

UPDATE

January 24, 2005

Foreign Facilities EXCLUDED From Record Maintenance Requirement

On December 6, 2004, FDA issued its Final Rule for the Record Keeping Requirements portion of the Bioterrorism Act. One important change in this final rule is that **FOREIGN FACILITIES ARE EXCLUDED.**

TechniCAL recently attended a public meeting on January 13, 2005 at FDA's Center for Food Safety and Applied Nutrition (CFSAN). The purpose of the meeting was for FDA to explain the new Record Maintenance requirements to the industry. The presentation given at this public meeting is available on FDA's website at ... <http://www.cfsan.fda.gov/~dms/fsbtac25.html>.

We asked FDA "What was the reasoning behind excluding foreign facilities from the record keeping requirement?" FDA answered that there were two main reasons:

1. FDA does not have direct jurisdiction over foreign facilities
2. All necessary information on the foreign facility and their product is already being submitted by the importer through the Prior Notice system.

FDA answers this question in more detail in the preamble to the Final Rule...

"FDA is exempting all foreign persons (except for foreign persons who transport food in the United States) from the final regulation because FDA does not believe such records would be needed. Much of this information is available to FDA from facilities required to provide prior notice under part 1, subpart I. FDA intends to work with the competent authorities in foreign countries to access records during public health emergencies to obtain additional information, if necessary..."

You can view the entire rule at <http://www.fda.gov/OHRMS/DOCKETS/98fr/04-26929.htm>

This means that foreign processors are not required to keep additional records under the Bioterrorism Act. However, it is important to note that pre-existing record keeping requirements in FDA regulations (LACF record keeping, HACCP record keeping, etc.) must still be followed by the processor.

If you have any questions about the requirements of the FDA Bioterrorism Act, please contact Mr. Scott Cabes, President, TechniCAL, Inc. at scabes@tcal.com.

