

**Conference for Food Protection
2020 Issue Form**

Issue: 2020 I-017

Council Recommendation: Accepted as Submitted _____ Accepted as Amended _____ No Action _____

Delegate Action: Accepted _____ Rejected _____

All information above the line is for conference use only.

Issue History:

This issue was submitted for consideration at a previous biennial meeting, see issue: 2018-I-027; new or additional information has been included or attached and the recommended solution has been revised.

Title:

Obtain Purchase Information as part of a Foodborne Outbreak Investigation

Issue you would like the Conference to consider:

We would like for the U.S. Food and Drug Administration (FDA) to add 8-304.11(L) to include providing available consumer purchase records to facilitate quicker identification of a food product that may be causing illness.

This will codify an existing practice and provide uniformity to both regulatory and industry segments about expectations, processes, and use of data. Many retailers already provide consumer purchase information; however, variations exist in the processes that retailers use to share this information, and the timeliness with which they provide it.

Public Health Significance:

Every year in the United States there are millions of cases of foodborne illness (Scallan et al., 2011). The U.S. Centers for Disease Control and Prevention's (CDC) Foodborne Disease Outbreak Surveillance System has identified an increase in multistate outbreaks from 2010-2014 (the most recent years available). While these multistate outbreaks comprise 3% of all reported outbreaks they account for 11% of the reported illnesses, 34% of the reported hospitalizations, and 56% of the reported deaths attributable to foodborne outbreaks (Crowe, Mahon, Vieira, Gould, & Report, 2015).

Quick and efficient identification of hazardous food products and their removal from commerce is critically important to minimize the number of people that become ill. Challenges to solving foodborne outbreaks include delays in reporting illnesses and consumer recall of potential exposures (such as brand and variety of food purchased). During multistate outbreaks, when people are geographically dispersed, purchase information is critical to identify a common source. Using consumer purchase data has assisted in the identification of contaminated product in outbreaks and allowed for its

removal from commerce (Barret et al., 2013; Miller, Rigdon, Robinson, Hedberg, & Smith, 2013; Møller, Mølbak, & Ethelberg, 2018).

A recent Association of Food and Drug Officials (AFDO) survey of state health and agriculture departments found that 41% of the responding jurisdictions already have authority to collect consumer food purchase information (personal communication). However, the structure and language of the authorizing legislation varies tremendously between States. By harmonizing the language in the Food Code, it will provide a uniform standard for industry to address requests for consumer purchase information.

Once an individual is diagnosed with a foodborne illness, they typically are interviewed about potential exposures by the public health program. During this interview, the patient may be asked where they have shopped for food, if investigators can access their purchase records, and for the account number or last several digits of their credit card. Provision of the account number or last several digits of the credit card number by the patient to investigators should suffice as evidence of consent.

During the 2018 biennial meeting, a concern was raised that some industry members also have stores in the European Union (EU) and that this may violate the EU's General Data Protection Regulation (GDPR). We believe that this would meet the intent of explicit consent within the GDPR regulations and would also at a minimum meet the standard for implied consent within the United States. The GDPR standard for explicit consent requires the information to be: 1) freely given; 2) specific and informed; and, 3) an unambiguous indication (by statement or clear affirmative action). Once an individual is diagnosed with a foodborne illness, public health officials may interview them about potential exposures including their food history and where they have shopped. During this interview, the patient may be asked if investigators can access their purchase records, and for the account number or last several digits of their credit/debit card. Provision of the account number or last several digits of the credit/debit card by the patient to investigators should suffice as evidence of consent. Additionally, any information obtained by the regulatory/health authorities would be covered under the same data protection laws that public health jurisdictions use to protect all investigation data (e.g., all other exposure/food consumption information provided by the patient during an interview).

Another concern voiced at the 2018 biennial meeting is that food establishments may be subject to the Health Insurance Portability and Accountability Act (HIPAA) regulations and that releasing any information may violate those requirements. 45CFR164.512(b) provides an exception for public health activities which allows disclosure of protected health information to prevent or control disease.

An additional concern was raised that some existing terms of service for industry incentive programs would not allow for this type of data sharing. However, by including this provision in the Food Code, the legal requirement would have precedent over the terms of service and would allow for data sharing.

A comprehensive best practices document is being finalized by the Shopper History Outbreak Partnership (SHOP), a group of state and federal public health and regulatory officials committed to identifying and promoting best practices for the use of shopper history during foodborne outbreaks to rapidly identify contaminated foods and prevent additional illness. The document, titled "Shopper History: Best Practices for use during Foodborne Illness Investigations", addresses the concerns that surfaced during the 2018

biennial meeting including data maintenance and confidentiality considerations. The finalized version will be posted at <http://www.afdo.org/shopper-cards> [afdo.org].

By adding these provisions to the Food Code, we will be able to: 1) more frequently and more quickly identify and remove food items that may be causing illness and, 2) provide a uniform standard for industry to address purchase history requests.

Barret, A. S., Charron, M., Mariani-Kurkdjian, P., Gouali, M., Loukiadis, E., Poinet-Leroux, B., . . . Mailles, A. (2013). Shopper cards data and storage practices for the investigation of an outbreak of Shiga-toxin producing *Escherichia coli* O157 infections. *Médecine et Maladies Infectieuses*, 43(9), 368-373. doi:<https://doi.org/10.1016/j.medmal.2013.05.004>

Crowe, S. J., Mahon, B. E., Vieira, A. R., Gould, L. H. J. M., & Report, M. W. (2015). Vital signs: multistate foodborne outbreaks-United States, 2010-2014. *64*(43), 1221-1225.

Miller, B. D., Rigdon, C. E., Robinson, T. J., Hedberg, C., & Smith, K. E. J. J. o. f. p. (2013). Use of global trade item numbers in the investigation of a *Salmonella* Newport outbreak associated with blueberries in Minnesota, 2010. *76*(5), 762-769.

Møller, F. T., Mølbak, K., & Ethelberg, S. (2018). Analysis of consumer food purchase data used for outbreak investigations, a review. *Eurosurveillance*, 23(24), 1700503. doi:<https://doi.org/10.2807/1560-7917.ES.2018.23.24.1700503>

Scallan, E., Hoekstra, R. M., Angulo, F. J., Tauxe, R. V., Widdowson, M. A., Roy, S. L., . . . Griffin, P. M. (2011). Foodborne illness acquired in the United States--major pathogens. *Emerg Infect Dis*, 17(1), 7-15. doi:10.3201/eid1701.091101p1

Recommended Solution: The Conference recommends...:

The Conference recommends...

that a letter be sent to the FDA requesting that the most current published version of the Food Code be amended as follows:

Add new section 8-304.11(L)

(L) Provide existing customer food purchase records as rapidly as possible with customer consent to the REGULATORY AUTHORITY during a foodborne illness investigation.

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Supporting Attachments:

- "Analysis of consumer food purchase data used for outbreak investigations"

It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.