

# Managing Adventitious Presence of Priority Allergens in Grain-derived Ingredients and Processed Foods: Process Controls, Voluntary Thresholds and Precautionary Labelling

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# Crop-based priority allergens in Canada's Food and Drug Regulations:

As of August 4 2012, “food allergen  
“means any protein, modified protein or  
protein fraction derived from any of:

- wheat or triticales
- soybeans
- mustard seeds**

**And,**

# Other food allergens:

- Almonds and other tree nuts
- Peanuts
- Sesame seeds
- Eggs
- Milk
- Crustaceans
- Shellfish
- Fish
- Added sulphites

# Crop-based priority allergens in Food and Drug Regulations:

“gluten” means any gluten protein or modified gluten protein including any gluten protein fraction from the grain of any of or hybridized strains of:

- barley
- oats
- rye
- triticale
- wheat

# Adventitious presence (AP):

- unintended
- unavoidable
- naturally occurring

# Unintended:

- Presence of priority allergens in unprocessed wheat and oats is unintended.
- Millers would prefer to buy and process wheat and oats free of seeds, seed fragments and dust of all other crop types including, **mustard, canola and soybeans.**
- Not practically achievable (**not possible**) in CDN (or US) grain production, storage, handling and transportation of unprocessed grain to mills. 40,000 car lots annually.

# Unavoidable:

- Seed purity and use of saved seed
- Crop rotation: use of farmland for multiple crop types in a planned, multi-year cycle.
- Shared use among multiple crop types of seeding, harvesting, on-farm storage, trucks, off-farm storage and handling elevators and rail cars **results in co-mingling of commodities**
- All wheat and oats delivered to mills contains AP of **soybeans, mustard and/or canola**, barley, rye, triticale, flax, field peas, lentils, etc.

# On-farm storage methods

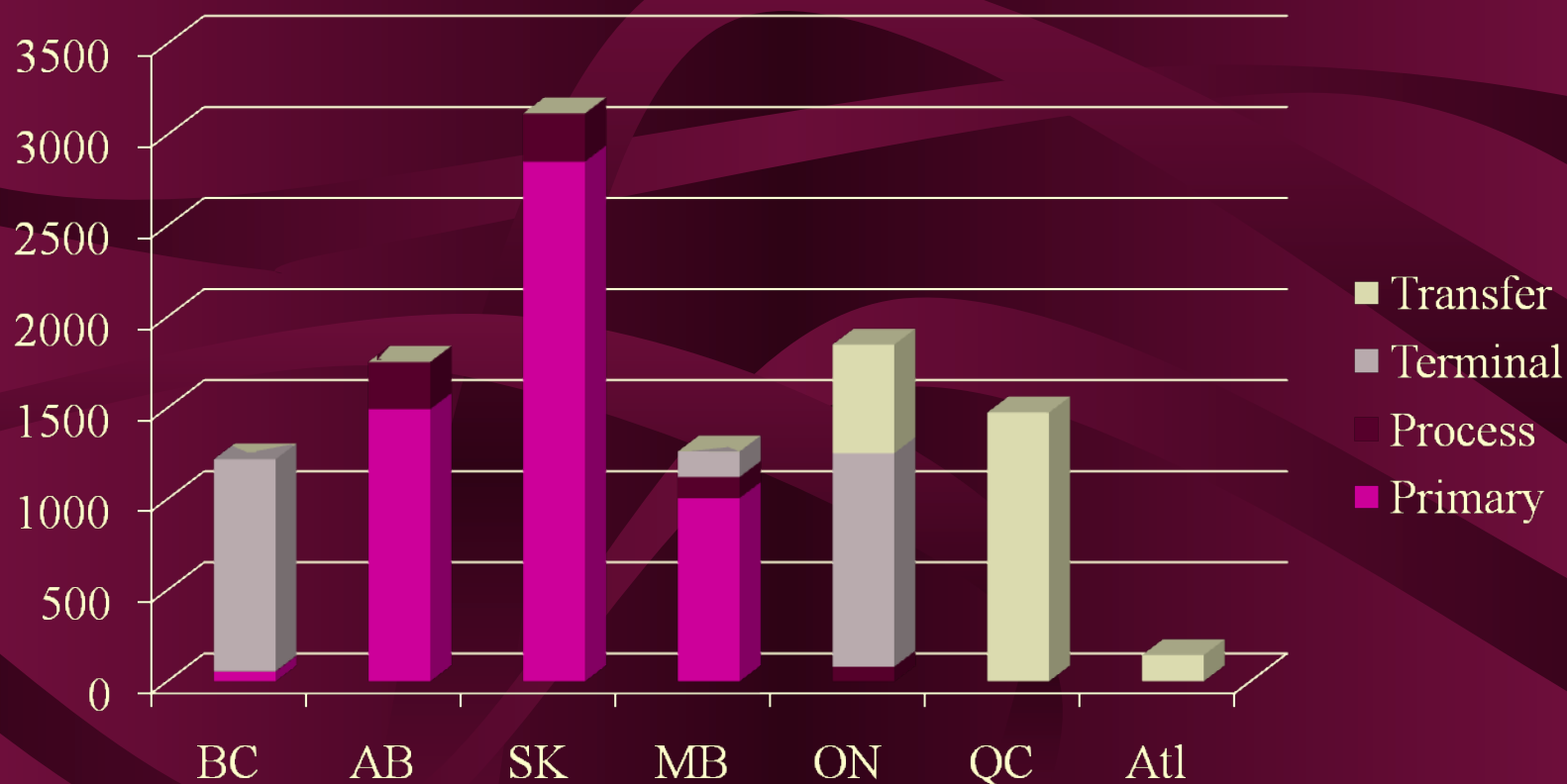
- Corrugated metal bins of various designs
- Wooden bins
- Concrete silos
- Various shed configurations
- On-ground covered storage
- Plastic grain bags, modeled after silage storage tunnels



# Western primary elevator system:

- 314 country (primary) elevators with average storage capacity of 18,000 tonnes
- Combined storage capacity of 5.4 million tonnes
- Annual handling capacity of 32 million tonnes
- Handles wheat, barley, oats, rye, canola, flax, soybeans, corn, peas, lentils, canary seed and mustard

# Regional distribution of off-farm storage capacity – CGC licensed elevators



# AP of mustard in wheat and oats:

- Mustard is a specialty crop which producers and handlers try to IP (identity preserve), avoiding co-mingling with other crops.
- Even so, co-mingling (AP) on-farm and off-farm in handling and transportation is a reality.

## AP of mustard – AAFC pilot studies of unload samples at mills:

- AAFC pilot study found AP of mustard in **12% of CWAD and CWRS wheat samples** visually inspected at SRC lab.
- AAFC pilot study found AP of mustard using ELISA method in **100% of oat samples ranging from 34 to 172 ppm** indicating a high % of false positives.

# Naturally occurring:

- Wild mustard: *Sinapis arvenis*  
and *Brassica kaber*
- common weed throughout all areas in Canada where mustard and Canola are commercially grown as field crops
- Seeds can survive in soil for over 10 years (some literature says up to 60 years)

# Mustard: Priority Allergen – Systematic Review

“Additional factors that make mustard allergy relevant to the Canadian scenario include the potential **cross reactivity between mustard and rape seed** and the facts that Canada is a major producer of both of these crops and sensitization to mustard can be acquired through dermal and respiratory exposure.”

# Mustard: Priority Allergen – Systematic Review

“The major allergen of mustard is a 2S albumin, which is seed storage protein... This seed storage protein has also been isolated from rapeseed, leguminous plants (peas and soya), walnuts, sesame seeds and brazil nuts....”

# Mustard: Priority Allergen – Systematic Review

*“...Brassica juncea and Sinapis alba have a homologous epitope...”*

*“These findings imply that individuals known to be sensitive to one species of mustard are likely to show sensitivity to other species.”*



# Mustard: Priority Allergen – Systematic Review

“Furthermore, a marked in vitro cross-reactivity between the principal allergen in of rape seed (*Bn III*) and *Sinapis alba* have been described in the literature.”

# What we conclude:

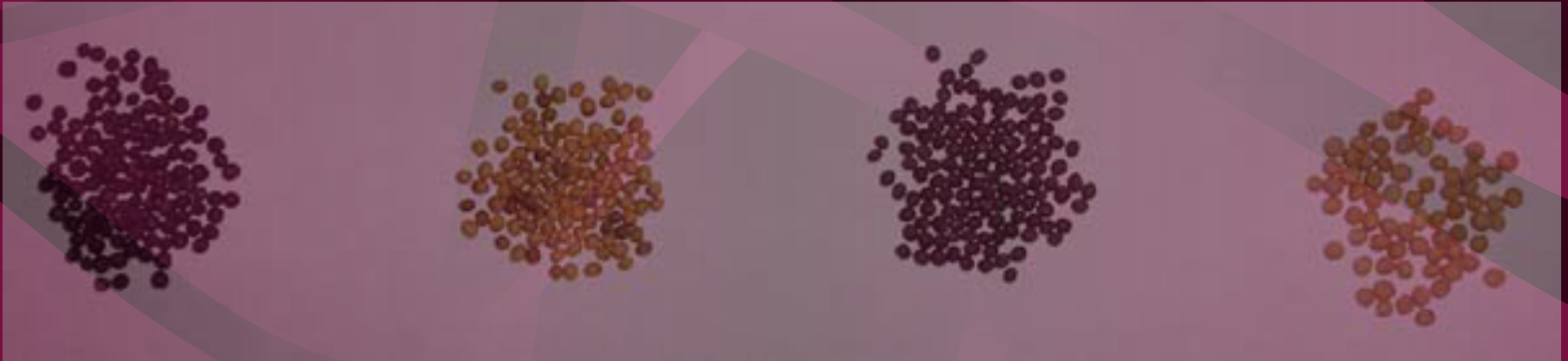
- Both mustard and canola (rapeseed varieties) seed are allergenic.
- Some cultivated mustard varieties (cultivars) and some canola varieties (cultivars) contain proteins that are either similar or identical.
- Differentiating mustard from canola in milled grain products is not possible using commercially available technologies suitable for use at farm, elevator or mill.

# *Sinapis arvenis, Brassica kaber*

- Yellow mustard – *Sinapis alba*
- Oriental mustard – *Brassica juncea*
- Brown mustard – *Brassica juncea*
- Juncea canola – *Brassica juncea*
- Argentine canola – *Brassica napus*
- Polish canola – *Brassica rapa*

# Visual distinguishability:

canola    oriental    brown    yellow



# Regulatory context:

- It is legal to sell cereal grains such as wheat, oats and barley to processors that contain mustard, soybeans, canola and seeds of other crop types, including weed seeds such as wild mustard
- Grading tolerances pursuant to the Canada Grain Act and Regulations permit this.

# CW and CE Grade Tolerances:

<b>GRADE</b>	<b>CWAD, CWRS, CPS</b>	<b>CERS , CERS,</b>	<b>OTHER CANADA EASTERN</b>	<b>TOTAL FOREIGN MATERIAL</b>
<b>1</b>	<b>0.2</b>	<b>0.2</b>	<b>0.2</b>	<b>0.5 to 1.0</b>
<b>2</b>	<b>0.3</b>	<b>0.3</b>	<b>0.3</b>	<b>1.2 to 2.0</b>
<b>3</b>	<b>0.5</b>	<b>0.5</b>	<b>0.5</b>	<b>1.5 to 3.0</b>

# Mustard production in Canada:

- Over 70% is in Saskatchewan, approximately 117 thousand tonnes in 2013
- SK also accounts for approximately 50% of CDN canola production, 8,917 thousand tonnes in 2013 or 75 times as much canola as mustard, and
- over 80% of production of durum wheat and approximately 40% of spring wheat
- 90% of CDN oat production

# Process controls: one only

- Grain cleaning is the first stage of grain milling and the only process control
- The grain (wheat/oat) **cleaning process does not remove all adventitious presence** of canola, mustard, soybean, barley, triticale
- Milled wheat products can contain in excess of 1,000 ppm of soy, perhaps several hundred ppm of **mustard and canola**
- Milled oat products can also contain several hundred ppm of **wheat, soy and canola**



## The allergen issue: risk management

- No regulatory maximum limits have been set for any of soybean, mustard or wheat/triticale
- There is insufficient scientific information to establish thresholds (MLs) that would be protective of health
- The surrogate for MLs is case by case risk assessments leading to a high incidence of investigations but few recalls

# Undeclared allergen recalls in Canada:

Reason	2012	2013	2014	2015	%
Mustard	5	15	15	7	6.8%
Soybean	3	1	7	6	2.8%
Wheat	2	5	15	9	5.1%
Gluten	3	1	1	2	1.1%
Other aller.	30	53	87	48	35.7%
Pathogens	76	44	69	63	41.2%
All recalls	128	126	203	154	611

# USDA recalls federally inspected meat/ poultry products:

Reason	2012	2013	2014	2015	%
Undeclared allergen	29	25	43	58	39%
Pathogens	23	22	14	17	19%
All recalls	82	75	94	150	401

# USFDA food recalls, selected examples :

Reason	2012	2013	2014	2015	%
Undeclared allergen	6	10	16	8	46%
Pathogens	8	5	22	7	49%
Sample N	15	16	40	15	86

## Conflicting guidance on precautionary labelling (PL)

- Long-standing policy encourages use of PL when allergens might be unintentionally present
- Industry has been directed to use PL for wheat in other cereal grain products
- Industry has been directed to not use PL for soybean
- Industry is being discouraged from using PL for mustard

# FALCPA on adventitious presence

- **FALCPA's labeling requirements do not apply to** major food allergens that are unintentionally added to a food as the result of **cross-contact**. In the context of food allergens, "cross-contact " occurs when a residue or other trace amount of an allergenic food is unintentionally incorporated into another food that is not intended to contain that allergenic food. **Cross-contact may result from customary methods of growing and harvesting crops, as well as from the use of shared storage, transportation, or production equipment.**
- **FSMA?????**

# The concept of added vs. naturally occurring

- The Canada Food and Drugs Act of 1953 never contemplated adventitious presence of allergenic foods, including crop based priority allergens.

# Food and Drugs Act in 2014 – Section 4

4.(1) No person shall sell an article of food that

- (a) has in or upon it any poisonous or harmful substance;
- (b) is unfit for human consumption;
- (c) consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance;
- (d) is adulterated; or
- (e) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions



## Section 5

- 5. (1) No person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

## Sec. 402. [21 USC §342] Adulterated Food

A food shall be deemed to be adulterated— 1

- (a) Poisonous, insanitary, or deleterious ingredients.
- (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health;

# Food Safety Imperatives – allergens

CFIA has interpreted Section 4.1(a) to apply to any contaminant in any food, including allergens:

- whether naturally occurring or not, and
- whether the presence of the naturally occurring contaminant is preventable or removal is practically achievable

## Section 4.1(a) is intact:

- Section 4.1(a) still prohibits the sale of food that contains any level of poisonous or harmful substance.
- Exemptions could be made if maximum limits were in force, but
- Science-based maximum limits have not been established for wheat/triticale, mustard and soybeans.
- There is insufficient science to proceed.

# The way forward:

- More and better science about health risk and thresholds of concern
- Adoption of science-based action levels and maximum limits to reduce need for case by case risk assessments and recalls
- Possible incorporation of MLs by reference into Food and Drug Regulations and compositional standards where science permits, compliance is achievable and there is alignment with US guidance and practice

# Meanwhile:

## Whereas:

- AP of mustard in wheat and oats is somewhat likely and AP of canola in wheat and oats is very likely.
- Section 5 of the Food and Drugs Act applies to all products of grain milling
- **The milling industry will most likely expand use of precautionary labelling.**