Association of Food and Drug Officials

2550 Kingston Road, Suite 311 York, PA 17402
Telephone (717)757-2888 • Fax (717)755-8089
E-Mail: afdo@afdo.org • Internet: www.afdo.org

President
Shirley B. Bohm
MN Dept. of Agriculture
Dairy/Food Inspection Division
90 W. Plato Blvd.
St. Paul, MN 55107
(651) 296-1590
(651) 297-5637 FAX
shirley.bohm@state.mn.us

President-Elect
Christopher H. Wogee
CA DHS/Food and Drug Branch
601 N. 7th - MS 357
P.O. Box 942732
Sacramento,CA 94234-7320
(916) 324-3991
(916) 440-5177 FAX
cwogee@dhs.ca.gov

Vice-President
Cameron M. Smoak
GA Dept. of Agriculture
19 Martin Luther King Jr. Dr.
Room 306
Atlanta, GA 30334
(404) 656-3627
(404) 463-6428 FAX
csmoak@agr.state.ga.us

Secretary-Treasurer
Alfred E. Bugenhagen
NY Dept of Agriculture & Markets
Div. of Food Safety & Inspection
One Winners Circle
Albany, NY 12235
(518) 457-5382
(518) 485-8986 FAX
Alfred.Bugenhagen@agmkt.state.ny.us

Director of Public Policy
J. Joseph Corby
NY Dept of Agriculture & Markets
One Winners Circle
Albany, NY 12235-0001
(518) 457-4492
(518) 485-8986 FAX
Joe.Corby@agmkt.state.ny.us

Executive Director
Denise C. Rooney
Association of Food and Drug Officials
2550 Kingston Road
Suite 311
York, PA 17402
(717) 757-2888
(717) 755-8089 FAX
drooney@afdo.org

August 30, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 02N-0276 (Section 305)
Docket No. 02N-0277 (Section 306)
Docket No. 02N-0278 (Section 307)
Docket No. 02N-0275 (Section 303)
Public Health Security and Bioterrorism Preparedness and Response Act of 2002

The Association of Food and Drug Officials (AFDO) sincerely appreciated the opportunity to attend the U.S. Food and Drug Administration's (FDA) August 2, 2002 briefing addressing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. AFDO has, for our 106 year existence, represented state and local government program officials dealing with the regulation of foods, drugs and medical devices within their respective jurisdictions. We are pleased to have been asked to comment on the proposed Act that would enhance the authorities of the FDA in order to better protect the security of the country's food supply.

In our opinion, any response to bioterrorist incidents that affect this country's food supply must include the coordinated efforts of state and local government officials, because it is these officials who serve as first responders in issues of food safety and security.

We view the current state of heightened alert in this country as an opportune time to transition to a concept of a nationally integrated food safety system. This is an idea that AFDO has promoted for many years and which has resulted in the formation of the National Food Safety System (NFSS) project that involves USDA, CDC, EPA, state and local program officials, in addition to FDA. Among the projects developed to enhance the integrated concept of NFSS that are currently being piloted are the following:

- ELEXNET – a secure electronic data sharing system for food safety laboratory data (By the end of the year 28 states will be sharing data.)
- ISO Accreditation – an internationally recognized laboratory accreditation aimed at assuring uniform methodologies for federal and state laboratories
- Directory of Laboratory Capabilities – a compilation to identify state and federal capabilities in event of emergency needs

02N-0277 C 14

- AFDO Recall Workgroup – an effort involving state and federal (FDA and USDA/FSIS) officials to streamline and better coordinate recalls for increased effectiveness in removal of contaminated product from the marketplace

- Validation of Laboratory Methodologies – a joint federal/state effort to standardize and develop national rapid detection methods

- Foodborne Illness Outbreak Coordination Guidelines – developed to provide uniform investigational procedures and information sharing protocols

- ORA-U – development of a comprehensive national training and certification system for federal, state and local field inspectors

- Uniform Criteria Workgroup – development of uniform national regulatory standards

- Integrated Food Safety Partnership – provides a pilot program that integrates the food safety functions of a state and the FDA

- FoodNet – participation and sharing of foodborne illness information from state and local government

- PulseNet – development and sharing of information related to DNA fingerprinting of pathogens associated with disease outbreaks to identify clusters of outbreaks

AFDO very strongly supports the goals of resource management at all levels of government to provide synergistic and effective response to all food safety emergencies, including bioterrorism. We strongly support the need to enhance FDA's authority, capacity and expertise and urge you to consider these NFSS efforts to integrate the food safety and security system as you transition into the new authorities granted you. FDA and the states have a tradition of working very closely in public health issues. Any improvement toward integrating the states with their federal counterparts will literally add thousands of food safety and security "foot soldiers" to what is clearly a national effort.

Our comments to the specific sections of the Act are as follows:

Section 305 (Registration) - Docket No. 02N-0276

- Section 301 requires the President's Council on Food Safety, in consultation with various stakeholders, to develop a crisis communication and education strategy, but does not mention collaboration with these stakeholders in any other areas. In Section 311 the Secretary is authorized to use the states, tribes and territories to make inspections, but does not mention these entities in the inspection planning process, as we believe it should. It should also direct FDA to utilize the states, through the grants process, to develop the list of firms that must register. Much of this information may already be available through state regulatory agencies.

- It is not clear whether fees will be associated with registration of facilities with FDA. Many states may already license or register food processors and distributors. Registration with states and FDA, particularly if significant fees are associated would be a burden on industry and seen as duplicative.

- The registration information that FDA collects, particularly the list of facilities, should be shared with the respective states and not be deemed confidential information.

- The registration requirement should apply to all food manufacturing and distribution facilities regardless of whether they fall under FDA jurisdiction.

- FDA should also consider annual grants or contracts with states for the purpose of maintaining the accuracy of registrations for all domestic food firms.

Section 306 (Recordkeeping) – Docket No. 02N-0277

- The review of these records should become a part of routine food establishment inspections and guidance on parameters for review will be needed.

- The words "sensitive information" need to be defined?

- The authority to have access to records seems to be limited to times when there is a "reasonable belief that an article of food is adulterated and presents a threat..." Such wording can oftentimes allow industry time to stall or inhibit prompt record review, which we believe weakens this Section.

- We do not believe size of business should matter relative to recordkeeping and traceback.

Section 307 (Prior Notice) – Docket No. 02N-0278

- AFDO believes that food imports are an area in critical need of added attention and that this Section will be immensely helpful in regulating food imports.

- Because of the enormity of state resources, AFDO believes that states must somehow be linked into this notification process and informed of illegal and legal entry items. AFDO encourages FDA to develop formal partnerships with state agencies to assist them in the regulating and control of imports.

Section 303 (Detention) – Docket No. 02N-0275

- There needs to be guidance provided that defines "a threat of serious adverse health consequences." If possible states should have prior notification before detention action is taken?

- We strongly support provisions that would enhance FDA authorities in the area of detention. However, we do not believe the enhanced authority should be limited to periods that have been declared a public health emergency. Detention authority, in particular, is an exposure prevention measure that should be used proactively. Denying use of the authority until an emergency has been declared denotes that an incident resulting in harm may have already occurred that otherwise could have been prevented with an unencumbered retention authority. AFDO would like to see this authority granted in a manner to be used proactively to prevent such an incident and not reactively. If there is a single large-scale incident, with no prior emergency

declaration, this authority would not be available to the FDA to prevent the tragedy, even in light of circumstantial evidence suggesting a contamination was possible.

- Detention authority for food imports should be extended to circumstances where state food safety programs have established credible evidence that an importer has repeatedly or deliberately imported an adulterated or misbranded product.

AFDO understands that the above four Sections of the Act require regulations to be promulgated and we hope the issues presented by us will be considered.

We, once again, thank FDA for the opportunity to comment.

Shirley Bohm
President
Association of Food and Drug Officials

cc: AFDO Board of Directors
Regional Affiliate Presidents

SPH41

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