

# Communicating with Consumers: Regulations on Protein Claims and Ingredients

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- (i) Compare and contrast the requirements for the approval of a novel protein ingredient in the United States (U.S.) and Canada.
- (ii) Discuss safety considerations that are unique to protein.
- (iii) Compare and contrast regulations in the U.S., Canada, the European Union (EU), and Mexico pertaining to nutrition and health claims.

- Replace proteins that are allergenic.
- Provide more options for foods that are gluten-free.
- Increase options for vegan diets.
- Satisfy consumer demands for more natural food additives.
- Provide consumers with “healthier” food options.

# The Regulation of Novel Proteins in the U.S. and Canada



- A food additive is defined as *“any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food ... (21 USC § 321 FFDCA).*
- Exclusion from the definition of a food additive, and the corresponding requirements for premarket authorization, is afforded to a substance that is *“generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use” (21 USC § 321 FFDCA).*

- Introduction of 'novel food' ingredients is typically conducted *via* the GRAS exemption procedure to avoid the costly delays associated with pre-market approval by FDA as a food additive
- Determination of GRAS status in the U.S. is unique in the global world of food regulations
- Evaluations are completed by the manufacturer (self-GRAS)
- A determination that the use of a food ingredient is GRAS can be conducted without formally petitioning the FDA
- FDA notification is voluntary
- It is the use and not the substance, per se, that is GRAS

- The GRAS status of a food substances is based on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food.
- Views are based on:
  - Scientific procedures; or
  - Experience based on common use in food (use prior to 1958)

- Scientific Procedure
  - GRAS status based on scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient (21 CFR 170.30)
  - Pivotal data must be generally available to the scientific community
  
- Common Use in Food (prior to 1958)
  - Less scientific evidence is required
  - There must be evidence of substantial history of consumption of the substance by a significant number of consumers
  - Common use in food outside of the U.S.:  
2 independent sources must confirm history and circumstances of use

## Food Additives

- “Food additive” is defined as “any substance the use of which results, or may reasonably be expected to result, in it or its by-products becoming a part of or affecting the characteristics of a food, but does not include
  - (a) any nutritive material that is used, recognized, or commonly sold as an article or ingredient of food,
  - (b) vitamins, mineral nutrients and **amino acids**, other than those listed in the tables to Division 16
  - (c) spices, seasonings, flavouring preparations, essential oils, oleoresins and natural extractives

## Novel Foods

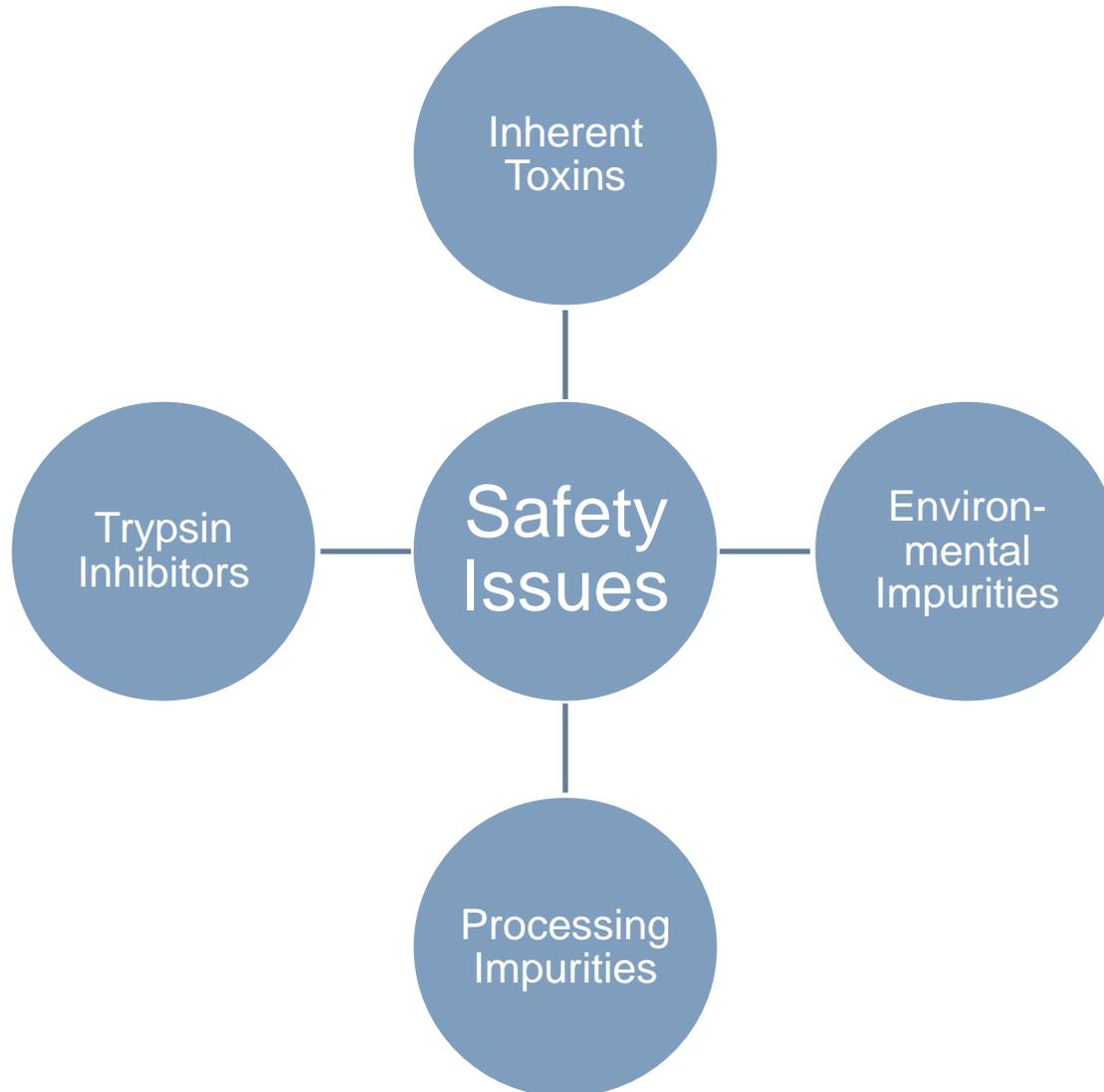
- (a) a substance, including a microorganism, that does not have a history of safe use as a food,
  - (b) a food that has been manufactured, prepared, preserved or packaged by a process that**
    - (i) has not been previously applied to that food, and**
    - (ii) causes the food to undergo a major change; and**
  - (c) a food that is derived from a plant, animal or microorganism that has been genetically modified ...
- 
- New protein coagulates/concentrates likely non-novel as such production methods have been commonly applied to protein
  - Selective isolation of trypsin inhibitors from plant protein using ion-exchange chromatography may be non-novel if the manufacturing method does not cause the protein to undergo a major change

## Novel Foods: Canada

- Pre-market notification process rather than pre-market approval process
  - Receive approval letter following technical approval
  - No requirement to promulgate law but based on positive list
- Time line much shorter than food additive e.g., 45 days with extensions of another 90 days
- Basis for approval is in public domain (available on internet)

# Safety Considerations Unique to Proteins





- Limits on naturally occurring toxins may need to be established.
- Glycoalkaloids ( $\alpha$ -solanine and  $\alpha$ -chaconine) represent a group of natural toxins specific to the *Solanaceae* family of plants (potatoes).
- Erucic acid is a natural toxin in canola.
- Soybean isoflavones may be undesirable in children at high levels.

# Safety Considerations – Environmental Impurities



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- Environmental toxins need to be considered for novel proteins derived from agricultural commodities (e.g., pesticides, heavy metals, polychlorinated biphenyls, dioxins, aflatoxins).
- Novel manufacturing/isolation methods may concentrate these undesirable substances.
- Protein isolates also may be rich in minerals and levels may be too high for nutritive uses at g levels in the diet (e.g., iron, zinc, aluminum).

- Lysinoalanine can be produced in proteins that are subjected to prolonged exposure to high temperatures and or alkali conditions.
- Acrylamide can be produced under conditions where proteins rich in asparagine are heated in the presence of reducing sugars.
- 3-Monochloropropanol may be produced when protein containing ingredients are processed for prolonged periods at acidic conditions and high temperatures

- Trypsin inhibitors are common constituents of many natural protein sources and can be present in significant quantities in plant derived protein isolates
  - Potatoes contain active trypsin inhibitors that inhibit all major digestive endo- and exo-peptidases necessary for protein digestion.
  - Use of novel extraction processes for production of protein isolates may further concentrate trypsin inhibitors in the ingredient.
  - Trypsin inhibitors contain extensive di-sulfide bonding and therefore production of trypsin inhibitor free fractions can result in deficiencies in cysteine and methionine
- Most food applications are subjected to thermal processing that denatures trypsin inhibitors; but, some trypsin inhibitors are thermostable.
- Adverse effects of trypsin inhibitors present in soy based infant formula in animals are not relevant to humans.

- Case-by-case
- In general toxicology studies of macronutrients do not provide meaningful information for a safety assessment
  - Potential effects of residual impurities/unknown substances will likely be at insufficient levels to be detected in rodent toxicity studies
  - Trypsin inhibitors are common constituents of many novel plant based novel proteins (*i.e.*, potato, canola, soy)
  - Trypsin inhibitors produce species-specific toxic effects in rodents (pancreatic hyperplasia) that lead to secondary effects on weight gain and overall poor health
- Short-term studies in pig models or well-designed clinical trials in humans may provide more meaningful and useful data on tolerance and nutritional value of a novel protein

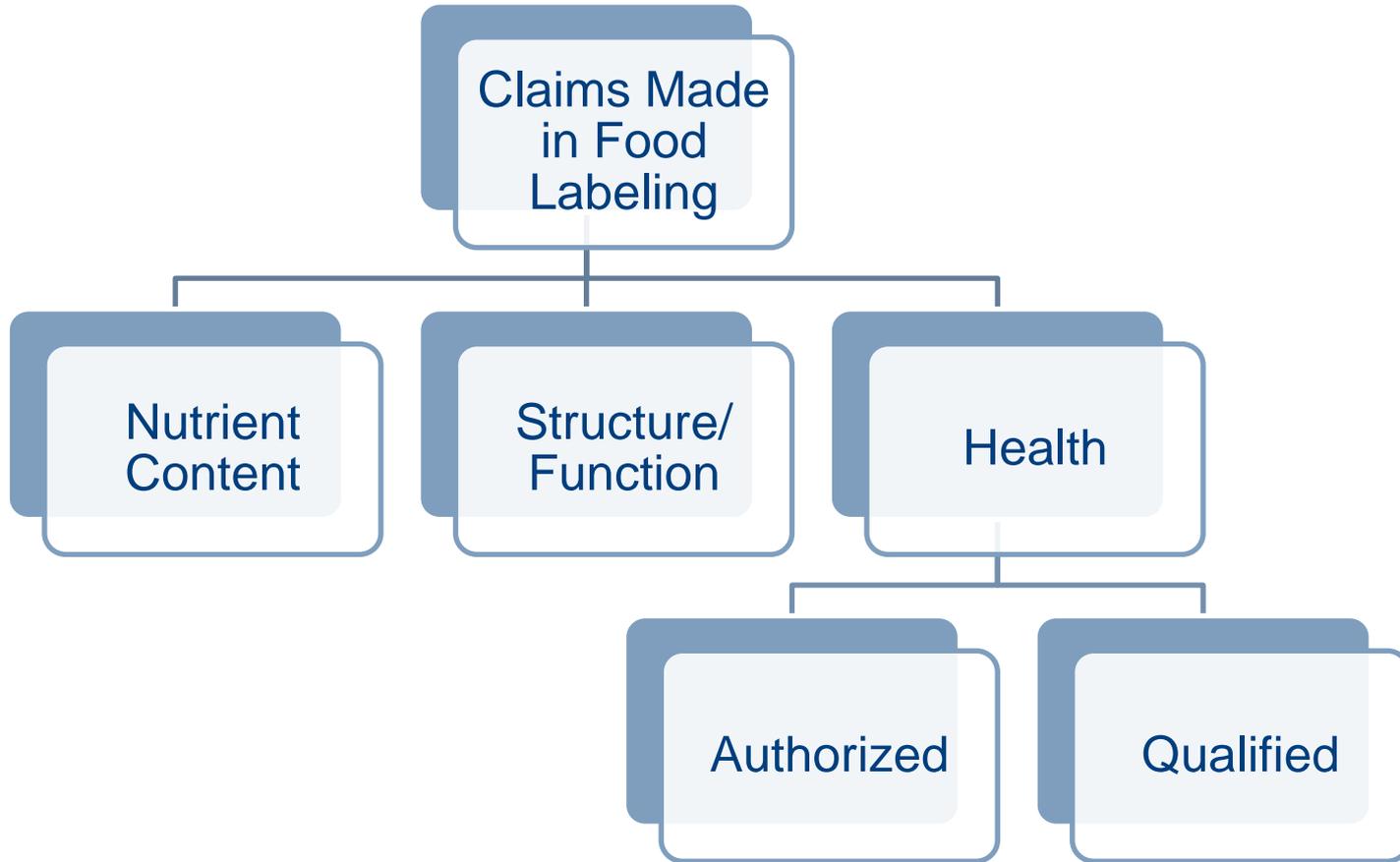
# Claims for Protein in the U.S., Canada, Mexico, and the EU



# Claims Permissible in the Labeling of Foods in the U.S.



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# Claims Permissible in the Labeling of Foods in the U.S.



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Claim	Description	
Nutrient Content (21 CFR 101.13)	<ul style="list-style-type: none"> <li>- Characterizes the level of a nutrient in the food.</li> <li>- A disclosure statement is required if a nutrient content claim is made <u>and</u> when a nutrient in that food exceeds certain prescribed levels.</li> </ul>	
Structure/Function [21 CFR 101.93(g)]	<ul style="list-style-type: none"> <li>- Describes the effect that a substance has on the structure or function of the body; reference to the diagnosis, cure, mitigation, or treatment of <u>disease</u> cannot be made.</li> <li>- Use in the labeling of a dietary supplement requires a <u>disclaimer</u>.</li> <li>- For foods, claims must be based on "<u>nutritive value</u>".</li> </ul>	
Health	Authorized (NLEA, 1990; FDAMA 1997)	<ul style="list-style-type: none"> <li>- Characterizes the relationship of any substance to a disease or health-related condition.</li> <li>- Must meet the significant scientific agreement (SSA) standard.</li> </ul>
	Qualified (2003 Consumer Health Information for Better Nutrition Initiative)	<ul style="list-style-type: none"> <li>- Characterizes the relationship of any substance to a disease or health-related condition.</li> <li>- Based on credible scientific evidence.</li> <li>- Qualifying language is used to convey to the consumer the level of evidence in support of the claim.</li> </ul>

# Examples of Claims that can be Made for Protein in the U.S.



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Claim		Examples Specific to Protein
Nutrient Content (21 CFR 101.13)		<ul style="list-style-type: none"> <li>- High, rich in, or excellent source of protein.</li> <li>- Good source of, contains, or provides protein.</li> <li>- More, fortified, enriched, added, extra, or plus protein.</li> </ul>
Structure/Function [21 CFR 101.93(g)]		<ul style="list-style-type: none"> <li>- e.g., Protein contributes to the maintenance of muscle mass.</li> </ul>
Health	Authorized (NLEA, 1990; FDAMA 1997)	<ul style="list-style-type: none"> <li>- For protein, there is only 1 authorized health claim.</li> <li>- "25 grams of <b>soy protein</b> a day, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies ___ grams of soy protein."</li> </ul>
	Qualified (2003 Consumer Health Information for Better Nutrition Initiative)	<ul style="list-style-type: none"> <li>- For protein, there is only 1 qualified health claim.</li> <li>- "For healthy infants who are not exclusively breastfed and who have a family history of allergy, feeding a <b>100% Whey-Protein Partially Hydrolyzed infant formula</b> from birth up to 4 months of age instead of a formula containing intact cow's milk proteins may reduce the risk of developing atopic dermatitis throughout the 1st year of life. FDA has concluded that the relationship between 100% Whey-Protein Partially Hydrolyzed infant formulas and the reduced risk of atopic dermatitis is uncertain, because there is little scientific evidence for the relationship."</li> </ul>

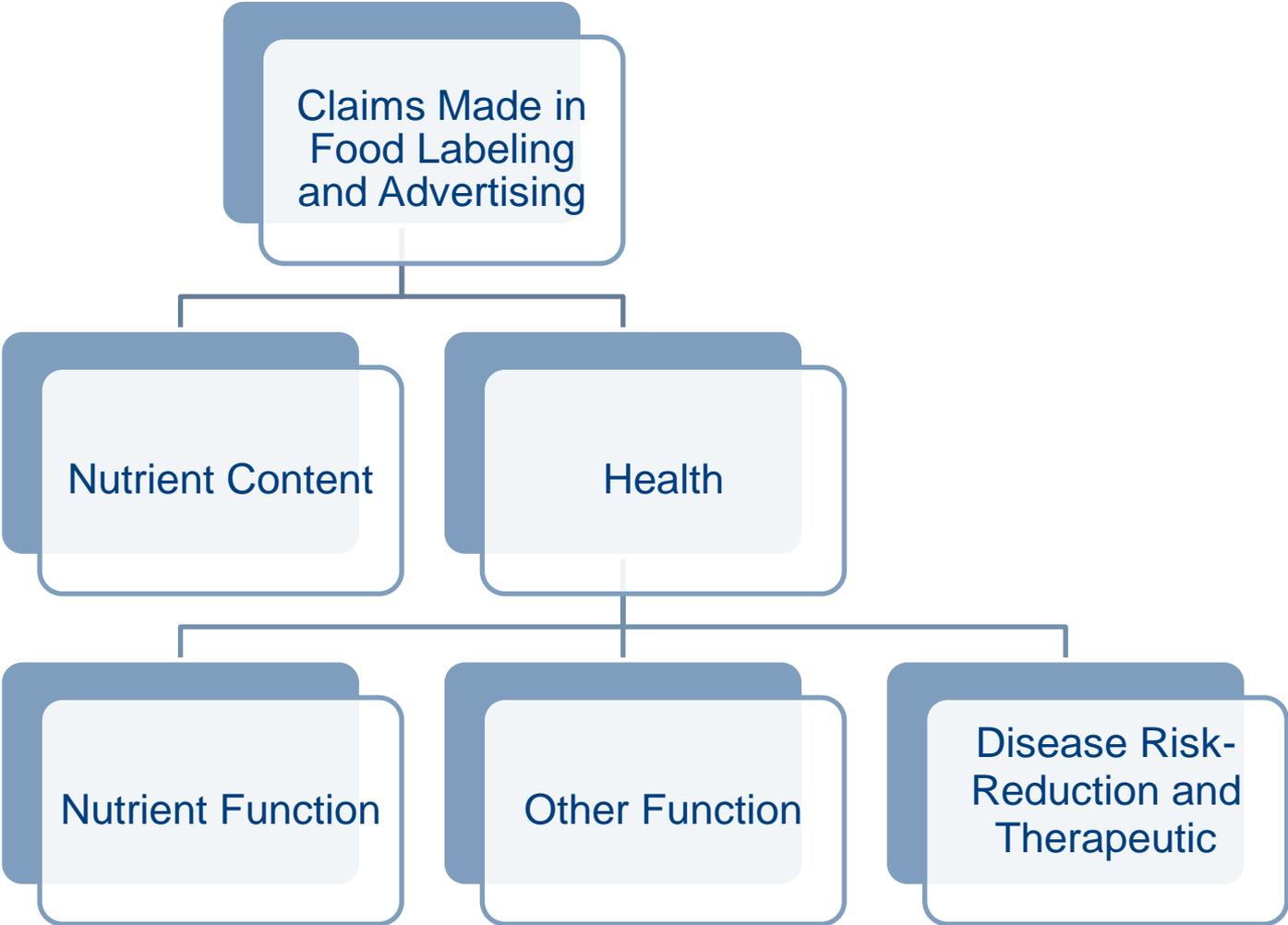
Claim	Conditions for Use of the Claim
High, rich in, or excellent source of protein.	The food contains 20% or more of the Daily Reference Value (DRV) for protein per reference amount customarily consumed (RACC).
Good source of, contains, or provides protein.	The food contains 10 to 19% of the DRV per RACC.
More, fortified, enriched, added, extra, or plus protein.	The food contains at least 10% more of the DRV for protein per RACC than an appropriate reference food.

# Nutrient Content Claims for Protein in the U.S. [21 CFR 101.9(c)(7)]



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- In the Nutrition Facts label, the level of protein per RACC is determined by multiplying the nitrogen content by 6.25.
- The calculation of the percent DV and the use of protein nutrient content claims requires the consideration of:
  - The amount of protein in the food per RACC;
  - The protein digestibility corrected amino acid score (PDCAAS);  
and
  - The Daily Reference Value for protein, which is 50 g for those 4 years of age and older.
- $\%DRV = [\text{Protein per RACC (grams)} \times \text{PDCAAS}] / \text{Daily Value for Protein (grams)} \times 100\%$



# Claims that can be Made in the Labeling and Advertising of Foods in Canada



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Claim	Description
Nutrient Content	- Statements or expressions which describe, directly or indirectly, the level of a <u>nutrient</u> or energy in a food or a group of foods.
Nutrient Function	- Describes the well-established roles of energy or nutrients that are essential for the maintenance of good health or for normal growth and development.
Other Function	- Describe the effects that a food has on the normal functions of the body.
Disease Risk-Reduction and Therapeutic	- Claims that refer to the treatment or mitigation of a disease or health-related condition, or about restoring, correcting or modifying body functions.

Acute alcoholism  
Acute anxiety state  
Acute infectious respiratory syndromes  
Acute, inflammatory and debilitating arthritis  
Acute psychotic conditions  
Addiction (except nicotine addiction)  
Appendicitis  
Arteriosclerosis  
Asthma  
Cancer  
Congestive heart failure  
Convulsions  
Dementia  
Depression  
Diabetes  
Gangrene

Glaucoma  
Haematologic bleeding disorders  
Hepatitis  
Hypertension  
Nausea and vomiting of pregnancy  
Obesity  
Rheumatic fever  
Septicemia  
Sexually transmitted diseases  
Strangulated hernia  
Thrombotic and Embolic disorders  
Thyroid disease  
Ulcer of the gastro-intestinal tract

Claim	Examples Specific to Protein
Nutrient Content	<ul style="list-style-type: none"> <li>- Low in protein.</li> <li>- Source of protein.</li> <li>- Excellent source of protein.</li> <li>- More protein.</li> </ul>
Nutrient Function	<ul style="list-style-type: none"> <li>- Food must be at least a source of protein:                             <ul style="list-style-type: none"> <li>- Protein helps build and repair body tissues.</li> <li>- Protein helps build antibodies.</li> <li>- Protein helps build strong muscles.</li> </ul> </li> <li>- Other <u>nutrient function</u> claims also are permitted.</li> </ul>
Other Function	<ul style="list-style-type: none"> <li>- None specific to protein have been endorsed by Health Canada.</li> <li>- Possibilities exist if claims can be scientifically substantiated (e.g., satiety, physical performance, body weight/composition, sarcopenia)</li> </ul>
Disease Risk-Reduction and Therapeutic	<ul style="list-style-type: none"> <li>- None specific to protein have been authorized by Health Canada.</li> <li>- Possibilities exist if claims can be scientifically substantiated (e.g., reduced risk of certain diseases, treatment of obesity)</li> </ul>

- Nutrient content claims for specific amino acids (e.g., high in leucine) are not permitted in the labeling or advertising of foods in Canada.
- Quantitative declarations outside of the Nutrition Facts table are permitted, so long as:
  - The food meets the conditions for a "source of protein" claim;
  - The declaration relates to the amount of the following essential amino acids present in the food: histidine, isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan and valine, expressed in grams per serving of stated size;
  - The declaration is not in the Nutrition Facts table; and
  - The declaration is presented in both English and French unless otherwise exempted.

# Nutrient Content Claims for Protein in Canada



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Claim	Conditions for use of the Claim
Low in protein	The food contains no more than 1 g of protein per 100 g of the food.
Source of protein	The food has a protein rating of 20 or more: (a) Per RDI; or (b) Per 30 g of breakfast cereal combined with 125 mL of milk.
Excellent source of protein	The food has a protein rating of 40 or more: (a) Per RDI; or (b) Per 30 g of breakfast cereal combined with 125 mL of milk.
More protein	The food: (a) Has a protein rating of: i. 20 or more per RDI; or ii. Per 30 g of breakfast cereal combined with 125 mL of milk. (b) Contains at least 25% more protein, totalling at least 7 g more, per RDI than a reference food of the same food group or a similar reference food

**RDI = Reasonable Daily Intake (Schedule K)**

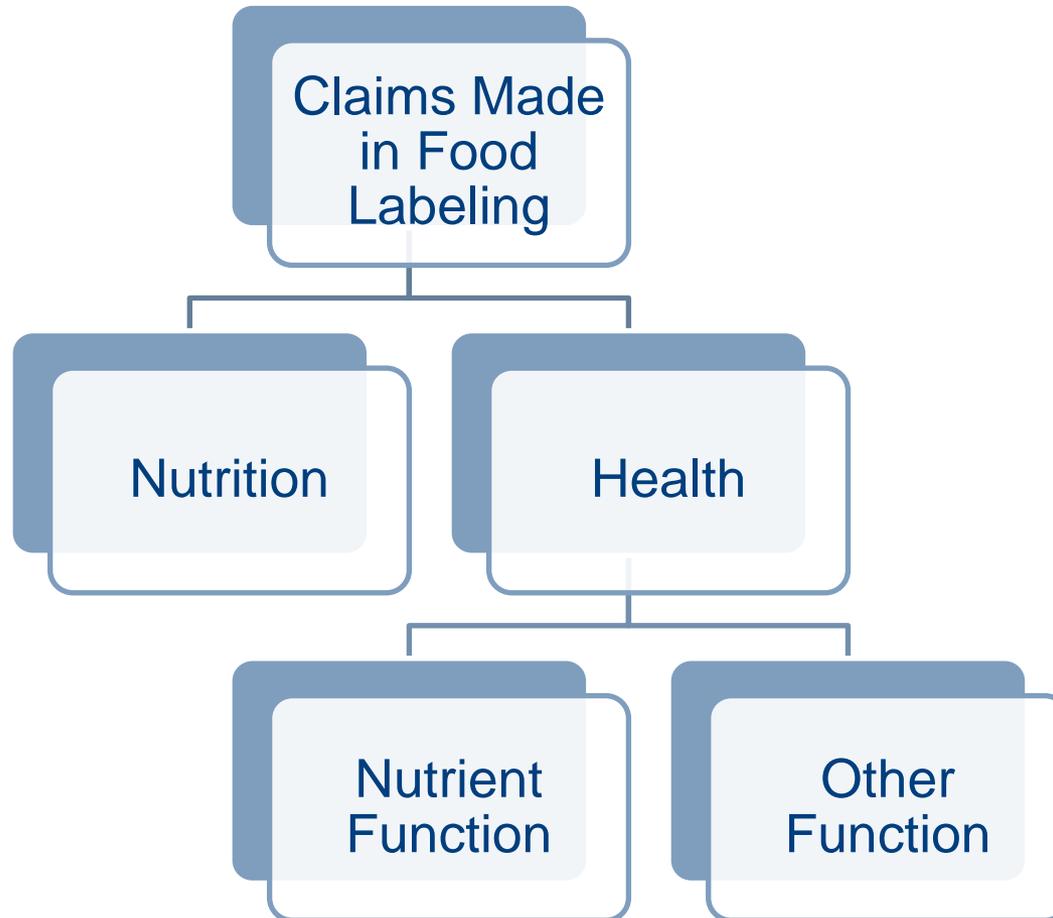
**Protein Rating, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981.**

- In the Nutrition Facts table, the level of protein is determined using the Dumas method, which yields results similar to the Kjeldahl method used in the U.S.
- In order to make protein nutrient content claims, the Protein Rating must be considered.
- Protein Rating = Protein in a RDI x Protein Efficiency Ratio (PER)
- RDIs are listed in Schedule K of the Food and Drug Regulations
- Established PERs are listed for approximately 50 items in the Canadian Food Inspection Agency Guide to Food Labelling and Advertising
  - PERs range from 0 for gelatin or hydrolyzed collagen to 3.1 for whole egg.
- If the PER is not known, Health Canada recommends that the PER be determined using the official method for determining the PER (*i.e.*, Method FO-1, October 15, 1981).
- Another method can be used to determine protein quality in relation to casein, such as the PDCAAS; however, Method FO-1 would be used for verification.

# Claims Permissible in the Labeling of Foods in the Mexico\*



Valued Quality. Delivered.



\* As per the Mexican Official Standard (*Norma Oficial Mexicana*) NOM-051-SCFI/SSAI-2010.

# Claims Permissible in the Labeling and Advertising of Foods in Mexico\*



Valued Quality. Delivered.

Claim		Description
Nutrition		- Describes the level of a nutrient contained in a food.
Health	Nutrient Function	- Describes the physiological role of the nutrient in growth, development and normal functions of the body.
	Other Function	- Describe specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet, on normal functions or biological activities of the body.

\* As per the Mexican Official Standard (*Norma Oficial Mexicana*) NOM-051-SCFI/SSAI-2010.

# Examples of Claims that can be Made for Protein in Mexico\*



Valued Quality. Delivered.

Claim		Examples Specific to Protein	Conditions for Use of the Claim
Nutrition		- Source of protein	- 10% of RDI/100 g (solids); 5% of RDI/100 mL (liquid); 5% of RDI/100 kcal
		- High, good source, rich in protein	- 2 times the value for “source of protein”
Health	Function	- Proteins are necessary for normal growth and bone development in children, when combined with eating a proper diet and healthy lifestyle.	- Food should be at least a source of protein.

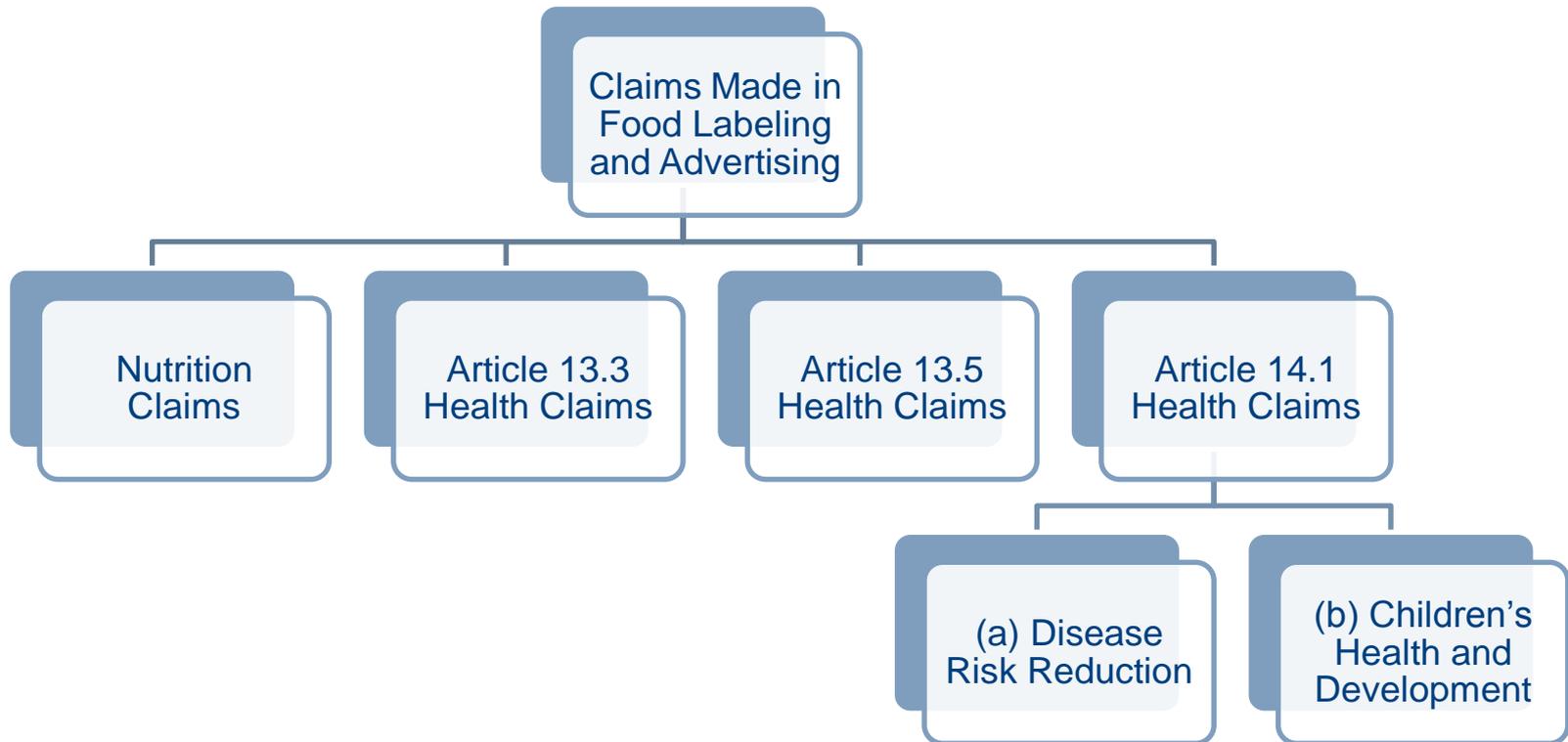
\*Based on a DRAFT version of NOM-086-SSA1-2011, which includes a more comprehensive list of content claim standards.

- According to NOM-051-SCFI/SSA1-2010, the protein content of a food is calculated by multiplying the total nitrogen content (kjeldahl) by 6.25.
- Thus far, there are no regulations relevant to the determination of the quality of the protein.

# Claims Permissible in the Labeling and Advertising of Foods in the EU



Valued Quality. Delivered.



# Claims Permissible in the Labeling and Advertising of Foods in the EU [Regulation (EC) No 1924/2006]



Valued Quality. Delivered.

Claim	Description
Nutrition Claim	Any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to: <ul style="list-style-type: none"> <li>a) the energy (calorific value) it                             <ul style="list-style-type: none"> <li>i) provides;</li> <li>ii) provides at a reduced or increased rate; or</li> <li>iii) does not provide; and/or</li> </ul> </li> <li>b) the nutrients or other substances it                             <ul style="list-style-type: none"> <li>i) contains;</li> <li>ii) contains in reduced or increased proportions; or</li> <li>iii) does not contain.</li> </ul> </li> </ul>
Article 13.3*	Describe the role of a nutrient or other substance in: <ul style="list-style-type: none"> <li>(a) growth, development, and the functions of the body;</li> <li>(b) psychological/ behavioural functions; or</li> <li>(c) slimming or weight control</li> </ul>
Article 13.5*	Based on emerging science and/or include a request for the protection of proprietary data
Article 14.1(a)*	Disease risk-reduction claims
Article 14.1(b)*	Claims related to children's health and development

\* A health claim is any claim that states, suggests or implies that a relationship exists between a food category, a food, or one of its constituents and health.

# Authorized Claims for Protein in the EU\*



Valued Quality. Delivered.

Claim Type	Claim	Condition for Use of the Claim
Nutrition Claims	Source of protein	≥12% of the energy value of the food is provided by protein
	High in protein	≥20% of the energy value of the food is provided by protein
	Increased protein	Food is at least a source of protein, and the increase in protein is ≥30% compared to a similar food.
	Reduced protein	Protein content of the food is reduced by ≥30% compared to a similar food.
Article 13.3 Health Claims	Protein contributes to a growth in muscle mass	Used only for food which is at least a <b>source of protein</b> [as per the Annex to Regulation (EC) No 1924/2006].
	Protein contributes to the maintenance of muscle mass	
	Protein contributes to the maintenance of normal bones	
Article 14.1(b) Health Claim	Protein is needed for normal growth and development of bone in children	

\* As of April 3, 2014.

# Non-authorized Article 13.3 Health Claims Related to Protein in the EU\*



Valued Quality. Delivered.

Food Constituent	Claimed Effect
Whey protein	<ul style="list-style-type: none"><li>• Increase in <b>satiety</b> leading to a reduction in energy intake</li><li>• Increase in <b>lean body mass</b> during energy restriction and resistance training</li><li>• Reduction of <b>body fat mass</b> during energy restriction and resistance training</li><li>• Increase in <b>muscle strength</b></li><li>• Increase in <b>endurance capacity</b> during the subsequent exercise bout after strenuous exercise</li><li>• Skeletal muscle tissue repair</li><li>• Enhances mood and mental well-being</li><li>• Helps athletes maintain a healthy immune system by increasing the levels of glutathione in the body</li><li>• Improves cognitive performance</li></ul>
<b>Whey protein/whey protein isolate</b>	<ul style="list-style-type: none"><li>• <b>Growth or maintenance of muscle mass</b></li></ul>
Whey protein/whey protein hydrolysate	<ul style="list-style-type: none"><li>• Faster recovery from muscle fatigue after exercise</li></ul>
Whey protein peptides	<ul style="list-style-type: none"><li>• Helps maintain a healthy vascular system</li></ul>
<b>Whey protein milk mineral complex</b>	<ul style="list-style-type: none"><li>• <b>Contribution to the maintenance or achievement of normal body weight</b></li></ul>

# Non-authorized Article 13.3 Health Claims Related to Protein in the EU (cont'd)\*



Valued Quality. Delivered.

Food Constituent	Claimed Effect
<b>Casein protein hydrolysates</b>	<ul style="list-style-type: none"><li>•Growth or maintenance of muscle mass</li><li>•Increase in endurance performance</li><li>•Faster recovery from muscle fatigue after exercise</li></ul>
Dairy products (low fat dairy), refers to cow's milk, yogurt and cheese	<ul style="list-style-type: none"><li>•Weight management</li><li>•Maintenance of tooth mineralisation</li></ul>
<b>Fish protein</b>	<ul style="list-style-type: none"><li>•Skin, hair, and nail health</li></ul>
Lactium milk protein hydrolysate	<ul style="list-style-type: none"><li>•Alleviation of psychological stress</li></ul>
Protein hydrolysate	<ul style="list-style-type: none"><li>•Insulin secretion and blood sugar levels</li></ul>
Raw or processed food products of animal origin, plus bread and panification products	<ul style="list-style-type: none"><li>•Maintenance of blood cholesterol concentrations</li><li>•Blood glucose control</li></ul>
Soy protein	<ul style="list-style-type: none"><li>•Protection of DNA, proteins and lipids from oxidative damage</li><li>•Maintenance of normal blood cholesterol concentrations</li><li>•Maintenance or achievement of normal body weight</li></ul>
Special hydrolysed milk proteins	<ul style="list-style-type: none"><li>•Maintenance of normal blood pressure</li></ul>

\* As of April 3, 2014.

# Non-authorized Article 13.5 and 14 Health Claims Related to Protein in the EU\*



Valued Quality. Delivered.

Claim Type	Food Constituent	Claimed Effect
Art. 13.5	Milk product, rich in fibre and protein	Reduces the sense of <b>hunger</b>
Art. 14.1(a)	<b>Soy protein</b>	Has been shown to lower/reduce blood cholesterol; blood cholesterol lowering may reduce the risk of (coronary) <b>heart disease</b>
Art. 14.1(a)	Lycopene-whey complex	Prevents oxidative damage of plasma lipoproteins, which reduces the build up of arterial plaques and reduces the risk of heart disease, stroke and other clinical complications of atherosclerosis

\* As of April 3, 2014.

# Claims – Similarities Across Jurisdictions



Valued Quality. Delivered.

	U.S.	Canada	Mexico	EU
Claims Required to be Truthful and Not Misleading	✓	✓	✓	✓
Nutrition Claims	✓	✓	✓	✓
Nutrient Function Claims	✓	✓	✓	✓

# Claims – Differences Across Jurisdictions

	U.S.	Canada	Mexico	EU
Scope	Labeling	Labeling & advertising	Labeling & advertising	Labeling & advertising
Other Function Claims	x	✓	✓	✓
Function Claims Considered Health Claims	x	✓	✓	✓
Disease Risk-Reduction Claims	✓	✓	x	✓
Therapeutic Claims	x	✓	x	x
Claim Category Specific to Children	x	x	x	✓
Pre-market Review and Authorisation of <b><u>ALL</u></b> Claims	x	x	x	✓
Potential for Claim Exclusivity	x	x	x	✓
Qualified Health Claims	✓	x	x	x
Consideration of Protein Quality in Nutrition Claims	✓	✓	x	x

- Opportunities are abound for the development of new proteins that are non-allergenic, gluten-free, and of high nutritional quality.
- In several key markets globally, there are mechanisms to communicate the health benefits of protein.

# Thank you!

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# Gluten-free Labeling



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Country/ Codex	Conditions in which gluten must be declared on the food label	Claim	Requirements for claim	Regulation(s)
U.S.	Voluntary. However, foods containing wheat must declare “wheat” as an ingredient.	“Gluten-free”	Less than 20 ppm gluten.	<ul style="list-style-type: none"> <li>•FALCPA</li> <li>•FDA Final Rule 78 FR 47154 (2013)</li> </ul>
Canada	Mandatory. Foods containing a potential source of gluten (wheat, barley, oats, rye, etc.) must be labeled on the list of ingredients or with a “contains” statement with the source of gluten. Requirements do not apply to gluten resulting from cross-contamination.	“Gluten-free”	Less than 20 ppm gluten. Products are regulated under “foods for special dietary use”.	Sections B.01.010.1 and B.24.018 of the Food and Drug Regulations
EU	Mandatory. Ingredients causing allergies or intolerances, including gluten, that are still present in the finished product must be labeled.	“Gluten-free”	20 ppm gluten or less.	<ul style="list-style-type: none"> <li>•Consumers Regulation (EU) No. 1169/2011</li> <li>•Commission Regulation 41/2009</li> </ul>
		“Very low gluten”	100 ppm gluten or less.	
Mexico	Mandatory. Cereals containing gluten, for example, wheat, rye, barley, oats, spelt or its hybrids and derived products.	“Gluten-free”, “does not contain gluten”, “zero gluten”, “0 gluten”	Not more than 0.05 g/100 g.	<ul style="list-style-type: none"> <li>•NOM-051-SCFI/SSA 1-2010</li> <li>•DRAFT NOM-086-SSA1-2011</li> </ul>

# Allergen Labeling in the U.S., Canada, and Mexico

Intertek

	U.S.	Canada	Mexico
Relevant Legislation	Food Allergen Labeling and Consumer Protection Act (FALCPA)	B.01.010.1 of the Food and Drug Regulations	Mexican Official Standard ( <i>Norma Oficial Mexicana</i> ) NOM-051-SCFI/SSAI-2010
Scope	Pre-packaged foods regulated under the Federal Food, Drug, and Cosmetic Act	Pre-packaged foods	Pre-packaged foods and non-alcoholic beverages
Effective Since	January 1, 2006	August 4, 2012	January 1, 2011
Allergens	<ul style="list-style-type: none"> <li>•Milk</li> <li>•Egg</li> <li>•Fish</li> <li>•Crustaceans</li> <li>•Shellfish</li> <li>•Tree nuts</li> <li>•Wheat</li> <li>•Peanuts</li> <li>•Soybeans</li> </ul>	<ul style="list-style-type: none"> <li>•Milk</li> <li>•Egg</li> <li>•Fish</li> <li>•Crustaceans</li> <li>•Shellfish</li> <li>•Tree nuts</li> <li>•Wheat or triticale</li> <li>•Peanuts</li> <li>•Soybeans</li> <li>•Sesame seeds</li> <li>•Mustard seeds</li> </ul>	<ul style="list-style-type: none"> <li>•Milk</li> <li>•Egg</li> <li>•Fish</li> <li>•Crustaceans</li> <li>•Tree nuts</li> <li>•Peanuts</li> <li>•Soybeans</li> </ul>

- Many protein ingredients are covered under 21 CFR 184.1553,:
  - Peptones are defined as “a variable mixture of polypeptides, oligopeptides, and amino acids that are produced by partial hydrolysis of casein, animal tissue, soy protein isolate, gelatin, defatted fatty tissue, egg albumin, or lactalbumin (whey protein)” (U.S. FDA, 2009).
  - Peptones are produced from these proteins using safe and suitable acids or heat to achieve denaturation or using proteolytic enzymes that either are considered to be Generally Recognized as Safe (GRAS) or are regulated as food additives.
  - Ingredients used in accordance with this regulation are permitted for use in food as a nutrient supplement, as processing aids, and as surface-active agents, with no limitation other than current good manufacturing practice.
  - If the specific food application of a “novel protein” is not permitted by an applicable U.S. regulation or other prior sanction, a GRAS determination is likely necessary