Congress of the United States
Washington, DC 20515

February 22, 2007

Andrew C. von Eschenbach, M.D.
Acting Commissioner
U.S. Food and Drug Administration
U.S. Department of Health and Human Services
5600 Fishers Lane, Room 15-47
Rockville, MD 20857

Dear. Dr. von Eschenbach:

The Committee on Oversight and Government Reform and the Appropriations Subcommittee on Agriculture will be conducting oversight of our nation's food safety system. We are writing to request information relevant to these oversight efforts.

The Committees requests that the Food and Drug Administration (FDA) provide the following information relating to food safety funding, food safety inspections, current guidelines and standards, and current enforcement efforts. For fiscal years 2007 and 2008, please provide responses based on projections where final figures or information are not available.

Food Safety Funding Questions

1. Please provide FDA's food safety resource requests for each fiscal year 2000-2008. Bioterrorism and food security activities should be reported separately from "traditional" food safety threats such as *E. coli, Salmonella, Listeria*, etc. For each budget cycle, food safety resource requests should be broken down as follows:

    a. Food safety resource requests to the Commissioner from: the Center for Food Safety and Applied Nutrition (CFSAN), the Office of Regulatory Affairs, and other centers such as the Center for Veterinary Medicine;
    b. FDA request to the Department of Health and Human Services (HHS);
    c. HHS request to the Office of Management and Budget (OMB);
    d. Initial response from OMB, including revisions to the request by OMB;
    e. HHS appeals of this OMB response;
    f. Final request in the President's budget; and
    g. Actual resources appropriated by Congress (break out any supplemental funds that may have been approved).

2. For each fiscal year 2000-2008, describe the food safety increases needed to maintain current services, after accounting for inflation and other mandatory cost increases (e.g., staff pay and infrastructure). Please describe the extent to which each of the President's budget requests provided for those increases. Increases for bioterrorism and food security activities should be reported separately from "traditional" food safety threats.

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3. Estimate the level of food safety resources necessary for fiscal years 2007 and 2008, if the 2000 level was adjusted for inflation and other mandatory cost increases (e.g., staff pay and infrastructure). Again, please report food security and "traditional" food safety activities separately.

4. Please describe the resources devoted to food bioterrorism for each fiscal year 2001-2008, field and headquarters. Please describe any actual or proposed transfers of resources (dollars or personnel) from "traditional" food safety activities to food security activities.

Inspection and Staffing Questions

1. Please provide the following information on food staffing levels in full time equivalents (FTEs), for each fiscal year 2000-2008:

    a. The number of FTEs located within CFSAN, including the total number of FTEs and FTE figures broken down for cosmetics, dietary supplements, nutrition programs; and
    b. The number of FTEs for food safety, including the total number of FTEs and FTE figures broken down for headquarters and field. Please report separately any FTEs devoted to bioterrorism or food security.

2. Please provide the following information regarding risk rankings:

    a. FDA's current risk rankings of food processing facilities, and how those risk rankings are determined;
    b. The number of food processing facilities in each of FDA's current risk ranking categories;
    c. The frequency of inspections for seafood, dairy, and produce processors and other "high risk" facilities for each of the fiscal years 2001-2008;
    d. The frequency of inspections for canned foods and other "low risk" processors for each of the fiscal years 2001-2008;
    e. A current list of the tomato, spinach, and lettuce firms that fall within FDA's definition of "high risk," and among these, the firms inspected by FDA yearly; and
    f. A current list of the tomato, spinach, and lettuce firms that do not fall within the definition of "high risk," and the frequency of inspection for these firms.

3. Please provide the following information regarding domestic food inspections, with inspections conducted by state or local officials under any type of agreement with FDA reported separately:

a. The budgetary resources allocated to inspections for fiscal years 2000-2008;
b. The staffing resources allocated to inspections for fiscal years 2000-2008, including the current number of field FTEs dedicated to food work and the current number actually performing inspections;
c. The number of domestic food inspections conducted for fiscal years 2000-2008, including the total number of inspections and inspection figures broken down by food product and type of facility;
d. The number of domestic food facilities inspected for the fiscal years 2000-2008, including the total number of facilities and facility figures broken down by food product and type of facility;
e. The number of domestic food facilities currently registered in accordance with the Bioterrorism Act of 2002;
f. Estimates for the total number of domestic facilities in existence that have not yet registered in accordance with the Bioterrorism Act of 2002;
g. The current number of FDA inspections and frequency of inspections for farms and produce distribution facilities;
h. A breakdown of food inspectors' average time allotments, including time spent preparing for inspections, doing inspections, following up on inspections, training, leave, travel, etc.;
i. The number of expected inspections per inspector for the fiscal years 2000-2008;
j. The total number of inspections done by states on FDA's behalf over the most recent fiscal year; and
k. A description of how these state inspections compare or differ from inspections done by FDA inspectors.

4. Please state whether FDA visits farms or produce distribution facilities in the absence of an outbreak and, if so, how often and under what circumstances.

5. Please provide the following information regarding foreign inspections:

a. The number of foreign food processors known to sell food in the United States, by food type and country of origin;
b. The number and country of foreign farms growing fresh fruits and vegetables intended for American consumption; and
c. The number of inspections of foreign farms, distribution facilities, and processing facilities inspected each year by FDA for fiscal years 2000-2008.

6. Please provide the following information regarding imported foods:

a. The number of import inspections for each fiscal year 2000-2008;
b. For each port of entry, the number and types of foods offered for entry;

c. For each port of entry, the number of products for each country of origin;
d. For each port of entry, the number of imports visually inspected;
e. For each port of entry, the number of products sampled;
f. For each port of entry, the number and type of products refused entry;
g. The number of ports of entry that are currently staffed with FDA inspectors every day of the year, and the average number of days staffed per year;
h. For each day a port of entry is staffed, the average number of hours per day an FDA inspector is present;
i. The number of ports of entry that relied on Customs rather than FDA inspectors to inspect imported food on any day over the past year;
j. The percentage of Customs staff inspecting food that have training in food safety; and
k. FDA's criteria for visual inspection of imported foods (e.g., country of origin, type of food, experience with importer).

7. Please provide the following information regarding FDA laboratory capacity:

   a. The number of FDA lab personnel (in FTEs) conducting activities related to food safety; and
   b. The number of food samples tested each year, by category (type of food, contaminant tested for, etc.).

Enforcement Questions

1. For each fiscal year since 2000, please provide the number of warning letters, seizures, injunctions, prosecutions, and voluntary recalls involving foods, by food type and facility type.

2. For each fiscal year since 2000, please provide the number of such enforcement actions recommended by District/Regional officials, and their ultimate disposition (e.g., number recommended by ORA headquarters, number submitted to General Counsel for review, number approved or denied by General Counsel).

Necessary Resources and Authorities Questions

1. Please provide the following information regarding efforts to protect against a terrorist attack using food as a vector:

   a. The assessment within CFSAN of efforts necessary to defend against such a terrorist attack (e.g., research on risks of various agents, rapid tests for agent detection, development of countermeasures, education and training of processors and transporters, development of standards for prevention and deterrence, border

inspection of imported foods, and inspection of domestic facilities to ensure compliance);

b. The resources necessary to complete these efforts, in dollars and staffing; and
c. The current shortfall from that level of resources, in dollars and staffing.

2. Please provide the following information regarding efforts for "traditional" food safety inspections:

   a. The assessment within CFSAN of a reasonable inspection frequency goal;
   b. The resources necessary to reach that inspection goal, in dollars and staffing;
   c. The current shortfall from that level of resources, in dollars and staffing;
   d. The assessment within CFSAN of the research gaps in food safety (e.g., information needed by agency scientists to better understand the sources and routes of contamination, including methods of contamination prevention);
   e. The resources necessary to reliably answer such research questions, in dollars and staffing; and
   f. The current shortfall from that level of resources, in dollars and staffing.

3. Please describe any additional safety standards that have been proposed within FDA to reduce the incidence of foodborne disease (e.g., HACCP for fruits and vegetables), including what tasks are necessary to create and implement these standards (e.g., gather the scientific basis for such standards, promulgate the necessary regulations, and effectuate their implementation) and what resources are necessary to complete these tasks, in dollars and staffing.

4. Please describe any work to create performance standards for acceptable pathogen levels in food.

5. Please describe any additional authorities that have been proposed within FDA to enhance food security (e.g., food detention and recall authority, authority to share deterrence information with producers without making such information publicly available).

6. Please describe the rapid tests that currently exist for the detection of pathogens in food and any shortfalls that exist in the development of such tests, as well as the resources that would be needed to develop rapid tests for the major pathogens associated with foodborne disease.

7. In 1999, FDA published the "Affirmative Agenda for International Activities," which proposed to establish guidance on equivalence criteria for foreign food safety systems, and also to conduct foreign equivalence evaluations. Please provide an update to this agenda.

8. CDC currently estimates 76 million Americans contract foodborne disease each year. California spinach growers estimated a loss of up to $74 million due to last fall's outbreak. Using traditional methods of economic calculation required for justifying rulemaking, please estimate:

   a. The annual costs to society due to foodborne illness, including costs to consumers (from deaths, illnesses and productivity losses); costs to producers (from lost sales, legal liability, recalls and destroyed product, job losses to farm workers, and diminished confidence in their products); and costs to state, local and federal governments (from disease outbreak investigation and in medical costs via Medicare/Medicaid); and
   b. The economic benefits to society of an enhanced FDA resource base for food safety (e.g., lives saved, illnesses prevented, and economic losses averted).

Additional Inspection and Enforcement Questions

1. Please provide the results for all food inspections for fiscal years 2000-2006, broken down by food product type and facility type. Please include the number of reinspections and their results, and the number of inspection reports classified as "no action indicated," "voluntary action indicated," and "official action indicated." Please also provide the final disposition of such recommended actions.

2. Please provide the number and location of foreign produce facilities associated with foodborne disease for fiscal years 2000-2006. Please also provide inspection information regarding each facility, including whether it was inspected prior to an outbreak or after an outbreak, the results of any inspection, and any remedial action taken.

3. Please provide all documentation of the inspection history since January 2001 for domestic firms producing packaged fresh spinach, including all records relevant to the firms that have been associated with the current outbreak. Such records should include the dates of inspection, inspection findings, and enforcement actions taken as a result of the findings.

4. Please provide documentation of any enforcement actions recommended by FDA staff, but ultimately not taken against firms producing packaged fresh spinach since January 2001. Please include documentation of FDA's reasons for disapproving such recommendations.

Conclusion

I request that you provide the answers to the questions regarding food safety funding, inspections and staffing, and enforcement by March 15, 2007. I also request that you provide answers to the questions regarding necessary resources and authorities and the additional questions regarding inspection and enforcement by April 5, 2007.

The Committee on Oversight and Government Reform is the principal oversight committee in the House of Representatives and has broad oversight jurisdiction as set forth in House Rule X. Similarly, the Appropriations Subcommittee on Agriculture has jurisdiction over appropriation of revenues and oversight responsibilities with respect to the Food and Drug Administration.

If you have any questions regarding this request, please contact Stephen Cha with the Committee staff at (202) 225-5056, or Martha Foley with the Appropriations Subcommittee on Agriculture at (202) 225-2638.

Sincerely,

Henry A. Waxman
Chairman
House Committee on Oversight and Government Reform

Rosa DeLauro
Chairwoman
House Appropriations Subcommittee on Agriculture, Rural Development, FDA, and Related Agencies

Enclosure

cc: Tom Davis
Ranking Minority Member