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An Outline of Food Packaging Regulations in Canada

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Global Food Contact

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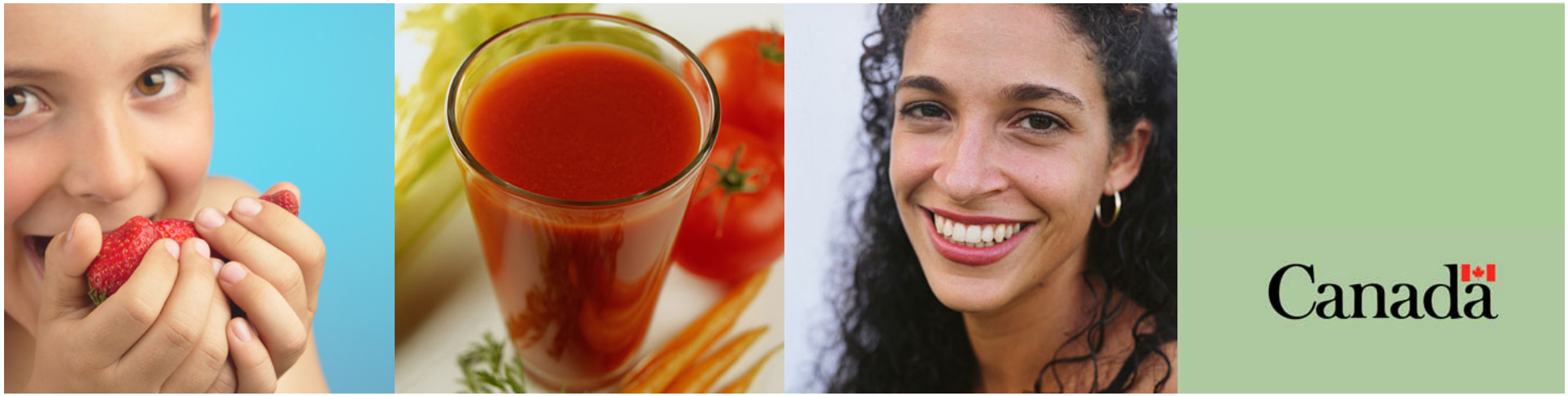

An Overview

- Canadian *Food and Drugs Act* and *Regulations*
- Pre-market process and the Submission Requirements in Canada and process to obtain a LONO
- A look to the future…




Health Canada's Food Directorate

Health Canada (HC)

Health Products and Food Branch (HPFB)

World Health Organization

WHO Collaborating Centre for food borne Viruses

WHO Collaborating Centre for Food Contamination Monitoring

World Health Organization

Food Directorate (FD)

Bureau of Microbial Hazards (BMH)

Bureau of Chemical Safety (BCS)

Bureau of Nutritional Sciences (BNS)

Pathogens : traditional and emerging, viruses in foods and BSE isues

Food additives, contaminants, and food contact chemicals: packaging materials, incidental additives

Nutrients, infant formula formulations, fats and oils, vitamins

Vancouver, BC | **Winnipeg, MB** | **Toronto, ON** | **Ottawa, ON** | **Montréal, QC**

Bureau of Food Surveillance and Science Integration(BFSSI)

Bureau of Policy, Regulatory and Governmental Affairs (BPRGA)

Office of Management Services and Planning (OMSP)




Food and Drugs Act and Regulations

Intended to protect Canadian consumers from health hazard and fraud in the sale and use of foods, drugs, cosmetics and medical devices.

Considered to be part of criminal law, and as such, falls within the authority of the federal government of Canada.

As the ***Food and Drugs Act*** is a federal law, violation of that regulation is a criminal offence.




Food and Drugs Act and Regulations

Section 4 (1) (a)

"No person shall sell an article of food that has in or on it any poisonous or harmful substance".




Food and Drugs Act and Regulations

Division 23: Food Packaging Materials

Section B.23.001

"No person shall sell any food in a package that may yield to its contents any substance that may be injurious to the health of a consumer of the food".




Food and Drugs Act and Regulations

Definition of a Food "Package" as stated in the Canadian *Food and Drugs Act.*

"Anything in which any food, drug, cosmetic or device is wholly or partly contained, placed or packed."

A package may be regarded as any article which comes in contact with food during processing, distribution and sale.




Food and Drugs Act and Regulations

Responsibility for Compliance:

The responsibility remains with the food seller (*i.e.* manufacturer, packager, distributor, *etc.*) to ensure that materials used in food contact applications are safe and are in compliance with Section B 23.001.




Food Directorate's Bureau of Chemical Safety

As a service to the industry, the **BCS**, upon request, conducts a safety evaluation of individual food packaging materials.

Acts as advisor to the Canadian Food Inspection Agency (**CFIA**) on the chemical safety of food packaging materials and their components.




Food Directorate's Bureau of Chemical Safety

- One of the groups tasked with administering specific portions of the *Food and Drug Act* and the *Food and Drug Regulations*

- Upon request, **BCS** conducts a **safety evaluation** of the food packaging materials on a case–by–case basis, taking into consideration the merits of each individual submission.

Canadian Food Inspection Agency (CFIA)

CFIA is Canada's federal agency responsible for inspection of food facilities and for enforcement of the food-related portions of the Canadian *Food and Drug Act and* the *Food and Drug Regulations*.

- In regard to food packaging materials, the **CFIA** calls upon the **BCS** for assistance in an advisory role.

CFIA website: www.inspection.gc.ca




Letter of No-Objection (LONO)

- The LONO's purpose is to communicate that Health Canada, based on a safety evaluation, has no objection to the use of subject products in food packaging applications for which they are intended.

- An **opinion** by BCS on the acceptability of a product in relation to Section B23.001.

- Does not constitute an approval and does not relieve food manufacturers of responsibilities under Division 23.




Duration of the Letter of No-Objection

- A letter of no-objection has no expiry date.
- It is considered valid as long as the chemical composition and intended use of the material remain as described in the original submission, and as long as the science continues to support the basis of the opinion.
- **BCS** reserves the right to challenge the equivalency determination made by the manufacturer/user upon receipt of the notification of the change.




Pre–market Process

- No statutory requirement for pre-market clearance of food packaging materials under the *Food and Drugs Act* and *Regulations*.

- Under the *Food and Drugs Regulations*, submissions to Health Canada are strictly voluntary from a legal standpoint




Confidentiality

Under Section 20 (1) (b) of the ***Access to Information Act***:

The information provided to Health Canada will be used in confidence for our evaluation purposes only, and will not be divulged to any third party, without express written consent of the person or company that originally provided the information.

http://laws.justice.gc.ca/en/A-1/FullText.html




Food Packaging Product Categories

- **Finished articles and formulated products:**
  - **Finished products**
    (*i.e.:* Laminate films, containers, *etc.*);
  - **Formulated products**
    (*i.e.:* Plastic resins, colour concentrates, *etc.*);
- **Single additives** (*i.e.:* antioxidants, pigments, *etc.*).




Information Requirements
(Formulated and Finished Products)

- Product identity
- Proposed Use




1. Product Identity
(Formulated and Finished Products)

- Trade name and grade;
- Type of structure;
- Composition
  - (Quantitative listing of all components, each one identified by its proper chemical name and/or trade name, grade, supplier and CAS number);
- Chemical/physical properties relevant to the proposed use




2. Proposed Usage
(Formulated and Finished Products)

- Form of finished package (*i.e.: film*, bottle);
- Dimensions of package (*i.e.:* thickness, volume);
- Types of food involved;
- Conditions (*i.e.:* time, temperature) to which the packaging material will be exposed during processing, distribution and use by the consumer;
- Packaging ratio (*i.e.* weight of food per unit area of packaging material).

Should the initial evaluation of a formulated or finished product reveal the presence of one or more new components, the safety of which has not been evaluated by BCS, the ingredients so identified will then fall into category of Single Additives.




Information Requirements

(Specific Constituents/Single Additives)

- Product identity
- Proposed usage
- Migration data / extraction data
- Toxicological data
- Regulatory status in other jurisdictions (recommended)




1. Product Identity

(Specific Constituents/Single Additives)

- Chemical name, chemical formula, and molecular weight
- Manufacturing process
- Purity specifications
- Chemical and physical properties




2. Proposed Use
(Specific Constituents/Single Additives)

- Intended technical effect
- Types of substrate
- Maximum use level in each substrate
- Types of foods involved
- Conditions of use (*i.e.*: temperature and time of exposure)
- Efficacy data




3. Migration / Extraction Data

(Specific Constituents/Single Additives)

- Data from extraction studies are required to identify and quantify the potential contaminants in foods.

- These studies are conducted using *food simulants* under the conditions that reflect as closely as possible those of the intended end-use applications.




Acceptable Food Simulants

Food Type	Simulant
Aqueous (pH > 5)	Water or 10% ethanol
Acidic (pH < 5)	3% acetic acid or 10% ethanol
Low alcoholic (< 10%)	10% ethanol
High alcoholic (> 10%)	50% ethanol
Fatty	Vegetable oil, HB307 or Miglyol 812




Alternate Fatty Food Simulants

Polymer Type	Simulant
Polyolefins and EVA	95% ethanol
Rigid PVC, PS and PET	50% ethanol




EVA ethylene-vinyl acetate copolymer
PVC polyvinyl chloride
PS polystyrene
PET polyethylene terephthalate

Alternate Food Simulants

Simulant	Type of food
10% ethanol	Aqueous (pH > 5)
	Acidic (pH < 5)
	Low alcoholic (< 10%)
95% ethanol	High alcoholic (> 10%)
	Fatty




Migration / Extraction Data

The final report should provide all the parameters used in the migration study:

- Volumes of food simulants, sample thickness
- Surface area exposed
- Time
- Temperature

Full details of the analytical methodology, including validation data and limit of detection.




Estimation of Probable Daily Intake

$$(\text{PDI } \mu g/kg \text{ bw}) = [(C_{aq} \times F_{aq}) + (C_{acid} \times F_{acid}) + (C_{fat} \times F_{fat}) + (C_{alc} \times F_{alc})] D_p M_p K_p / Bw$$

Where:

PDI	Probable daily intake
C	Concentration (µg/kg) of extracted constituent in aqueous, acidic, alcoholic and fatty food simulants, normalized to an exposure ratio of $5 g/in^2$
F	Intake of aqueous, acidic, alcoholic and fatty foods in the daily diet (g/day) (total of 2 kg/day)
D_p	Fraction of the total diet likely to be packaged in a particular material P in which the substance may be present
M_p	Fraction of P type packaging material, which realistically is likely to contain the constituent
K_p	Market penetration fraction for additives only
Bw	The average adult body weight in kg (use 70 kg)




Comparison of Exposure Calculations

	Canada	United States
Packaging Ratio	5 g / in^2	10 g / in^2
Total Daily Diet	2 kg / person	3 kg / person
Market Penetration Factor	Applied	Not Applied




4. Toxicological Data Requirements

(Specific Constituents/Single Additives)

Concern Level	Probable Daily Intake (µg/kg bw)	Toxicity Test
Threshold	<0.025	
1. Very Low	0.025 – 0.1	Structure activity
2. Low	0.1 – 2.5	Short term genotoxicity 28–day feeding, rodent
3. Medium	2.5 – 25	90–day feeding, rodent Multi generation, rodent Teratology, rodent
4. High	> 25	1–year feeding, non-rodent Chronic toxicity / oncogenicity in 2 rodent species




Food Directorate Listings for Polymers

- Table 1 (PE's), since November 2003
- Table 2 to 13, January 2004
- Listings are not retroactive
- Non-objection letters issued before those dates can be listed after composition is confirmed (in writing) by the manufacturer (*i.e.* there has been no change in composition since original submission).




Lists of Acceptable Polymers

for Use in Food Packaging Applications

Polymer Categories

Table No.	Polymer Type	Code
1	Polyethylenes	PE
2	Polypropylenes	PP
3	Poly(ethylene-vinyl acetate)	EVA
4	Polystyrenes	PS
5	Polyvinyl chlorides	PVC
6	Ionomers	I
7	Polyethylene terephthalates	PET




Lists of Acceptable Polymers
for Use in Food Packaging Applications

Polymer Categories

Table No.	Polymer Type	Code
8	Polyvinyl acetates	PVAc
9	Polycarbonates	PC
10	Polyamides	PA
11	Polyvinyl alcohols	PVOH
12	Polyvinylidene chlorides	PVDC
13	Others	O




Table 2 – Polypropylenes

Examples

Trade name & Grade	Code	Manufacturer	Issue Date (dd/mm/yy)	Limitations
Pro-fax Ultra SC973Y	PP	Equistar Chemicals, LP	31/08/10	Not to be used during cooking
R12C-00	PP	INEOS Olefins & Polymers USA	02/12/09	T ≤49°C
Versify 3300	PP	Dow Chemical Company	07/12/10	
Vistamaxx 3020	PP	ExxonMobil Chemical	07/11/11	T ≤100°C

Comparison of Approaches

Canada	Unites States
Trade names	Chemical names
No lists (except resins) maintained by HC	Positive lists
Packaging ingredients are not considered as food additives	Packaging ingredients are considered as food additives
Pre-market clearance voluntary under the F&DR	Pre-market clearance mandatory
Responsibility lies with food seller	Responsibility lies with packaging manufacturer




Recommendations

- In order to significantly reduce the amount of time that elapses between submitting a product for evaluation and obtaining a letter of no objection (LONO) for said product, we suggest that you contact your suppliers, in advance, and advise them to submit to the Bureau of Chemical Safety a complete disclosure of the chemical compositions of their products that pertain to your submission.

- Additionally, it is necessary that trade names and grades disclosed by a petitioner and their suppliers remain consistent.




In the Future…

- Amendments to the *Canadian Meat Inspection Regulations* are to be published in the *Canada Gazette, Part II*. One of the amendments repeals the requirement for pre-market registration of non-food chemical products and packaging materials used in federally-registered establishments. *Canadian Meat Inspection Regulations* are administered by CFIA.
- Health Canada is reviewing its operational requirements to respond to the significant number of food packaging materials and non-food chemical submissions.

Health Canada Website Links

Health Canada:
www.hc-sc.gc.ca

Food Packaging Materials:
http://www.hc-sc.gc.ca/fn-an/securit/packag-emball/index_e.html

Listing of Acceptable Resins:
http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/polymers_tc-polymere_tm-eng.php




Thank you!

Questions?