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Recent Developments in Prior Notice Requirements for Food Imports

On November 7, 2008, the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services published in the Federal Register:

- Its final rule on providing prior notification to the U.S. government for human and animal food shipments imported or offered for import into the United States (<http://edocket.access.gpo.gov/2008/pdf/E8-26282.pdf>) and
- Its draft Compliance Policy Guide (CPG), which advises FDA and U.S. Customs and Border Protection (CBP) staff on how to implement the rule (<http://www.cfsan.fda.gov/~pn/cpgpn7.html>).

The final rule becomes effective May 8, 2009; comments on the draft CPG are due by December 8, 2008. The rule applies to articles of food and drink for man and other animals, chewing gum and articles used as components of any such article, excluding food contact substances or pesticides.

PRIOR NOTICE

The final rule implements section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which added section 801(m) to the Federal Food, Drug, and Cosmetic Act (the FDC Act) to require that the FDA receive advance notice of imported food shipments. The final rule revises the interim final rule, which has been in effect since December 12, 2003 and was jointly issued by the FDA and CBP.

The rule requires that prior notice of imported food shipments be submitted to the FDA electronically via either the CBP Automated Broker Interface (ABI) of the Automated Commercial System (ACS) or the FDA Prior Notice System Interface (PNSI). Before the food arrives at the port, the information must be submitted and confirmed electronically as facially complete by the FDA for review no less than eight hours prior for food arriving by water, four hours prior for food arriving by air or land via rail and two hours prior for food arriving by land via road. Food imported or offered for import without adequate prior notice is subject to refusal, and, if refused, must be held. Departing from the interim rule, which had shorter notice periods, the final rule allows parties to provide notice up to 15 days prior to arrival for submissions made through the FDA PNSI and up to 30 days prior for submissions made through the CBP ABI/ACS.



PRIOR NOTICE EXEMPTIONS

While the “food” definition of the FDA’s prior notice rule appears broad, the rule has significant exceptions. It does not apply to:

- Food for an individual’s personal use when it is carried by or otherwise accompanies the individual when arriving in the United States;
- Food made by an individual in his/her personal residence and sent by that individual as a personal gift to an individual in the United States;
- Food imported then exported without leaving the port of arrival until export;
- Meat food products that at the time of importation are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act;
- Poultry products that at the time of importation are subject to the exclusive jurisdiction of the USDA under the Poultry Products Inspection Act;
- Egg products that at the time of importation are subject to the exclusive jurisdiction of the USDA under the Egg Products Inspection Act; or
- Articles of food shipped as baggage or cargo in a diplomatic pouch.

PRACTICAL APPLICATION OF PRIOR NOTICE

The draft CPG identifies specific instances when the FDA and the CBP should not take action when a party fails to provide prior notice to the U.S. government for food shipments imported or offered for import into the United States. FDA and CBP staff are advised that no prior notice is required when the food is imported or offered for import for:

- Non-commercial purposes with a non-commercial shipper;
- Quality assurance, research or analysis purposes only, not for human or animal consumption or resale;
- “In vivo” testing in non-food producing laboratory animals;
- International mail or courier service, and there is no U.S. recipient/consignee;
- Official U.S. federal government shipments;
- Immediate return to the same country without use in the United States; or
- Cultivation as seeds.



PENALTIES

The penalties for failing to provide prior notice will depend on the severity of the violations, whether they are flagrant and whether the party has had previous violations, particularly if they are repeated or similar. In certain instances, the FDA will allow parties an opportunity to take voluntary and prompt corrective measures before it will take action. Penalties include seizure, debarment, monetary fines and criminal penalties.

FOR MORE INFORMATION

Please contact **Elizabeth D. Gobeil** of our **Life Sciences** practice group or **Julia M. McCalmon** of our **International Trade & Customs** practice group for more information.

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