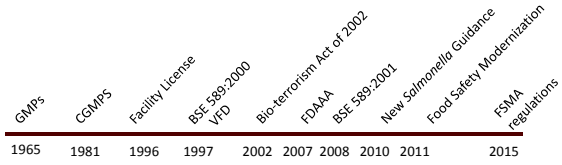
## Regulatory Prerequisites

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

TEXAS A&M AGRILIFE RESEARCH

## Regulatory Requirements and their Timeline






## Table of Contents





## 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

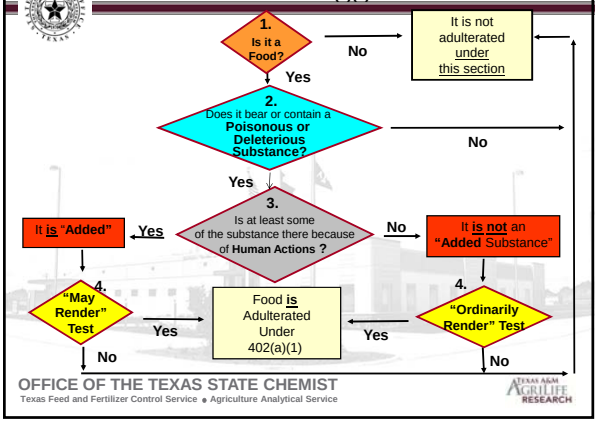
## Section 402(a): A food shall be deemed to be adulterated if it bears or contains:

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



## Adulterated Food Under 402(a)(1) Decision Tree




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

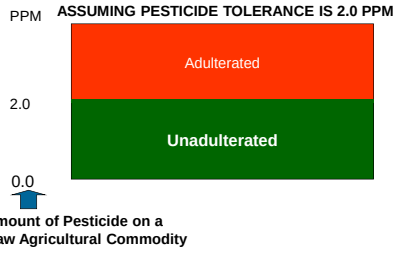
402(a)(2)(B) Pesticide chemicals are unsafe under 408

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

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



## 408 TOLERANCE AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES






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

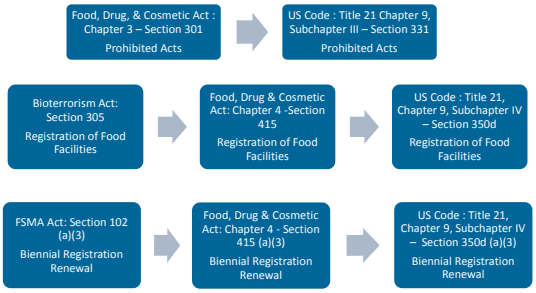
402(a)(2)(C)(i) and (ii) Unsafe Food Additives and New Animal Drugs

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



## How to Read the FD&C Act



## 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

Dr. Tim Herrman
Professor, State Chemist & Director
Office of the State Chemist
Texas A&M University
(979) 845-1121
tjh@otsc.tamu.edu

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