# Global Fresh Produce Regulatory Food Safety Standards Register (current as of June 2016)

Category	Developer/	Scope	Comment	Weblink
	Owner			
Australian Food Standards Code	Food Standards Australia New Zealand (FSANZ)	Food safety standards place obligations on Australian food businesses to produce food that is safe and suitable to eat. A food business is any business or activity that involves the handling of any type of food for sale, or the sale of food.  The standards also contain health and hygiene obligations for food handlers.  Charity and community groups, temporary events and home-based businesses are exempt from <b>some</b> of the requirements in the food safety standards.  FSANZ has developed separate standards for food businesses in the primary production and processing sectors.	Independent certification to a HACCP-based food safety program would meet the compliance requirements of the Australian regulator for 'food businesses'.  The definition of food businesses includes farm-based businesses that retail fresh produce direct to consumers and those that conduct on-farm processing.  Primary producers that grow and pack are specifically exempt from the food safety standards but there is provision for them to be included. As of 2016, standards for eggs and egg products, seafood, poultry meat, meat and meat products, dairy and seed sprouts have been developed and implemented.  Currently, the only plant-based sector with a production and processing standard is seed sprouts. Fresh fruit, vegetable and nut businesses are indirectly implicated by virtue of the approved supplier programs of food businesses. All retailer, wholesaler and most processor approved supplier programs require suppliers to be certified to a HACCP-based, independently audited and usually GFSI-equivalent food safety program.  A proposal for horticultural production was considered but did not progress. FSANZ considered that the current (high) levels of food safety certification, through the industry coverage by the approved supplier programs of retailers, wholesalers and processors, adequately covered the sector.  It is estimated that greater than 75% of Australian fresh produce production is covered by independently audited certification to HACCP-based standards.	https://www.comlaw.gov.au/Sear ch/Australia%20New%20Zealand %20Food%20Standards
		Specific provisions for <i>Listeria monocytogenes</i>	In 2014, FSANZ amended the Food Standards Code by including limits for <i>L. monocytogenes</i> in RTE foods based	Approval Report – Proposal P1017 Criteria for <i>Listeria</i>

Canada	Food and Drugs Act (FDA) and Food and Drugs Regulations (FDR)	Food Provisions - Prohibits sale of food that: has in or on it any poisonous or harmful substance; is unfit for human consumption; consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance; is adulterated; or was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.	<ul> <li>on whether growth of <i>L. monocytogenes</i> can or will not occur in the RTE food:</li> <li>RTE foods in which growth of <i>L. monocytogenes</i> will not occur (less than 100 cfu/g).</li> <li>RTE foods in which growth of <i>L. monocytogenes</i> can occur (not detected in 25 g).</li> <li>This approach recognises that the potential for foods to support growth of <i>L. monocytogenes</i> is a main factor in the risk of acquiring listeriosis. For foods in which the growth of <i>L monocytogenes</i> will not occur, occasional low level detections (less than 100 cfu/g) do not present a public health risk.</li> <li>The (not detected in 25 g) Standard applies to RTE produce that has not been treated with a listericidal process and is destined for consumption without cooking. This would include minimally processed produce items such as all packaged and loose freshcut fruit and vegetables.</li> </ul>	monocytogenes – Microbiological Limits for Foods http://www.foodstandards.gov.a u/code/proposals/Documents/P1 O17-MicroAppR.pdf  Supporting Document 1. Guidance on the application of microbiological criteria for Listeria monocytogenes in RTE food (at Approval) http://www.foodstandards.gov.a u/code/proposals/Documents/P1 O17-MicroAppR-SD1.pdf  Supporting document 2. Scientific basis for Listeria monocytogenes limits – Proposal P1017 (at Approval) Criteria for Listeria monocytogenes – Microbiological Limits for Foods http://www.foodstandards.gov.a u/code/proposals/Documents/P1 O17-MicroAppR-SD2.pdf  Act: http://laws.justice.gc.ca/eng/acts /F-27/index.html  Regulations: http://laws.justice.gc.ca/eng/regu lations/C.R.C.%2C_c. 870/index.h tml
	Fresh Fruit and Vegetable Regulations	Regulations Respecting the Grading, Packing and Marking of Fresh Fruit and Vegetables Includes: Health and Safety provisions (for marketing of product including preparation in sanitary manner,		http://laws- lois.justice.gc.ca/eng/regulations/ C.R.C., c. 285/FullText.html
	Policy on <i>Listeria</i> monocytogenes	not contaminated)  The purpose of this policy is to provide guidance to stakeholders regarding verification and control, as well		http://www.hc-sc.gc.ca/fn- an/legislation/pol/policy_listeria_

	in Ready-to-Eat (RTE) foods (2011) Safe Food for Canadians Act	as regulatory oversight and compliance activities of RTE foods with respect to their potential to support the growth of <i>Listeria monocytogenes</i> .  Consolidates food provisions, new prohibitions on food tampering, increased traceability requirements, licencing food importers, prevention of imports that pose health risk	Royal assent in 2012 –  Comes into force when Safe Food for Canadians Regulations are enacted	http://laws-lois.justice.gc.ca/eng/acts/S-1.1/index.html
	Safe Food for Canadian Regulations (SFCR)	Will include provisions for Licencing, Food Safety Requirements and Elements, Preventive Control Plan, Traceability, and Commodity Specific Requirements	Pending – Pre publication in Canada Gazette Part 1 Publication anticipated for late 2016	Proposed Regulations - 2015 <a href="http://laws-lois.justice.gc.ca/eng/acts/S-1.1/index.html">http://laws-lois.justice.gc.ca/eng/acts/S-1.1/index.html</a>
United Kingdom Food Safety Standards	UK Food Standards Agency	The majority of UK food safety legislation is derived from EU legislation.  Food Safety Act 1990 (as amended): provides framework for all food legislation in Great Britain, with similar legislation applying in Northern Ireland.  Food Safety (General Food Hygiene) Regulations 1995  Food Safety Temperature Control Regulations 1995  Food Standards Act 1999  Food Hygiene Regulations 2006  The General Food Law Regulation (EC) 178/2002: general food safety  General Food Regulations 2004 (as amended): provides for enforcement.  EU Regulations 852/2004 on the hygiene of foodstuffs: brought primary production into scope of food hygiene for the first time.  EU Official Feed and Food Controls Regulation 882/2004: 'umbrella regulation' currently under review		http://www.legislation.gov.uk/uk pga/1990/16/contents

		EU Regulation 2073/2005 on microbiological criteria: covering Listeria moncytogenes (ready to eat foods), Salmonella spp. (ready to eat sprouted seeds/sprouts) and E.coli in pre-cut ready to eat fruit and vegetables.  EU 1169/2011 Regulation Food Information for Consumers: covers labelling requirements, including allergens.  Specifically relating to seeds intended for sprouting (following major E.coli incidents in Germany/France):  EU Regulation 208/2013: traceability requirements  EU Regulation 210/2013: approval of establishments producing sprouted seeds  EU Regulation 209/2013: microbiological criteria of foodstuffs (sprouted seeds) in relation to E.coli STEC O157, O111, O103, O145 and O104H:4.		
United States of America	US Food and Drug Administration	In the United States, Local, State, Tribal and Federal Agencies are responsible for enforcing compliance with food safety laws and regulations for produce raw agricultural commodities (i.e. whole produce) and fresh-cut produce (e.g. bagged salads).  United States Federal Authority  The United States Food and Drug Administration is the preeminent produce safety regulatory agency in the United States and the agency derives its authority from a number of laws but predominantly from the Federal Food, Drug, and Cosmetic Act (FFD&C Act), Public Health Service Act, Fair Packaging and Labeling Act, Food Allergen Labeling and Consumer Protection Act, Sanitary Food Transportation Act and others.  The USDA Agricultural Marketing Services (AMS) is	Seven major FSMA implementing regulations are briefly described below.  1) Produce Safety Regulation: This regulation affects both international and domestic produce growers, in that it establishes science-based standards focused on the growing, harvesting, packing and holding of produce onfarms. The key provision areas include agricultural water quality standards and testing, standards for using raw manure and compost, training, control of domestic and wild animals, equipment, tools, buildings, sanitation as well as worker health and hygiene. This on-farm produce safety regulation is significant in that FDA will now put in place an enforceable implementing regulation which explicitly articulates on-farm standards of conduct for the safe growing, harvesting, packing and holding of fresh produce.	https://www.gpo.gov/fdsys/pkg/ FR-2015-11-27/pdf/2015- 28159.pdf

authorized to develop and issue produce quality grades and standards but has no produce safety regulatory role. However, the USDA AMS does maintain a strong working relationship with state government agencies to provide market access produce safety audits on a fee for services basis.

The U.S. Environmental Protection (U.S. EPA) has regulatory authority regarding the use of crop protection chemicals such as pesticides, fungicides, etc. when used on raw agricultural commodities.

#### State, Tribal and Local Government

States, tribal and local governments also play an important role in enforcing produce safety regulations with many states having what are called "mini – food drug and cosmetic acts" which codify into state law provisions similar to the Federal Food Drug and Cosmetic Act. Produce safety regulatory enforcement and compliance activities may be carried out by State Departments of Public Health, Agriculture, Environmental Protection or other agencies depending upon the statutory authority provided for by state law.

#### The Federal Food Drug and Cosmetic Act

As it applies to food, the Federal Food Drug and Cosmetic Act (FFD&C Act) prohibits distribution in the United States, or importation, of articles that are adulterated or misbranded. A product may be "adulterated" if it is defective, unsafe, filthy, or produced under unsanitary conditions. A product may be deemed "misbranded" if its label includes statements, designs, or pictures that are false or misleading, or if it fails to provide required

## 2) Preventive Controls (PC) for Human Food Regulation:

This regulation sets standards for firms which manufacture, process, pack or hold human food. This regulations affects produce businesses throughout the supply chain such as packing operations that are FDA registered facilities and fresh-cut processors. Firms covered by this rule are required to have written plans that identify hazards, specify the steps that will be put in place to minimize or prevent those hazards, identify monitoring procedures and record monitoring results and specify what actions will be taken to correct problems that arise.

# 3) Preventive Controls for Animal Food Regulation (Animal Feed Rule):

This regulation focuses on improving the safety of animal feed by preventing its adulteration. This regulation applies to domestic and imported animal food, including pet food, animal feed, and raw materials and ingredients. Facilities producing animal food are required to have written plans that identify hazards, specify the steps that will be put in place to minimize or prevent those hazards, identify monitoring procedures and record monitoring results, and specify what actions would be taken to correct problems that arise. The rule also establishes certain Current Good Manufacturing Practices (CGMPs) that specifically address animal food. The produce industry has a limited role in the production of animal feed; however produce of insufficient quality is routinely culled from a harvest or process operation and may be used for animal feed.

### 4) Foreign Supplier Verification Programs (FSVP) Rule:

This regulation, addresses import safety and it is closely tied to the preventive controls and produce safety requirements. In that, importers are required to verify that food imported into the US has been produced to the same

https://www.gpo.gov/fdsys/pkg/ FR-2015-09-17/pdf/2015-21920.pdf

https://www.gpo.gov/fdsys/pkg/ FR-2015-09-17/pdf/2015-21921.pdf information.

In 2011 the Food Safety Modernization Act (FSMA) was signed into law and provided a sweeping overhaul of the food safety regulatory framework in the United States and significantly amended the Federal Food Drug and Cosmetic Act (FFD&C Act). FSMA also mandated that FDA develop numerous specific implementing regulations.

food safety standards that are required of US producers. Food importers are required to develop Foreign Supplier Verification Programs (FSVP) that comply with U.S. standards, including FDA's produce safety and preventive controls regulations.

- **5) 3**<sup>rd</sup> **Party Accreditation of Auditors:** This regulation establishes a comprehensive, credible and reliable program of oversight based on third-party audits and certification of foreign food facilities to help FDA make decisions regarding the admissibility of imported foods.
- 6) Mitigation Strategies to Protect Food Against **Intentional Adulteration Regulation:** This regulation require the largest food businesses (i.e. businesses with \$10M or more in total annual food sales) in the U.S. and abroad to take steps to prevent FDA registered food facilities from being the target of intentional attempts to contaminate the food supply. Intentional adulteration of the food supply with intent to cause public health harm is unlikely to occur. However, acts of intentional adulteration may take several forms, including those where the intention is to cause large-scale public health harm; acts of disgruntled employees, consumers, or competitors; and economically motivated adulteration. This regulation may or may not apply to produce businesses that are FDA registered food facilities such as fresh-cut processors, packinghouses and distribution centers depending on enterprise size and the types of activities in which they are engaged.
- 7) Sanitary Food Transportation Regulation: This regulation requires certain shippers, receivers, loaders and carriers who transport food that will be consumed or distributed in the United States, to take steps to prevent the contamination of human and animal food during transportation. Specifically the regulation establishes criteria for sanitary transportation practices for shippers,

https://www.gpo.gov/fdsys/pkg/ FR-2015-11-27/pdf/2015-28158.pdf

http://www.fda.gov/Food/Guida nceRegulation/FSMA/ucm361903 .htm

This final rule is pending and should be published shortly i.e. by the end of the May 2016.

		loaders, carriers and receivers regarding; vehicles and transportation equipment, transportation operations, information exchange, training and recordkeeping. This regulation fulfils FDA's statutory obligation to issue and implement provisions of the 2005 Safe Food Transportation Act as well as the requirements in section 111 of FSMA.	https://www.gpo.gov/fdsys/pkg/ FR-2016-04-06/pdf/2016- 07330.pdf
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