



Patrick J. McConnon, MPH
Executive Director
Council of State and Territorial Epidemiologists (CSTE)
2872 Woodcock Boulevard, Suite 303
Atlanta, Georgia 30341-4015

AUG - 2 2004

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Dear Dr. McConnon:

Thank you for your June 18, 2004, letter to Secretary Ann M. Veneman on behalf of the Executive Committee and members of the Council of State and Territorial Epidemiologists (CSTE) about the CSTE position statement, "*Disclosing Food Distribution Information to Protect the Public Health*." The Secretary has asked the Food Safety and Inspection Service (FSIS) to respond to your letter. We appreciate the opportunity to update you on the FSIS' initiatives in this area.

As you are aware, distribution lists are part of an establishment's confidential commercial information, which is valuable to a firm and its competitors. Currently, firms conducting recalls voluntarily share this information with FSIS, knowing it will not be disclosed publicly, but rather used to facilitate the removal of a product from commerce. Because the names of the businesses that received the product are considered proprietary, FSIS may not release the information. Access to this information protects public health by allowing the Agency to verify that recalls are proceeding effectively.

While FSIS believes that the recall process enables the Agency to respond promptly to potential threats to public health, we are committed to continuous improvement. For example, in a recently issued directive, FSIS has implemented new recall procedures that allow FSIS to begin the process of collecting recall information even before a microbiological sample confirms positive. This will allow the Agency to reach the public with recall information even more quickly, further enhancing consumer awareness and public health protection.

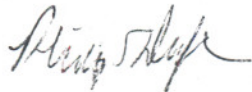
To further strengthen the food recall process, FSIS negotiated a memorandum of understanding with several States, including Georgia, under the terms of which FSIS shares distribution lists with the States. The participating States take an active role in verifying that recall activities are effective. Sharing these distribution lists with State officials contributes to improved public health protection by permitting a timely verification that products are removed from commerce. We believe this is in the best interests of protecting public health.

Patrick J. McConnon, MPH

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To further pursue food safety, the Agency is considering whether additional changes in its policies are appropriate and will advance its goal in recalling product. We appreciate your continued interest in food safety. Your comments are appreciated and thank you for writing.

Sincerely,

A handwritten signature in black ink, appearing to read "Philip S. Derfler", with a stylized, cursive script.

Philip S. Derfler

Assistant Administrator

Office of Policy, Program, and Employee Development



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 3 2004

Patrick J. McConnon, MPH
Executive Director
Council of State and Territorial Epidemiologists
2872 Woodcock Boulevard
Suite 303
Atlanta, Georgia 30341

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Dear Mr. McConnon:

Thank you for your letter of June 18, 2004 to Acting Commissioner Crawford providing him with the Council of State and Territorial Epidemiologists' position statement 04-ID-02 entitled, "Disclosing Food Distribution Information to Protect the Public Health."

We agree that foodborne diseases and outbreaks caused by contaminated commercial foods certainly pose a serious threat to the public's health and appreciate the concerns that you have expressed regarding sharing critical information with public health agencies. The Food and Drug Administration's (FDA) policy is to ensure that information regarding foodborne illnesses and recalls related to potentially serious life-threatening situations are brought to the immediate attention of the public and other Federal and state government agencies. Routinely, this is done through the issuance of FDA press releases and talk papers to the public and the dissemination of state and US Department of Agriculture (USDA) press releases. This is accomplished by FDA's Division of Federal-State Relations, which transmits the documents to appropriate state and major city health agencies via e-mail. A glimpse of FDA's web site testifies to FDA's persistent efforts to provide the public with information as soon as possible. A quick look at the press releases for June 2004 on FDA's web site provide examples of FDA's efforts to keep the public informed on emerging problems. See <http://www.fda.gov/po/indexes/2004news.html#june>.

FDA works routinely with the Centers for Disease Control and Prevention (CDC), USDA, and state health and/or agricultural agencies in the investigation, control, and management of foodborne illness outbreaks in which the agencies share information openly.

One example of that cooperation is the outbreak of Hepatitis in March/April 1997 when approximately 200 students and teachers developed hepatitis A in Michigan from eating "tainted" strawberries. The FDA, state and local officials, CDC, and USDA shared information and worked aggressively to deal with the public health threat. Numerous similar situations such as *Escherichia coli* O157:H7 illnesses associated with consumption of Odwalla apple juice in 1996, numerous foodborne outbreaks associated with sprout consumption, and the recent Paramount Almond recall due to *Salmonella* all resulted from sharing information and cooperation between CDC, FDA and state agencies.

You reference proprietary information that USDA and FDA cannot share without written agreements. I refer you to Title 21 of the Code of Federal Regulations (CFR) - Food and Drugs, Section 20.88, "Communications with State and local government officials." Section 20.88 does provide for specific agreements between FDA and state and local government officials in the sharing of confidential commercial information. FDA has signed such agreements with a number of states, but not with all. Also, FDA commissions state and local regulators to receive and use such confidential information for regulatory purposes. In many cases, it is state laws that inhibit our ability to share information as they cannot maintain the confidentiality of the information, e.g., use the information internally to support a recall without allowing the confidential information to become public.

However, more important to this discussion is the fact that Title 21 of the CFR – Food and Drugs, Section 20.91, "Use of data or information for administrative or court enforcement action," states, "Nothing in this part or this chapter shall prevent the Food and Drug Administration from using any data or information, whether obtained voluntarily or involuntarily and whether or not it is available for public disclosure, as the basis for taking any administrative action or court enforcement action within its jurisdiction. Data and information otherwise exempt from public disclosure are nevertheless available for public disclosure to the extent necessary to effectuate such action, e.g., the brand name, code designation, and distribution information are released when a product is recalled."

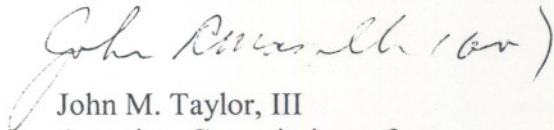
It is under the authority of this section that FDA has provided to state and local authorities information received from recalling firms regarding distribution to the wholesale and, occasionally, retail levels. This information has been provided both at the request of state and local authorities and on FDA's initiative to request assistance in conducting audit checks to assess the effectiveness of recall actions. We will continue to follow this policy as the need arises.

Your Statement of the Problem identified the inability of USDA to provide a list or issue a press release identifying restaurants and retail stores involved in the USDA beef recall. Your Statement of the Desired Actions to be Taken suggests that the policy of both USDA and FDA should be changed to disclose "food distribution 'end points' or 'points of sale' information to local, state, territorial, and federal public health agencies when such foods have been found to be contaminated or implicated in human illnesses and deaths..." We appreciate the desire of state and local governments to have such information and often press releases issued by FDA or recalling firms will list grocery chains or particular distributors that will allow follow-up at retail locations. However, usually, we have distribution only from the recalling firm to its direct accounts, which may be secondary distributors to other wholesale or retail consignees.

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We appreciate your concern on this issue. FDA will continue in its efforts to communicate effectively with our state and Federal counterparts.

Sincerely,

A handwritten signature in dark ink, appearing to read "John M. Taylor, III", with a stylized flourish extending from the bottom left of the signature.

John M. Taylor, III
Associate Commissioner for
Regulatory Affairs



Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

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AUG 24 2004

Patrick J. McConnon, M.P.H.
Executive Director
Council of State and Territorial Epidemiologists
2872 Woodcock Boulevard, Suite 303
Atlanta, Georgia 30341-4015

Dear Mr. McConnon:

Thank you for your letter regarding the Council of State and Territorial Epidemiologists' (CSTE) position statement 04-ID-02 entitled "Disclosing Food Distribution Information to Protect the Public Health." As stated in the position statement, this issue affects the extent and effectiveness of investigations and interventions aimed at preventing foodborne illnesses in outbreak situations.

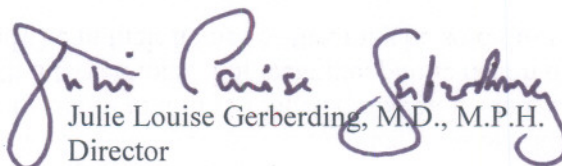
Disclosure of distribution information for food products implicated in foodborne outbreaks can allow quicker determination of potential victims, and geographic areas likely to have high rates of disease can be efficiently targeted for coordination and assistance. Further, having food distribution information available during the preliminary stages of a food-related outbreak investigation may allow for timely and effective public health interventions. For example, public health officials could warn the public about food that may already be in their homes or that may be sold through secondary distributors.

Distribution information also allows investigators to target their efforts to areas of potential high exposure and thereby enhance efficiency and better define the scope and breadth of outbreaks. Cases found outside the areas of distribution may indicate an important alternative source of the contaminated food item.

Thus, food distribution information can play an important role in the investigation of outbreaks and the implementation of public health interventions. The Centers for Disease Control and Prevention (CDC) recognizes the primary role of federal regulatory partners in the collection and distribution of this type of information and the associated legal limitations of such activities.

CDC will collaborate with CSTE, other public health organizations, and our regulatory partners (the Food and Drug Administration and the U.S. Department of Agriculture's Food Safety Inspection Service) to determine the most effective solution for this issue.

Sincerely,


Julie Louise Gerberding, M.D., M.P.H.
Director

cc:
Dr. Duc Vugia