

**HOUSE COMMITTEE ON ENERGY AND COMMERCE  
SECTION-BY-SECTION ANALYSIS OF  
PUBLIC HEALTH SECURITY AND BIOTERRORISM RESPONSE ACT OF 2001**

**TITLE I – NATIONAL PREPAREDNESS FOR BIOTERRORISM AND  
OTHER PUBLIC HEALTH EMERGENCIES**

**SUBTITLE A -- NATIONAL PREPAREDNESS AND RESPONSE PLANNING,  
COORDINATING, AND REPORTING**

**Sec. 101: National Preparedness and Response**

Requires the Secretary of HHS to continue the process of developing and implementing a coordinated strategy, including the preparation of a National plan for carrying out health-related activities to prepare for and respond effectively to bioterrorism and other public health emergencies. The plan would be in consultation with other Federal agencies and other appropriate public and private entities. The plan also would coordinate with activities of State and local governments to meet preparedness goals set out under the Act. National preparedness goals include providing effective assistance to State and local governments to ensure that they and their health care facilities have adequate capacity and properly trained response personnel; a coordinated plan, effective communications networks, and laboratory readiness, training and surveillance; developing and maintaining medical countermeasures against biological agents; and effective coordination at all levels of government. There would be evaluations and reports of progress.

**Sec. 102. Assistant Secretary for Emergency Preparedness; National Disaster Medical System**

Establishes new position of Assistant Secretary for Emergency Preparedness to coordinate HHS activities under the new Act. Authorizes the National Disaster Medical System, under the new Assistant Secretary to provide for further National capacity during public health emergencies.

**Sec. 103. Improving ability of Centers for Disease Control and Prevention with respect to bioterrorism and other public health emergencies**

Provides authorization and multi-year contracting authority for the renovation, development and security at facilities for the Centers for Disease Control and Prevention. Requires enhanced training and nationwide laboratory capacity, and the establishment of integrated, national public health communications and surveillance networks.

**Sec. 104. Advisory committees and communications**

Establishes an advisory committee on children and terrorism and also one on emergency public information and communications. Requires a coordinated strategy on public health communications during a bioterrorism attack.

**Sec. 105. Education of health care personnel; training regarding pediatric issues**

Requires the establishment of core curriculum education materials for public health emergencies, and training of health care personnel. Requires development of education programs to recognize special needs of children and other vulnerable populations with respect to public health emergencies.

**Sec. 106. Grants regarding shortages of certain health professionals**

Provides grants for training and education for where there are shortages in categories of health care professionals to respond to public health emergencies.

**Sec. 107. Emergency system for verification of credentials of health professions volunteers**

Establishes National system to help verify the licenses, credentials and hospital privileges of health professionals who volunteer to respond during public health emergencies.

**Sec. 108. Enhancing preparedness activities for bioterrorism and other public health emergency**

Improves coordination of preparedness for bioterrorism and public health emergencies. Expands grant authorizations for training of medical personnel and purchases of countermeasures. Directs improved coordination of communications functions. Encourages community-wide planning activities.

**Sec. 109. Improving State and local core public health capacities**

Authorizes grants for purchases or upgrades of equipment, supplies, pharmaceuticals or other countermeasures to enhance preparedness. Authorizes grants for exercises to test the capacity to respond to public health emergencies.

**Sec. 110. Antimicrobial Resistance Program**

Authorizes further research and DNA analysis of priority pathogens that may be used by bioterrorists.

**Sec. 111. Study regarding communications abilities of public health agencies**

Provides for a study to improve telecommunication infrastructure and connectivity during public health emergencies.

**Sec. 112. Supplies and Services in lieu of award of funds**

Provides flexibility to allow the Secretary of HHS to supply actual supplies, equipment, or services instead of, or in conjunction with, grants.

**Sec. 113. Additional amendments**

Makes revisions to time frames to speed up preparedness planning.

**Sec. 114. Study regarding local emergency response methods**

Requires the Secretary to conduct a study of best-practices methods for the provision of emergency response services through local governments.

**SUBTITLE B -- NATIONAL STOCKPILE; DEVELOPMENT OF PRIORITY COUNTERMEASURES**

**Sec. 121. National Stockpile**

Authorizes a National stockpile or stockpiles of drugs, vaccines, biologic products, medical devices and supplies to meet the health security needs of the United States. Requires enhanced procedures for coordination, maintenance, delivery, and distribution.

**Sec. 122. Accelerated approval of priority countermeasures**

Clarifies certain fast-track authority for drug priority countermeasures under the FDCA.

**Sec. 123. Use of animal trials in the approval of certain drugs and biologics; issuance of rule**

Requires FDA to issue a final rule within six months allowing reliance on animal trials for certain priority countermeasures for public health emergencies.

**Sec. 124. Security for countermeasure development and production**

Authorizes the Secretary, in consultation with the Attorney General and Secretary of Defense, to provide technical or other assistance to enhance security at facilities that conduct development, production, distribution or storage of priority countermeasures.

**Sec. 125. Accelerated countermeasure research and development**

Directs the Secretary to conduct an accelerated program and award grants for biomedical research, development of vaccines, and diagnostic tests for priority countermeasures.

**Sec. 126. Evaluation of new and emerging technologies regarding bioterrorist attacks and other public health emergencies**

Requires the Secretary to evaluate new and emerging technologies to help detect, identify, diagnose, or conduct public health surveillance activities for public health emergencies, and prioritize development and deployment where warranted.

**Sec. 127. Potassium Iodide**

Requires the Secretary to make potassium iodide available to States and local governments that submit a plan for local stockpile and distribution for the population within 20 miles of a nuclear power plants. This will allow for immediate response to minimize the risk of adverse thyroid conditions following any nuclear incident.

**SUBTITLE C -- EMERGENCY AUTHORITIES; ADDITIONAL PROVISIONS**

**Sec. 131. Expanded authority of Secretary of Health and Human Services to respond to public health emergencies**

Authorizes the transfer of funds during public health emergencies without lengthy waiting periods.

**Sec. 132. Streamlining and clarifying communicable disease quarantine provisions**

Technical change to allow the Secretary, in consultation with the Surgeon General, to specify diseases that are subject to individual detention orders.

**Sec. 133. Emergency waiver of Medicare, Medicaid, and SCHIP requirements**

Remove certain requirements under Medicare, Medicaid, and SCHIP during public health emergencies.

**Sec. 134. Provision for expiration of public health emergencies**

Provides that public health emergencies expire by announcement of the Secretary or after 90 days. The Secretary may renew emergency declarations at his discretion.

**Sec. 135. Designated State public emergency announcement plan**

Amends Stafford Act to provide for coordinated communications response.

**Sec. 136. Expanded research by the Secretary of Energy**

Expands current research at DOE and NNSA on rapid detection and pathogens likely to be used in bioterrorist attacks or other agents that may cause a public health emergency.

**Sec. 137. Agency for Toxic Substances and Disease Registry**

Recognizes the role of the Agency for Toxic Substances and Disease Registry in bioterrorism and public health emergency planning and response. Authorizes funding under the Public Health Service Act.

**Sec. 138. Expanded research on worker health and safety**

Authorizes NIOSH to expand research on health and safety of workers who are at risk for bioterrorist threats or attacks in the workplace.

**Sec. 139. Technology Opportunities Program support for national public health communication and surveillance networks**

Provides telecommunications infrastructure grants to health care providers to facilitate participation in the public health communications and surveillance networks.

**SUBTITLE D -- AUTHORIZATION OF APPROPRIATIONS**

**Section 151. Authorizations of Appropriations**

Authorizes a total of \$ 2,720,000,000 for bioterrorism and other public health emergency preparedness and response for the Department of Health and Human Services for FY 2002, and such sums as necessary thereafter. The funding includes \$1,000,000,000 for making awards of grants and other assistance to States and other public and private entities. This total also includes \$1,155,000,000 for the national stockpile of drugs, vaccines, supplies, and devices. Of this latter number, \$509,000,000 is authorized to acquire smallpox vaccine. The total also includes \$450,000,000 to enhance the facilities and capabilities of the Centers for Disease Control and Prevention. Research authorizations are provided for various activities, including research on countermeasures for biological pathogens and \$25,000,000 in FY 2002 for antimicrobial resistance programs. Funding for the National Institutes of Health is authorized separately and not subject to the total authorization number.

**TITLE II – ENHANCING CONTROLS ON DANGEROUS BIOLOGICAL AGENTS AND TOXINS**

**Section 201: Regulation of Certain Biological Agents and Toxins**

Registration of All Persons Possessing Deadly Biological Agents and Toxins. Expands current transfer regulations governing “select agents” (the 36 biological agents or toxins determined by CDC to pose “a severe threat to public health and safety”) to require that all

persons who possess or use such agents register with the Secretary of Health and Human Services and be subject to reasonable safety and security requirements and inspections. Directs that the Secretary maintain a national database of all such agents, with sufficient information to facilitate their identification and traceability. Requires notification to the Secretary by all possessors within 60 days of enactment.

Imposition of Security Requirements and Personnel Screening Protocols. Directs that the Secretary, in consultation with the Attorney General, establish specific security requirements for registered facilities and a personnel screening protocol to ensure that access to such agents is not permitted by individuals who have criminal felony records, are named in a warrant for violent criminal or terrorist activity, are fugitives from justice, are under investigation for involvement in domestic or international terrorist or criminal organizations, or are foreign nationals illegally in the United States, from terrorist-sponsoring countries, or suspected of spying for the military or intelligence operations of a foreign nation. Provides the Secretary with grant authority to assist public and nonprofit private entities in meeting such security requirements.

Enhancement of Criminal and Civil Penalties for Enforcement. Imposes tough new criminal and civil penalties for those who violate the regulations, including up to five years in jail and civil penalties up to \$500,000 for those who are caught either possessing or transferring such agents without registration and approval.

Establishment of Exemptions Consistent with Protecting Public Health and Safety. Permits the Secretary to make exemptions to the registration requirements only where those exemptions are consistent with protecting the public health and safety -- for example, with respect to inactivated or attenuated strains of select agents used in vaccines or other products for legitimate medical research or use -- or when the agent is presented for diagnosis, verification or proficiency testing purposes at a clinical laboratory and is promptly destroyed or transferred to a registered facility after such identification.

Coordination with USDA Regulations on Dangerous Animal Agents and Toxins. Ensures that the Secretary coordinate these regulations with the regulations of the Department of Agriculture governing certain of the select agents that are used in the development of vaccines or other products for the treatment of domestic animals, in order to minimize conflict and duplication of administrative burdens on registered persons. Clarifies that the HHS Secretary's new authorities do not limit the existing authorities of the Secretary of Agriculture in such circumstances.

Protection of Sensitive Information from Mandatory Public Disclosure. Exempts from mandatory disclosure under the Freedom of Information Act site-specific or identifying information submitted under these regulations concerning registered persons, registered agents, and security mechanisms.

### **TITLE III: AMENDMENTS TO THE FEDERAL FOOD DRUG AND COSMETIC ACT**

#### **SUBTITLE A - PROTECTION OF THE FOOD SUPPLY**

## **Section 301: Protection Against Intentional Adulteration of Food**

Increased Inspections for Detection of Intentional Adulteration of Food. Directs the HHS Secretary to give high priority to increasing FDA inspections at ports of entry for the purpose of enabling the Secretary to inspect imported foods, with highest priority on inspections to detect intentional adulteration of food; and to report to Congress on these increased activities.

Testing for Rapid Detection of Adulteration of Food. Directs the Secretary to develop improved tests and sampling methods for the purpose of rapidly detecting adulterated foods, with highest priority on detection of intentional adulteration.

Assessment of Threat of Intentional Adulteration of Food. Directs the Secretary to complete an assessment of threats to food posed by intentional adulteration (assessment already underway) and report the findings to Congress within six months.

Upgrades to Information Management Systems. Directs the Secretary to give a high priority to improving the information management systems that support FDA inspection programs for the purpose of improving the ability of the Secretary to detect intentional adulteration of food.

Authorization of Appropriations. Authorizes to be appropriated \$100,000,000 for FY 2002, and such sums as may be necessary for FY 2003-2006, to carry out the purposes of this section, in addition to other authorizations for appropriations for such purposes.

## **Section 302: Administrative Detention Authority**

Provides authority to the Secretary to order the detention of articles of food for 20 days, and where needed up to 30 days, where there is credible evidence or information indicating that the food presents a threat of serious adverse health consequences to humans or animals. Where the Secretary already has credible evidence or information indicating that an imported article of food presents a threat of serious adverse health consequences to humans or animals, this section also authorizes the HHS Secretary to request the Secretary of Treasury to temporarily hold imported food at a port of entry for up to 24 hours to enable the Secretary to inspect examine or investigate the food and make a determination about whether to detain it. This section also requires the Secretary to notify the State in which the port of entry involved is located.

## **Section 303: Permissive Debarment Regarding Food Importation**

Provides authority to the Secretary to debar from importing articles of food, any person that is convicted of a felony relating to food importation, or any person that repeatedly imports food and who knew, or should have known, that the food was adulterated.

## **Section 304: Maintenance and Inspection of Records**

Inspection of Records. Provides the Secretary the authority to inspect and copy all records

relating to an article of food if the Secretary has credible evidence or information indicating that an article of food presents a threat of serious health consequences or death to humans or animals. This provision excludes farms and restaurants and is subject to certain limitations, including limitations to ensure the protection of trade secrets and confidential information.

Additional Record keeping Regulations. Authorizes the Secretary to issue a regulation requiring maintenance of additional records that are needed to trace the source and chain of distribution of food, in order to address credible evidence or information of serious adverse health consequences to humans or animals. This provision excludes restaurants and farms, and the Secretary is provided the authority to take into account the size of the business when imposing any record keeping requirements.

### **Section 305: Registration**

Requires all facilities (excluding farms) that manufacture, process, pack or hold food for consumption in the United States to file with the Secretary, and keep up to date, a registration that contains the identity and address of the facility and the general category of food manufactured, processed, packed or held at the facility. Authorizes the Secretary to exempt certain retail establishments only if the Secretary determines that the registration of such facilities is not needed for effective enforcement of this Act. Enforcement of this section would be delayed 180 days from the date of enactment, and this section requires the Secretary to notify and issue guidance within 60 days identifying facilities required to register.

### **Section 306: Prior Notice of Imported Food Shipments**

Authorizes the Secretary by regulation to require importers of articles of food to provide up to 72 hours, but not less than 24 hours prior notice that food will be imported or offered for import into the United States. This notice requires the importer to provide the following information prior to importation: a description of food to be imported; the identity of the manufacturer and shipper; and, if known within the specified period of time that notice is required to be provided, the identity of the grower; the country of origin of the article; the country from which the food is being shipped; and the anticipated port of entry into the United States. In the event notice is not provided in advance in accordance with the Secretary's regulation, the article shall be held at the port of entry until notice is properly provided and the Secretary determines whether there is credible evidence or information in his possession indicating that the article presents a threat of serious adverse health consequences or death to humans or animals.

### **Section 307: Authority to Mark Articles Refused Admission to United States**

Requires that food which has been refused admission to the United States, but has not been ordered destroyed, must have a label affixed to its container at the expense of the owner or consignee indicating that it has been refused admission.

### **Section 308: Prohibition Against Port Shopping for Importation**

Requires any person attempting to re-offer for admission into the United States an article of food, after it has been previously refused admission, to affirmatively establish that the food is not adulterated.

### **Section 309: Notices to States Regarding Imported Food**

Requires that where the Secretary has credible evidence or information indicating that an article of food presents a threat of serious adverse health consequences or death to humans or animals, the Secretary shall provide notice regarding the threat posed by such food to those States in which the food is held or will be held and shall request that such States take appropriate remedial action.

### **Section 310: Grants to States for Inspections**

Authorizes the Secretary to make grants to States for increased food safety inspections, examinations, investigations and related activities and to assist States in taking appropriate actions to respond to any Federal notice received pursuant to Section 309. Authorizes to be appropriated such sums as may be necessary for FY 2002 through FY 2006 to establish and carry out the grants under the section.

## **SUBTITLE B. PROTECTION OF DRUG SUPPLY**

### **Section 311: Annual Registration of Foreign Manufacturers; Shipping Information; Drug and Device Listing**

Mandates annual registration of foreign manufacturers engaged in the import of drug and device products into United States. Requires that the annual registration include information on each importer or carrier transporting the foreign manufacturer's drug or device products. Directs that the registration and listing numbers be included in the declaration for the products when offered for import.

### **Section 312: Requirement of Additional Information Regarding Import Components Intended for Use in Export Products**

Mandates a chain of possession identification and a customs bond for those firms that seek to import components of drugs, devices, food additives, color additives, or dietary supplements for further processing and export. Requires certificates of analysis for components containing any chemical substance or biological substance intended for export.

Clarifies that the provisions permitting import-for-export do not apply to articles in which the Secretary of Health and Human Services determines that there is credible evidence or information indicating that the article presents a threat of serious adverse health consequences to humans or animals.

## **TITLE IV – DRINKING WATER SECURITY AND SAFETY**

### **Section 401: Amendment to Safe Drinking Water Act**

#### **Terrorist and Other Intentional Acts**

This provision amends the existing emergency powers part of the Safe Drinking Water Act (SDWA) to establish a new section 1433 to require community water systems serving over 3,300 individuals to conduct a vulnerability assessment. Systems are to certify to the Environmental Protection Agency (EPA) that the assessment has been completed by specified dates. Prior to March 1, 2002, EPA is required provide information to such systems concerning probable threats which could substantially disrupt supply or otherwise present significant public health concerns.

Section 1433 also requires community water systems serving over 3,300 individuals to prepare or revise an emergency response plan that incorporates the results of the vulnerability assessment. In preparing or revising emergency response plans, to the extent possible, water systems are to coordinate with local emergency planning commissions. EPA is also to provide guidance to systems serving under 3,300 persons on how to conduct vulnerability assessments, prepare emergency response plans and address threats. The section authorizes EPA to provide \$120 million in Fiscal Year 2002 and such sums as may be necessary in Fiscal Year 2003 and 2004 to assist water systems in conducting vulnerability assessments, preparing or revising emergency response plans, addressing basic security enhancements of critical importance and addressing significant threats to public health.

#### **Contaminant Prevention, Detection and Response**

This provision establishes a new section 1434 of the SDWA that requires EPA in consultation with the Centers for Disease Control and other appropriate departments and agencies of government to review current and future methods to prevent, detect and respond to the intentional introduction of chemical, biological or radiological contaminants into drinking water systems. This review is to include methods to provide sufficient notice to operators and individuals served by water systems of intentional contamination, methods, means and equipment to negate or mitigate the consequences of contamination, and biomedical research into the public health impacts of such contamination.

#### **Supply Disruption Prevention, Detection and Response**

This provision establishes a new section 1435 of the SDWA that requires EPA to review methods and means by which terrorists or other intentional actors could disrupt the supply of safe drinking water or take action to make drinking water unsafe. The review is to

include methods and means by which elements of community water systems could be destroyed or disrupted as well as methods or means by which they can be reasonably protected. For both contaminant prevention, detection and response as well as supply disruption prevention, detection and response, \$15 million is authorized in Fiscal Year 2002 with such sums as may be necessary provided in Fiscal Years 2003 and 2004.

#### **Other Amendments to SDWA**

Title IV also amends section 1431 of the SDWA, the current emergency power provision, to include legislative language concerning threatened or potential terrorist attack, or other intentional acts designed to disrupt the supply of adversely impact the safety of drinking water. In addition, the Title increases penalties to tampering with drinking water systems and provides \$35 million in Fiscal Year 2002 and such sums as may be necessary thereafter for existing section 1442 of the SDWA.