



9928 03 DEC 24 11:59

December 19, 2003

Dockets Management Branch
(HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

RE: Docket No. 02N-0276. Registration of Food Facilities under the
Public Health Security and Bioterrorism Preparedness and
Response Act of 2002.
(68 Federal Register 58894; October 10, 2003)

Dear Sir or Madam:

Birds Eye Foods Inc. is pleased to have this opportunity to provide comments on the interim final rule of the Food and Drug Administration ("FDA") to implement section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act"), which requires registration of facilities that manufacture/process, pack, or hold food for human or animal consumption.

The Agency is to be applauded for their timely publication of these interim final rules well in advance of the mandated compliance date. The numerous education and outreach opportunities that were offered by the FDA and the availability of Agency staff to discuss interpretations and answer questions are greatly appreciated. We welcome this opportunity to provide comments on these rules and appreciate the opportunity to make any necessary additional comments in March 2004.

As is generally the case with regulations as broad in scope and reach as the facility registration requirements, there are unforeseen and unintended circumstances that affect their efficient implementation. Birds Eye Foods has expressed our concerns with a majority of these circumstances through our participation in the preparation and review of comments submitted to the Agency by the food trade associations of which we are active members.

2002N-0275

There is, however, a provision of the final interim rule that we feel needs comment from our individual perspective. Birds Eye Foods would appreciate FDA review of conditions where vehicles, including trailers, are reclassified from "transport" use to "holding" use, thereby requiring registration under these rules.

It is clear that trailers, railcars, and various other transportation equipment must be registered with the FDA when they are specifically used as temporary storage for materials covered under the Act. It is relatively clear that when this equipment is modified so that it can no longer be used for transportation purposes and used for storage, it is included in the facility registration. What is unclear, however, is the registration status of transportation equipment that is not promptly unloaded and must remain at the facility for a period of time before unloading and return to the transportation system.

There are situations where trailers, and especially railcars, can not be promptly unloaded and returned to service due to scheduling errors, mechanical breakdowns or other similar problems. Rail cars pose a particular problem. Food companies generally have no control over their movement. The servicing rail line schedules and controls car movement. Exceptions to planned movements are difficult to implement and costly.

It is not unusual for food companies to schedule rail shipments to arrive several days early to assure the material is on hand when needed. This may result in early arrival of the railcar. It may take a period of time before facility bulk storage tanks are drawn down to a level able to accommodate the contents of the rail car. Once the car is empty, it may be several days before the rail line picks up the car and returns it to transport service. Strict interpretation of the interim final rules would suggest that the rail car would be considered a "holding" facility and, as such, would have to be registered. Additionally, the registration would have to be cancelled when the car was returned to transport service.

Birds Eye Foods feels that this interpretation is extremely burdensome to the facility, especially since they have no control over rail movements, and is extremely burdensome to the registration system. Registration of transport vehicles that may "hold" covered materials for relatively brief periods before returning to transport service provides no apparent benefit to the facility or to the Agency. Security concerns that may arise from the material being transported will be addressed by the recordkeeping rules scheduled for publication by the Agency in March 2004.

Thank you for the opportunity to comment on this important issue.



Stanley J. Iwanicki
Vice President
Science & Technology