

## **Summary Of Title III, Subtitle A Of The Public Health Security And Bioterrorism Preparedness And Response Act Of 2002**

### **Title III – Protecting Safety And Security Of Food And Drug Supply**

#### **Subtitle A – Protection of Food Supply**

##### **Sec. 301. Food Safety and Security Strategy**

?? Requires the President's Council on Food Safety, in consultation with the Secretaries of Transportation and Treasury, other relevant Federal agencies, food industry, consumer and producer groups, scientific organizations, and the States, to develop a crisis communications and education strategy regarding bioterrorist threats to the food supply. The strategy shall address threat assessments; technologies and procedures for securing food processing and manufacturing facilities and modes of transportation; response and notification procedures; and risk communications to the public.

##### **Sec. 302. Protection Against Adulteration of Food**

?? Amends Section 801 to direct the Secretary to give high priority to increasing the number of inspections of food offered for import with the greatest priority given to inspections to detect intentional adulteration.

?? Directs the Secretary to give high priority to making improvements to the FDA information management systems for imported foods to improve our ability to allocate resources, detect intentional adulteration, and facilitate the importation of food that is in compliance with the Act.

?? Directs the Secretary to improve linkages with other Federal, State and tribal food safety agencies;

?? Requires the Secretary to provide for research on development of tests and sampling methodologies to rapidly detect the adulteration of food, with the greatest priority given to detect intentional adulteration, and whose results offer significant improvements over available technology in terms of accuracy, timing, or costs

?? Directs the Secretary to give priority to research on the development of tests suitable for inspections of food at ports of entry.

?? Directs the Secretary to coordinate as appropriate on the research with CDC, NIH, EPA, and USDA.

- ?? Requires the Secretary to submit an annual report to Congress describing progress made in research.
- ?? Requires the Secretary, through the FDA Commissioner, within 6 months of enactment, to ensure that the threat assessment being conducted on the threat of intentional adulteration of the food supply is completed and that a report describing the findings is submitted to Congress.

### **Sec. 303 Administrative Detention**

- ?? Amends Section 304 to authorize FDA to order the detention of food if an officer or qualified FDA employee finds, during an inspection, examination, or investigation, credible evidence or information indicating the article presents a threat of serious adverse health consequences or death to humans or animals.
- ?? Specifies the detention must be approved by an official at the district director level or higher.
- ?? Specifies period of detention may not exceed 20 days unless a greater period, not to exceed 30 days, is necessary to enable the Secretary to pursue a seizure under Section 304(a) or to seek an injunction under Section 302. Requires the Secretary to establish regulations for expedited procedures for instituting such actions for perishable foods, such as fresh produce, fresh fish and fresh seafood products.
- ?? Allows the detention order to require that the article be labeled or marked as detained; requires the article to be removed to a secure facility, as appropriate. Specifies that a detained article may not be transferred until released or detention expires.
- ?? Specifies an appeals process which requires the Secretary, after providing for an informal hearing, to confirm or terminate an order within 5 days of an appeal. This confirmation or termination shall be considered final agency action. If the Secretary fails to comply with the above requirements, the order is deemed terminated. The appeals process terminates if the Secretary institutes action under Section 304(a) or Section 302.
- ?? Amends Section 301 making it a prohibited act to transfer an article of food in violation of a detention order or to remove or alter any required mark or label identifying the article as detained.
- ?? Amends Section 801 to provide for temporary holds at ports of entry. Authorizes an officer or qualified FDA employee to request the Secretary of the Treasury to hold food at the port of entry for a period not to exceed 24 hours. This is to occur when

the employee has credible evidence or information that an article of food presents a threat of serious adverse health consequences or death to humans or animals; and the officer needs more time to inspect, examine, or investigate. The request must be approved at the district director level or higher.

- ?? Directs the Secretary to ask the Secretary of the Treasury to remove a held article to a secure facility, as appropriate. States the article may not be transferred during the holding period.
- ?? Requires the Secretary to notify the State in which the port of entry is located.
- ?? Requires us to issue a regulation to expedite hearing procedures for perishable foods.
- ?? The FDA plans to establish informal hearing procedure.

### **Sec. 304. Debarment for Repeated or Serious Food Import Violations**

- ?? Amends Section 306(b) to establish debarment for persons convicted of a felony for conduct relating to the importation of any food or for persons who have engaged in a pattern of importing or offering for import adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.
- ?? Amends Section 301 to make it a prohibited act the importing or offering for import of food by, with the assistance of, or at the direction of a debarred person.
- ?? Amends Section 801 to require that food being imported or offered for import by a debarred person be held at the port of entry, at a secure facility as appropriate, and not transferred. The article of food may be delivered to a non-debarred person if that person establishes at their expense that the article is in compliance.

### **Sec. 305. Registration of Food Facilities**

- ?? Amends the Act by adding new section 415 to require registration for food facilities. Requires the owner, operator, or agent in charge of a domestic or foreign facility to submit a registration to the Secretary. For a foreign facility, the registration must include the name of the U.S. agent for the facility.
- ?? The registration shall contain information necessary to notify the Secretary of the name and address of each facility at which, and all trade names under which, the registrant conducts business and, when determined necessary by the Secretary through guidance, the general food category as identified under 21 CFR 170.3. Requires the registrant to notify the Secretary in a timely manner of changes to such information.

- ?? Requires the Secretary to notify the registrant of receipt of the registration and to assign a registration number to each facility. Requires the Secretary to compile and maintain an up-to-date list of registered facilities. Protects the list and any registration documents from disclosure under Section 552 of Title V, U.S. Code.
- ?? Defines facility as any factory, warehouse, or establishment of an importer that manufactures, processes, packs, or holds food. Specifically excludes farms, restaurants, other retail food establishments, nonprofit food establishments in which food is prepared for or served directly to the consumer; and fishing vessels (except such vessels engaged in processing as defined in 21 CFR 123.3(k). [Note: this covers animal feed and dietary supplement manufacturers.] Limits foreign facilities to those that manufacture, process, pack, or hold food only if food from such facility is exported to the U.S. without further processing or packaging outside the U.S.
- ?? Amends Section 301 making failure to register a prohibited act.
- ?? Amends Section 801 to require that an article of food offered for import from an unregistered foreign facility be held at the port of entry until the facility is registered.
- ?? Authorizes the Secretary to provide for and encourage the use of electronic methods of registration; however, paper registration is allowed.
- ?? Requires the Secretary to promulgate proposed and final regulations within 18 months of enactment. The requirement takes effect upon the expiration of the 18-month period even if the Secretary does not meet the deadline.

### **Sec. 306. Maintenance and Inspection of Records for Foods**

- ?? Amends Chapter IV to authorize the Secretary to have access to certain records when there is a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. It applies to all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of the food. It excludes farms and restaurants. It also excludes information such as recipes, financial data, personnel data, research data, and sales data (other than shipment data regarding sales).
- ?? Requires the Secretary to promulgate proposed and final regulations within 18 months of enactment to establish requirements for the establishment and maintenance of records needed to determine the immediate previous sources and the immediate subsequent recipients of food. Limits recordkeeping requirement to two years.
- ?? Directs the Secretary to consider the size of a business in promulgating the regulations.

- ?? Directs the Secretary to take appropriate measures to ensure protection from disclosure of sensitive information.
- ?? Amends Section 704 to reflect the requirement to provide the Secretary with access to records.
- ?? Amends Section 301 making it a prohibited act to refuse to permit access to or copying of any required record or to fail to establish or maintain any required record.

### **Sec. 307. Prior Notice of Imported Food Shipments**

- ?? Amends Section 801 to require prior notice of imported food shipments. The notice is required to provide the article, the manufacturer and shipper, the grower (if known within the specified time in which notice is required), the country of origin, the country from which the article is shipped, and the anticipated port of entry. States that, if notice is not provided, the article shall be refused admission.
- ?? Requires the Secretary, after consultation with Secretary of the Treasury, to issue regulations that specify the period of advance notice and says that shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification. It states the period may not exceed five days.
- ?? Requires the Secretary to promulgate proposed and final regulations within 18 months of enactment. If the Secretary fails to meet the deadline, the requirement takes effect upon expiration of the 18-month period. In that event, the default period of notice will be no less than 8 hours and no more than five days.
- ?? States that an article of food offered for import and prior notice has not been provided, such article shall be held at the port of entry until the importer, owner, or consignee complies. Directs the Secretary, in carrying out this requirement, to determine whether there is any credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.
- ?? Amends Section 301 making it a prohibited act to import or offer for import an article of food in violation of these requirements.

### **Sec. 308. Authority to Mark Articles Refused Admission into United States**

- ?? Amends Section 801 to authorize the Secretary to require the marking of refused food (other than food required to be destroyed). Marking is to be done at owner's expense.

- ?? Amends Section 403 to make food misbranded if it fails to bear the required label when the Secretary has found that the food presents a threat of serious adverse health consequences or death to humans and animals and the Secretary has notified the owner or consignee that the label is required and that the food presents such a threat.
- ?? Provides a rule of construction stating this does not limit the authority of the Secretary of HHS or the Secretary of the Treasury to require the marking of refused articles of food under any other provision of law.

### **Sec. 309. Prohibition Against Port Shopping**

- ?? Amends Section 402 to deem food adulterated if a food is offered for import that has been previously refused admission unless the person reoffering the food establishes that the article is in compliance.

### **Sec. 310. Notices to States Regarding Imported Food**

- ?? Amends Chapter IX to require the Secretary to notify States when there is credible evidence or information indicating that a shipment, or portions of shipment, of imported food presents a threat of serious adverse health consequences or death to humans or animals. If known, the Secretary must provide notice to the States in which the food is held or will be held and to the States in which the manufacturer, packer, or distributor of the food is located. The Secretary is directed to request the State to take appropriate action to protect the public health.
- ?? Provides a savings clause saying this does not limit the authority of the Secretary with respect to food under any other provision.

### **Sec. 311. Grants to States for Inspections**

- ?? Authorizes the Secretary to make grants to States, territories, and Indian tribes that undertake examinations, inspections, and investigations, and related activities under Section 702.
- ?? Authorizes the Secretary to make grants to the States to assist them with the costs of taking appropriate action after receiving notification under the preceding section.
- ?? Authorizes appropriations of \$10 million for FY02 and such sums as may be necessary for fiscal years 03 through 06; however, funds have not been appropriated yet.

### **Sec. 312. Surveillance and Information Grants and Authorities**

- ?? Amends Part B of Title III of the Public Health Service Act to authorize the Secretary to award grants to States and Indian tribes to expand participation in networks to enhance Federal, State, and local food safety efforts. This may include meeting the costs of establishing and maintaining the food safety surveillance, technical, and laboratory capacity needed for such participation.
- ?? Authorizes appropriations of \$19.5 million for FY02 and such sums as may be necessary for fiscal years 03 through 06; however, funds have not been appropriated yet.

### **Sec. 313. Surveillance of Zoonotic Diseases**

- ?? Directs the Secretary of HHS, through the FDA Commissioner and the CDC Director, and the Secretary of Agriculture to coordinate the surveillance of zoonotic diseases.

### **Sec. 314. Authority to Commission Other Federal Officials to Conduct Inspections**

- ?? Amends Section 702 to authorize the Secretary to commission other Federal employees to conduct examinations and inspections. Requires a memorandum of understanding (MOU) between the Secretary and the head of the other Federal agency. The MOU must address training and reimbursement. It is restricted to facilities or other locations that are jointly regulated by the Secretary and the other department or agency.
- ?? Requires the Secretary and the head of the other Federal department or agency to submit a report to Congress each fiscal year that provides the number of employees that carried out one or more activities, the number of additional articles that were inspected or examined, and the number of additional examinations or investigations that were carried out pursuant to the memorandum.

### **Sec. 315. Rule of Construction**

- ?? States that nothing in this title shall be construed to alter the jurisdiction between USDA and HHS under applicable statutes and regulations.

## **Subtitle B – Protection of Drug Supply**

### **Sec. 322. Requirement of Additional Information Regarding Import Components Intended for Use in Export Products**

- ?? Requires a statement at the time of importation of food additives, color additives, or dietary supplements, that such article is intended to be further processed and exported.
- ?? Requires a certificate of analysis, as necessary, and a bond.
- ?? Requires the article of food to be used in accordance with the submitted statement.
- ?? Requires records to be maintained on the use, destruction, exportation, and compliance, and requires the records to be provided to FDA upon request.
- ?? Authorizes the Secretary to refuse admission of the article if there is credible evidence or information indicating further processing is not intended or not incorporated into the product to be exported.
- ?? Effective September 9, 2002.