

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

### 21 CFR Parts 1 and 16

[Docket No. 02N-0275]

RIN 0910-AC38

### Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing a regulation that provides procedures for the detention of an article of food, if an officer or qualified employee of FDA has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals ("administrative detention"). The proposed regulation implements the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which authorizes the use of administrative detentions and requires regulations establishing procedures for instituting on an expedited basis certain enforcement actions against perishable food subject to a detention order.

**DATES:** Submit written or electronic comments by July 8, 2003.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Marquita Steadman, Center for Food Safety and Applied Nutrition (HFS-007), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-827-6733.

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#### I. Background and Legal Authority

The events of September 11, 2001, highlighted the need to enhance the security of the U.S. food supply. Congress responded by passing the Bioterrorism Act (Public Law 107-188), which was signed into law on June 12, 2002. The Bioterrorism Act includes a provision in title III (Protecting Safety and Security of the Food and Drug Supply), Subtitle A (Protection of Food Supply), section 303, which amends section 304 of the Federal Food, Drug,

and Cosmetic Act (the act) (21 U.S.C. 334 *et seq.*) by adding paragraph (h) to provide that an officer or qualified employee of FDA may order the detention of any article of food that is found during an inspection, examination, or investigation under the act if the officer or qualified employee has credible evidence or information indicating that the article of food presents a threat of serious adverse health consequences or death to humans or animals. This provision also requires the Secretary of Health and Human Services (the Secretary) to provide by regulation procedures for instituting on an expedited basis certain enforcement actions against perishable food subject to a detention order. Section 303 of the Bioterrorism Act also amends the act by adding a new prohibited act as paragraph (bb) to section 301 of the act (21 U.S.C. 331).

The major components of section 303 of the Bioterrorism Act are as follows:

- *Criteria used to trigger an administrative detention:* Amends section 304 of the act to authorize an officer or qualified employee of FDA to order the detention of any article of food that is found during an inspection, examination, or investigation under the act, if the officer or qualified employee has credible evidence or information indicating such article presents a threat of serious adverse health consequences or death to humans or animals.
- *Approval required:* The Secretary, or an official designated by the Secretary, must approve the detention order. An "official designated by the Secretary" means the District Director of the district where the detained article of food is located, or an FDA official senior to such director.

- *Period of detention:* The detention period will be for a reasonable period, not to exceed 20 days, unless a greater period, not to exceed 30 days, is necessary to enable the Secretary to institute a seizure or injunction action.

- *Required rulemaking:* The Secretary must by regulation provide for procedures for instituting certain enforcement actions on an expedited basis with respect to perishable food subject to a detention order.

- *Security of detained article of food:* The detention order may require that the detained article of food be labeled or marked as detained. The order must require the removal of the detained article of food to a secure facility, as appropriate.

- *Appeal procedure:* Any person who would be entitled to claim the detained article of food if such article were seized may appeal the detention order to the Secretary. Within 5 days after such