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


The Center for Science in the Public Interest (CSPI)\(^1\) appreciates the opportunity to comment on Docket No. FDA-2011-N-0391 regarding the risk-based inspection mandate under the FDA Food Safety Modernization Act (FSMA). CSPI filed additional comments to this docket as a member of the Safe Food Coalition and the Make Our Food Safe Coalition and incorporates those comments by reference. The purpose of this letter is to comment in answer to the request for information on data that can assist the agency in designating high-risk facilities.

Since 1997, CSPI has collected and maintained attribution data on foodborne illness outbreaks in its Outbreak Alert database. We have made the data available to the public in a searchable format on the CSPI website, share the database on a case-by-case basis with researchers, and each year summarize and analyze the most recent data in the *Outbreak Alert!* report. The methodology has been peer reviewed (attached) and the food categories developed for it are used for attribution by the Food Safety Research Consortium, World Health Organization, and University of Florida Emerging Pathogens Institute.

In addition to informing decisions on classifying facilities for inspection, the attribution data in the Outbreak Alert database would be useful for implementing other areas of FSMA which require the Food and Drug Administration (FDA) to base its actions on known safety risks. FSMA requires the use of attribution data for categorizing high-risk foods under the traceability recordkeeping provision in section 204, which states in part:

(2) DESIGNATION OF HIGH-RISK FOODS.—
(A) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, and thereafter as the Secretary determines necessary, the Secretary shall designate high-risk foods for which the additional recordkeeping requirements described in paragraph (1) are appropriate and

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\(^1\) The Center for Science in the Public Interest is a nonprofit health advocacy and education organization focused on food safety, nutrition, and alcohol issues. CSPI is supported principally by the 850,000 subscribers to its *Nutrition Action HealthLetter* and by foundation grants. We accept no government or industry funding.
necessary to protect the public health. Each such designation shall be based on—
(i) the known safety risks of a particular food, including the history and severity of foodborne illness outbreaks attributed to such food, taking into consideration foodborne illness data collected by the Centers for Disease Control and Prevention;
(ii) the likelihood that a particular food has a high potential risk for microbiological or chemical contamination or would support the growth of pathogenic microorganisms due to the nature of the food or the processes used to produce such food;
(iii) the point in the manufacturing process of the food where contamination is most likely to occur;
(iv) the likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination;
(v) the likelihood that consuming a particular food will result in a foodborne illness due to contamination of the food; and
(vi) the likely or known severity, including health and economic impacts, of a foodborne illness attributed to a particular food.

FDA is also required to identify risks for fresh produce, targeting border inspections, assessing eligibility for an expedited import program, and determining when certification of imports will be required. (Attachment)

We have attached tables drawn from the database that describe the number of outbreaks, number of illnesses, etiologies associated with foods, and the relative rates of illnesses by food category, adjusted for consumption. These demonstrate how the database may be used to identify the known safety risks of foods that are regulated by FDA. We are also happy to discuss how the database in whole or in part may be made available to FDA to assist in implementing FSMA.

Sincerely,

Cindy Roberts     Caroline Smith DeWaal
Food Safety Research Associate  Director of Food Safety

Attachments (4)