From: Marisol Figueroa B. [marisolfigueroa@fepach.cl]
Sent: Monday, May 17, 2004 12:46 PM
To: FDA
Cc: Stuart Shapiro (Office of information and Regulatory Affairs)
Subject: Docket 2002N-0276 and Docket 2002N-0278

Importance: High

Dear Sirs,

On Friday 14 th 2004, I connected to http://www.fda.gov/dockets/ecomments

I was trying to send electronically FEPACH´s comments about IFR Prior Notice and IFR Registration Food Facilities, but in the table named "Dockets Open for Comment" only appears the following:

"2002N-0278 Small Entity Compliance Guides on Registration of Food Facilities and Prior Notice of Imported Food; Availability.

2002N-0276 Small Entity Compliance Guides on Registration of Food Facilities and Prior Notice of Imported Food; Availability."

I checked the whole table, but it does not appear the other two dockets.

I have checked the number in bracket at the Federal Register notes, and they are correct.

The problem was that the docket number was repeated for each IFR and a third document.

So I continue searching in the section Docket Summary Report, and in the text notes the followings 04 tittles:

"2002N-0278 Small Entity Compliance Guides on Registration of Food Facilities and Prior Notice of Imported Food; Availability

2002N-0278 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Reopening of Commen Period FR Type: Interim Final Rule Action: Extension /Reopening of Comment Period

2002N-0276 Small Entity Compliance Guides on Registration of Food Facilities and Prior Notice of Imported Food; Availability."

2002N-0276 Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Reopening of Commen Period FR Type: Interim Final Rule Action: Extension /Reopening of Comment Period"

Under these situation, I send our comments by the electronically alternative available for the first option ("Small. entity....."), one for IFR Prior Notice and IFR Registration of Food Facilities.

If you can see the comments for "Small entity....." at Dockets 2002N-0276 and 2002N-0278, you will confirm that I have send the comments at the dates required.

I want to be sure that our comments will reach the correct dockets. Please, can you help with this problem. I understand that I do all according your instructions at Federal register notes. Please, let me know any forwards from you.

Thank you very much.

Best regards.

Marisol Figueroa
FEPACH A.G.
Chile

[Docket No. 2002N-O278]: Interim final rule; reopening of comment period.

Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

Specific comments

Sec. 1.281 What information must be in a prior notice? / (a) General

The FDA notes:

,....."The **estimated** quantity of food that will be shipped, described from largest container to smallest package size; .....
.....
.....The **anticipated time** of that arrival;....."

It is a problem to indicate in this part **"estimated quantity"**, and in the Section 1282 (a)(1) to put only **"quantity"**, because in the first section gives an idea of relatively and in the second section (1282) gives a very exact parameter.

Also is a problem for food arriving by ocean vessel or arriving as containerized cargo by water, to indicate an anticipated time, because in these cases the indication of a specific date is already difficult. So to give an exact hour of arrival is impossible.

Sec. 1.282 What must you do if information changes after you have received confirmation of a prior notice from FDA?

The text notes:

"(a)(1) If any of the information required in Sec. 1.281(a) except the information required in:
(i) Sec. 1.281(a)(5)(iii) **(quantity)**,
(ii) Sec. 1.281(a)(11) (**anticipated arrival information**), or
(iii) Sec. 1.281(a)(17) (**planned shipment information**) changes after you receive notice that FDA has confirmed your prior notice submission for review, you must resubmit prior notice in accordance with this subpart unless the article of food will not be offered for import or imported into the United States....."

FDA does not specifies what happens with the food if the information of **quantity, anticipated arrival information and planned shipment information** changes.

During the "Embassy Training Seminar", in Washington at 6 - 7 November, it was explained that :

"If change is to *estimated quantity, anticipated arrival information, planned shipment information or estimated date of mailing* – no action required".

But that no action is required from the submitter or the transmitter does not clarifies if the food will be "accepted". As "accepted", we mean that the prior notice will be considered adequate.

Therefore the requirement of "estimated quantity" and "anticipated time" become more important.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

DDM

Display Date APR -9 2004 @ 3
Publication Date 4-14-04
Certifier R LEDESMA

[Docket No. 2002N–0278]

Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) and the Bureau of Customs and Border Protection (CBP) are reopening for 30 days the comment period for FDA's prior notice interim final rule (IFR) that published in the **Federal Register** of October 10, 2003 (68 FR 58974). The prior notice interim final rule requires the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the United States. FDA is taking this action consistent with its statement in the preamble of the prior notice IFR (68 FR 58974 at 59023) that it would reopen the comment period for an additional 30 days in March 2004, to ensure that those who comment on this interim final rule would have had the benefit of our outreach and education efforts and would have had some experience with the systems, timeframes, and data elements of the prior notice system.

DATES: Submit written or electronic comments by [*insert date 30 days after date of publication in the* **Federal Register**].

cf0417

NEC

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: May D. Nelson, Center for Food Safety and Applied Nutrition (HFS–24), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1722.

SUPPLEMENTARY INFORMATION:

I. Background

On October 10, 2003, FDA and CBP issued an IFR to implement new section 801(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(m)), added by section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), which required prior notification of imported food to begin on December 12, 2003. The prior notice IFR requires the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the United States (68 FR 58974). The interim final rule requires that the prior notice be submitted to FDA electronically via either CBP's Automated Broker Interface (ABI) of the Automated Commercial System (ACS) or FDA's Prior Notice System Interface (FDA PN System Interface) (21 CFR 1.280). Food imported or offered for import without adequate prior notice is subject to refusal and, if refused, must be held (21 CFR 1.283).

Under section 801(m)(2)(A) of the FD&C Act, FDA is to choose timeframes that "shall be no less than the minimum amount of time necessary for the Secretary [of Health and Human Services] to receive, review, and appropriately respond to such notification* * *" Using this standard, the prior notice IFR

requires that the information must be submitted and confirmed electronically as facially complete by FDA for review no more than 5 days and no less than 8 hours (for food arriving by water), 4 hours (for food arriving by air or land/ rail), and 2 hours (for food arriving by land/road) before the food arrives at the port of arrival (21 CFR 1.279). However, when we issued the interim final rule, FDA committed to exploring ways to increase integration of advance electronic notification processes with CBP and to reduce prior notice timeframes. Indeed, we stated in the preamble to the interim final rule (68 FR 58974 at 58995) that, by March 12, 2004, FDA and CBP would publish a plan, including an implementation schedule, to achieve the goal of a uniform, integrated system and to coordinate timeframes for import prior notice information while fulfilling the Bioterrorism Act mandates for air and truck modes of transportation with timeframes finalized by CBP when they finalize their rule entitled "Required Advance Electronic Presentation of Cargo Information," (68 FR 43574, July 23, 2003).

For this reason, as well as to obtain comments on other aspects of the rule, we issued this rule as an interim final rule, with an opportunity for public comment for 75 days. Moreover, to ensure that those who comment on this interim final rule would have had the benefit of actual experience with the systems, timeframes, and data elements, FDA also stated it intended to reopen the comment period for an additional 30 days in March 2004, coinciding with the issuance of the plan by FDA and CBP relating to timeframes.

In light of the significance of the prior notice IFR, in December 2003 FDA and CBP issued a compliance policy guide (CPG) that describes our strategy for maintaining an uninterrupted flow of food imports while implementing the prior notice requirements of the Bioterrorism Act. (See Compliance Policy

Guide Sec. 110.310—"Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002;" Availability (68 FR 69708, December 15, 2003), *http://www.cfsan.fda.gov/guidance.html*). The prior notice CPG states that until August 12, 2004, FDA and CBP intend to primarily emphasize educating the affected firms and individuals. During this period, the agencies intend to utilize communication and education initiatives, escalating imposition of civil monetary penalties, and ultimately refusal of imported food shipments. Upon issuance of the CPG, both agencies stated that they expected affected firms and individuals to demonstrate a good faith effort at compliance while the transitional policy was in place.

II. Comments

We previously issued this rule as an interim final rule, with an opportunity for public comment for 75 days. Moreover, to ensure that those that comment on this interim final rule would have had the benefit of actual experience with the systems, timeframes, and data elements, FDA also stated it intended to reopen the comment period for an additional 30 days in March 2004. Accordingly, we are seeking comments on all aspects of the prior notice IFR.

In the prior notice IFR, we expressed interest in exploring flexible alternatives for submission of prior notice for foods or firms covered by programs of other agencies, such as CBP's Customs-Trade Partnership Against Terrorism (C–TPAT) and the Free and Secure Trade (FAST) program, or food imported by other government agencies (68 FR 58995).

C–TPAT is a government/business initiative to increase cargo security while improving the flow of trade. Under this program, businesses must

conduct comprehensive self-assessments of their supply chain using the security guidelines developed jointly with CBP, and they must familiarize companies in their supply chain with the guidelines and the program. These businesses must provide CBP with specific and relevant information about their trucks, drivers, cargo, suppliers, and routes. As C–TPAT members, companies may become eligible for expedited processing and reduced inspections, but are not exempt from advance electronic information requirements. (See CBP's Required Advance Electronic Presentation of Cargo Information Final Rule (the Advance Electronic Information Rule) (68 FR 68140)).

FAST, an acronym for Free and Secure Trade between the United States and Canada, and the United States and Mexico, is an expedited-clearance system designed to improve border security without slowing the flow of legitimate trade across the northern and southern U.S. borders. FAST processing is available to importers, carriers and foreign manufacturers (southern border) who participate in C–TPAT and who use a FAST-registered driver. The initiative builds on the same concepts that drove the rapid, post-9/11 construction and implementation of C–TPAT.

FDA and CBP plan to assess the feasibility of including the FAST timeframes in FDA's prior notice final rule, as well as other flexible alternatives raised by comments. To assist in this assessment, FDA and CBP request comment on the following questions:

C–TPAT/FAST Questions:

1. Should food products subject to FDA's prior notice requirements be eligible for the full expedited processing and information transmission benefits allowed with C–TPAT and FAST? If so, how should this be accomplished?

2. If the timeframe for submitting prior notice for food arriving by land via road is reduced to 1 hour consistent with the timeframe in the advance electronic information rule, would a shorter timeframe be needed for members of FAST?

3. Should the security and verification processes in C–TPAT be modified in any way to handle food and animal feed shipments regulated by FDA? If so, how?

Any membership in C–TPAT or FAST, or any benefit received as a result of membership will not be affected by commenting in this rulemaking.

Flexible Alternative Questions:

1. If timeframes are reduced in FDA's prior notice rule, would other flexible alternatives for participants in FAST or for food imported by other agencies be needed?

2. In considering flexible alternatives for food imported by other government agencies, what factors or criteria should FDA consider when examining alternatives? Should participation be voluntary? If so, should FDA consider inspection of companies in the supply chain from the manufacturer to those who may hold the product, including reviews of their security plans to determine what procedures are in place to prevent infiltration of their facilities as a condition of participation?

3. In considering flexible alternatives for submission of prior notice, should FDA consider additional means of ensuring that all companies subject to the registration of food facilities interim final rule ((68 FR 58894, October 10, 2003) (21 CFR part 1, subpart H)), have an updated registration on file with FDA that has been verified?

4. Are there conditions of participation that FDA should consider, e.g., inspections of companies in the supply chain from the manufacturer to those who may hold the product, reviews of their security plans to determine what procedures are in place to prevent infiltration of their facilities?

5. Should the food product category be considered as a criteria or element of expedited prior notice processing or other flexible alternatives? If so, should certain foods be excluded from expedited prior notice processing? If so, what should be the basis for determining which foods should be excluded?

6. If FDA adopts reduced timeframes in the prior notice final rule, should FDA phase in the shorter timeframes as CBP phases in the advance electronic information rule?

7. Should FDA offer a prior notice submission training program for submitters and transmitters, including brokers, to ensure the accuracy of the data being submitted?

Interested persons must submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the prior notice IFR as indicated in the **DATES** section of this document. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

As noted, this regulation was effective on December 12, 2003. We will address comments received during this reopened comment period and the previous comment period that closed on December 24, 2003, and will confirm or amend the interim final rule in a final rule. We, however, will not address any comments that have been previously considered during this rulemaking.

Dated: MAR. 24, 2004

March 24, 2004.

cf0417

Lester M. Crawford

Lester M. Crawford,
Acting Commissioner for Food and Drugs.

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Dated: April 6, 2004.

Robert C. Bonner,
Commissioner, Customs and Border Protection.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 20

DDM

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[Docket No. 2002N–0276]

Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule; reopening of comment period

SUMMARY: The Food and Drug Administration (FDA) is reopening for 30 days, on a limited set of issues, the comment period on the Registration of Food Facilities Interim Final Rule (IFR) that appeared in the **Federal Register** of October 10, 2003 (68 FR 58894). The IFR requires domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States to register with FDA by December 12, 2003. FDA is taking this action consistent with its statement in the IFR that it would reopen the comment period for 30 days in March 2004 to ensure that those commenting on the IFR have had the benefit of FDA's outreach and educational efforts and have had experience with the systems, timeframes, and data elements of the registration program.

DATES: Submit written or electronic comments on the identified set of issues for the IFR by [*insert date 30 days after date of publication in the* **Federal Register**].

cf0416

NEC 1

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Melissa S. Scales, Center for Food Safety and Applied Nutrition (HFS–24), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2378.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 10, 2003 (68 FR 58894), FDA issued an IFR to implement section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). The registration regulation requires facilities that manufacture/process, pack, or hold food (including animal feed) for consumption in the United States to register with FDA by December 12, 2003. In the "Request for Comments" section of the IFR, FDA requested comments on specific issues in order to improve the assumptions used in its economic analysis. The IFR stated that its comment period would coincide with that of the prior notice IFR, given the relatedness of the two rules. Therefore, the registration IFR was open for comments for 75 days following the publication of the IFR. The IFR also stated that "to ensure that those commenting on this interim final rule have had the benefit of FDA's outreach and educational efforts and have had experience with the systems, timeframes, and data elements of this interim final rule," FDA would reopen the comment period for an additional 30 days in March 2004.

II. Comments

Consistent with the intent expressed in the preamble to the IFR, we are seeking comments on the following issues in order to improve FDA's economic analysis:

1. The cost to foreign facilities of hiring and retaining a U.S. agent. Specifically, FDA invites comment, and the submission of data or other information, on the following:

a. The costs to a foreign facility of hiring a U.S. agent;

b. The number of foreign facilities that have hired a U.S. agent or negotiated additional duties from someone with whom they have an existing relationship, in response to the IFR, instead of relying on an existing relationship with a person who qualifies as a U.S. agent;

c. The number of foreign facilities that have ceased exporting to the United States because they have decided not to hire/retain a U.S. agent for registration purposes;

d. The distribution of costs between submitting registrations and other services offered by the U.S. agent; and

e. The assumptions underlying FDA's estimates of the costs of hiring and retaining a U.S. agent.

2. The effects on domestic small businesses, if any, if some foreign facilities cease exporting to the United States due to the U.S. agent requirement for registration. Specifically, FDA invites comment, and the submission of data or other information, on the following:

a. The number of domestic small businesses that have been adversely affected by trading partners that have ceased exporting to the United States due to the U.S. agent requirement for foreign facility registration; and

b. The costs incurred by these domestic small businesses due to the loss of these trading partners.

To be timely, interested persons must submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the above issues as indicated in the **DATES** section of this document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

As noted, the IFR was effective on December 12, 2003. The agency will address comments on the identified set of issues that are received during this reopened comment period and were received during the previous comment period that closed on December 24, 2003, and will confirm or amend the IFR in a final rule. The agency, however, will not address any comments that have been previously considered during this rulemaking.

Dated: March 24, 2004

March 24, 2004.

Lester M. Crawford,
Acting Commissioner for Food and Drugs.

Dated: April 6, 2004

Robert C. Bonner,
Commissioner, Customs and Border Protection.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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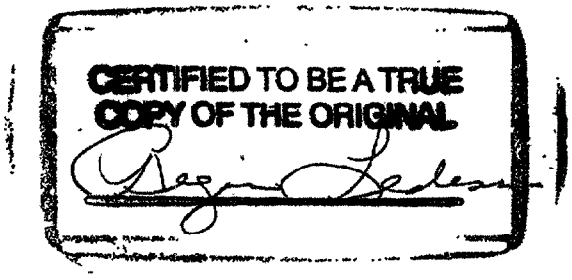

[DocketNo.2002N-O276]: Interim final rule; reopening of comment period

Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Specific comments

01 exporter had told us that in his case, the customs agents are charging about US$ 25 per prior notice.