MERIEUX NutriSciences

NORTH AMERICAN REGULATORY UPDATE

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Quarterly Review of U.S. Food Recalls

Food products are recalled from the marketplace for various food safety, quality and regulatory issues. The Food and Drug Administration (FDA) is responsible for ensuring the safety of approximately 80% of the U.S. food supply, which includes the oversight of approximately 150,000 domestic and foreign food facilities. In recent years, the vast majority of recall events involving FDA-regulated food products were triggered by microbiological pathogens and labeling errors such as undeclared allergens.

During the third quarter of 2018 (July – September), the FDA classified 136 food recall events within its weekly Enforcement Report. The Q3 FDA food recall total is comparable to the quarterly totals of 139 and 147 recall events from the first and second quarters of 2018, respectively.

Salmonella was the pathogen linked to the majority of FDA recall events due to microbial contaminants. While 19 recall events were triggered by *Salmonella* contamination, these recalls involved more than 100 food products. In many cases, contaminated whey powder was supplied to various manufacturers, which resulted in recalls of various food products such as bread, crackers, cereal, seasonings and yogurt.

Cyclospora is an unusual reason for a food recall, but the parasite was the second leading cause of FDA food recalls due to microbial contaminants between July 1 and September 30. During Q3, the Enforcement Report lists eight FDA recall events involving 46 products due to *Cyclospora*. In September, the Centers for Disease Control and Prevention (CDC) reported 511 laboratory confirmed cases of *Cyclospora* infections in 15 states that were linked to prepared salads, and 250 cases in four states that were associated with pre-packaged vegetable trays. The majority of recalls due to *Cyclospora* involved spinach and kale, but other vegetable products were also recalled due to the parasite.

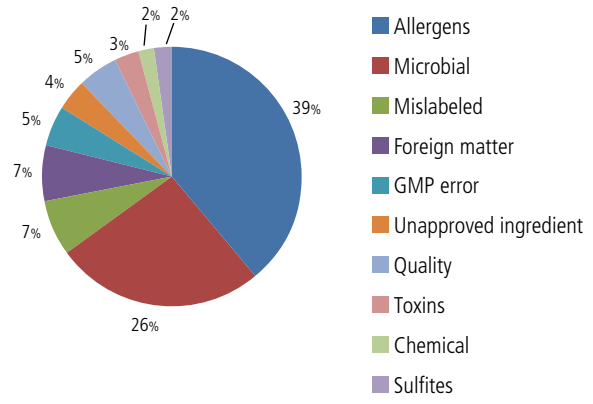
During the fourth quarter of 2018, numerous food recalls were triggered by the contamination of fruit or vegetable products with pathogens such as *Salmonella* spp and *Listeria monocytogenes*. In the final months of 2018, microbial hazards prompted recalls of products such as ice cream, nuts, salsa, jalapenos, onions, pepper, mushroom, corn, spinach, prepared meals and pasta.

Chemical contaminants resulted in very few FDA recall events. In fact, no recalls were attributed to heavy metals or pesticide residues during this period. Natural toxins, such as patulin or aflatoxin, were identified as the reason for four recalls during Q3.

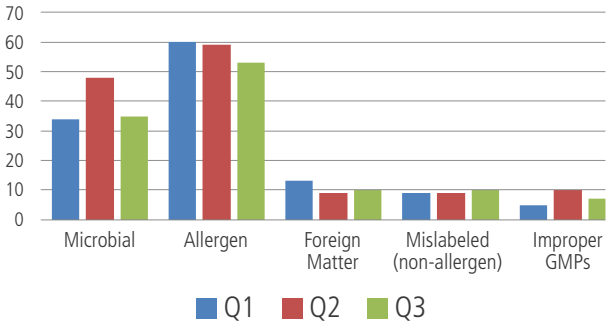
Undeclared allergens triggered 39% of the FDA food recall events during the third quarter of 2018. The food categories most commonly implicated in allergen-related recalls include: bakery goods, chocolate confectionery products, nut and seed mixes, dressings, sauces and snacks.

The USDA Food Safety and Inspection Service (FSIS) monitors all recalls of meat, poultry and certain egg products. During Q3 of 2018, the total number of FSIS recalls was less than 20% of the total number of FDA food recall events for the same period. The majority of FSIS recalls were due to microbial contaminants, inadequate inspection and labeling errors such as undeclared allergens. Non-O157 *E. coli* was named in three of the six recalls due to microbial hazards. In one case, *E. coli* O26 resulted in a recall of ground beef linked to an outbreak with 18 illnesses in four states.

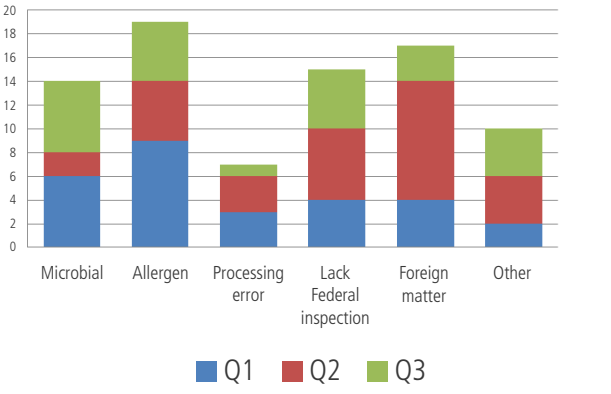
Reasons for FDA Food Recalls - Q3 2018



Top 5 Reasons for FDA Food Recalls (Jan-Sept 2018)



Reasons for FSIS Recalls (Jan-Sept 2018)



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Food & Drug Administration

Food Safety Modernization Act (FSMA) Update

The U.S. FDA is continuing the gradual implementation and enforcement of the (FSMA) regulations despite the current federal budget limitations and deregulatory environment. In an effort to improve industry compliance, the agency postponed enforcement of certain requirements of the core FSMA regulations beginning in January 2018. Despite the postponement of certain rules, several rules are in effect now and food businesses should be aware of additional FSMA requirements that will take effect in 2019. Below is a synopsis of recent activities related to several FSMA regulations.

Activity	Synopsis
Animal Food Preventive Controls	The regulatory compliance dates for the animal food preventive controls are now in effect for all three business sizes (large, small and very small). Effective September 2018, all large animal food businesses should be prepared for routine federal inspections that will scrutinize both Current Good Manufacturing Practices (CGMPs) and preventive controls. Large animal food facilities were required to comply with the preventive controls rule by September 18, 2017, but inspections were delayed as part of the FDA "educate before and while we regulate" approach. Recently, the FDA has shifted its focus for small and very small businesses to increase the oversight of CGMPs through more routine facility inspections.
Mandatory Food Recalls	The FDA released the guidance, ***Questions and Answers Regarding Mandatory Food Recalls***, in November 2018. Under FSMA, the FDA was authorized to increase food facility inspections and to implement mandatory recalls when needed. Moreover, the FSMA rule for preventive controls requires firms to identify hazards requiring a preventive control, assess hazards that would need to be addressed in a recall plan and establish procedures to ensure the effectiveness of a recall. In January 2018, the agency issued a **draft guidance** to advise the industry of circumstances mandating a public warning and notification of a recall, the timeline for issuing a warning and situations that would provoke FDA actions. The latest FDA document provides examples of serious health hazards that could require the need for a public warning, including but not limited to positive pathogen results from environmental testing of food contact surfaces and ready-to-eat foods, undeclared allergens in food products and manufacturing deviations permitting botulinum toxin found in food products.
Produce Safety	In October 2018, the FDA issued a draft guidance, ***Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption***, and a related draft guidance, ***Guide to Minimize Food Safety Hazards of Fresh-cut Produce***. The FDA **final rule on Produce Safety** took effect in January 2018 for large farms other than sprout operations. The rule established the first federal science-based minimum standards to ensure the safe growing, harvesting, packing and holding of raw agricultural commodities. The FDA is planning to begin routine inspections to verify industry compliance with the rule by Spring 2019, and upcoming **compliance dates** for certain requirements are slated for small farms and very small farms.

Activity	Synopsis
Qualified Facility Exemption	The core regulations of FSMA permit some exemptions for qualified facilities. For example, facilities currently subject to HACCP requirements (e.g. seafood and juice producers), dietary supplement facilities subject to CGMP requirements and low-acid canned food facilities are exempt from several FSMA rules. In September 2018, the FDA issued **guidance** to clarify the determination of a qualified facility exemption related to the preventive controls rules for human food (Part 117) and animal food (Part 507).
Food Facility Registration	In August, the FDA released the guidance, ***Questions and Answers Regarding Food Facility Registration*** (Seventh Edition), and the draft guidance, ***Supplemental Questions and Answers Regarding Food Facility Registration***. Domestic and foreign facilities that manufacture, process, pack or hold food for human or animal consumption are required to renew their registration every even-numbered year. Under FSMA, the FDA can suspend a facility's registration if the agency determines that "food manufactured, processed, packed, received, or held by a facility registered under this section has a reasonable probability of causing serious adverse health consequences or death to humans or animals."
Laboratory Accreditation	The Fall 2018 federal regulatory agenda indicated the FDA would issue the proposed rule for laboratory accreditation before the end of 2018. The objective of laboratory accreditation per FSMA is to align commercial laboratories with government labs, which would enable the FDA to accept analytical data from third-party labs. The use of accredited laboratories, both foreign and domestic, would be required only for regulatory testing.
Voluntary Qualified Importer Program (VQIP)	Importers seeking to participate in the **Voluntary Qualified Importer Program (VQIP)** are required to apply between January and March for the upcoming fiscal year. In 2018, the FDA opened the application portal on October 1 to permit importers additional time to complete their Notice of Intent to Participate and VQIP applications for FY 2020. The VQIP program is commonly described as the "fast lane" system for facilitating the entry of imported food shipments into the United States. The program will provide benefits such as expedited review and limited FDA examination and/or sampling of food imports. The agency has provided resources to facilitate industry compliance with the VQIP program, including the **final guidance** for VQIP (2016) and **instructions for submission of a VQIP application**.
FSMA fee rates for FY 2019	The FDA has issued the fiscal year 2019 fee rates for certain activities as mandated by the FSMA regulations. The ***Federal Register* notice** provides information concerning the FDA fees for the re-inspection of domestic or foreign food facilities, fees for non-compliance with a mandatory recall order and importer re-inspection fees. The fees took effect on October 1, 2018.

FDA Food Labeling Update

Labeling Enforcement Discretion Planned for Supplements Containing Live Microbials

In recent years, the International Probiotics Association has urged the FDA to modify the labeling of quantitative amounts of dietary ingredients that are live microorganisms in order to be declared in "terms of the minimum number of colony forming units (CFUs) per serving at the end of the product's shelf life."

In the case of dietary supplements containing "probiotics," the current labeling requirement does not accurately state the number of live microorganisms. According to new FDA **guidance** (November 2018): "The weight of microbial dietary ingredient in a product represents the product's total cellular mass, consisting of both live and dead microorganisms, and therefore does not necessarily correlate with the number of viable microorganisms in that product." Moreover, the FDA guidance states the number of live microorganisms will likely decline during a product's shelf life.

According to the guidance, the FDA intends to "exercise enforcement discretion with respect to the declaration of live microbial quantity in colony forming units (CFUs), in addition to the quantitative amount by weight declaration required by regulation, within the Supplement Facts label of dietary supplements containing live microbials, provided that certain conditions are met."

Furthermore, the guidance states that "allowing firms to declare live microbial quantity in terms of CFUs would permit consumers to more readily identify the amount of viable microorganisms for each product and more easily compare products," and labels "declaring quantity in terms of CFUs also would promote confidence that a particular dietary supplement product contains the labeled amount of live microbial ingredient, providing the specified number of viable microorganisms throughout the shelf life of the product."

Should Sesame be a Major Food Allergen?

The U.S. Congress established the mandatory allergen labeling law known as the Food Allergen Labeling and Consumer Protection Act (FALCPA) and the FDA is responsible for enforcing the labeling requirements. As mandated by the law and the Federal Food, Drug and Cosmetic Act (FD&C Act), allergen labeling is mandatory for any packaged food containing a major food allergen commonly referred to as major food allergens or "Big 8" allergen (i.e. milk, soy, peanuts, tree nuts, wheat, egg, fish, shellfish).

In recent years, the prevalence of sesame food allergies has caught the attention of several researchers. In fact, recent research has suggested the prevalence of sesame allergies in North America is approximately 0.1%, which is similar to the prevalence estimates for soy and fish allergies. While sesame is recognized as a significant food allergen in several countries, including Canada, it is not yet recognized as a major food allergen in the United States.

In response to petitions from U.S. senators, consumer advocacy groups and medical professionals, the FDA is currently evaluating the need to designate sesame as a priority food allergen for mandatory labeling.

On October 29, the FDA requested information regarding the prevalence of sesame allergies in the U.S. as well as the prevalence of sesame in foods. According to the FDA, small amounts of sesame are common in food products containing "natural flavors" or spices. In addition to the request for information, the FDA will continue to monitor the scientific literature for information about emerging food allergens.

A recent statement by FDA Commissioner Scott Gottlieb M.D., revealed the researchers who developed the agency's xMAP Food Allergen Detection Assay are now evaluating the expansion of this method to include sesame.

The agency has confirmed that it has the "authority to issue regulations requiring the disclosure of spices, flavorings, colorings and incidental additives that are, or contain, allergens other than the eight major food allergens and FDA is not restricted from requiring labeling regarding other food allergens" (29 Oct 2018).

FDA Amends Vitamin D3 Food Additive Regulation

An industry petition filed by the Juice Products Association prompted the FDA to reconsider the food additive regulation for vitamin D3 (21 CFR 172.380). On September 20, the agency issued a final rule to replace the current Reference Daily Intake (RDI) percentage values of calcium in 100% fruit juices and fruit juice drinks with absolute values and to update the reference for vitamin D3 specifications. The petition requested the replacement of the RDI values of calcium in 100% fruit juice and fruit drinks in the regulations with the absolute values of added calcium of 330 mg and 100 mg per 240 mL, respectively. According to the FDA, the change should serve to maintain equivalent calcium levels between fortified juice products and milk.

Approval of Seven Food Additives Revoked

On October 5, the FDA amended the food additive regulations to revoke approval of seven synthetic flavoring substances and flavoring enhancers (adjuvants). After research demonstrated a link to cancer in laboratory animals, the agency de-listed six flavoring substances, including synthetically-derived benzophenone, ethyl acrylate, eurgenyl methyl ether (methyl eugenol), myrcene, pulegeone and pyridine. The recent decision applies to the synthetic substances only and does not apply to natural forms of the flavoring substances. Additionally, the agency revoked approval of styrene, a flavoring substance and adjuvant, which is no longer used by the industry.

Qualified Health Claim Approved for Oleic Acid

A qualified health claim supporting the relationship between oleic acid from edible oils and a reduced risk of coronary heart disease was approved by the Food and Drug Administration in November. The decision was based on an evaluation of seven clinical studies that investigated the consumption of oils containing high levels of oleic acid (at least 70% per serving) and improved cholesterol levels in humans. Six of the studies suggested the consumption of high levels of oleic acid in place of other types of fats and oils higher in saturated fats resulted in a lowering of total cholesterol and low-density lipoprotein (LDL) cholesterol levels in the subjects.

The FDA intends to exercise enforcement discretion for the following qualified health claims:

> "Supportive, but not conclusive, scientific evidence suggests that daily consumption of about 1½ tablespoons (20 grams) of oils containing high levels of oleic acid, when replaced for fats and oils higher in saturated fat, may reduce the risk of coronary heart disease. To achieve this possible benefit, oleic acid-containing oils should not increase the total number of calories you eat in a day. One serving of [x] oil provides [x] grams of oleic acid (which is [x] grams of monounsaturated fatty acid").

> "Supportive, but not conclusive, scientific evidence suggests that daily consumption of about 1½ tablespoons (20 grams) of oils containing high levels of oleic acid, may reduce the risk of coronary heart disease. To achieve this possible benefit, oleic acid-containing oils should replace fats and oils higher in saturated fat and not increase the total number of calories you eat in a day. One serving of [x] oil provides [x] grams of oleic acid (which is [x] grams of monounsaturated fatty acid").

Oleic acid occurs naturally in various sources, including edible oils, meat, dairy foods, avocados, eggs and sunflower seeds. Edible oils containing at least 70% oleic acid per serving include: high oleic sunflower oil, high oleic safflower oil, high oleic canola oil, olive oil and high oleic algal oil.

FDA Questions Nutritional Value of Plant-Based "Milk" Products

Many dairy foods are produced according to federal standards of identity, which require the use of milk or ingredients derived from milk as defined in the FDA regulations (21 CFR 131.110). In recent years, there has been a proliferation of plant-based products that are labeled as "milk" (e.g. "soy milk" or "almond milk yogurt") and packaged in containers similar to traditional dairy products. Due to concerns about the nutritional value of such non-dairy "milk" products, the FDA requested public comments to understand how consumers use these products and their understanding of terms such as "milk" or "yogurt" used in the labeling of plant-based products. The agency has expressed concerns that certain plant-based "milk" products "contain less nutrients than their dairy counterparts and may not meet the recommendation for dairy food group intake in the 2015-2020 Dietary Guidelines for Americans." In November 2018, the FDA extended the **public comment** period until January 28, 2019.

Nutrition Facts Guidance Issued, Compliance Date Extended Until 2020

The FDA released a final rule in May 2018 to confirm the extension of the compliance dates for the revised **Nutrition Facts** labeling rules for manufacturers with $10 million or more in annual food sales. As previously announced, the compliance dates were extended from July 26, 2018, to January 1, 2020. Manufacturers with less than $10 million in annual food sales would have their compliance date extended from July 26, 2019, to January 1, 2021.

In November, the FDA issued guidance to support industry compliance with the upcoming rules:

- **Guidance for Industry: Nutrition and Supplement Facts Labels: Questions and Answers Related to the Compliance Date, Added Sugars and Declaration of Quantitative Amounts of Vitamins and Minerals**
- **Draft Guidance for Industry: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion, Reference Amounts Customarily Consumed, Serving Size-Related Issues, Dual-Column Labeling and Miscellaneous Topics**

FDA Sets Uniform Compliance Date for Labeling Rules

On December 19, the FDA announced that January 1, 2022, will be the uniform compliance date for all final food labeling regulations issued in 2019 and 2020. The compliance date does not apply to final rules issued by the FDA before January 1, 2019.

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U.S. Department of Agriculture (USDA)

USDA Issues Final Rule for Bioengineered Food Labeling

The long-awaited final rule to establish a mandatory standard for disclosing the presence of bioengineered (BE) food or food ingredients derived from bioengineering was issued on December 21, 2018.

The National Bioengineered Food Disclosure Standard, a U.S. federal law enacted in July 2016, required the USDA to develop regulations to establish a national mandatory food labeling standard. Following the release of the proposed rule in May 2018, the USDA evaluated more than 14,000 public comments prior to releasing the **final rule** in December.

As defined by both the Act and the rule, the term "bioengineering" refers to a food that contains "genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques," and the resulting "modification could not otherwise be obtained through conventional breeding or found in nature." The final rule states that "an incidental additive present in food at an insignificant level and that does not have any technical or functional effect in the food" would not be defined as bioengineered food.

The final rule affirms the USDA's stance that undetectable genetically modified material is not recognized as a bioengineered food subject to mandatory disclosure.

The USDA Agricultural Marketing Service recently developed a **List of Bioengineered Foods** in an effort to facilitate industry compliance with the final rule for disclosure. While the list will evolve, the foods currently identified as available in bioengineered form include: alfalfa, apple, canola, corn, eggplant, papaya, pineapple, potato, salmon, soybean, squash and sugarbeet. According to the USDA, "If a food or food ingredient is on the List of Bioengineered Foods, and the regulated entity's records show that the food is a bioengineered food or does not indicate whether or not the food is bioengineered, the food must bear a BE disclosure."

The final rule identified the following exemptions (§ 66.5) for mandatory disclosure:

(a) Food served in a restaurant or similar retail food establishment.
(b) Very small food manufacturers.
(c) A food in which no ingredient intentionally contains a bioengineered (BE) substance, with an allowance for inadvertent or technically unavoidable BE presence of up to five percent (5%) for each ingredient.
(d) A food derived from an animal shall not be considered a bioengineered food solely because the animal consumed feed produced from, containing or consisting of a bioengineered substance.
(e) Food certified under the National Organic Program.

The proposed rule suggested a 0.9% threshold, but the USDA determined the traceability requirements associated with this limit would be "overly burdensome" for the food industry. The 5% threshold of the final rule is not aligned with the 0.9% threshold of the European Union. The use of a "may contain" statement is not permitted.

Under the proposed rule, a food product subject to the labeling rule would disclose the bioengineered or genetically modified (GM) content of products using three methods: a labeling statement, a symbol, or an electronic /digital link such as a QR code that will direct consumers to the bioengineering disclosure. The final rule added text message as a fourth option for complying with the disclosure requirement. If the text message option is selected, the food label must include the statement: "Text [command word] to [number] for bioengineered food information."

The USDA has approved the following on-pack symbols:

In addition to the issues described here, food manufacturers should be aware of additional issues described within the final rule, including: detectability (§ 66.9) and record keeping requirements (§ 66.300)

The implementation date of the disclosure requirement is January 1, 2020, but small food manufacturers will have an extra year to comply. Mandatory compliance with the requirements will begin on January 1, 2022.

For more information, see the USDA industry support site:
https://www.ams.usda.gov/rules-regulations/be/regulated-entities

Uniform Compliance Date for FSIS Labeling Regulations

The USDA Food Safety and Inspection Service (FSIS) has established January 1, 2022, as the uniform compliance date for all meat and poultry product labeling regulations issued between January 1, 2019 and December 31, 2020.

USDA FSIS Directives & Notices

The following tables list selected USDA FSIS Directives and Notices issued in recent months.

Directives

Directive #	Title	Date
7120.1	Safe and suitable ingredients used in the production of meat, poultry and egg products – Revision 48	Dec 6, 2018
7230.1	Ongoing verification of product formulation and labeling targeting the eight most common (Big 8) food allergens	Sept 26, 2018
7530.1	Handling a process deviation or abnormal container of thermally processed, commercially sterile canned product – Revision 4	Sept 27, 2018
7530.2	Verification activities in canning operations that choose to follow the canning regulations – Revision 1	Aug 20, 2018
7320.1	Prevention and control of *Trichinella* in pork products	Aug 6, 2018

Notices

Notice #	Title	Date
67-18	Import residue sampling types of inspection	Dec 17, 2018
64-18	Eligibility of Argentina to export raw beef to the United States	Nov 26, 2018
58-18	Discontinuation of residue testing of siluriformes fish at further processing establishments	Oct 26, 2018
46-18	Analysis of *Salmonella* of all imported beef products sampled for shiga toxin producing Escherichia coli (E. coli)	Sept 6, 2018

States

California - Proposition 65 Update

Acrylamide

Proposition 65 is a California law requiring "clear and reasonable" warning labels on products containing chemicals determined by the state to cause cancer, birth defects or other reproductive harm.

Effective August 30, the Proposition 65 law was revised to require that companies post a new warning statement that identifies at least one chemical per health risk (if applicable) – cancer and/or reproductive toxicity.

Acrylamide is a natural byproduct of the coffee roasting process and also forms during the high-temperature cooking of certain carbohydrate-rich foods, including potato-based foods and cereal foods (e.g. cookies, crackers, etc). In March 2018, a California Superior Court judge ruled that California businesses must post a warning about the potential cancer risk of acrylamide. However, the state agency responsible for enforcing Proposition 65, the Office of Environmental Health Hazard Assessment (OEHHA), proposed a regulation in July that would exempt coffee from the Proposition 65 warning requirements. The legal requirement for Proposition 65 warnings for retail coffee sales is still undecided.

In a related court decision involving food labeling, a California appeals court concluded in July 2018, that breakfast cereals would be exempt from the Proposition 65 warning statement despite the presence of acrylamide. The state court ruled that warning statements on breakfast cereals, peanut butter, whole wheat bread and similar products would discourage consumers from eating "otherwise healthy foods."

In early November 2018, the California Supreme Court denied a public petition that had challenged an appeals court ruling that exempts cereal manufacturers from the Proposition 65 labeling requirement. However, the Supreme Court ruled the decision does not extend to other food manufacturers. Food manufacturers, other than cereal manufacturers, are not permitted to cite this case as a precedent for circumventing the Proposition 65 warning labels.

Nickel

On October 26, the OEHHA announced the listing of Nickel and Nickel Compounds (soluble compounds) as a reproductive toxicant under the state's Proposition 65 law, but the agency has not yet defined soluble nickel. Nickel was previously listed as a carcinogen under Proposition 65. The listing excludes metal and insoluble compounds of nickel from the warning requirement. Several U.S. food industry associations had submitted comments to the OEHHA in opposition to the proposed listing of nickel as a reproductive toxicant. The Grocery Manufacturers Association (GMA), Council for Responsible Nutrition (CRN) and the American Herbal Products Association (AHPA) submitted their final comments to OEHHA on October 9, 2018. According to GMA, the Proposition 65 listing of nickel could impact a variety of food products, particularly the foods identified in a **2013 study** including cocoa, chocolate, soya beans, oatmeal, nuts, almonds and fresh and dried legumes.

On October 24, the GMA stated that its lobbying efforts had successfully limited the scope of the Proposition 65 listing to soluble nickel compounds related to developmental and male reproductive toxicity.

New York - Nutrition Regulations

Since 2006, the NYC health department has spearheaded several notable efforts related to nutrition and consumer education. The city voted to ban trans fats in restaurants in 2006 and later amended the health code to require calorie counts on the menus of chain restaurants. The city proposed a ban on sales of high-sugar beverages larger than 16 ounces in 2012, and implemented a rule in 2015 that requires restaurants with at least 15 locations nationwide to post a warning label near menu items containing more than 2,300 mg of sodium.

Recently, the NYC Health Department organized a coalition of roughly 100 health organizations nationwide to form the National Salt and Sugar Reduction Initiative (**NSSRI**), which is currently focused on reducing sugar in packaged food and beverages. In October 2018, the NSSRI proposed voluntary targets for the reduction of the sugar content of food and beverage products. Initially, the NSSRI proposal seeks to reduce the sugar content of **13 categories** of packaged food and beverage products.

The target sugar levels for the food categories are based on a 10% and 20% reduction from a baseline sugar density level. According to the proposal, companies would not be permitted to increase non-nutritive sweeteners, saturated fat, calories or sodium to meet the sugar-reduction targets by 2022 (10%) and 2025 (20%). While the voluntary NSSRI targets are not driven by regulations, the industry should anticipate pressure from non-governmental organizations and consumers to comply with these targets.

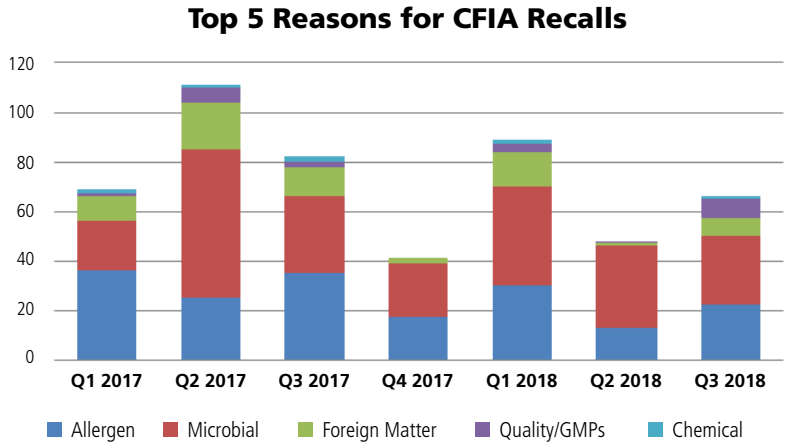
Quarterly Review of Canadian Food Recalls

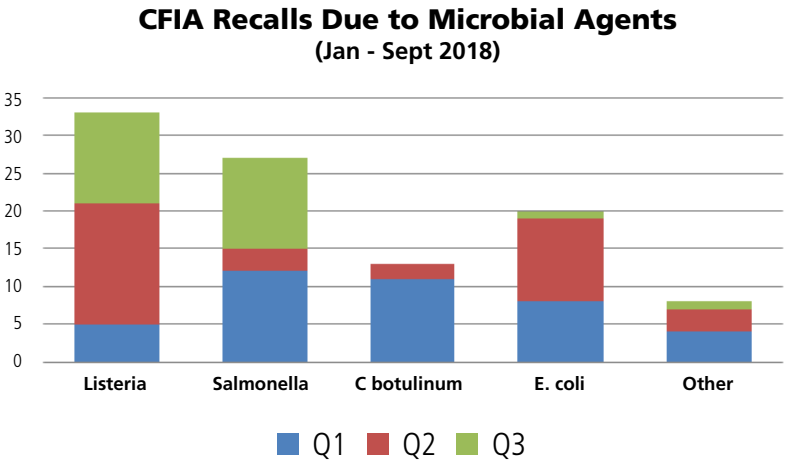
Historically, labeling errors and microbiological contaminants are responsible for the majority of food product recalls in Canada. Based on a review of food recalls and alerts recorded by the Canadian Food Inspection Agency (CFIA), it seems that microbial contaminants accounted for nearly half of the recalls during the third quarter of 2018 and could be the top reason for food recalls for the year.

Salmonella and *Listeria monocytogenes* were identified in the majority of Canadian food recalls attributed to microbial contaminants between July and September. *Listeria* was identified as the reason for several recalls of salad greens and chicken products. *Salmonella* was most commonly associated with recalls of oysters, crackers and breaded chicken products.

Undeclared allergens were previously the top reason for Canadian food recalls, but labeling errors involving allergens have become less prevalent. Between July 1 and September 30, the CFIA announced more than twenty recalls and alerts due to undeclared allergens. Allergen labeling errors were linked to 53 CFIA recalls during the first six months of 2018. As classified within the CFIA database of food recalls, the category 'Allergens' includes: crustacean / shellfish, egg, coconut, fish, gluten, milk, mustard, peanut, sesame seeds, soy, sulphites, tree nuts and wheat.

In 2019, the scope and type of food recalls are likely to be impacted by the implementation of the **Safe Food for Canadians Regulations** (SFCR). The regulations will come into force on January 15, 2019, but some requirements will be phased in during a 12 to 30-month period depending on the food commodity, type of activity and business size. The regulations apply to all foods imported into Canada, sold across provinces or prepared for export. The CFIA has issued **guidance** concerning the SFCR recall procedures.





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Food Safety & Labeling Updates

Safe Food for Canadians Regulations

The **Safe Food for Canadians Regulations** (SFCR) were developed in order to streamline Canada's food safety regulations, improve regulatory oversight and to increase international regulatory alignment with key trading partners. The regulations apply to all foods imported into Canada, sold across provinces or prepared for export. While the majority of regulations take effect in January 2019, some requirements will be phased in during a 12 to 30-month period depending on the food commodity, type of activity and business size.

SFCR Timeline

SFCR Requirement	Dairy products; Eggs; Fish; Honey; Maple products; Processed egg products and processed fruit or vegetable products	Fresh Fruits or Vegetables	All Other Foods		
			More than $100K in annual food sales AND more than 4 employees	More than $100K in annual food sales AND 4 employees or less	$100K or less in annual food sales OR 4 employees or less
License	January 15, 2019	January 15, 2019 (N/A for growing and harvesting)	July 15, 2020	July 15, 2020	July 15, 2020
Traceability	January 15, 2019	January 15, 2019 (except growing and harvesting) January 15, 2020 (growing and harvesting)	July 15, 2020	July 15, 2020	July 15, 2020
Preventive Controls	January 15, 2019	January 15, 2020	July 15, 2020	July 16, 2021	July 16, 2021
Written PCP	January 15, 2019 (not required for maple products and honey if annual food sales are $100K or less)	January 15, 2020 (not required if annual food sales are $100K or less)	July 15, 2020	July 16, 2021	Not required if annual food sales are $100K or less (regardless of number of employees)

Source: Table adapted from CFIA (2018)

The three core elements of the new Canadian regulations are: preventive controls, licensing and traceability.

- **Preventive controls** – All food businesses will be expected to develop and implement preventive controls related to specific food safety hazards. A **preventive control plan (PCP)**, similar to the U.S. FSMA requirement for a food safety plan, is required for most food businesses impacted by the law. In contrast to the U.S. FSMA regulation for preventive controls, the Canadian mandate does not require a preventive controls qualified individual (PCQI).

- **Licensing** – Canada will have one licensing system for foods and all food importers, while businesses preparing food for export or inter-provincial trade must register to obtain a license. The licensing requirement is similar to the FDA's bioterrorism requirement for facility registration. American companies seeking to market food in Canada will be required to have a Canadian food import license.

- **Traceability** – The regulations mandate an international standard for traceability, which requires traceability information in the form of electronic or paper records. The traceability requirements are aligned with the FSMA requirements for a food safety plan, record keeping and mandatory recalls.

Food industry stakeholders are advised to consult the CFIA online interactive tools listed below to determine the applicability of the key elements to their business:

- **Will your facility require a Preventive Control Plan?**
- **Will you need a license?**
- **What are the traceability requirements for your business?**

Legalization of Cannabis in Canada

Effective October 17, 2018, the ***Cannabis Act*** established a regulatory framework for the production, distribution, sale and possession of cannabis throughout Canada. Under the law, the possession and sale of cannabis is limited to dried and non-dried cannabis, including cannabis oil, seeds and plants.

On December 22, Canadian regulators published a draft plan for amending the Cannabis Regulations to permit a broader variety of products, including foods, beverages, cannabis extracts and cannabis topicals. The proposed regulations for additional cannabis products include specific limitations per product type. Health Canada recently posted **a table** of the proposed expansion of the cannabis regulations and the related limits.

The commercial sale of edible cannabis products (e.g. baked goods, candy,etc.) is not currently permitted, but authorization of the sale of cannabis edible products and concentrates is expected by October 2019.

Health Canada will require a license for the commercial sale and production of cannabis. Additionally, a license will be required to conduct laboratory tests of cannabis and for commercial research involving cannabis. The Canada Revenue Agency (CRA) will impose an additional license requirement for cultivators, producers and packagers of cannabis products.

For more information, see the following Health Canada resources:

- **Licensed cultivators, processors and sellers of cannabis**
- **Proposed Approach to the Regulation of Cannabis: Summary of Comments Received During the Public Consultation**
- **Import and export of cannabis by licensed producers**
- **Supply chain for the commercial production and sale of cannabis**

Front-of-Package Labeling Rules Expected Soon

Currently, more than 20 countries permit some form of front-of-package (FOP) label on pre-packaged foods to highlight certain nutritional attributes. A few months ago, Health Canada

proposed mandatory front-of-package labeling to require food manufacturers to use approved symbols to alert consumers to high levels of sugars, sodium or saturated fat. As proposed, food manufacturers would utilize FOP symbols approved by Health Canada when a product contains 15% or more daily value of any of the three nutrients in prepackaged foods and 30% or more for prepackaged meals.

Health Canada intended to publish the final regulations for FOP labeling within the Canada Gazette before the end of 2018. The compliance date for the Canadian FOP requirement was expected to be aligned with the transition period for the 2016 nutrition labeling regulation with a compliance date for both regulations of December 14, 2022.

The 2018 proposal requested public comments on the **following schemes for FOP labels**.

Health Canada Implements PHOs Ban

Health Canada has banned the use of partially hydrogenated oils (PHOs) in foods as part of a national effort to reduce the primary dietary source of artificial trans fat in the food supply. On September 15, Health Canada added PHOs to its *List of Contaminants and Other Adulterating Substances in Food*, which should effectively ban PHOs from the Canadian food supply.

The Canadian ban is aligned with the U.S. FDA's 2015 decision to withdraw the 'generally recognized as safe' (GRAS) status of PHOs. Due to a link between the artificial trans fat and coronary heart disease, the FDA advised food manufacturers to "either reformulate products without PHOs and/or petition the FDA to permit specific uses of PHOs" within three years.

Health Canada will permit foods containing PHOs and manufactured prior to September 17, 2018 to be sold for up to two years. To dissuade food manufacturers from replacing PHOs with saturated fats, the Canadian government might require a front of pack warning to alert consumers to products high in saturated fats.

Canada to Prioritize Sodium Reduction Efforts in 2019

During 2019, Health Canada is expected to establish new targets or to revise targets for sodium reduction by restaurants and pre-packaged foods. Canadian food manufacturers are advised to expect regulatory monitoring of the industry's progress toward meeting the targets.

Health Canada initially issued a guidance document to drive food industry efforts to reduce sodium in processed foods in an effort to achieve an intake goal of 2,300 mg per day by 2016. Last year, Health Canada announced the results of a study of the effectiveness of industry efforts to reduce sodium in processed foods.

Health Canada disclosed that a **study** of 10,500 products representing 94 food categories evaluated the voluntary industry initiative to reduce sodium in processed foods. In fact, the government study revealed sodium levels were not significantly reduced in nearly half of food categories and the sodium content of several food categories actually increased. According to the Health Canada report, only 14% of the food categories had met the sodium reduction targets. The majority of Canadians exceed the dietary recommendations for sodium, and over 75% of sodium consumed by Canadians is derived from commercially processed foods, according to Health Canada.

Canada Announces MRLs for Chemical Residues

Following are selected Canadian notifications of proposed maximum residue limits (MRLs) that were published in recent months.

Date	Notice Type	Chemical
August 15, 2018	Re-evaluation	Plan to phase out most uses of the neonicotinoids clothianidin and thiamethoxam
August 20, 2018	Adopted MRL	Pyrimethanil
August 21, 2018	Adopted MRL	Abamectin
August 21, 2018	Proposed MRL	Fludioxonil
August 21, 2018	Proposed MRL	Diquat
August 21, 2018	Proposed MRL	2,4-D
August 21, 2018	Proposed MRL	Diethofencarb
August 23, 2018	Proposed MRL	Ethalfluralin
August 23, 2018	Proposed MRL	Benzovindiflupyr
August 23, 2018	Proposed MRL	Difenoconazole
August 23, 2018	Proposed MRL	Indaziflam
August 24, 2018	Withdrawal	Mancozeb
August 28, 2018	Proposed MRL	Flonicamid
August 28, 2018	Proposed MRL	Clomazone
August 28, 2018	Proposed MRL	Dodin
August 29, 2018	Proposed MRL	Bifenthrin
August 29, 2018	Proposed MRL	Fenhexamid
August 30, 2018	Proposed MRL	Afidopyropen
August 31, 2018	Proposed MRL	Picoxystrobin
September 5, 2018	Consultation	Bacillus subtilis strain BU1814
September 12, 2018	Re-evaluation	Fomesafen
September 26, 2018	Re-evaluation	Clodinafop-propargyl
October 5, 2018	Re-evaluation	Mancozeb
November 8, 2018	Consultation	Proposed revision or revocation of MRLs for discontinued agricultural pest control products – Update 2

Date	Notice Type	Chemical
November 8, 2018	Proposed MRL	Kresoxim-methyl
November 20, 2018	Proposed MRL	Acequinocyl
November 20, 2018	Proposed MRL	Chlorothalonil
November 20, 2018	Proposed MRL	Clethodim
November 22, 2018	Proposed MRL	Metaldehyde
November 22, 2018	Proposed MRL	Novaluron
November 27, 2018	Proposed MRL	Fluazifop-butyl

Food Additive Regulations – New or Modified Regulations

Date	Summary
July 9, 2018	Modification to the List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents to Enable the Use of Gellan Gum in Certain Standardized Flavoured Milks – Reference Number: NOM/ADM-0119
July 18, 2018	Modification to the List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents to Extend the Use of Sucrose Esters of Fatty Acids in Dry Sauce or Dry Soup Bases or Mixes and Unstandardized Dairy-Based Beverages – Reference Number: NOM/ADM-0121
July 18, 2018	Modification to the List of Permitted Food Enzymes to Enable the Use of Glucose Oxidase from Trichoderma reesei RF11400 in Certain Grain and Bakery Products, Certain Liquid Egg Products and Pasta - Reference Number: NOM/ADM-0120
September 6, 2018	Modification to the List of Permitted Colouring Agents to Enable the Use of Calcium Carbonate in Unstandardized Confectionery – Reference Number: NOM/ADM-0124
September 6, 2018	Modification to the List of Permitted Food Enzymes to Enable the Use of Lipase from Trichoderma reesei RF10625 in Bread, Flour, Whole Wheat Flour and Unstandardized Bakery Products - Reference Number: NOM/ADM-0123
September 15, 2018	Addition of Partially Hydrogenated Oils (PHOs) to List of Contaminants and other Adulterating Substances in Foods
November 8, 2018	Modification to the List of Permitted Food Enzymes to Enable the Use of Maltogenic alpha-Amylase from Bacillus subtilis RF12029 in Bread, Flour, Whole Wheat Flour and Unstandardized Bakery Products – Reference Number: NOM/ADM-0125
November 19, 2018	Modification to the List of Permitted Food Enzymes to Enable the Use of Lipase from Ogataea polymorpha B14-CBSsynt for specified uses in bakery products and pasta

Mexico Issues First SQF Certification

In November 2018, the Mexican Accreditation Entity (EMA) granted the country's first accreditation of the Safe Quality Food (SQF) program to the independent body, Agency Certification of Establishments TIF. In Mexico, the TIF designation refers to federally inspected establishments involved with animal slaughter, meat processing and meat storage. The National Service of Health, Safety and Agri-Food Quality (SENASICA) and other regulatory agencies in Mexico have expressed support for the SQF program and its impact on the food industry. Currently, there are 454 establishments in Mexico with TIF certification granted by SENASICA.TIF establishments generate products derived from beef, pork, equine, goat, poultry and bees.

Australia, Canada, Mexico and the United States are currently authorized to grant the SQF certification, which is intended to harmonize food safety requirements in order to facilitate increased global trade. The SQF certification of TIF facilities is expected to increase the quality and volume of products exported from Mexico.

Mérieux NutriSciences consultants can support the development and enhancement of food safety programs for facilities in preparation for certification against one of the GFSI benchmarked schemes, including Safe Quality Food (SQF), BRC (British Retail Consortium) and FSSC (Food Safety System Certification) 22000.

Chlorine Dioxide in Flours

On August 20, an **amendment** of the Food Additives Annex was published for the use of chlorine dioxide as a treatment agent for cereals, specifically semolina and semolina flour. As a flour treatment agent, the maximum limit is 300 mg/kg and the residual level should not exceed 5 mg/kg.

COFEPRIS Amends Food Additive Regulations

On July 12, the Commission for the Protection against Sanitary Risk (COFEPRIS) published amendments to Annex II, III and VI of the food additive regulations.

Annex II (Spanish)
Annex III (Spanish)
Annex IV (Spanish)

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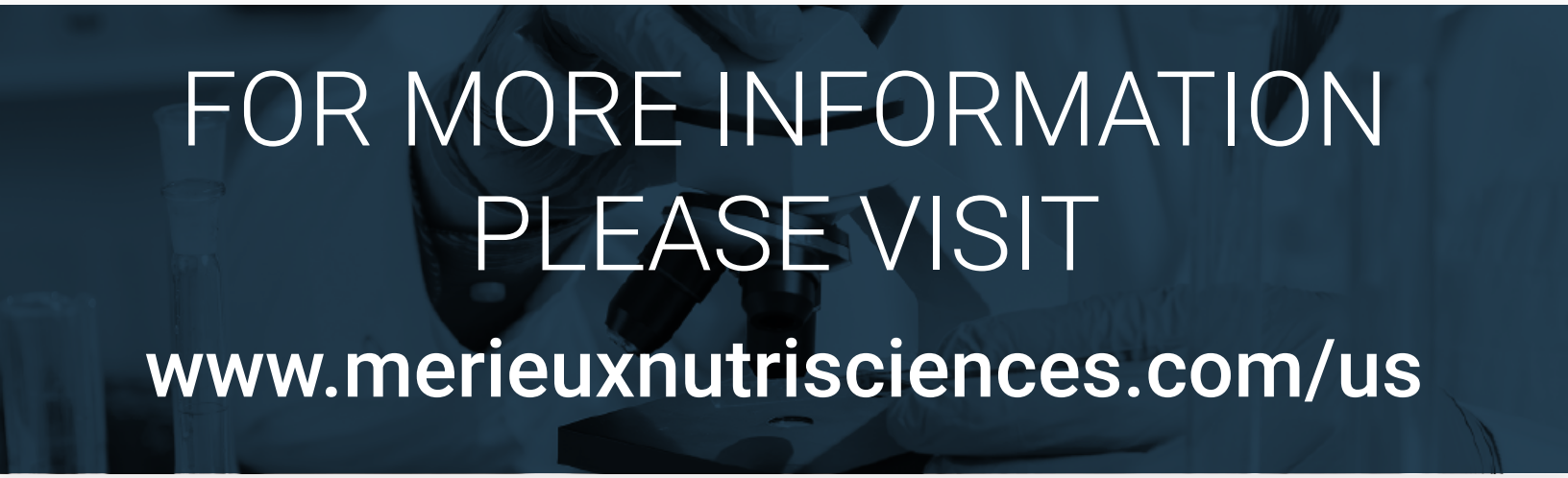

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