Federal Food Regulation Changes Under COVID-19

Agency	Guidance	Applicable Regulation; Description	Normal Requirement	Modified Requirement	Start Date	Deadline	Comment
FDA	Temporary Policy Regarding Nutrition Labeling of Certain Packaged Food During the COVID-19 Public Health Emergency	21 CFR 101.9(a)(1) and 101.9(j)(2)) Nutrition Labeling of Food	If restaurants sell packaged food to consumers directly or to other businesses for sale to consumers, nutrition information may be required.	FDA does not intend to object to the sale of packaged foods by restaurants directly to consumers or to the sale of packaged foods by food manufacturers to restaurants, even if the packaged food does not contain a nutrition label, provided that the food does not have a nutrition claim **and** contains the following: Statement of identity; Ingredient statement; Name and place of business of the food manufacturer, packer, or distributor; Net quantity of contents; **and** Allergen information required by the Food Allergen Labeling and Consumer Protection Act. Additionally, FDA will not object to continued production of food labeled for restaurant use **until retail packaging is available.**	26-Mar-20	When HHS declares the public health emergency over.	
FDA	Temporary Policy Regarding Nutrition Labeling of Standard Menu Items in Chain Restaurants and Similar	FD&C Act 403(q)(5)(H) and 21 CFR 101.11: Nutrition Labeling for Standard Menu Items at Chain Restaurants and	Chain restaurants and food establishments with over 20 locations are required to provide the nutrition information of standard menu items on menus and menu boards.	FDA will not object if covered restaurants and food establishments do not meet the normal menu food labeling requirements under FD&C Act 403(q)(5)(H) and 21 CFR 101.11.	1-Apr-20	When HHS declares the public health emergency over.	FDA encourages covered establishments to continue complying with the menu labeling requirements.

	Retail Food Establishments During the COVID-19 Public Health Emergency	Food Establishments					
FDA	Temporary Policy Regarding Packaging and Labeling of Shell Eggs Sold by Retail Food Establishments During the COVID-19 Public Health Emergency	21 CFR, Part 100 and FD&C Act (21 U.S.C. 343) Food Labeling Requirements	Egg Cartons must include: Statement of identity; Name and place of business of the manufacturer (the shell egg producer), packer or distributor; Nutrition labeling; Net quantity of contents; and Safe handling instructions.	FDA does not intend to object to the sale by retail food establishments of shell eggs in cartons or flats without labels, provided that: 1) The retail and safe handling instructions for unprocessed shell eggs destroy all Salmonella; 2) It is clear to consumers which label applies to which of the shell eggs being sold; 3) The shell eggs are sold by the complete carton or flat; and 4) There are no nutrition claims at the point of purchase for the shell eggs.	3-Apr-20	When HHS declares the public health emergency over.	As availability of packing and labeling materials improves, FDA encourages industry to resume full labeling as soon as practicable.

FDA	Temporary Policy Regarding Enforcement of 21 CFR Part 118 (the Egg Safety Rule) During the COVID-19 Public Health Emergency	The Egg Safety Rule	Under 21 CFR 118.5 of the Egg Safety Rule, producers selling to the table egg market must test the poultry house environment when laying hens in the house are between **40 - 45 weeks of age** because that is when Salmonella Enteritidis is most likely to be detected, if present, in the environment.	**FDA is allowing producers who normally sell eggs for further processing only, to begin selling eggs to the table market (sold directly to consumers in retail establishments), provided that:** The poultry house consists solely of laying hens up to 45 weeks of age and: **For providers already selling to the table market:** • A producer complies and has been in compliance with all requirements of the Egg Safety Rule for the poultry house for the life of the flock; • Before sending any eggs to the table egg market, a producer simultaneously conducts environmental and egg testing and none of the results are positive for SE in the poultry house. **For providers not previously selling to the table market:** • Before sending any eggs to the table egg market, a producer complies with all requirements of the Egg Safety Rule for poultry houses that are not sending eggs to the table egg market except for testing and SE monitored pullets.	6-Apr-20	When HHS declares the public health emergency over.	This policy does not apply to poultry houses with laying hens over 45 weeks of age at the time this guidance is issued. Laying hens older than 45 weeks of age are not included because environmental samples collected after 45 weeks are less likely to detect SE, if present, than samples collected at 40-45 weeks.

FDA	Temporary Policy Regarding Preventive Controls and FSVP Food Supplier Verification Onsite Audit Requirements During the COVID-19 Public Health Emergency: Guidance for Industry	Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (21 CFR part 117) Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (21 CFR part 507) Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (21 CFR part 1 subpart L)	Under these regulations, importers are required to conduct a hazard analysis to determine whether there are any hazards that require a control and determine the appropriate type and frequency of verification activity. **Often, the appropriate verification activity is an onsite audit.**	FDA does not intend to enforce the requirement for an onsite audit if: (1) An onsite audit is the appropriate verification activity for an approved supplier; (2) The supplier is in a region or country covered by a government travel restriction or travel advisory related to COVID-19; (3) Thus, it is temporarily impracticable for the receiving facility or FSVP importer to conduct or obtain the onsite audit of the supplier; **and** (4) The receiving facility or FSVP importer temporarily selects an alternative verification activity or activities.	17-Mar-20	No definitive end date; FDA just says "within a reasonable time."	Onsite audits will resume within a reasonable period after it becomes practicable to do so; meanwhile, receiving facilities and FSVP importers should update their food safety plans and FSVPs; FDA intends to provide timely notice before withdrawing this policy.
FDA	Coronavirus Disease 2019 (COVID-19) Update: Foreign Inspections	FDA Food Safety Modernization Act (FSMA)	FDA inspects foreign food facilities under the jurisdiction of the FDA that export to the United States (i.e., processors/manufacturers, packers/repackers, and holders of foods)	FDA is postponing most foreign inspections; only inspections outside the United States deemed mission-critical will still be considered on a case-by-case basis.	10-Mar-20	Tentatively April 30, 2020	FDA will use other measures to ensure product safety, such as denying entry of unsafe products into the United States, physical examinations and/or product sampling at the borders, reviewing a firm's previous compliance history, using information sharing from foreign governments as part of mutual recognition

							and confidentiality agreements, and requesting records "in advance of or in lieu of" on-site drug inspections. Additionally, FDA will use its risk-based import screening tool (PREDICT) to focus examinations and sample collections based on heightened concerns of specific products being entered into U.S. commerce.
FDA	Coronavirus (COVID-19) Update: FDA Focuses on Safety of Regulated Products While Scaling Back Domestic Inspections	FDA Food Safety Modernization Act (FSMA)	FDA traditionally conducts domestic facility inspections every few years based on a risk analysis.	FDA is postponing all domestic routine surveillance facility inspections. All domestic for-cause inspection assignments will be evaluated and will proceed if mission-critical.	18-Mar-20	No definitive end date	FDA will use other measures to ensure product safety, such as requesting records "in advance of or in lieu of" onsite inspections. There are safety controls in place, such as the requirement for food and medical product facilities to comply with cGMP standards.

FDA	Temporary Policy Regarding Accredited Third-Party Certification Program Onsite Observation and Certificate Duration Requirements During the COVID-19 Public Health Emergency	The Accredited Third-Party Certification Program regulation (21 CFR part 1, subpart M)	The Accredited Third-Party Certification Program regulation establishes a voluntary program for the recognition of accreditation bodies (ABs) that accredit third-party certification bodies (CBs) to conduct food safety audits and issue food or facility certifications to eligible foreign entities for specified purposes in the FD&C Act. The regulation requires (*inter alia*): • ABs to monitor the performance of CBs they have accredited, including remote activities, onsite observations of regulatory audits, and visiting the accredited CB's headquarters, no later than 1 year after the initial date of accreditation of the CB and every 2 years thereafter. • Accreditation certificate to expire after 12 months for already issued certificates	FDA will not enforce requirements for onsite observations and CB's headquarters visits when: • It is impracticable to do so because of government travel restrictions or advisories related to COVID-19; **and** • The recognized AB conducts the annual comprehensive assessment of the performance of a CB it has accredited to determine whether the accredited CB compliant with the regulation. For already-issued certificates, FDA does not intend to enforce 12-month max term when: • it is impracticable to conduct a regulatory audit because of government travel restrictions or advisories related to COVID-19; • The regulatory audit would ordinarily be needed to support the issuance of a new certificate under 21 CFR 1.653(a)(1); • The accredited CB has already issued a food or facility certificates to the eligible entity under	22-Apr-20	No definitive end date	Recognized ABs should resume onsite observations and visits within a reasonable period of time after it becomes practicable to do so. Accredited CBs should resume conducting regulatory audits to determine if the eligible entities should be issued new certificates within a reasonable period after it becomes practicable to conduct the onsite examinations required for regulatory audits.

				21 CFR 1.653 that is due to expire; • The food or facility certificate has not been suspended or withdrawn by the accredited CB; **and** • The accredited CB continues to adhere to the requirements of 21 CFR 1.654 regarding monitoring eligible entities to which they have issued certificates.			
USDA (FSIS)	Constituent Update: Special Alert – March 23, 2020: Temporary Allowances for Labels Going to Retail	9 CFR 317.400 and 381.500; Labeling at a Federal Establishment	Under 9 CFR 317.400 and 381.500: Federal establishments that usually distribute foods to hotels, restaurants, or similar institutions (HRI) must meet FSIS labeling requirements in the event that they sell their foods to retail stores. The absence of nutrition label requires an establishment to submit for temporary approval under 9 CFR 412.1(f)(1). Relatedly, establishments must satisfy an exemption under 9 CFR 317.400 and 381.500 in order to not include a nutrition label.	FSIS will not object to deficiencies in labeling. Establishments are not required to include a nutrition label unless they make nutrition claims. If the proposed label has other deficiencies from FSIS labeling requirements (e.g., formulation changes not reflected in the ingredients statement), establishments will need to submit the label for temporary approval for an evaluation on a case-by-case basis.	23-Mar-20	**Extended to July 26, 2020**	Only applies to products already in commerce; products in production must comply with normal requirements. FSIS expects that establishments and retailers will use this 60-day period to update their labeling so that any labeling applied to product after May 26, 2020 is fully compliant.

USDA (FSIS)	Constituent Update: Special Alert – March 23, 2020: Temporary Allowances for Labels Going to Retail	9 CFR 317.8 and 381.129; Labeling at Retail for Bulk Product Already in Commerce	Under 9 CFR 317.8 and 381.129: Bulk products, even if intended for HRI, may be distributed to retail, where the retailer will repackage the product into smaller consumer-sized packages and apply a label. The retail label applied to the repackaged product must bear all required features except for the USDA mark of inspection.	Bulk product may be distributed in a manner that is inconsistent with a statement of limited use on the outer box. E.g., a box labeled "for school food service use only" can now be distributed to a retail outlet for repackaging and labeling.	23-Mar-20	**Extended to July 26, 2020**	Only applies to products already in commerce; products in production must comply with normal requirements.
USDA (FSIS)	Constituent Update: Special Alert – March 23, 2020: Temporary Allowances for Labels Going to Retail	9 CFR 317.1 and 381.115; Labeling at Retail for Product in Unlabeled Protective Coverings Already in Commerce	Under 9 CFR 317.1 and 381.115: Meat or poultry products produced for HRI distribution may be distributed to a retailer, but must be in a fully labeled container AND in a **labeled** protective covering. Limited-use statements are required. Nutrition labeling is also required, unless food establishments are exempt under 9 CFR 317.1 and 381.115.	Meat or poultry products produced for HRI distribution may be distributed to a retailer **for labeling.** Such products must be in a fully labeled container, but can be in an **unlabeled** protective covering. Federal establishments may provide retail stores with an insert label, or retail stores may print their own. **Insert labels must match the shipping container in which they arrived, and may not bear USDA's mark of inspection.**	23-Mar-20	**Extended to July 26, 2020**	Only applies to products already in commerce; products in production must comply with normal requirements.