



## Advisory – US Bioterrorism Regulations

### **US Bioterrorism Rules Published**

A pair of interim final rules under the US Bioterrorism Act were published on October 12 in the US Federal Register. These rules pertain to the registration of facilities and prior notice of shipments.

#### ***Registration of Facilities***

The USFDA is requiring all, "...owners, operators, or agents in charge of domestic or foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States...to register the facility with the FDA by December 12, 2003."

Exempt under the regulation are "**Farms**, i.e., facilities in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves, and cooling of produce are considered part of harvesting. The term "farm" also includes facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership, and facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership." (Source: FDA Fact Sheet <http://www.cfsan.fda.gov/~dms/fsbtac12.html> )

**As the interim final rule is currently being presented, it is expected that farms will not have to register as a foreign facility with the FDA.**

#### ***Prior Notice of Shipments***

The Bioterrorism Act, "...requires that FDA now receive advance information on import shipments. This would allow FDA time to review, evaluate, and assess information before a food product arrives, and shift resources to target inspections, to help intercept contaminated products, and to help ensure movement of safe food to market."

As the interim final rule now reads, notice of shipments must be given no more than five days prior to its arrival and:

For shipments by truck – up to 2 hours before the arrival of the shipment

By train and airplane – up to 4 hours before arrival of the shipment

By boat – up to 8 hours before arrival of the shipment

Items exempt from this regulation are as follows: "Foods that are excluded from the prior notice requirement are: (1) food carried by or otherwise accompanying an individual arriving in the United

States for that individual's personal use (i.e., for consumption by themselves, family, or friends, and not for sale or other distribution); (2) food that is exported without leaving the port of arrival until export; (3) **meat food products**, poultry products and egg products that are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act; and (4) food that was made by an individual in his/her personal residence and sent by that individual as a personal gift (i.e., for non-business reasons) to an individual in the United States.” (Source, FDA Fact Sheet <http://www.cfsan.fda.gov/~dms/fsbtac13.html> )

**As the interim final rule is currently being presented, live food animals are included under this regulation as food. It can be expected, therefore, that an electronic submission of prior notice will be required for live food animals being shipped to the US, effective December 12, 2003. “Any individual with knowledge of the required information may submit the prior notice, including, but not limited to, brokers, importers, US agents”, and producers. (Source, FDA Fact Sheet <http://www.cfsan.fda.gov/~dms/fsbtac13.html> )**

\*\*\* Please note \*\*\*

There is a 75-day comment period on the interim final rules. On December 12, 2003, these rules will become law. The comment period will end on December 24, giving two weeks of “living with” the new regulations in place to offer comments based on our experiences with the new laws in place. (FDA will have an additional comment period in March, 2004 on these regulations.) CPC will avail itself of every opportunity to submit feedback to the FDA on these regulations, and receive further clarification on the extent to which they may impact Canadian hog producers.

Also, FDA will post a "Compliance Policy Guide" in the next two to three weeks that will explain how it plans to enforce these rules.

For more information:

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