香港特別行政區政府　工業貿易署
Trade and Industry Department
The Government of the Hong Kong Special Administrative Region
Trade and Industry Department Tower, 700 Nathan Road, Kowloon, Hong Kong

24-hour hotline : 23 922 922　　*e-mail address : enquiry@tid.gov.hk*

Ref : EIC 111/2　　14 October 2003

Dear Sirs,

Commercial Information Circular No. 258/2003

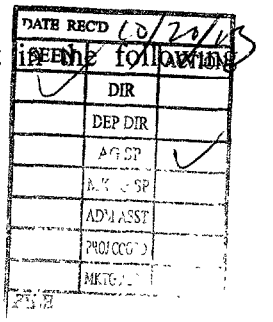
US : Interim Final Regulations on Registration of Food Facilities and Prior Notice of Importation of Food

Further to Commercial Information Circulars Nos. 52/2003 dated 11 February 2003 and 141/2003 dated 15 May 2003, the Food and Drug Administration (FDA) of the US Department of Health and Human Services published in the Federal Register (FR) notice of 10 October 2003 two interim final regulations as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 on protecting food supply for the US against terrorism and food-related emergencies, namely Registration of Food Facilities and Prior Notice of Imported Food Shipments.

2. FDA is now providing a 75-day comment period on the two interim final rules. Interested parties may send their written comments by mail to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852, US or by e-mail to http://www.fda.gov/dockets/ecomments before **24 December 2003**. To ensure those commenting on the interim final rules had the benefit of FDA's outreach and educational efforts and have had experience with the systems, timeframes, and data elements of the interim final rules, FDA intends to reopen the comment period in March 2004 for an additional 30 days.

3. The interim final rules takes effect on **12 December 2003**. Recognizing that a number of affected parties may need assistance in understanding the final rules' requirements and how to comply, FDA intends to put into place, during the initial months following the effective date, a policy that emphasizes assisting covered entities to this effect. It will shortly publish a notice of availaibility for a Compliance Policy Guide that will outline how FDA generally intends to exercise its enforcement discretion.

4. Highlights of the two interim final rules are set out in the following paragraphs.



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(A) Rule on Registration of Food Facilities

5. Under the interim final regulation, the owner, operator, or agent in charge of a domestic or foreign facility that manufactures/processes, packs or holds food [1] for human or animal consumption in the US or an individual authorized by one of them must register that facility with FDA by **12 December 2003**. A foreign facility must designate an US agent (for example a facility's importer or broker), who must be physically present in the US for purposes of registration. Exemption will be given to foreign facilities if the food from such facilities undergoes further processing or packaging by another foreign facility before it is exported to the US. However, such exemption would not apply if the processing or packaging activities of the subsequent facility are limited to affixing label to a package or other de minimis activity. The facility that conducts the de minimis activity must also register.

6. Registration can be done online via the Internet at http://www.fda.gov/furls, by completing the Form 3537 (attached in the FR notice) or by submitting to FDA a CD-ROM. The online registration system will be available for use from 16 October 2003 onward.

(B) Rule on Prior Notice of Imported Food Shipment

7. The interim final regulation requires notice of food [2] imported into the US to be provided to the FDA in advance of the arrival of shipment. The requirement takes effect on **12 December 2003**. The prior notice must be submitted electronically via, as applicable, the Bureau of Customs and Border Protection (CBP)'s Automated Broker Interface (ABI) of the Automated Commercial System (ACS) or FDA's Prior Notice (PN) System Interface. The information must be received and confirmed electronically by FDA no more than 5 days before arrival, and no less than 2 hours before arrival by land by road; 4 hours by air or by land by rail; and 8 hours by water [3].

8. Information that must be contained in the prior notice includes identification of the submitter, manufacturer, shipper and importer; country from which the article of food is shipped and anticipated arrival information (location, date and time), etc.

9. For more details and information on the specific requirements of the two regulations, traders may refer to the relevant FR notice and Fact Sheets at http://www.fda.gov/oc/bioterrorism/furls/.

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(1) Examples of food as defined in the regulation include fruits and vegetables, fish and seafood, diary products and shell eggs, raw agricultural commodities for use as food or components of food, animal feeds and pet food, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack food and candy (including chewing gum), canned and frozen foods.

(2) For purpose of the interim final rule, "food" is defined by reference to section 201(f) of the Federal Food, Drug, and Cosmetic Act. Section 201(f) defines "food" as articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such articles.

(3) This provision replaces that of the proposed rule issued earlier this year which requires importers to give notice by noon the day before the arrival of a shipment of food into the US for all modes of transportation.

10. FDA will hold a satellite downlink public meeting on 28 October 2003 to discuss the two regulations. Information about the meeting is available at http://www.fda.gov/OHRMS/DOCKETS/98fr/03-24921.htm.

ENQUIRIES

11. Interested parties may contact FDA's help desk regarding the registration and prior notice requirements. The contact information is 1-301-575-0156 (by phone), 1-301-210-0247 (by fax) or furls@fda.gov (by e-mail). Traders may call the undersigned at 2398 5403 concerning the content of this circular.

Yours faithfully,

(Ms. Shirley TSE)
for Director-General of Trade and Industry

Electronic services for Restrained Textiles Export Licence, Production Notification and Certificate of Origin enable traders to make the relevant applications directly through their office computer faster and easier. Electronic service has now been extended to the submission of Cargo Manifests and Textiles Notifications.
For details and enquiries, please call Tradelink at 2599 1700.

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