

Fact Sheet on Smuggled Food

Section 309 of the FDA Food Safety Modernization Act (FSMA) directs the Department of Health and Human Services (HHS) and the Department of Homeland Security (DHS) to develop a strategy to better identify and prevent entry of smuggled food into the United States. This strategy is due to be implemented by HHS and DHS on July 3rd, 2011. FSMA also requires HHS to notify DHS within 10 days when HHS identifies a smuggled food that it believes would cause serious adverse health consequences or death to humans or animals.

The HHS Strategy for Identifying and Preventing Smuggled Food will help ensure consumer protection from smuggled food. When smuggled food goes un-examined by regulators it presents a hazard to consumers, and erodes confidence in the safety of the food supply. Therefore, a comprehensive strategy to combat the entry of smuggled food is needed to protect the public health.

The strategy contains six steps, including notifications to DHS of serious health threats, and will be implemented in two phases. The first phase will involve historical data analysis which will lead to the development of smuggled food electronic targeting rules and criteria. The goal is to allow for both the Food and Drug Administration (FDA) and Customs and Border Protection's (CBP) electronic systems to better identify those import shipments that may include smuggled food. Armed with better targeting mechanisms, FDA and CBP will conduct field examinations of imports with greater probability of finding smuggled food and then share the findings with each other. Enforcement actions against smuggled food will be determined based on the circumstances surrounding the shipment, and will consider the risk to the public health.

The second phase of the strategy involves a continuous post-operational analysis of data and results obtained from examinations and subsequent enforcement actions. This ongoing analysis will allow FDA and CBP to make adjustments to targeting mechanisms previously established in order to increase the likelihood that smuggled food shipments will be identified and held for examination. Finally, in looking to deter future violations, the strategy also seeks to publicize enforcement actions taken against smuggled food as widely as possible.

Regarding notification of smuggled food to both Homeland Security and the public as mandated by FSMA, FDA will immediately notify DHS when it discovers a smuggled food that could cause serious adverse health consequences or death, given these situations call for notification to DHS in much less than 10 days. The public will also be notified through press release and/or other appropriate communication when FDA identifies a shipment of smuggled food that it reasonably believes would have a serious adverse health impact, reasonably believes has entered U.S. commerce, and is likely to be consumed by the public.

Will FDA be targeting all smuggled food, including those foods transported in luggage for personal use?

Section 309 of FSMA defines smuggled food as “any food that a person introduces into the United States through fraudulent means or with the intent to defraud or mislead.” While this could be interpreted to apply to a single undeclared low risk food item carried in personal luggage, FDA and DHS will focus resources on imported food that poses the greatest risk to public health.

How will FDA notify the public of potentially dangerous smuggled food?

FSMA provides for public notifications of harmful and dangerous smuggled food “reasonably believe[d] to [have] entered domestic commerce” and “likely to be consumed”. FDA intends to issue a press release and use other appropriate emergency communications or recall networks in order to warn consumers, distributors, and vendors about the threat.

How will FDA evaluate the impact of this strategy?

FDA and CBP will measure the number of food import examinations targeted to alert for smuggled food against the number of shipments where food smuggling is actually discovered and acted upon. Outcomes will be measured according to metrics developed under the strategy at regular intervals and any adjustments to strategy will be made after consideration of these results.