NORTH AMERICAN
REGULATORY UPDATE

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June 2018

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Quarterly Review of U.S. Food Recalls

Food products are recalled from the marketplace due to various food safety, quality and regulatory issues. During the first quarter (Q1) of calendar year (CY) 2018, the vast majority of recall events involving FDA-regulated food products were triggered by microbial contaminants and labeling errors such as 'undeclared allergens'

Under the Food Safety Modernization Act (FSMA), the FDA was granted mandatory recall authority, but the agency has rarely needed this authority. On April 3, the FDA issued its first mandatory recall due to the detection of Salmonella in a powdered kratom product. As of April 5, federal health authorities had linked kratom products to a multi-state Salmonella outbreak with at least 132 cases.

The FDA classified 139 food recall events during the first quarter of 2018 within its Enforcement Report. During calendar year 2017, nearly 700 food recalls were classified. Undeclared allergens and microbial hazards accounted for 40% and 35% ,respectively, of FDA food recalls last year.

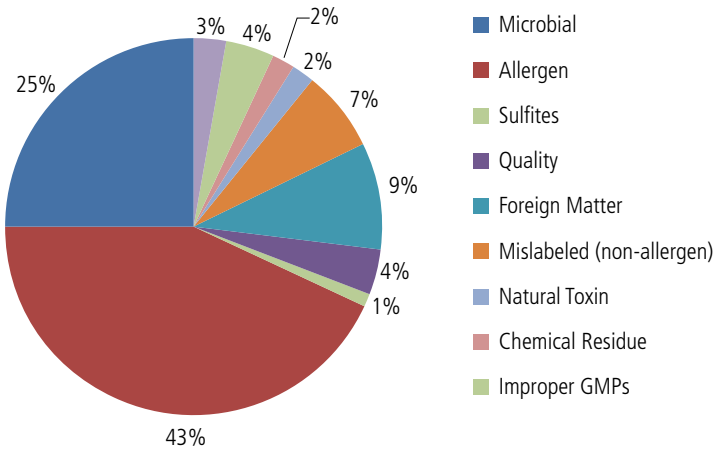
Microbiological contaminants were responsible for 25% of all FDA food recalls during Q1 of this year. Listeria was responsible for the majority of recalls in Q1, including recalls of smoked salmon, cheese, sliced apples, ice cream and other frozen products.

The most significant recall event involved the recall of 206 million eggs from nine states due to Salmonella. The eggs were linked to a multi-state outbreak beginning in early March. Salmonella Braenderup was identified as the outbreak strain.

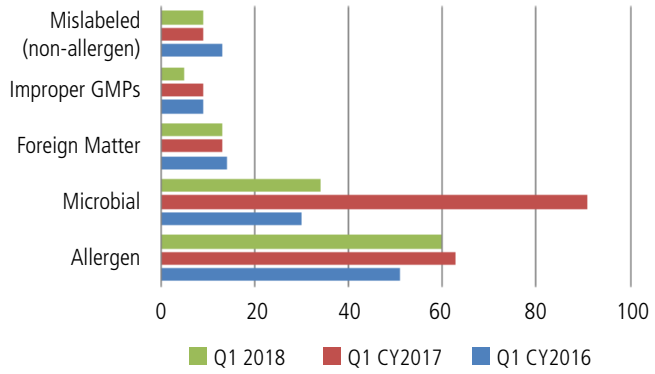
Undeclared allergens triggered 43% of the FDA food recall events during Q1 2018. Historically, the food categories most commonly involved in allergen-related recalls include: bakery, sugar and sweets, mixed dishes, nuts and seeds, sauces and snacks.

The USDA Food Safety and Inspection Service (FSIS) monitors recalls of meat, poultry and egg products. During Q1 of this year, the majority of FSIS recalls were attributed to undeclared allergens, but microbial contaminants were a close second. In recent years, the agency has attempted to address the reasons for the upward trend in recalls due to undeclared allergens.

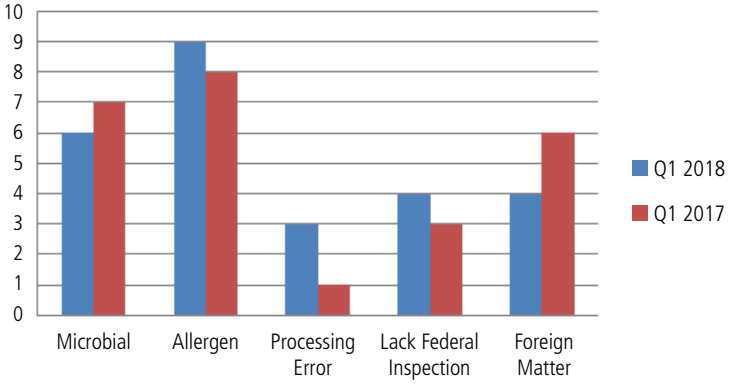
Reasons for FDA Recalls - Q1



FDA Recalls - Top 5 Reasons During Q1



Reasons for FSIS Recalls - Q1



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FOOD & DRUG ADMINISTRATION

Food Safety Regulatory Update

The Food and Drug Administration (FDA) has issued several guidance documents since January to facilitate industry compliance with the regulations mandated by the Food Safety Modernization Act (FSMA), including:

- Guidance for Industry: Application of the Foreign Supplier Verification Program Regulation to the Importation of Live Animals
- Guidance for Industry: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals: What You Need to Know About the FDA Regulation; Small Entity Compliance Guide
- Guidance for Industry: Application of the Foreign Supplier Verification Program Regulation to Importers of Grain Raw Agricultural Commodities
- Draft Guidance for Industry: Considerations for Determining Whether a Measure Provides the Same Level of Public Health Protection as the Corresponding Requirement in 21 CFR part 112 or the Preventive Controls Requirements in part 117 or 507
- Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food; Chapter 15: Supply-Chain Program for Human Food Products
- Guidance for Industry: #245 - Hazard Analysis and Risk-Based Preventive Controls for Food for Animals
- Guidance for Industry: Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety and/or Foreign Supplier Verification Programs
- Draft Guidance for Industry: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals

Since the majority of FSMA regulations have been developed, the industry is currently in the implementation and enforcement stages of the regulations. During the first few months of 2018, the FDA has concentrated on guidance documents as the agency continues its "educate rather than regulate" stage of enforcement. Below is a synopsis of recent regulatory activities and upcoming FSMA initiatives.

Activity	Synopsis
Voluntary Qualified Importer Program (VQIP)	The FDA launched the Voluntary Qualified Importer Program (VQIP) in January. 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.
Accredited Third-Party Certification Program	In January, the FDA announced the approval of ANSI-ASQ National Accreditation Board (ANAB) as the first accreditation body recognized under the voluntary Accredited Third-Party Certification Program. Under the program, accreditation bodies will evaluate third-party certification bodies for accreditation, monitor the performance of certification bodies, conduct self-assessments and submit reports and other notifications to the FDA, as stipulated by the final rule. A certification body is defined by the rule as a foreign government, foreign cooperative or another third-party, such as a single individual or organization.
Produce Safety Rule	In recent months, the FDA has issued guidance and proposed an extension of the compliance date for produce firms, excluding those growing sprouts, covered by the FSMA rule, "Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption." Also, the agency proposed a two-year extension of the water testing requirements and may issue a final rule this year. Later this year, the FDA plans to clarify the "registration requirements for food facilities to better align how facilities and farms that perform similar activities are treated under the preventive controls rules and the produce safety rule."

Activity	Synopsis
Guidance Clarifies 'Small Business' Concepts Related to FSMA Rules	In March, the FDA issued a draft guidance in response to industry questions concerning the definition of a "small business", related to the preventive controls rules for human food (21 CFR 117) and animal food (21 CFR 507). According to the guidance, the FDA has defined a "small business" to be a "business (including any subsidiaries or affiliates) employing fewer than 500 full-time equivalent employees", whereby the total employee count is "not limited to the employees at a particular facility." In addition, the guidance explains the FDA definition of other FSMA terms and concepts, including "subsidiary," "affiliate," full-time equivalent employee" and "facility."
Guidance for Co-Manufacturers	Responding to industry concerns about the FSMA supply chain program requirements, the FDA issued guidance in November to postpone enforcement of the supplier approval and verification requirements until November 6, 2019. The supply chain program requirements are mandated by certain FSMA rules. The guidance pertains to firms involved in "co-manufacturing" agreements whereby a brand owner contracts with a second party to manufacture or process the food. The rules require co-manufacturers to approve their ingredient suppliers and to conduct supplier verification activities. The enforcement delay will permit firms additional time to establish new contracts between brand owners and co-manufacturers to share certain information, such as supplier audit results.
Written Assurance Requirements	The 'written assurance' disclosure statements are mandated by four of the foundational FSMA rules, including the rules for Preventive Controls for Human Food, Preventive Controls for Animal Food, Produce Safety and the Foreign Supplier Verification Program (FSVP). Enforcement of this requirement has been postponed. In effect, companies are no longer required to obtain written assurance from customers that an identified hazard will be controlled. The requirements were related to situations in which food safety controls would be applied downstream by a customer of a manufacturer/processor. According to the latest regulatory agenda, the FDA intends to issue a proposed rule by August 2018 to revoke the customer assurance requirements. Manufacturers, processors, importers and farmers are still required to provide documentation to notify customers when hazards have not been controlled.
Laboratory Accreditation Rule	To ensure consistent quality in laboratory testing and analytical data, the FDA will issue a rule to require the accreditation of both foreign and domestic laboratories for all regulatory testing. According to the latest federal regulatory agenda, the FDA is expected to propose the laboratory accreditation rule by September 2018.
Guidance for Sanitary Transportation	Under the FSMA rule for the sanitary transportation of food, the majority of operations that transport food in the United States by motor or rail, as well as foreign entities shipping food to the United States in an international freight container by sea or air, must implement actions to mitigate food safety risks. Large businesses were required to comply with the new requirements by April 6, 2017. The compliance date for small businesses was April 6, 2018.

FDA Updates Food Code for Retail, Foodservice Operations

The FDA Food Code, a science-based reference widely adopted by public health agencies at all levels of government throughout the United States, is a critical resource for ensuring that uniform food safety best practices are implemented within retail food stores and foodservice operations. In response to evolving food safety knowledge, the FDA issued a revised version of the Food Code in February 2018.

The FDA identified the following changes as the most significant new recommendations within the 2017 Food Code:

- Revised requirement for the Person in Charge (PIC) to be a Certified Food Protection Manager (CFPM) (Section 2-102.12)
- Added a new section that addresses the use of bandages, finger cots or finger stalls (Section 2-401.13)
- Harmonized cooking time/temperature parameters for intact and non-intact meat and poultry in accordance with guidance from the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA-FSIS) (Section 3-401.11)
- Updated procedures for retail food establishment operations to continue during an extended water or electrical outage if a written emergency operation plan has been pre-approved by the Regulatory Authority, immediate corrective action taken and the Regulatory Authority has been notified upon implementation of the plan (Section 8-404.11)

The new Food Code is available from the FDA website: http://www.fda.gov/FoodCode

FDA Survey of Salmonella Prevalence in Retail Spices

Researchers from the FDA have published the results of a survey on the prevalence of Salmonella in 7,250 samples of 11 types of retail spices marketed within the United States. In February, the agency announced that the survey results indicated the prevalence of Salmonella in 9 out of 11 types of U.S. retail spices was less than the initial prevalence of the pathogen in shipments of imported spices. Pathogen reduction treatments applied to imported spices prior to retail sale were associated with a reduction in the prevalence of Salmonella in most spices. The survey updated the agency's 2013 risk profile on pathogens and filth in spices. The results of the latest survey were published in the Journal of Food Protection.

FDA Food Labeling Update

Final Menu Labeling Guidance Tackles Industry Concerns

Under a 2014 federal rule, retail establishments with more than 20 locations, including restaurants, convenience stores and similar establishments, are required to post calorie information for standard menu items on printed menus, menu boards and drive-through menus. The FDA had delayed implementation of the menu labeling rule twice, but it finally took effect on May 7, 2018. Due to numerous industry concerns about the new requirements, the FDA issued a draft guidance in November 2017 that covered various topics, including: calorie disclosure signage for self-service food; various methods for providing calorie disclosure information; compliance and enforcement; criteria for covered establishments; and standard menu items. On May 8, the agency released the final guidance for menu labeling to address various industry concerns prompted by the draft guidance. Notably, the final guidance confirmed the FDA will use enforcement discretion regarding the "calories from fat" declaration mandate, which requires alignment with the 2016 revision of the nutrition labeling rules. Moreover, the final guidance clarifies the requirements for distinguishing between menus and marketing material. During the first year of implementation by retail establishments, the FDA will focus on education rather than enforcement.

FDA Extends Deadline for Nutrition Facts Rules by 18 Months

On May 4, the Food and Drug Administration (FDA) released a final rule 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 within a proposed rule issued in September 2017, the compliance dates were extended from July 26, 2018, to January 1, 2020. Manufacturers with less than $10 million in annual food sales will have their compliance date extended from July 26, 2019, to January 1, 2021.

Regulatory Definition of "Healthy" Expected

In March, the FDA Commissioner Gottlieb suggested the healthy claim is "ripe for change." Concurrently, the agency revealed plans to define "healthy" foods and to establish a "healthy" symbol for packaged food labels. It has been suggested that the definition of 'healthy' should extend beyond nutrients to encompass dietary patterns and food groups such as whole grains, low-fat dairy, fruits and vegetables. Currently, if a product is labeled as "healthy," manufacturers are at risk for a class action lawsuit if the product fails to meet certain criteria. The FDA is considering pending industry petitions requesting approval of the claim on certain food products, including a recent petition from an organic egg company that urged the agency to allow eggs to bear the "healthy" claim. The FDA's current position on the Use of the Term 'Healthy' in the Labeling of Human Food Products was established within a 2016 guidance document.

Soy Protein Health Claim Supported by U.S. Dietary Supplement Industry

Dietary supplement industry trade groups have cited evidence that shows soy protein consumption can lower cholesterol in an effort to persuade the FDA to reconsider its recent decision about a related health claim. In October 2017, the FDA concluded that insufficient evidence is available to support the health claim regarding the benefits of soy protein intake for reducing the risk of coronary heart disease (CHD). In effect, the agency released a proposed rule last year to revoke the 1999 regulation that permitted the health claim. The agency later extended the comment period for this proposal until March 19, 2018. The agency received more than 1,000 comments in response to the proposal and the majority of public comments supported the decision to rescind the health claim. A final rule is expected later this year.

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Guidance for Scientific Evaluation of Dietary Fiber

To resolve industry questions about the regulatory definition of dietary fiber, the agency issued a guidance entitled, Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition (21 CFR 10.30) in March. Under the 2016 final rule for revising the Nutrition Fact labels, the FDA permitted only seven non-digestible carbohydrates to be listed as dietary fiber: oat and barley beta-glucan; psyllium husk; guar gum; pectin; locust bean gum; and hydroxylpropyl methylcellulose. Last year, the FDA published a regulatory notice requesting scientific data and other information related to the definition of dietary fiber. The agency indicated it would amend the list of dietary fibers to include an isolated or synthetic nondigestible carbohydrate if it meets the updated regulatory definition for "dietary fiber." According to the March 2018 guidance, the FDA's scientific evaluation would involve the following steps: **1)** the assessment of publicly available scientific studies and other data **2)** the elimination of studies that cannot provide scientific conclusions about the physiological effects of an added non-digestible carbohydrate and **3)** the evaluation of the strength of the scientific evidence to determine whether the carbohydrate provides a physiological effect that is beneficial to human health.

Guidance Released on "Added Sugar" Labeling

The FDA released a draft guidance in February entitled, The Declaration of Added Sugars on Honey, Maple Syrup and Certain Cranberry Products, in response to industry concerns. According to the draft guidance, the agency will exercise enforcement discretion if companies use the symbol "†" immediately after the added sugars percent Daily Value information on single packages and/or containers of pure honey, pure maple syrup and certain cranberry products. According to the guidance, the symbol would direct consumers to statements providing additional information concerning the added sugars.

Allergen Labeling Update - Sesame, Barley, Rye

Under the Food Allergen Labeling and Consumer Protection Act (FALCPA), food manufacturers are required to disclose the presence of the 'Big 8' allergens (milk, egg, wheat, fish, crustacean shellfish, peanuts, tree nuts and soy) on food labels. Recently, the FDA announced it would consider an amendment to require the disclosure of sesame as a food allergen. In March 2018, several U.S. senators submitted a letter to FDA Commissioner Scott Gottlieb, which urged the FDA to add sesame to the list of allergens since sesame is commonly recognized as a food allergen. The agency recently denied a public petition that requested the addition of barley and rye to the list of common allergens in order to protect individuals with gluten sensitivities.

US DEPARTMENT OF AGRICULTURE

Proposed Rule Issued for National GM Food Labeling

Under a 2016 law, the U.S. Department of Agriculture was required to develop regulations to "establish a national mandatory bioengineered food disclosure standard with respect to any bioengineered food and any food that may be bioengineered" by July 2018. On May 4, the agency issued the long-anticipated proposed rule to implement the National Bioengineered Food Disclosure Standard as mandated by Congress. The regulation would establish a consistent national approach to the labeling of food or food ingredients derived from genetic engineering.

A food product subject to the labeling rule must disclose the bioengineered or genetically modified (GM) content of products using various labeling options including: a labeling statement, a symbol or an electronic / digital link such as a QR code that will direct consumers to the bioengineering disclosure.

The USDA regulation sought to clarify many of the uncertainties of the Act, including the definition of "bioengineering." As defined by the Act and the proposed rule, "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." Under this definition the majority of crops harvested in the US would be considered genetically engineered. The proposed 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.

According to the 2016 law, the USDA should establish a threshold labeling exemption and other exemptions from the labeling requirement. Several industry trade groups and public comments have expressed concerns about the labeling of highly processed foods that are derived from genetically modified seeds, but after processing, the products contain insignificant traces of genetic modification. Addressing these concerns, the proposed rule suggested three options to support a labeling threshold, including:

- Food in which an ingredient contains a bioengineered substance that is inadvertent or technically unavoidable, and accounts for no more than five percent (5%) by weight of the specific ingredient.
- Food in which an ingredient contains a bioengineered substance that is inadvertent or technically unavoidable, and accounts for no more than nine-tenths percent (0.9%) by weight of the specific ingredient.
- Food in which the ingredient or ingredients that contain a bioengineered substance account for no more than five percent (5%) of the total weight of the food in final form.

If a food is not derived from bioengineering or lacks a bioengineered ingredient, then the product would be exempt from the labeling rule. In addition, the agency proposed the following labeling exemptions: food served in a restaurant or similar retail food establishment; very small food manufacturers; food derived from an animal that consumed bioengineered feed; and food certified as organic.

Under the proposed rule, bioengineering labels could be required for multi-ingredient meat and poultry products, but this would depend on the product's formulation and the predominance of ingredients. In the case of a product containing multiple ingredients, the predominant ingredient would determine if the product is subject to labeling. For example, a product containing beef as the predominant ingredient is unlikely to be subject to the labeling despite the presence of lesser ingredients that are derived from bioengineering.

The USDA has requested public comments on the key provisions of the rule by July 3, 2018. The agency is unlikely to meet the July 29, 2018 deadline for the final rule as mandated by Congress, but the proposed rule suggested a compliance date of January 1, 2020.

Final Rule to Modernize Swine Inspection Under Development

The USDA Food Safety and Inspection Service (FSIS) recently closed the comment period on a proposed rule for a new inspection system for swine slaughter, and the agency is expected to issue a final rule by April 2019. Earlier this year, the agency published a proposed rule for a New Swine Slaughter Inspection System (NSIS) for market hog establishments based on the HACCP-based Inspection Models Project (HIMP) for hogs. As proposed, the rule would revoke hog slaughter line speed limits and permit plants to voluntarily reconfigure evisceration lines. According to FSIS, the new system would permit federal inspectors the flexibility to address offline inspection activities related to sanitation, HACCP and humane handling requirements. NSIS is a voluntary program and as such, market hog slaughter establishments will have the option to continue to operate under their current inspection system. All swine slaughter establishments would be required to conduct additional pathogen sampling, but establishments would have greater flexibility in developing sampling plans.

Comment Period Closing on Egg Products Inspection Rule

On June 13, the USDA will close a public comment period related to a proposal to require egg product plants to develop and implement Hazard Analysis and Critical Control Point (HACCP) Systems and Sanitation Standard Operating Procedures (SOPs) similar to the current requirements for meat and poultry products. As proposed, egg product plants would be required to use a process to eliminate detectable pathogens from the finished products and develop HACCP systems that prevent the presence of pathogens in FSIS-regulated egg products, including dried, frozen or liquid eggs.

USDA to Launch Dioxin Survey of Meat, Poultry and Fish

On June 1, the USDA Food Safety and Inspection Service (FSIS) will begin a 12-month survey to evaluate the levels of dioxins and dioxin-like compounds in U.S. beef, pork and poultry. Later, the agency plans to extend its dioxin surveillance program to include Siluriformes fish and fish products. While dioxins are ubiquitous as environmental contaminants, the highest concentrations of dioxins in food are associated with animal products. The FSIS has been conducting dioxin surveys of animal products on a 5-year cycle. Details of the FY 2018 survey are found in FSIS Notice 24-18.

FSIS Nutrition Labeling Rule in Limbo

A proposed rule, Revision of the Nutrition Facts Panels for Meat and Poultry Products and Updating Certain Reference Amounts Customarily Consumed (0583-AD56) was issued in January 2017, but the proposal has been designated as a long-term action within the latest federal regulatory agenda. Based on the latest scientific research and the federal dietary guidelines for Americans, the proposal was closely aligned with the 2016 revisions of the FDA final rule for nutrition labeling. In fact, the USDA indicated meat and poultry products can voluntarily comply with the FDA's Nutrition Facts label format finalized in 2016, while the USDA rule is being finalized.

USDA FSIS DIRECTIVES & NOTICES

The following are selected USDA FSIS Directives and Notices issued between January 1 and April 30, 2018.

Directive #	Title	Date
5000.1	Verifying an Establishment's Food Safety System Meat and Poultry Hazards and Controls Guide (March 2018)	March 2018
7120.1	Safe and Suitable Ingredients Used in the Production of Meat, Poultry and Egg Products – Revision 46 • List of Approved On Line Reprocessing (OLR) and Off Line Reprocessing (OFLR) List of Approved On Line Reprocessing (OLR) and Off Line Reprocessing (OFLR) Antimicrobial Systems for Poultry: Updated March 2018 • Table of Safe and Suitable Ingredients for Fish in the order of Siluriformes • Access additional information and related documents • Table of Safe and Suitable Ingredients	March 29, 2018
7150.1	Descriptive Designation for Needle or Blade Tenderized Raw Beef Products as Required by 9 CFR 317.2(e)(3)	April 3, 2018

FSIS Notices

Notice #	Title	Date
25-18	Criteria for Recommending an Onsite Verification Audit as Part of a Reinstatement of Equivalence Determination	Apr 30, 2018
24-18	Fiscal Year 2018 Dioxin Survey	Apr 30, 2018
23-18	Notification of Export Certificates to The People's Republic of China	Apr 18, 2018
18-18	Follow-Up Sampling in Raw Poultry Establishments Not Meeting Salmonella Performance Standards	Mar 23, 2018
17-18	Delayed Implementation of Verification of Revised Appendix A and B	Mar 22, 2018
14-18	Eligibility of Foreign Countries to Export Siluriformes Fish and Fish Products to the United States	Mar 05, 2018
09-18	Requirements for the Disposition of Non-Ambulatory Disabled Veal Calves	Feb 07, 2018
02-18	Update to Sampling Supplies for Routine Risk Based Lm Sampling and IVT Programs	Jan 03, 2018

STATES

California - Proposition 65 Warning for Acrylamide in Coffee

Under the California law commonly known as Proposition 65, companies are required to post a warning or label on products containing any chemical at levels known to cause cancer or reproductive toxicity. Due to the formation of acrylamide in roasted coffee, a consumer lawsuit was filed in 2010 in order to require all manufacturers, distributors and retailers to post a warning label on coffee products sold in California. The lawsuit accused retailers of violating the California law by selling coffee with acrylamide levels exceeding the Proposition 65 safe harbor level, despite the fact that acrylamide is a natural byproduct of coffee roasting. Historically, the coffee industry has argued the 'naturally occurring' exemption of the Proposition 65 law should apply to coffee.

On March 28, 2018, a California Superior Court judge issued a preliminary decision in the case, Council for Education and Research on Toxics v. Starbucks Corp et al (BC435759). The judge ruled in favor of the advocacy group (i.e. CERT) to require California retail establishments to post a warning about the potential cancer risk associated with the formation of acrylamide in roasted coffee.

In California, the presence of acrylamide in food and other consumer products requires a warning statement on the package or at the point of sale. The warning statement is required if the level of acrylamide exceeds the state's Proposition 65 'Safe Harbor' levels.

- (Cancer) No Significant Risk Level (NSRL): 0.2 micrograms/day
- (Reproductive risk) Maximum Allowable Dose Level (MADL): 140 micrograms/day

Washington – PFAS Chemicals Banned in Paper Food Packaging

Washington state enacted a new law in March to ban the use of perfluoroalkyl and polyfluoroalkyl substances, or "PFAS," in food packaging. Under the law, the state ban will not take effect if the Washington Department of Ecology cannot identify safer alternatives to the use of PFAS in paper food packaging by January 1, 2020. The law stipulates that "safer alternatives" must be FDA-approved for food contact applications and available in sufficient quantities for commercial applications. If Washington can identify safer alternatives to PFAS in paper food packaging, then the state ban would take effect on January 1, 2022. Washington is the first U.S. state to approve a ban of PFAS chemicals in food packaging.

In November 2017, California established new consumer product labeling requirements for the most extensively produced PFAS chemicals. Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS) are chemicals commonly utilized in paper coatings for food packaging. The surfactants are also employed in various consumer products, including non-stick cookware, leather, carpets and textiles. Based on a review of the findings of a U.S. Environmental Protection Agency (EPA) report of the toxicity of PFOA and PFOS, the state of California added PFOA and PFOS to its Proposition 65 list of chemicals known to cause reproductive toxicity. In effect, any product containing the chemicals above the legal threshold must comply with California's Proposition 65 labeling requirement.

Hawaii - State Bans Agricultural Uses of Chlorpyrifos

Effective January 2019, Hawaii will impose a statewide ban on all agricultural uses of the controversial pesticide chlorpyrifos. Recently, Hawaii became the first U.S. state to ban the chemical by enacting the legislation known as SB 3095.The legislation provides opportunities for exemptions that would permit the use of chlorpyrifos after January 2019, but all exemptions will end in 2022.

Chlorpyrifos is a pesticide commonly detected in agricultural commodities, which has been added to California's Proposition 65 list of chemicals known to cause reproductive toxicity. Proposition 65 is a California law requiring "clear and reasonable" warning labels on products that contain chemicals determined to cause cancer, birth defects or other reproductive harm. Currently, the Proposition 65 requirements apply to more than 900 naturally occurring and synthetic chemicals, including additives and ingredients in food, drugs and other products.

Quarterly Update of Canadian Food Recalls

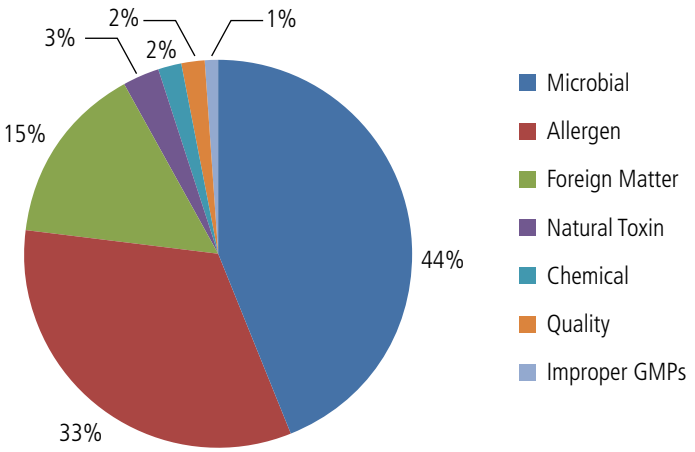
According to data from the Canadian Food Inspection Agency (CFIA), microbial contaminants and undeclared allergens were linked to the majority of food product recalls and alerts during the first quarter of 2018.

Microbial contaminants triggered 44% of CFIA recall and alert announcements from January through March, 2018.

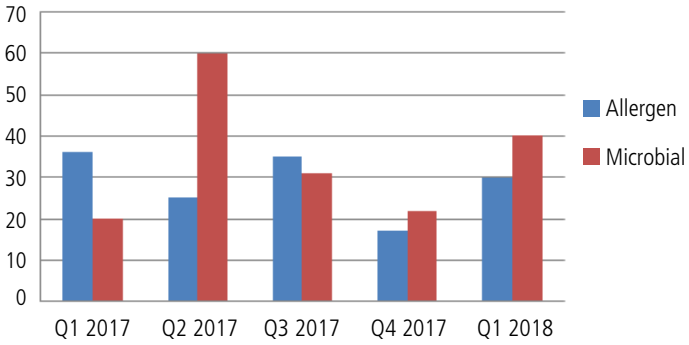
The majority of Q1 CFIA food safety notifications linked to microbial contaminants were attributed to the following pathogens: Listeria monocytogenes (5),E. coli O157:H7 (8), Salmonella (12), Clostridium botulinum (11) and Staphylococcus (1). Notably, nearly all of the recalls due to Clostridium botulinum involved fish products, including whitefish and salmon.

Undeclared allergens have been responsible for the majority of Canadian food recalls in recent years, but this trend ended in 2017. During Q1 of this year, allergen labeling errors were linked to 33% of CFIA food safety recalls. 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.

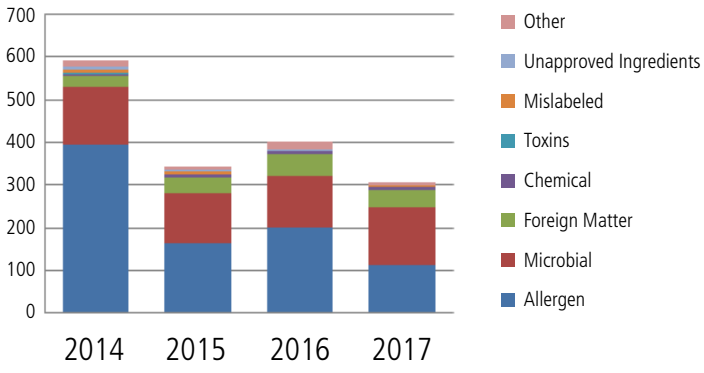
CFIA Food Recalls & Alerts - Q1 CY 2018



CFIA Quarterly Trends - Allergens and Microbial Contaminants



Reasons for CFIA Recalls & Alerts (CY 2014 - CY 2017)



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Canada Proposes Symbols for Front-of-Pack Labeling

Health Canada is developing a mandatory front-of-package (FOP) labeling proposal to require food manufacturers to use approved symbols that alert consumers to high levels of sugars, sodium or saturated fat. In February 2018, the agency introduced four options for the new FOP symbols.

The proposed options for the FOP symbols are meant to alert consumers to a product containing a high concentration of ingredients related to adverse health effects. One of the proposed symbols features a black exclamation mark on a white background and a second option includes a black magnifying glass symbol. The third and fourth options highlight the words "High in" within a rectangle with a red or black background. Health Canada has estimated that approximately half of all food products would qualify for the "High in" warning label. The proposed FOP nutrition symbols can be viewed on the Health Canada web site.

Under the Canadian FOP labeling proposal, food manufacturers must utilize 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 accepted public comments on the proposed symbols until April 26, 2018. The final nutrition labeling regulation is expected later this year. At this time, the mandatory FOP labeling scheme will not be required on packages until 2021, which aligns with the compliance date for the revised Canadian nutrition labeling rules.

Canada Evaluates Voluntary Sodium Reduction Efforts

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. Addressing public health concerns associated with excessive sodium in the Canadian diet, Health Canada issued a guidance document in 2012 to drive food industry efforts to reduce sodium in processed foods to achieve an intake goal of 2,300 mg per day by 2016. Recently, Health Canada announced the results of a study of the effectiveness of industry efforts to reduce sodium in processed foods.

In 2012, Canadian food manufacturers were advised to reformulate foods with added sodium using Health Canada's Guiding Benchmark Sodium Reduction Levels for Processed Foods, which were developed in consultation with the industry. Health Canada's guidance suggested specific sodium target levels for all processed food categories intended for consumers, other manufacturers, foodservice and restaurants. The guidance provided recommendations for the multi-stage reduction of sodium to meet the target goal. Canadian food manufacturers were urged to reduce sodium to the lowest level possible with proper consideration for ensuring microbial safety, quality and consumer acceptance.

The Canadian study of industry efforts to reduce sodium involved an evaluation of 10,500 products representing 94 food categories. In fact, the government study revealed sodium levels were not significantly reduced in nearly half of the 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.

Canada Announces MRLs for Chemical Residues

The following are selected Canadian notifications of regulatory notices, including proposed or adopted maximum residue limits (MRLs), published between January 1 and March 31, 2018.

Date	Notice Type	Chemical
January 3	Adopted MRLs	Tolpyralate
January 5	Adopted MRLs	Chlorantraniliprole Thiabendazole
January 24	Proposed MRLs	Sulfoxaflor
February 2	Adopted MRLs	Clethodim Tioxazafen

Food Additive Regulations - New or Amended Regulations

The following are selected Canadian notices posted between January 1 and March 31, 2018.

Date	Summary
February 1	Amendment to List of Permitted Food Enzymes: Pectinase from new sources added to the List of Permitted Food Enzymes

Mexico Issues Draft Regulations for Dairy Products

In February 2018, Mexico published three draft regulations to address gaps in the regulation of dairy products, particularly milk powder, cheese and yogurt. The USDA Foreign Agricultural Service published a report containing the following summaries of the three proposed regulations:

Draft Regulation for Milk Powder

Title: PROY-NOM-222-SCFI/SAGARPA-2017, Powder or Dehydrated Milk – Raw Material – Specification, Commercial Information, and Testing Methods.
Summary: This draft regulation establishes the characteristics of milk powder or dehydrated milk marketed as a raw material within Mexico (domestic or imported). It also addresses the physicochemical specifications, commercial information and testing methods with which product must comply.
Date Published in the Diario Oficial: February 1, 2018

Draft Regulation for Yogurt

Title: PROY-NOM-181-SCFI/SAGARPA-2017, Yogurt – Denomination, Physical-Chemical and Microbiological Specifications, Commercial Information, and Testing Methods.
Summary: This draft regulation establishes the name, physiochemical and microbiological specifications, commercial information and testing methods with which all commercial types (domestic or imported) of yogurt marketed in Mexico must comply.
Date Published in the Diario Oficial: February 1, 2018

Draft Regulation for Cheese

Title: PROY-NOM-223-SCFI/SAGARPA-2017, Cheese – Denomination, Specifications, Commercial Information and Testing Methods.
Summary: This draft regulation establishes the names and physicochemical specifications that must be met to display the name, the testing methods to demonstrate compliance, and the commercial information that must be detailed on the label in order for the cheese to be commercialized in Mexico.
Date Published in the Diario Oficial: February 19, 2018

Mexico Evaluating Front-of-Pack Labels

Currently, more than 20 countries permit some form of front-of-package (FOP) label on pre-packaged foods to highlight certain nutritional attributes. In Latin America, Chile implemented a labeling law in 2016 requiring the use of a stop sign symbol on the label of all packaged food containing high levels of sugar, calories, sodium or saturated fats. Canada, Mexico and Brazil are a few countries currently considering the implementation of nutrition warning labels similar to Chile, which emphasize colors and symbols over quantitative values.

Mexico's Ministry of Health and the World Health Organization support FOP labeling regulations to bolster public health efforts combating chronic disease, particularly diabetes. To date, Mexico has not yet proposed labeling regulations to mandate the use of symbols to warn consumers of foods high in sugar, fat or salt.

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