



Organización Internacional del Café
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**U.S. bioterrorism regulations –
important reminder**

1. The Executive Director presents his compliments and wishes to remind Members about the need to ensure that all coffee shipments to the United States comply with the Food and Drug Administration (FDA) bioterrorism regulations for registration of food facilities and prior notice of imported food shipments. These regulations took effect on 12 December 2003. Information about these regulations was previously circulated to Members in 2003 in documents ED-1897/03 and ED-1900/03.
2. All those in the coffee sector that manufacture, process or hold coffee for consumption in the U.S. should register their facility promptly to ensure the smooth flow of coffee trade, and ensure that prior notice is submitted in accordance with the deadlines established by the FDA. As previously announced (document ED-1897/03), the National Coffee Association of USA, Inc. (NCA) provides a service to its U.S. and Foreign members permitting them to arrange to name it as their “United States agent”. Failure to comply with the regulations can result in coffee shipments being held or confiscated.
3. Further information about the regulations has been provided by the NCA and is attached to this document.



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United States Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bio-Security Act).

Facilities Registration

In accordance with the Bio-Security Act, effective December 12 of last year (2003), all facilities that engage in the "manufacturing, processing, packing, or holding food for consumption in the United States" must register with the FDA unless the food from such facility undergoes further processing or packaging outside the United States. Foreign facilities subject to the Act must also include the name and contact information of a "United States agent."

Although FDA's focus has been on education during the past few months, it is expected that rigid enforcement of the Act's facilities registration provisions will begin during the summer months. Compliance with the Facilities Registration requirement will in part be determined by examining Prior Notice forms to confirm that they contain a valid facility registration number. Failure to comply can result in holding of all U.S. imports from any non-registered facility.

Facilities that "manufacture, process, pack or hold food for consumption in the United States can register on the internet at <http://www.cfsan.fda.gov/~furls/ovffreg.html>.

As announced previously, National Coffee Association of USA will provide a service to its foreign members that permits members to arrange to name the NCA as their "United States Agent" when registering foreign facilities with the FDA. Information on NCA membership and the NCA U.S. Agent program can be located on the NCA Web site www.ncausa.org.

All those in the coffee sector that manufacture, process or hold coffee for consumption in the United States are urged to register their facility(ies) promptly in order to ensure the smooth flow of coffee commerce. If one has not registered all covered facilities, or has not begun filing advance notice of food shipments, such company is operating in violation of federal U.S. law. As such, violators are subject to penalties provided for in the Bioterrorism Act, which include confiscation of shipments.

Prior Notice of Imported Food

The Prior Notice provisions of the Act apply to all food that is imported or offered for import into the United States for use, storage, or distribution in the United States. Prior Notice must be submitted and FDA must confirm the prior notice submission for review as follows: 1. If the article of food is arriving by land by road, no less than 2 hours before arriving at the port of arrival; 2. if the article of food is arriving by land by rail, no less than 4 hours before arriving at the port of arrival; 3. if the article of food is arriving by water, no less than 8 hours before arriving at the port of arrival; 4 if the article of food is arriving by air, no less than 4 hours before arriving at the port of arrival.

For further information on FDA Prior Notice of Imported Food refer to FDA's Web site at: <http://www.cfsan.fda.gov/~pn/pnoview.html>.