flavour-enhancer preparations, food additives

*Administrative guideline for seasonings

- when < 2% of final product no listing of components except for B.01.009[3] requirements

Keep in Mind:

Health Canada

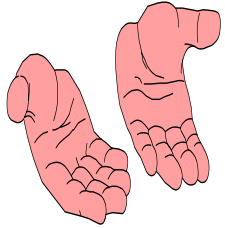
**is proposing
changes to the Regulations !**

Always list the following when they are present as ingredients or components:

- **peanuts**
- **tree nuts** (almonds, Brazil nuts, cashews, hazelnuts [filberts], macadamia nuts, pecans, pine nuts, pistachios, walnuts)
- **sesame seeds**
- **milk**
- **eggs**
- **fish, crustaceans** (e.g., crab, crayfish, lobster, shrimp) **and shellfish** (e.g., clams, mussels, oysters, scallops)
- **soy**
- **wheat**
- **sulphites (to be a separate proposal)**

Recommendation

(if using precautionary labelling)



- **Use the “may contain” statement**
[Health Field Compliance Guide 94-02]
- **WHY?**
 - Phrases “manufactured in a plant ... same line as” although correct statement of facts, do not suggest an increased risk (possible allergen crossover) for the allergic person



Precautionary Labelling (...1994) ("may contain...")

- **must be risk based**
- **not to be used as a substitute for GMP's**
- **use only as a last resort**
- **follow the list ingredients (when used)***

ALLERGEN PREVENTION PLAN

- a very systematic approach to prevent inadvertent allergen crossover within YOUR establishment*



Starting an APP

- establish a risk assessment team
- ID key allergens for your operation
- conduct a risk evaluation for your entire operation
- allergen map your plant
- assess and update your APP routinely
- communicate & assess allergy awareness to all employees including suppliers*



Key Procedures (to be Assessed)

- Product Formulation*
- Label Accuracy*
- Incoming Ingredient Control
- Storage*
- Product Preparation / Blending
- Equipment Design and Installation
- Label Control
- Allergen Awareness
- Sanitation Program*

*** applies to importers**

1. Product Formulation

- Current written formulae are available for each product

2. Label Accuracy

- The manufacturer ensures that the composition of the product is accurately represented on the label

3. Incoming Ingredient Control

- The manufacturer controls incoming ingredients to avoid the presence of undeclared food allergens

4. Storage

- Storage and handling of ingredients, products and packaging materials are controlled to avoid the presence of undeclared food allergens

5. Product Preparation/Blending

- Product preparation/blending is controlled to avoid the presence of undeclared food allergens

6. Equipment Design & Installation

- Equipment and utensils are designed, constructed and/or installed to permit effective cleaning necessary to avoid the presence of undeclared food allergens

7. Labelling Control

- The manufacturer has controls in place to prevent mislabelling

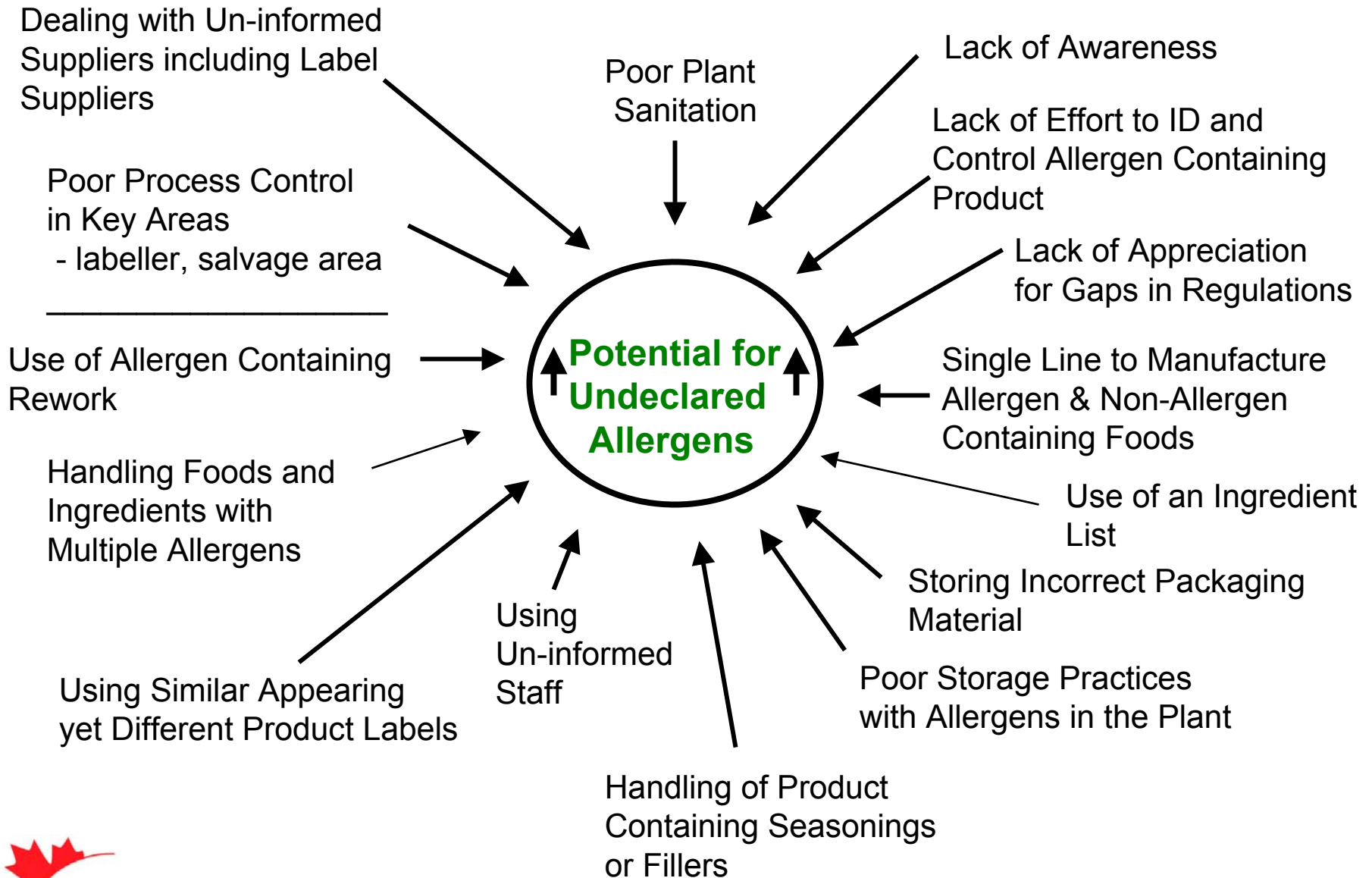
8. Allergen Awareness

- The manufacturer is aware of, and has implemented policies, including employee training, to avoid hazards related to food allergens

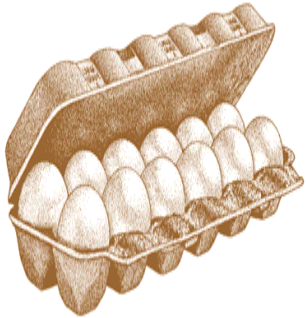
9. Cleaning Program

- An effective cleaning program for equipment and premises is in place to avoid the presence of undeclared food allergens

Taking the Barometer Reading for Undeclared Allergens



Filler and Binder Ingredients in Meat and Poultry Products



Fillers may contain (B.14.001):

- **any vegetable material (except tomato or beetroot)**
- **milk**
- **egg**
- **yeast, and**



Meat Binders, Pumping Pickle and Dry Cures may contain (B.14.007, B.14.009) :

- **seasoning**

Filler and Binder Ingredients in Fish Products

Fillers may contain (B.21.002 a...e)

- **flour** or meal prepared from grain or potato
- processed wheat , flour, **milk**
- bread, biscuit, or bakery products
- milk powder, skim milk powder, buttermilk powder, or whey powder
- starch

Binders may contain (B.21.007) sugar, **glucose**, **spices** and **seasonings**

Seasonings

A blend of flavouring agents and carriers
(* not to exceed 2% of product)

* note this is an administrative guideline

CARRIERS may include
salt, sugar, corn sugar, lactose, whey powder,
milk powder, cereal flours and starches

CARtoon



Recall Definitions (Traditional)

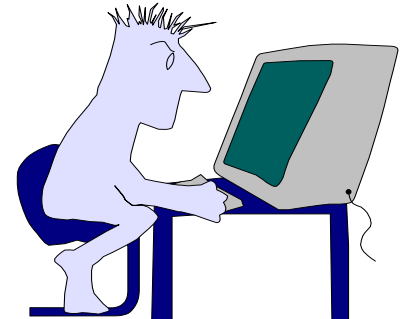
- “Recall’ means:
 - a firm’s removal from further sale or use, or correction, of a marketed product that violates legislation administered by the CFIA

Recall Definitions

- **Class 1**
 - serious health consequences or death
- **Class 2**
 - temporary health consequences or likelihood of serious is remote
- **Class 3**
 - no health consequences likely

Determining Recall Classifications

- type of allergen involved
- history of reactions to product
- quantity of product in the marketplace
- frequency and level of allergen in product
- possibility for observation of allergen (by the consumer)
- regulatory violation



CFIA Act & Recalls

Section 19.(1)

*Where he believes that the product represents a health risk, **the Minister may, ... order that the product be recalled ...***

Risk Management Options

- Inform industry of legal requirements
- Establishment inspection
- Development of Good Manufacturing/Importing Practices
- Sampling and Analysis
- Compliance and enforcement actions
- Product recall for high risk situations

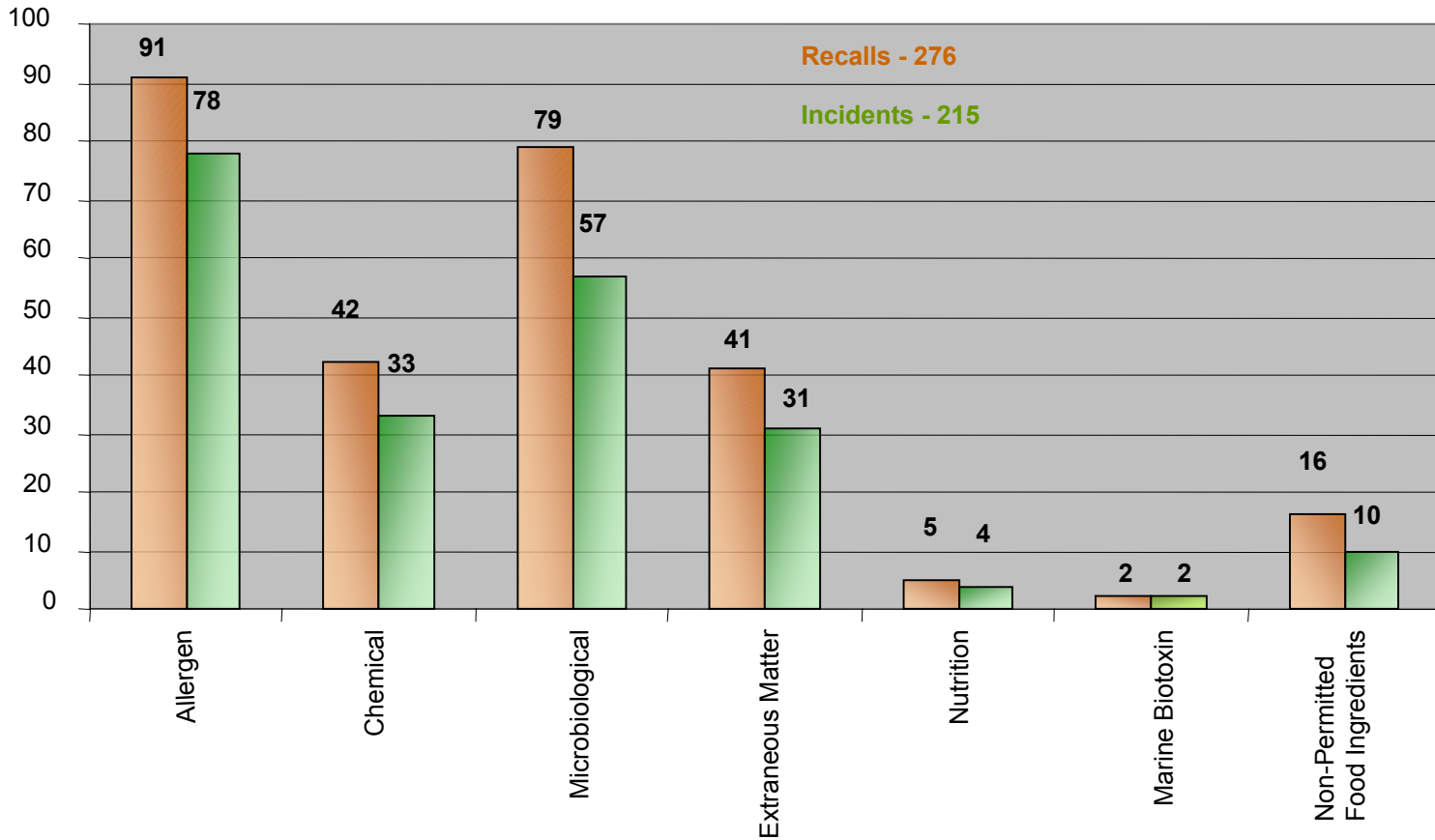
Class 1 Recall

- Recommended on the confirmed and undeclared presence of any of the 9 highest risk allergens at levels likely to cause anaphylaxis
 - peanuts
 - tree nuts
 - sesame seeds
 - milk
 - eggs
 - fish, crustaceans, shellfish
 - soy
 - wheat
 - sulfite (>10ppm)

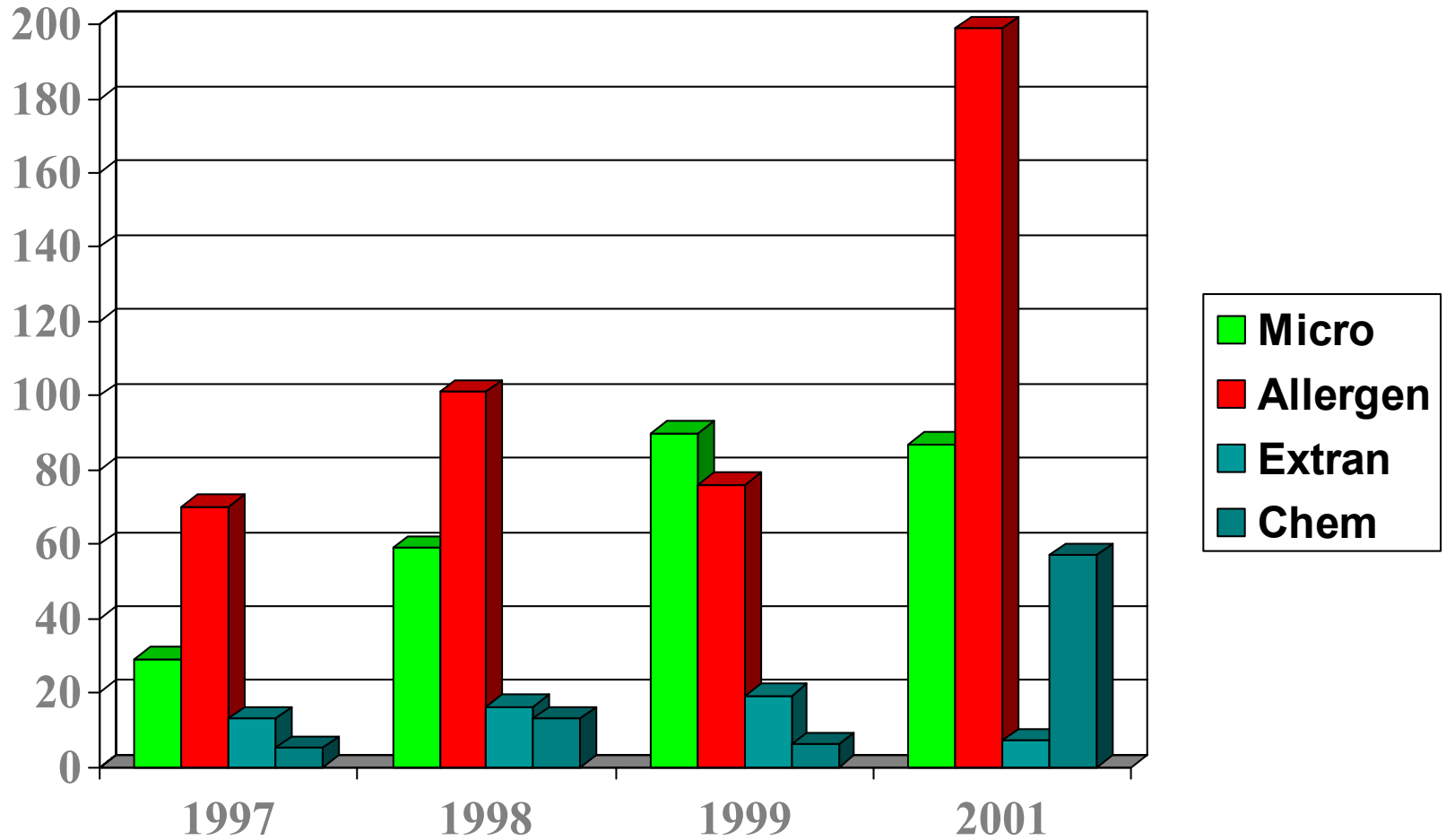


Recalls / Incidents by Area of Concern

April 1, 2004 to March 31, 2005



Recall Statistics



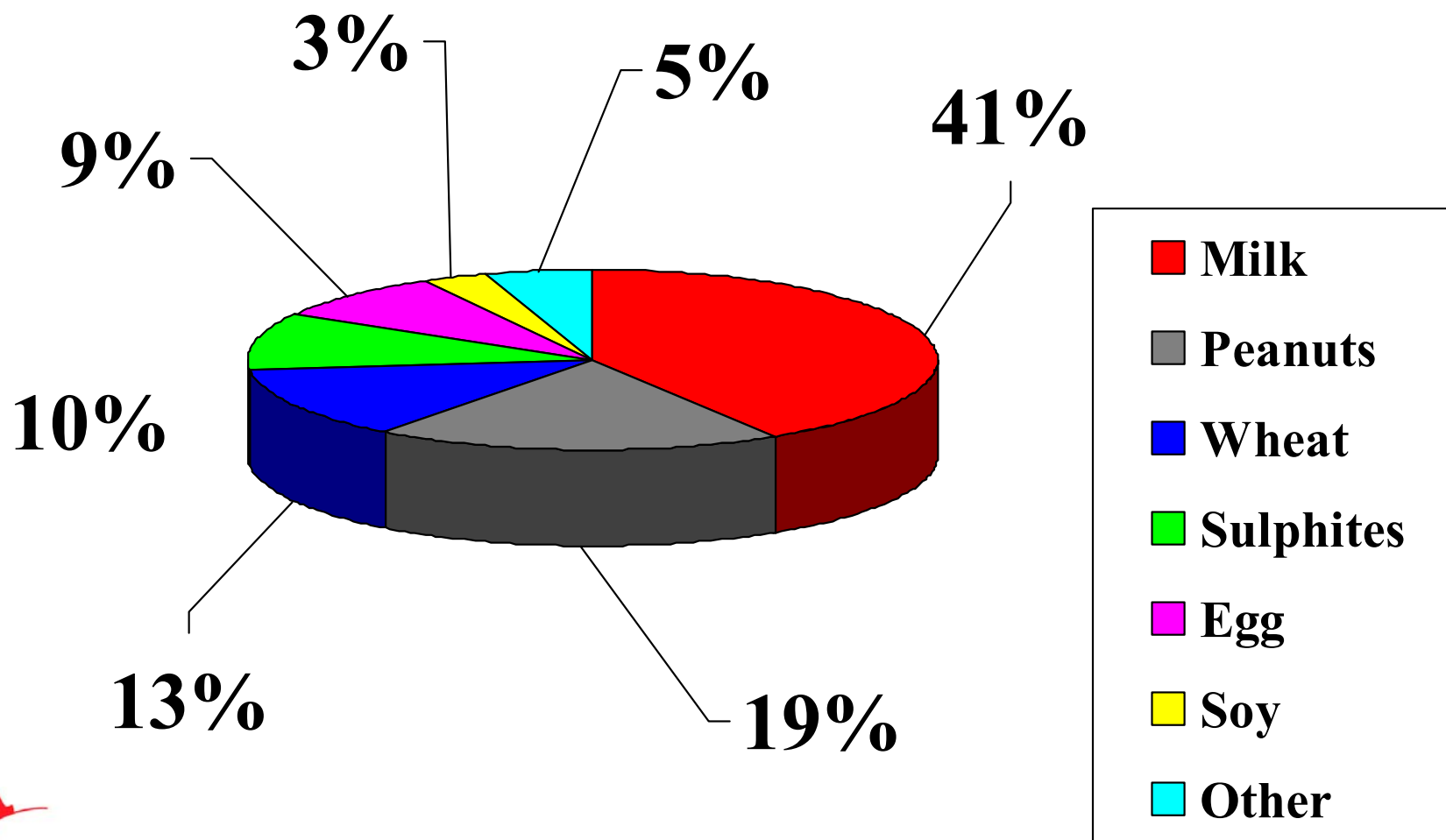
Recall Statistics

April 1, 2001 - March 31, 2002

Allergen	258	(54%)
Micro	107	(23%)
Chemical	66	(14%)
Extraneous	37	(8%)
Other	6	(1%)
Total	<u>474</u>	

Undeclared Allergens In Food Products

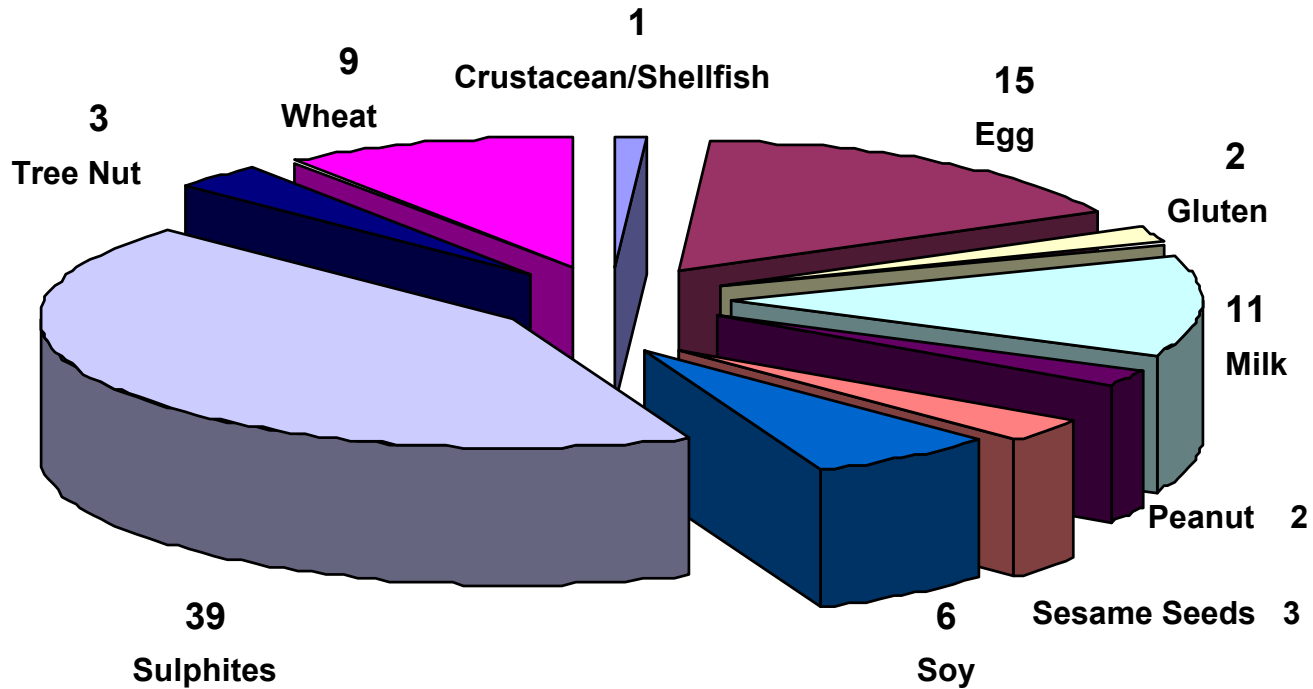
April 01, 2000 - March 31, 2001





Allergens - Number of Recalls

April 1, 2004 to March 31, 2005



TOTAL: 91

Allergen Capabilities

- Allergens we currently can test for:
 - peanuts
 - milk
 - egg
 - soy
 - hazelnuts
 - brazil nuts
 - sulfites (treated as an allergen)

For Additional Information:

CFIA Recall & Allergy Alerts

<http://www.inspection.gc.ca/english/corpaffr/recarapp/recaltoce.shtml>

CFIA Resource Centre

<http://www.inspection.gc.ca/english/corpaffr/educ/alerte.shtml>

Thank You

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