THE ONTARIO Agri-Food Exporter

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Special Report

# APRIL DEADLINE *for input on new FDA regulations*

*On February 3, 2003, the United States Food and Drug Administration (FDA) published draft regulations on registration of food facilities and prior notice of importation of all food and beverage products into the U.S.*

These proposed changes will impact all Ontario food and beverage exporters selling in the U.S. Businesses and other interested parties now have until April 4th to provide feedback on the proposals. Copies of the proposed rules are available at www.fda.gov/oc/bioterrorism/bioact.html

"We strongly encourage Ontario exporters to make their voices heard on the potential impact of these proposals," says Dermod Mark, manager of OMAF's Export Marketing Unit. The regulations are part of the implementation of the U.S. Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (also known as the Bioterrorism Act).

The Bioterrorism Act provides the FDA with new authority to protect the U.S. food supply against terrorist acts and other threats. "Improving the FDA's food safety inspection, detection and monitoring capabilities is and has been a top priority of the Department even before the events of 9/11. Since then we have taken strong steps to enhance the FDA's ability to make our food supply safer," said U.S. Secretary of Health and Human Services Tommy G. Thompson in announcing the proposed regulations.

"This measure will bolster our ability to regulate effectively the more than 400,000 domestic and foreign facilities that deal with food within our country," said FDA Commissioner Dr. Mark McClellan at the time of the announcement. "Our ability to efficiently and effectively help protect the nation's food supply is a critical part in our agency's counterterrorism mission."

## *Striking a balance*

The regulations are designed to allow the FDA to assess the risk associated with various shipments, moving low-risk shipments through the system quickly and adequately investigating higher-risk shipments, while also enabling the Agency to track possible points of contamination. "We're asking for just enough information to allow us to make good judgments about what to inspect, while not unnecessarily holding up shipments that don't require inspection," says an FDA representative. "We recognize the challenges of just-in-time shipments, and shipping fresh produce and fresh fish. We're trying to strike a balance of deciding where to deploy our investigators without unnecessarily holding up shipments. The fundamental question we're seeking comments on under this process is have we struck the right balance?"

## *What the regulations say*

### Registration of food facilities

**Who must register:** Under the proposed regulations, owners, operators or agents in charge of a domestic or foreign food facility that manufactures, processes, packs or holds food for human or animal consumption in the United States must register with the FDA by December 12, 2003. This registration must include the name and address of each facility at which the registrant conducts business, the trade names under which that business is conducted and the categories of food the facility handles. For foreign facilities, the registration must include the name of a U.S. resident agent for the facility.

**Who is exempt:** Farms, restaurants, other food retail establishments, nonprofit food establishments in which food is prepared for or served directly to the consumer, certain fishing vessels and facilities such as meat and poultry slaughterhouses that are regulated exclusively by the U.S. Department of Agriculture are exempted.

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Some foreign facilities are also exempted, if the food from the facility undergoes further processing or packaging by another foreign facility before it is imported to the U.S. However, the foreign facility is not exempt if the further processing or packaging is limited to the affixing of a label to a package or other minimal activity. In that case, both the manufacturing facility and the packaging facility would have to register.

**How registration will be handled:** Registration may take place electronically (over the Internet) or by paper through surface mail, with the FDA strongly encouraging electronic registration which will be available 24 hours a day, seven days a week. The FDA will provide a receipt of registration and assign each facility a unique registration number. There is no fee for registration. The FDA plans to have its registration system operational by October 12, 2003. Facilities must be registered by December 12, 2003. FDA will not accept registration prior to October 12, 2003.

**Penalties for nonregistration:** Failure to register will become a prohibited act beginning December 12, 2003, subject to criminal sanction and will result in the goods being held at the port of entry unless FDA directs its removal to a secure facility. FDA is proposing that, when the food must be moved, the private parties involved (the owner, purchaser, importer or receiver of the food) must arrange for moving it and promptly notify FDA of its location. The private parties would also be reponsible for any costs associated with moving or storing the food.

## Prior notice of imported foods

**What is required:** Under this proposed regulation, FDA must be notified by noon of the calendar day before the day the imported food will arrive at the U.S. border crossing or at the port of entry. The prior notice must be submitted electronically through an FDA Internet-based system that will be operational 24 hours a day, seven days a week. Final regulations will be in place by October 12, 2003, with prior notice to commence beginning on December 12, 2003.

**What foods are covered:** The proposed rule does not apply to food carried in an individual's personal baggage for that person's personal use. It also does not apply to meat, poultry or egg products that are exclusively regulated by the U.S. Department of Agriculture at the time of importation. All other imported foods, including beverages, would be subject to the prior notice requirements. This includes food that is not intended for consumption in the United States, but is enroute to another destination through the United States.

**What prior notice information will be required:** The proposed regulation requires the purchaser or importer (or their qualified agent) who resides or maintains a place of business in the United States to submit prior notice of the importation of food. That notice must include:

- Identification of the submitter, including name and firm information
- Entry type and U.S. Customs System (ACS) entry number, or other U.S. Customs identification number for the import
- The location of any imported food products held at the port of entry for failure to submit an adequate prior notice
- The identification of the articles of food, including complete FDA product code, the common/usual/market name, the trade or brand name, the quantity described from the smallest package to the largest container, and the lot or code numbers or other identifier (if applicable)
- The identification of the manufacturer
- The identification of the grower, if known
- The originating country
- The identification of the shipper
- The country from which the article of food was shipped
- The anticipated arrival information, including location, date and time
- U.S. Customs entry process information
- The indentification of the importer, owner and consignee
- The identification of the carrier

The current proposed regulation allows product identity information in prior notices to be amended if complete product information does not exist by the prior notice deadline. Amendments may include the quantity of products but must not be a change in the nature of items (e.g. you can amend the number of cartons of wheat crackers, but cannot add cheese crackers to the shipment). Furthermore, the proposed regulations allow for an update to be submitted. An update may include the time and port of entry. Both amendments and updates must be submitted no later than two hours prior to arrival.

**Penalties for noncompliance:** Beginning December 12, 2003, importation of food without prior notice will be prohibited, and food imported or offered for import without adequate prior notice will be refused admission and held at the port of entry until adequate prior notice is received, unless FDA directs its removal to a secure facility. The purchaser, owner, importer or consignee would be responsible for transportation and storage expenses.

## *Why your input is required*

"We are trying to implement these regulations in such a way as to allow us to fulfill our obligations to enhance the security of the U.S. food supply, without adding unnecessarily to the workload of businesses," says a senior FDA source. "We take our obligations under the WTO and NAFTA seriously, and are looking at not unduly disrupting trade with our trade partners. We're not saying we want input simply because we're told to say that. We're saying it because input will ensure that these regulations are implemented in a way that balances our security needs with the needs of business."

## How you can comment

**1. Directly:** Comments on the proposed registration of food facilities and prior notice of imported food must be made by April 4th, 2003. Written comments can be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Comments can be sent electronically to www.fda.gov/dockets/ecomments. When commenting on the registration of food facilties, please quote Docket Number 02N-0276. When commenting on the prior notice of imported food, please quote Docket Number 02N-0278.

"The more specific your comments, the more valuable they will be to us," says an FDA representative.

**2. Through OMAF and the Government of Canada:** OMAF is working with the Government of Canada through Agriculture and Agri-Food Canada in developing a formal submission to be issued to FDA. OMAF trade officials are working closely with federal officials in the development of these comments. In this context, you are invited to share your concerns and suggestions regarding the implications of the proposed border protocols on your sector, with Bobby Seeber, Senior Policy Advisor (Trade) at 519-826-3253; e-mail at bobby.seeber@omaf.gov.on.ca.

The most effective representations will be those that not only point out operational problems with the proposed regulations, but offer suggested solutions that still address the security concerns which are paramount for FDA.

**For more information**

For a complete description of the FDA's proposed regulations please visit their website at: www.fda.gov/oc/bioterrorism.bioact.html




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