

Allergen UPDATE II Regulatory Perspective CFIA

Consumer perspective Anaphylaxis Canada

Regulatory Perspective – Labelling of Food Allergens

- The Food and Drug Regulations B.01.010.1(2) require that sources of the food allergen or gluten must be declared either in:
- The list of ingredients
- In a "contains" statement
- Scope: Does not apply to a food allergen or gluten that is present in a prepackaged product as a result of crosscontamination. B.01.010.1(3)

Regulatory Perspective – Inspections

- Inspection focus has been on undeclared allergens as a result of product formulations- not testing
- 76 recalls from August 2012 to Feb. 2015 for undeclared mustard allergen

59 domestic

17 imported

35 class I

18 class II

23 class III

Food Allergen Precautionary Statements (PL)

- Voluntary statements regarding the possible inadvertent presence of an allergen in the food.
- To be used when, despite all reasonable measures, the inadvertent presence of allergens in food is unavoidable.
- Precautionary statements are not a substitute for Good Manufacturing Practices.
- There is no regulatory requirement for, or prohibition of, precautionary labelling, however statements must be truthful and not misleading (FDA and CPLA).

Consumer perspective

- About 2.5 million Canadians have self reported at least one food allergy, representing 7% of the population
- There is no cure for food allergy; strict avoidance key to staying safe:
- A small amount can trigger a reaction
- Reading food labels, asking "What's in the food?"

Food labels are an allergic consumer's life-line

YET....the anaphylaxis community wants

- Fewer products with precautionary statements
- Wider choice of safe products
- Standards for the food industry
- Ongoing education of consumer

"Only 0 is good enough" for acceptance of specific thresholds



Allergen UPDATE III Thresholds

Thresholds

- Undeclared allergens should not be present
- If present, recall based on risk assessment:

Risk assessments are based:

- on amount of allergen in the product in ppm
- reference amount- qty of the food usually eaten by an individual at one sitting
- level of exposure to an allergen which will trigger a reaction in an allergic individual

Thresholds cont'd

Thresholds are based:

- Individual allergen
- on data which is very limited
- -LOAEL (lowest observed adverse effect level)
- No internationally agreed safe threshold levels
- No clear definition of what is trace vs gross contamination

Thresholds cont'd

- FARRP (Food Allergy research and Resource Program)
- Vital- (Voluntary Incidental Trace Allergen Labelling)
- Eliciting dose (ED) trigger point at which 99% of allergic individuals will not trigger an allergic reaction



Allergen UPDATE IV Testing

Correction - Food Recall Warning - Rescindment of Food Recall Warnings (Allergen)

- laboratory testing indicated that cumin contained undeclared almond
- additional testing has confirmed that the original laboratory results were false positives
- Cross-reactivity with mahleb
- Significant monetary and reputational cost for the manufacturer

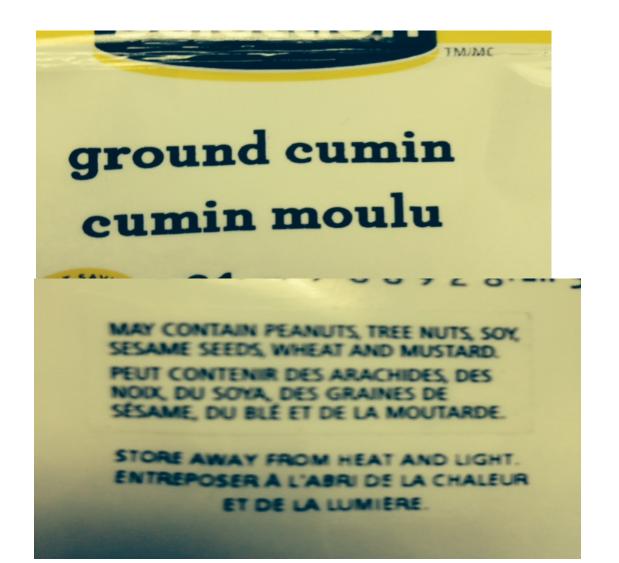
Testing cont'd

- •Test methods:
 - Elisa- quantitative within a standard range
 - Some issues with cross-reactivity
 - PCR (polymerase chain reaction)- qualitative-DNA
- LOD
- Sampling protocol

The way Forward for the spice industry

- Supply chain improvement
 - -How realistic to change agricultural methods in source countries?
- Increased testing-
 - Expensive, time consuming and possibility of error
- Individual risk assessment-
 - carries risk for the supplier
- Industry-consumer-govt agreement on maximum threshold levels for each allergen that are science based –

The way forward for the spice industry



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Is the spice industry able to 'contain' the use of 'may contain'?
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