

Regulatory Prerequisites

OFFICE OF THE TEXAS STATE CHEMIST
Texas Feed and Fertilizer Control Service • Agriculture Analytical Service

TEXAS A&M
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RESEARCH

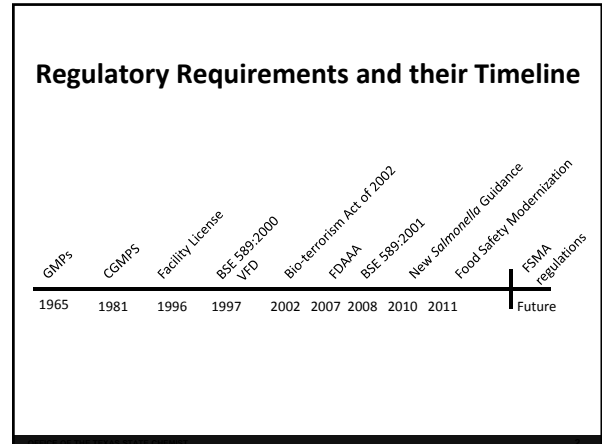


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- Rationale of Food Regulation**
- The FD&C Act focuses on things
 - The types of violations include
 - Adulterated product
 - Misbranded product
 - Products marketed without FDA approval
 - The overriding concern of FDA is to protect the public
 - The expansion of FDA authority has coincided with expansion of administrative tools
 - FDA is a scientific regulatory agency

Chapter III – Prohibited Acts and Penalties

Prohibited Act 301 (Person)

- 301(a) Introduction or delivery for introduction into interstate commerce of adulterated or misbranded products
- 301(b) adulteration or misbranding "in" interstate commerce
- 301(c) receipt in interstate commerce and delivery of an adulterated or misbranded product
- 301(d) introduction or delivery for introduction into interstate commerce of articles that violate 404, 505, or 564
- 301(k) causing adulteration or misbranding after interstate before it gets to the consumer

CHAPTER IV Food

- Sec. 401 Definitions and Standards for Food
- Sec. 402 Adulterated Food
- Sec. 403 Misbranded Food
- Sec. 406 Tolerances for Poisonous Ingredients in Food
- Sec. 408 Tolerances and exemptions for Pesticide Chemical Residues
- Sec. 409 Food Additives
- Sec. 414 Maintenance and Inspection of Records
- Sec. 415 Registration of Food Facilities
- Sec. 416 Sanitary Transportation Practices
- Sec. 417 Reportable Food Registry
- Sec. 418 Hazard Analysis and Risk-Based Preventive Controls
- Sec. 419 Standards for Produce Safety
- Sec. 420 Protection Against Intentional Adulteration
- Sec. 421 Targeting of Inspection Resources ...
- Sec. 422 Laboratory Accreditation for Analyses of Foods
- Sec. 423 Mandatory Recall Authority

Section 402(a): A food shall be deemed to be adulterated if it bears or contains:

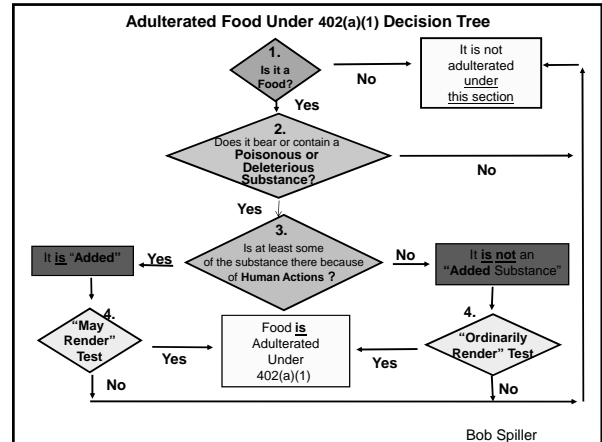
402(a)(1) Poisonous or deleterious substances injurious to health

If "added" use the "may render" - test

If "not added" use the "ordinarily render" test

FDA Action Levels for Aflatoxins in Animal Feeds	
Action Level	End Use of Grain
300 ppb	Corn and peanut products intended for finishing beef cattle; cottonseed meal intended for beef cattle, swine, or poultry (regardless of age or breeding status)
200 ppb	Corn and peanut products intended for finishing swine of 100 pounds or greater
100 ppb	Corn and peanut products intended for breeding beef cattle, breeding swine, or mature poultry
20 ppb	Corn, peanut products, cottonseed meal, and feed ingredients intended for dairy, for animal species or uses not specified above, or when the intended use is not known
20 ppb	Human consumption

FDA Compliance Policy Guide Sec. 683.100

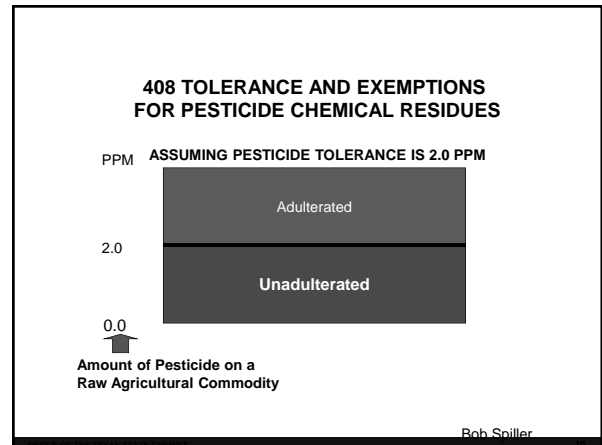


Section 402(a): A food shall be deemed to be adulterated if it bears or contains:

402(a)(2)(B) Pesticide chemicals are unsafe under 408

408(a) a pesticide chemical on food is "unsafe" unless

1. There is a tolerance and it is within tolerance
2. It is exempted



Section 402(a): A food shall be deemed to be adulterated if it bears or contains:

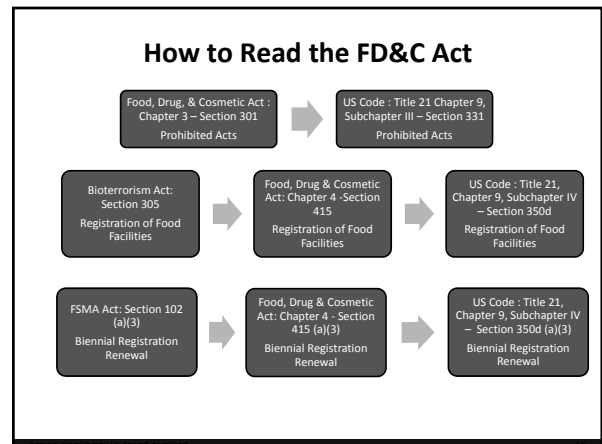
402(a)(2)(C)(i) and (ii) Unsafe Food Additives and New Animal Drugs

409 all Food Additives are "unsafe" unless

1. It has been exempted; or
2. there has been a regulation permitting its use and it is within tolerance

512 a New Animal Drug is "unsafe" unless;

1. There is an approved New Animal Drug Application (NADA) for such use; and
2. Its labeling and use conforms to such regulation



Bioterrorism Act of 2002

SEC. 414 [21 U.S.C. 350c]. MAINTENANCE AND INSPECTION OF RECORDS

(a) Records Inspection

1. Adulterated Food- is adulterated and presents a threat of serious adverse health consequences or death... "access to all records"

(b) Regulations Concerning Recordkeeping (two years by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receiving, hold, or import food .. immediate previous sources and the immediate subsequent recipients of food

Bioterrorism Act of 2002

SEC. 415 [21 U.S.C. 350D]. REGISTRATION OF FEED FACILITIES

(a) Registration.-

(1) In General. – The Secretary shall by regulation require that any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the Secretary

(3) Biennial Registration Renewal. – During the period beginning on Oct 1 and ending on Dec. 31 of each even numbered year, ... (1) shall submit a renewal registration

**Food and Drug Administration
Amendment Act of 2007**

SEC. 417 [21 U.S.C. 350F]. REPORTABLE FOOD REGISTRY

(a) Definitions

(1) Responsible party. – The term "responsible party", with respect to an article of food, means a person that submits the registration under section 415(a) for a food facility that is required to register

(2) Reportable Food. –The term "reportable food" means an article of food (other than infant formula) for which there is a reasonable probability that ... adverse health consequences or death

Food Safety Modernization Act of 2011

SEC. 418 [21 U.S.C. 350g]. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS.

"(b) HAZARD ANALYSIS.—The owner, operator, or agent in charge of a facility shall—

"(1) identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility, including—

"(A) biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives; and

"(B) hazards that occur naturally, or may be unintentionally introduced; and

"(2) identify and evaluate hazards that may be intentionally introduced, including by acts of terrorism; and

"(3) develop a written analysis of the hazards.

FSMA cont.

"(c) PREVENTIVE CONTROLS.—The owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that—

"(1) hazards identified in the hazard analysis conducted under subsection (b)(1) will be significantly minimized or prevented;

"(2) any hazards identified in the hazard analysis conducted under subsection (b)(2) will be significantly minimized or prevented and addressed, consistent with section 420, as applicable; and

FSMA cont.

"(d) MONITORING OF EFFECTIVENESS.—The owner, operator, or agent in charge of a facility shall monitor the effectiveness of the preventive controls implemented under subsection (c) to provide assurances that the outcomes described in subsection (c) shall be achieved.

FSMA cont.

“(e) CORRECTIVE ACTIONS.—The owner, operator, or agent in charge of a facility shall establish procedures to ensure that, if the preventive controls implemented under subsection (c) are not properly implemented or are found to be ineffective—

“(1) appropriate action is taken to reduce the likelihood of recurrence of the implementation failure;

“(2) all affected food is evaluated for safety; and

“(3) all affected food is prevented from entering into commerce if the owner, operator or agent in charge of such facility cannot ensure that the affected food is not adulterated under section 402 or misbranded under section 403(w).

FSMA cont.

“(f) VERIFICATION.—The owner, operator, or agent in charge of a facility shall verify that—

“(1) the preventive controls implemented under subsection (c) are adequate to control the hazards identified under subsection (b);

“(2) the owner, operator, or agent is conducting monitoring in accordance with subsection (d);

FSMA cont.

“(g) RECORDKEEPING.—The owner, operator, or agent in charge of a facility shall maintain, for not less than 2 years, records documenting the monitoring of the preventive controls implemented under subsection (c), instances of nonconformance material to food safety, the results of testing and other appropriate means of verification under subsection (f)(4), instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions.

FSMA cont.


“(h) WRITTEN PLAN AND DOCUMENTATION.—The owner, operator, or agent in charge of a facility shall prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of this section, including analyzing the hazards under subsection (b) and identifying the preventive controls adopted under subsection (c) to address those hazards.

Such written plan, together with the documentation described in subsection (g), shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request.

“(i) REQUIREMENT TO REANALYZE.

Salmonella

- ❑ Animal feed and ingredients containing *Salmonella* are adulterated as defined by 21 CFR 500.35.
- ❑ Guidance for FDA Staff Compliance Policy Guide Sec. 690.800 *Salmonella* in Animal Feed
 - Contains nonbinding recommendations
 - <http://www.fda.gov/downloads/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/UCM361105.pdf>



END

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