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THE 2016 GLUTEN-FREE STAKEHOLDER UPDATE & PLANNING SESSION PRESENTED IN COOPERATION WITH:



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# GOVERNMENT UPDATE – CFIA

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Canadian Food Inspection Agency

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# CFIA MISSION & VISION

- The Canadian Food Inspection Agency (CFIA) is Canada's largest science-based regulatory agency: ~7000 employees, including inspectors, scientists, veterinarians, operational specialists, technical personnel, administrative professionals and many others.
- The CFIA is dedicated to safeguarding food, animal and plant resource bases, which enhances the health and well-being of Canada's people, environment, and economy.
- We develop legal requirements and deliver inspection and other services to:
  - Prevent and manage food safety risks
  - Protect plant resources from pests, diseases and invasive species
  - Prevent and manage animal diseases
  - Contribute to consumer protection
  - Contribute to market access for Canada's food, animals and plants
- Our vision is to excel as a science-based regulator, trusted and respected by Canadians and the international community.

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# ORGANIZATIONAL UPDATE - REALIGNMENT

Health Canada (HC) establishes policies and standards respecting consumer health, food safety and nutritional quality of food. The CFIA is tasked with enforcing the policies and legislation

## Policy and Programs Branch

- The CFIA's Policy and Programs Branch sets the non-safety food labelling policy and regulations

## Domestic Food Safety Systems and Meat Hygiene Directorate

### Food Import/Export and Consumer Protection Directorate

- Consumer Protection and Market Fairness Division
- Import and Export Division




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# ORGANIZATIONAL UPDATE - REALIGNMENT

## Operations Branch



The Inspectorate continues to conduct inspections and enforcement activities for food, animal and plant health inspection programs and their respective acts, regulations, and policies

Functions at national headquarters, area and regional levels realigned to ensure the branch is organized to carry out its roles and responsibilities and is prepared to deliver new regulations, inspection and enforcement work according to the new inspection model.

New Operational Guidance and Expertise groups for Food, Animal and Plant business lines, supports the Inspectorate and the AskCFIA initiative.

- We have 3 OGEs for Food: Food Processing  
Food Labelling, Composition and Claims  
Food Import & Export

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# ORGANIZATIONAL UPDATE - REALIGNMENT

## Science Branch

Science Branch provides expert scientific advice and guidance on the management and interpretation of complex scientific issues including:

- Early identification of emerging issues
- Risk assessment
- Disease modeling
- Surveillance activities
- Animal health and plant pest risk assessments
- Environmental risk assessments for plants with novel traits and new species



Network of 13 laboratories across Canada delivering laboratory services related to food safety, animal health and/or plant health.

Conducts research and technology development, regulatory and policy analysis and development

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# FDR AMENDMENTS FOR ENHANCED LABELLING OF ALLERGENS, GLUTEN SOURCES & SULPHITES

Amendments to the *Food and Drug Regulations* (FDR) for enhanced labelling of food allergens, gluten sources and added sulphites came into force on August 4, 2012.

## For most pre-packaged products:

**Added** priority food allergens and gluten must be declared by their prescribed source names and **added** sulphites when present at 10 ppm or more must be declared either:

- in the list of ingredients
- OR
- in the statement “Contains:...”

**\*\*** Any level of allergens detected in a food but not declared on the label is a food safety risk to allergic consumers **\*\***

A precautionary statement may be used to alert allergic consumers of the possible presence of allergens, gluten and sulphites through inadvertent means

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# "FOOD ALLERGEN", "SULPHITES" DEFINITIONS

**"Food Allergen"** means any protein from any of the following foods or any modified protein, including any protein fraction (e.g. hydrolyzed protein), that is derived from the following foods [B.01.010.1(1), FDR]:

- Almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios, walnuts
- Peanuts
- Sesame seeds
- Wheat or triticale
- Eggs
- Milk
- Soybeans
- Fish, crustaceans and shellfish
- Mustard seeds



**"Sulphites"** means one or more of the **food additives** listed in column I of item 21 of the table to paragraph B.01.010(3)(b), FDR

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# GLUTEN FREE DEFINITION & GF CLAIMS

FDR B.01.010.1(1) defines *gluten* as any gluten protein, modified protein or protein fractions from the grain of any of the following cereals or from the grain of a hybridized strain created from at least one of the following cereals: barley, oats, rye, triticale, wheat

**B.24.018** It is prohibited to label, package, sell or advertise a food in a manner likely to create an impression that it is a gluten-free food if the food **contains any gluten protein or modified gluten protein, including any gluten protein fraction**, referred to in the definition *gluten* in subsection B.01.010.1(1).

Division 24 covers **Foods for Special Dietary Use**, which are *specially processed or formulated* to meet the particular requirements of a person

(a) in whom a physical or physiological condition exists as a result of a disease, disorder or injury, or  
(b) for whom a particular effect, including but not limited to weight loss, is to be obtained by a controlled intake of foods

[Health Canada's Position on Gluten Free Claims](#) (2012) is that gluten levels not exceeding 20 ppm as a result of cross-contamination, when GMPs are followed, would meet the safety intent of the FDR when a gluten free claim is made.

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# INSPECTIONS / AUDITS / ASSESSMENTS

Could be based on any of the following:



- National workplans for the fiscal year, which may include projects focussed on allergens, allergen controls and labelling; e.g. IMFP's Grain Based Foods
- Regular inspections
- Food Safety Action Plan (FSAP) sampling, targeted surveys
- Triggers such as:
  - consumer complaints
  - trade complaints
  - referrals from other government departments e.g. HC, PHAC, provinces
  - referrals from industry associations



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# FOOD SAFETY ACTION PLAN (FSAP)

The Food Safety Action Plan (FSAP) aims to modernize and enhance Canada's food safety system.

The goal of FSAP is to:

- identify risks in the food supply
- limit the possibility that these risks occur
- improve import and domestic food controls
- identify food importers and manufacturers.

FSAP also looks to verify that the food industry is actively applying preventative measures.

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# FSAP & TARGETED SURVEYS

As part of the FSAP enhanced surveillance initiative, targeted surveys:

- are used to analyze various foods for specific hazards
- complement regular monitoring programs and inspection activities
- largely directed towards the 70% of domestic and imported foods that are covered exclusively by the *Food and Drugs Act*; generally referred to as *non-federally registered commodities*
- gather baseline data for risk mapping, to assess and prioritize potential food safety issues

Samples may be directed, or taken at the inspector's discretion to verify inspection observations

Surveys have samples analyzed throughout the year, data analysis is completed and a report is published on CFIA website

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# FSAP SURVEYS FOR UNDECLARED GLUTEN

Targeted surveys focussing on the presence of undeclared allergens and/or gluten began in 2009. Examples:

- Undeclared Allergens in Baby Food 0-12 months
- Gluten in Spices
- Undeclared Allergens in Flavour Packets
- Undeclared Allergens in Imported Sauces
- Undeclared Allergens in Children's Food
- Undeclared Allergens in Protein Substitutes
- Undeclared Allergens in Snack Foods with Free Claims
- Undeclared Allergens and Gluten in Domestic and Imported Products
- Undeclared Allergens and Gluten in Soup
- Undeclared Allergens and Gluten in Infant Cereals

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# FSAP SURVEY: UNDECLARED ALLERGENS AND GLUTEN IN DOMESTIC AND IMPORTED PRODUCTS

Targeted survey conducted in 2012-2013 to gather information on the levels and prevalence of undeclared allergens and/or gluten in domestic and imported prepackaged food products.

Main objectives of this targeted survey were to:

- obtain baseline information regarding the presence and levels of undeclared priority allergens and gluten in domestic and imported prepackaged products.
- identify potential food safety concerns relating to undeclared allergens and gluten in domestic and imported prepackaged products.

This survey targeted domestic and imported prepackaged products such as desserts, snacks, RTE meals, spices and flavour packets available in the Canadian marketplace in 2012-2013. Samples were collected from major retail stores and smaller speciality retailers across Canada. No specific brands were targeted.

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# FSAP SURVEY: UNDECLARED ALLERGENS AND GLUTEN IN DOMESTIC AND IMPORTED PRODUCTS

For this survey 594 domestic and 586 imported prepackaged products were sampled.

The majority were analysed for more than one undeclared allergen or gluten, including soy, egg, milk (beta-lactoglobulin and casein), peanuts, almonds, hazelnuts, sesame and gluten.

- **Domestic products:** 3705 analyses conducted, 23 products tested positive for one or more undeclared allergens → **3.9% unsatisfactory**
- **Imported products:** 3739 analyses conducted, 50 products tested positive for one or more undeclared allergens → **8.5% unsatisfactory**

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# FSAP SURVEY TABLE 1: POSITIVE SAMPLE DISTRIBUTION FOR EACH ALLERGEN AND GLUTEN

Analyte	Domestic		Imported	
	# tests	# positive (%)	# tests	# positive (%)
Almond	528	1 (0.19)	483	0 (0)
BLG	320	1 (0.31)	330	4 (1.2)
Casein	320	5 (1.6)	332	2 (0.60)
Egg	461	1 (0.22)	484	1 (0.21)
<b>Gluten</b>	<b>181</b>	<b>7 (3.9)</b>	<b>239</b>	<b>22 (9.2)</b>
Hazelnut	535	0 (0)	494	0 (0)
Peanut	549	0 (0)	510	1 (0.20)
Sesame	566	1 (0.18)	551	3 (0.54)
Soy	245	10 (4.1)	316	20 (6.3)
Total	3705	26* (0.70)	3739	53** (1.4)

\* There were 26 positive analyses on 23 samples as some samples contained multiple allergens

\*\* There were 53 positive analyses on 50 samples as some samples contained multiple allergens

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# FSAP SURVEY- RESULTS FOR GLUTEN

It is important to distinguish wheat allergy from gluten sensitivity and celiac disease. In this survey, samples were tested for undeclared gluten.

## Domestic samples

181 tested: 6 positive for gluten >20 ppm (39 - 120 ppm) → **3.3% unsatisfactory**  
1 positive for gluten, 8 ppm → investigative

## Imported samples:

239 tested: 15 positive for gluten >20 ppm (24 - 460 ppm) → **6.3% unsatisfactory**  
7 positive for gluten, ranging 9.2 - 18 ppm → investigative

Table 2 shows the product types that were positive for undeclared gluten and the results associated with those samples.

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# FSAP SURVEY: RESULTS FOR GLUTEN

**Table 2: Positive results of gluten analysis**

DOMESTIC SAMPLES		
Sample description	Sample type	Gluten (ppm)
Cereal	Maple and Brown Sugar Oatmeal	65
Ready to eat meal	Carrot and Orange Soup*	58
	Curry chicken with Rice	71
	Leek and Tomato Soup	47
	Pickled Sausage	120
	Flavour Packet - Dried	Montreal Style Chicken Spice Mix
	Organic Curry Culinary Mix	8

\* This sample also tested positive for soy

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# FSAP SURVEY: RESULTS FOR GLUTEN

**Table 2: Positive results of gluten analysis (continued)**

IMPORTED SAMPLES				
Sample description	Sample type	Gluten (ppm)	Sample type	Gluten (ppm)
Flavour Packet - Dried	Beef Spice*	27	Poultry Seasoning	26
	Chinese Special Spice	13	Poultry Seasoning	45
	Chow Mein Seasoning Mix	25	Spice Mix for Bombay Biryani	24
	Chunky Chat Masala**	9.2	Spice Mix for Chicken with Vegetables	18
	Gravy Mix	75	Spice Mix for Delhi Nihari	15
	Louisiana Cajun seasoning	57	Spice Mix for Murgh Cholay	57
	Naturally Flavoured Brown Gravy Mix	17	Spice Mix for Shahi Daal	10
	Oriental Gravy Mix	91	Spice Mix for Punjabi Chana	17
	Palabok Oriental Gravy	50	Steak seasoning rub	40
	Palabok Oriental Gravy Mix	97	Sweet & Sticky Chicken Seasoning	460
	Poultry Seasoning	25	Texan steakhouse seasoning	270
* This sample also tested positive for soy			Sweet & Sticky Chicken Seasoning	460
** This sample also tested positive for peanut				

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# OTHER TARGETED SURVEYS FOR GLUTEN

## 2012-2013 Undeclared allergens and gluten in soup:



A total of 499 soup products sampled and analysed for undeclared soy, egg, milk (beta-lactoglobulin and casein), peanuts, almonds, hazelnuts, sesame and gluten. The majority were tested for more than one undeclared allergen or gluten

There were 3411 analyses completed; 22 products contained 26 positive results:

- 8 milk (7 products positive: 3 casein, 3 beta-lactoglobulin, 1 product tested positive for both)
- 4 egg
- **6 gluten**
- 1 hazelnut
- 7 soy



The majority of the positive results (23/26, 88%) were from dried soups and bouillons.

There were no undeclared almond, peanut or sesame found in any of the samples.

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# OTHER TARGETED SURVEYS FOR GLUTEN

2013-2014 [Undeclared soy and gluten in infant cereal:](#)

Objective was to obtain baseline information regarding the presence and levels of undeclared soy and gluten in prepackaged infant cereals, and to identify potential food safety concerns related to undeclared soy and gluten for the allergic and sensitive population

196 samples of prepackaged infant cereal were collected at retail (including single, mixed grain, and flavoured infant cereals):

- 98 samples analyzed for undeclared soy → no positives
- 98 samples for undeclared gluten → no positives

Follow-up actions were not deemed necessary given that none of the samples were positive for soy or gluten.

The CFIA will continue its surveillance activities and inform the Canadian public and other stakeholders of its findings.

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# FSAP SAMPLING FOR ALLERGENS IN 2016-17

Planned FSAP sampling for allergens in the 2016-17 fiscal year includes (no distinction between domestic & imported):

1. Gluten in gluten-free oat products: **300 samples**
2. Undeclared allergens & gluten in RTE meals: **500 samples**
3. Undeclared allergens & gluten in refrigerated dips & spreads: **400 samples**
4. Undeclared allergens & gluten in meal replacements & nutritional supplements: **300 samples**
5. Undeclared gluten & sesame in salty snacks & crackers: **500 samples**
6. Undeclared hazelnut & almond in milk alternatives: **400 samples**
7. Undeclared cashew, pecan & brazil-nut pilot study in various foods: **300 samples**

**Total: 2,700 samples**

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# FOLLOW UP ON SAMPLES

Regulated parties are responsible for complying with all relevant Agency Acts and regulations.

All positive sample results for allergens or gluten were followed up by the CFIA with the legal agent in Canada (e.g. manufacturer or importer).

Follow up action may involve additional sampling and testing, a food safety investigation, referral to the CFIA's Office of Food Safety & Recall, a health risk assessment conducted by HC's Food Directorate and a recall, determined on a case-by-case basis.

Non-compliance is handled in accordance with the CFIA's [Enforcement and Compliance Operational Policy](#).

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# CFIA ENFORCEMENT AND COMPLIANCE OPERATIONAL POLICY

The [Enforcement and Compliance Operational Policy](#) reflects CFIA's practices and protocols with respect to enforcing its legislation and improving compliance through enforcement activities, consistent with the Government of Canada's priorities.

The CFIA takes a risk-based approach to compliance management. Where compliance with the legislation administered and enforced by the CFIA is not achieved, there is a progression of tools in place to respond to non-compliance. With respect to labelling, examples include:

- Information letters,
- Commitment to correct
- Immediate correction; e.g. re-labelling, over stickering
- Letter of non-compliance, Warning letters
- Seizure / detention
- Recall
- Disposal, destruction
- Prosecution



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# MARKETING AUTHORIZATION FOR GLUTEN FREE OATS

May 19, 2015: Health Canada registered a Marketing Authorization (MA) that allows specially produced gluten-free oats, and foods made using gluten-free oats as ingredients, to be labelled as "Gluten Free", provided they meet all Conditions of MA:

- a. The food contains no oats other than specially produced "gluten-free oats";
- b. The finished product does not contain greater than 20 ppm of gluten from wheat, rye, barley or their hybridized strains;
- c. The food contains no intentionally added gluten from wheat, rye, barley, or their hybridized strains; and
- d. The "gluten-free oats" are clearly identified as such in all cases where 'oats' are referenced, including in the list of ingredients.

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# SPECIALLY PRODUCED GLUTEN FREE OATS

The MA does not specify *how* these oats arrive at this state of purity.

The regulated party must demonstrate they took measures to avoid contaminating their oats with gluten from barley, rye, triticale, wheat or from a hybridized strain of these cereals, and do not contain more than 20 ppm of gluten from these cereals

“Specially Produced” and/or “Specially Processed” may include, but is not limited to the following examples:

- pure seed sources
- dedicated growing fields (not adjacent to other cereal fields)
- dedicated harvesting, transportation, storage and processing equipment
- advanced sorting techniques and GMPs.

Future innovations in production and processing techniques may result in additional examples.

The inspector may gather the substantiating information, consult with CFIA and HC Specialists as appropriate, to determine on a case-by-case basis if a specific product meets the gluten-free criteria.

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# RESOURCES

Stay connected with the CFIA, sign up for our Listserv E-mail Notification Services: [www.inspection.gc.ca/stayconnected](http://www.inspection.gc.ca/stayconnected)

Follow us on social media:



## Food Labelling Enquiries

- **Food Labelling for Industry** (webpages): <http://inspection.gc.ca/food/labelling/food-labelling-for-industry/eng/1383607266489/1383607344939>
- **CFIA Regional Offices** (contact info): <http://inspection.gc.ca/about-the-cfia/offices/eng/1313255382836/1313256130232>
- **Ask CFIA:** [www.inspection.gc.ca/AskCFIA](http://www.inspection.gc.ca/AskCFIA) dairy, fresh fruit & vegetables, fish, other commodities coming soon

## Health Canada's Electronic Mailing Lists

Nutrition Bulletin <http://www.hc-sc.gc.ca/fn-an/nutrition/listserv-eng.php>

Food Additives e-notice <http://www.hc-sc.gc.ca/fn-an/securit/addit/enot-add-avis-eng.php>

Food Allergies e-notice [http://www.hc-sc.gc.ca/fn-an/securit/allerg/fa-aa/allergen\\_e-notice\\_avis-eng.php](http://www.hc-sc.gc.ca/fn-an/securit/allerg/fa-aa/allergen_e-notice_avis-eng.php)

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# Questions?



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