

# UPDATE

Food and Drug Law, Regulation and Education



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# 2015 Year in Review—Top 10 Food Regulatory Issues in Canada

By Albert Chan, Yolande Dufresne, Eileen McMahon, and Teresa Reguly

Below is our list of top 10 food regulatory issues in Canada, including what to watch for as we head into 2016.

## New Federal Government in 2015 - Possible Impact on Food Regulation

In the Canadian federal election on October 19, 2015, the Liberal Party led by Justin Trudeau won a majority government. The Liberal Party election campaign platform included a number of policy statements related to food regulation in Canada.

First, the Liberal Party has pledged to introduce restrictions on advertising unhealthy food and beverages to children, similar to current advertising regulations imposed in the province of Québec. The newly elected federal government's platform also included promises to implement measures to reduce trans fats, similar to current US regulations, as well as measures to reduce salt in processed foods.

The Liberal Party has also pledged to invest an additional C\$80 million in the Canadian Food Inspection Agency over four years. This investment is intended to allow for additional food safety inspections of both domestic and imported foods. An additional investment of C\$40 million

will be made in the Nutrition North program, which is tasked with ensuring that residents in Canada's northern territories have access to affordable, healthy food choices.

The Forward Regulatory Plan, which will provide more details on proposed changes to food regulation, is expected to be published in the coming months.

## Canada's Food Modernization Act

The Safe Food for Canadians Act<sup>1</sup> (the Act), which was passed in 2012, introduces the most significant changes in decades to Canada's legal framework for food products. Companies dealing in both US and Canadian food commodities will recognize that the Act follows the US Food Safety Modernization Act (FSMA). The Canadian Act is focused on interprovincial and international food commodities, and is directed at aligning Canada's food safety system with those of Canada's trading partners, including the United States. The Act consolidates into a single statute four pieces of existing Canadian legislation, namely the Fish Inspection Act, the Canada Agricultural Products Act, the Meat Inspection Act and the food provisions of the Consumer Packaging and Labeling Act, which were created at various times over the past decades.



**Albert Chan's** practice at Torys LLP focuses on intellectual property and regulatory matters, particularly with respect to food, pharmaceutical, and medical device industries. He assists clients with filing and prosecuting patent applications. He also advises on Food and Drug Act compliance, packaging and labeling, and establishment licensing.



**Yolande Dufresne's** practice at Torys LLP focuses on food and drug regulatory and intellectual property matters. Yolande advises clients with regulated products in the food, pharmaceutical, biotechnology, and medical device industries, in areas including product licensing, labeling and advertising, product recalls and corrective actions, and privacy.



**Eileen McMahon** is Co-Chair of the Food and Drug Regulatory/Intellectual Property practices at Torys LLP. Practicing exclusively in these areas, Eileen is one of a handful of Canadian lawyers who advise on regulatory clearance and intellectual property protection of products in Canada.



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The Act also introduces increased enforcement and penalties, including fines of up to \$5,000,000, for activities that put health and safety at risk.

Before the Act comes into force, however, supporting regulations must be enacted and in June 2015, the Canadian Government published much-anticipated draft regulations.<sup>2</sup> The preliminary draft includes regulations related to the Canadian Food Inspection Agency's (CFIA) tracing and recalling of food, certification of food commodities for export, and licensing and registration of imports of regulated food commodities to ensure a consistent approach for all food commodities. Food manufacturers, distributors, and retailers in Canada will want to continue to monitor the status of the draft regulations, and participate in stakeholder consultations where appropriate, to keep themselves informed of the significant upcoming changes.

### Import Certifications and Permit Requirements

One of the provisions of the Act requires food importers and exporters to be licensed by the Minister of Agriculture and Agri-Food. Although the licensing of food importers and exporters was originally expected to begin in 2015, the preliminary regulated text for the Act was only published in July 31, 2015—in draft form—and no firm timeline has been established for when import and export licensing might begin.

The preliminary text that was published for consultation and comments provides some details on the planned licensing scheme, although these details may change

prior to the regulations coming into force. The preliminary text specifies that licenses expire after a term of two years. Licenses will be required for the import of food, and for the export or inter-provincial conveyance of food or food animals. Exporter licenses will also allow exporters to carry out manufacturing, processing, packaging, and labeling activities related to food. Further, a license may be suspended by the Minister immediately upon providing notice to a license holder, if there is a risk of injury to human health.

### Nutrition Fact Table Changes to Better Inform Consumers—No “North American” Food Label

On June 12, 2015 Health Canada announced changes to Canada's Nutrition Facts Table (NFT) required to be displayed on packaged food items in Canada. The proposed changes will involve amendments to the nutrition labeling sections of the federal Food and Drug Regulations (FDR).<sup>3</sup> According to Health Canada, the purpose of the revised NFT is to “enable consumers to make informed food choices about the food they consume to maintain or improve health.”

Proposed changes targeted toward the required elements of the NFT include the following:

- a percent daily value (% DV) will be added for sugars along with a footnote below the table to help consumers understand how much sugar is in the particular food product (e.g., “15% or more is a lot”);
- potassium content will be added to the table, as Health Canada believes potassium is under-consumed by

Canadians;

- vitamin A and C nutrient information will be removed from the table, as these nutrients are already abundant in the diets of most Canadians; and
- serving sizes will be altered to better reflect the amount that Canadians typically eat in one sitting to help consumers compare the nutritional content for similar foods packaged in different quantities.

The coming-into-force period for the eventual amendments to the FDR is set for five years to give businesses sufficient time to manage the changes in labeling requirements. For companies that do business on both sides of the Canada/US border, these NFT changes which do not mirror current nutrition facts label requirements in the US—reinforce the view that we are unlikely to see a “North American” food label anytime soon.

### Ingredient List Format for Prepackaged Food Products

Canada's amendments to the FDR,<sup>4</sup> announced on June 12, 2015 also include several changes to the standard ingredient list format applied to prepackaged food products. Proposed changes to the ingredients list include the following:

- all sugar-based ingredients (e.g., molasses, brown sugar) will be grouped in brackets after the common name “sugars,” with the particular sources of sugars appearing by weight from most to least;
- all words in the list will be in sentence case, with ingredients separated by bullets; and

- any food coloring will be listed by its common name.

These changes are directed at easing the difficulties some consumers have expressed in reading the current list of ingredients, as well as supporting the goal of reducing sugar intake among Canadians.

## Changes in Enforcement, Impact on Food Recalls and Reporting Trends

Another important change brought about by the Act is the elimination of separate meat, fish, and agricultural inspector authorities in Canada. The new legislation eliminates the distinction between inspectors for different food products and provides industry with greater certainty and consistency in terms of inspection and enforcement powers.

It will be interesting to see how these changes in inspection and enforcement structure impact recalls in Canada. By way of background, the CFIA indicates that about 200 food recalls are reported each year. Recalls are conducted for various reasons—microbial contamination and undeclared allergens are common, and extraneous material, chemical residues, labeling defects or tampering are also the basis for removal of product from distribution chains. Recalls are classified as either Class I, II, or III: Class I is a situation where use of the impacted food will likely have serious adverse health consequences; Class II recalls involve products that may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote; and Class III recalls are for products that violate legislative

requirements but are not likely to cause any adverse health consequences.

The majority of recalls in Canada are conducted voluntarily by the manufacturer, importer, or distributor of the impacted product. The CFIA has the power to order a mandatory recall if there are reasonable grounds that a food product poses a risk to public, animal or plant health. This power is rarely used since manufacturers/distributors want to mitigate liability by removing unsafe products from the market as quickly as possible. The majority of recalls are Class I recalls—about one-quarter of reported recalls in any given year are Class II, and very few (generally five or less) are Class III.

With the increased focus on inspection consistency, as well as food safety and transparency, some industry members are anticipating that a greater number of recalls will be conducted, or mandated, in the coming years, particularly for lower risk violative products that have not typically been reported.

## Guidance on Food Processing Aids (As Distinct From Food Additives)

Following earlier policy statements on the differentiation between food additives (which affect the characteristics of a food and become part of the food after processing) and food processing aids (which do not remain in the food after processing in more than negligible amounts), Health Canada released guidance this year on the preparation and approval of food processing aid submissions. While manufacturers are not required to submit food processing aids for formal review, with the exception of

antimicrobial agents applied directly on foods in federally registered meat establishments, manufacturers can request a “letter of no objection” (LONO) from Health Canada indicating that in Health Canada’s opinion, adequate evidence has been presented that use of the food processing aid will not result in unsafe food. The LONO may also address efficacy claims associated with the sale, marketing, or use of the food processing aid.

Health Canada has also announced that it will grant an “interim letter of no objection” (ILONO) for food processing aids that have been assessed for safety and accepted by a “like-minded” food regulatory agency. Health Canada will review an ILONO submission within 60 days. Following the issuance of an ILONO, Health Canada retains the option of conducting a full assessment of the processing aid submission, which may result in a LONO or the revocation of the ILONO.

## Genetically Engineered Foods—What’s Next for Canada?

The US Food and Drug Administration recently issued the first approval for a genetically engineered (GE) animal intended for food—AquAdvantage Salmon is an Atlantic salmon that reaches market size more quickly than non-genetically engineered farm-raised salmon. Health Canada has approved several GE plant foods<sup>5</sup> but has yet to approve an animal food—with the US approval, it may only be a matter of time before GE animal foods appear on the Canadian market.

In order for a GE food to be sold in Canada, it must be approved for sale by Health Canada as a “novel food,” defined by the FDR as a food derived from a plant, animal, or microorganism that has been genetically modified such that the plant, animal or microorganism exhibits characteristics or no longer exhibits characteristics that were previously observed, or has a characteristic that no longer falls within the anticipated range for that plant, animal, or microorganism. Similar to the US process, for a novel food to be approved for sale, a manufacturer must provide data to Health Canada to establish that the food is safe for human consumption. Like the US, Canada currently has voluntary standards<sup>6</sup> for the advertising and labeling of GE foods, and some consumer groups argue that regulations should be in place for transparency.

GE products have the potential to provide lower-cost, nutritious food alternatives but we expect that public debate on how “good” GE products are for consumers and the environment will continue for some time. Demands from constituent groups may place pressure on Health Canada to examine its policies, both on the time frame and the substantive requirements for novel food approvals and the advertising of products and ingredients that are produced by genetic engineering.

## Canadian Food Exports and International Agreements: CETA and TPP

Another important outlook for Canadian food law this past year and into 2016 is Canada’s participation in

international trade agreements, notably the Canada-European Union (EU) Comprehensive Economic and Trade Agreement (CETA) and the Trans-Pacific Partnership (TPP).

After negotiations were completed in September 2014, CETA is finally expected to come into effect in 2016, following anticipated ratification. The EU represents Canada’s 4th largest agricultural export market despite historically high tariffs on Canadian exports to the EU. If ratified, CETA would eliminate most tariffs for agriculture and processed food products, such as beef, pork, and wheat.

On October 5, 2015, the TPP was announced by 12 countries: Canada, United States, Japan, Mexico, Australia, New Zealand, Chile, Peru, Singapore, Malaysia, Vietnam, and Brunei. The TPP is expected to provide new market access opportunities in participating countries for food products including Canadian pork, beef, fruits and vegetables, grains, wines and spirits, baked goods, and processed foods and beverages.

CETA and the TPP are expected to provide significant export gains to companies exporting agricultural food products from Canada to the EU and TPP member countries, as the agreements are expected to phase out tariffs in these countries on a number of Canadian agricultural food products. Companies exporting food products from Canada to EU and TPP should begin adapting their business plans to seize opportunities and navigate the changing international landscape created by these agreements.

## Ontario Legislates Calorie Posting in Food Establishments

On May 28, 2015, the Ontario government enacted the Making Healthier Choices Act S.O. 2015 C.7 (Healthier Choices Act).<sup>7</sup> The Healthier Choices Act, which comes into force on January 1, 2017, imposes requirements on certain food service establishments to post calorie counts on their menus.<sup>8</sup>

The legislation applies to any food service establishment that prepares, sells, or serves meals or meal portions in a form that can be consumed immediately and that operates 20 or more establishments in Ontario under the same or substantially the same name. Together, these requirements capture a wide range of food service establishments, including chain restaurants, fast-food outlets, grocery stores, and convenience stores. Establishments that meet the above criteria will be required to post the calorie content of: (i) each standardized portion of food or drink directly on the menu; (ii) any food item on display on an identifying tag or label; and (iii) any standardized combination of food or drink items directly on the menu. Failure to comply with Ontario’s forthcoming requirements could result in fines of up to \$10,000 per day for corporations.

Unlike the United States’ federal Food, Drug, and Cosmetic Act, which creates calorie disclosure obligations on menus for businesses with 20 or more locations nationwide in the US, Ontario’s provincial regulations apply only to businesses operating 20 or more establishments in the province, which means that only Ontario’s largest food service establishments will be required to comply. It is yet

to be seen whether other provinces in Canada will follow suit and enact similar legislation.  $\Delta$

1. 1 S.C. 2012, c. 24.
2. [http://www.inspection.gc.ca/DAM/DAM-aboutcfia-sujetacia/STAGING/text-texte/regs\\_safe\\_food\\_regulations\\_cnsldtn\\_foodregs\\_1427726282343\\_eng.pdf](http://www.inspection.gc.ca/DAM/DAM-aboutcfia-sujetacia/STAGING/text-texte/regs_safe_food_regulations_cnsldtn_foodregs_1427726282343_eng.pdf).
3. <http://www.gazette.gc.ca/rp-pr/p1/2015/2015-06-13/html/reg1-eng.php>.
4. <http://www.gazette.gc.ca/rp-pr/p1/2015/2015-06-13/html/reg1-eng.php>.
5. A list of approved novel foods in Canada can be found here: <http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/index-eng.php>.
6. See: <http://www.tpsgc-pwgsc.gc.ca/ongc-cgsb/programme-program/normes-standards/internet/032-0315/index-eng.html#a5>.
7. This legislation was passed as Bill 45. The predecessor bill, Bill 162, the “Making Healthier Choices Act, 2014” was introduced on February 24, 2014.
8. The Healthier Choices Act also contains restrictions on e-cigarettes and flavored tobacco.



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