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By Email to www.fda.gov/dockets/ecomments

Division of Dockets Management
(HFA-305),
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 2002N-0278 – Comments On Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 -- Reopening Comment Period

Robin Hood Multifoods Corporation (RHMC) is pleased to submit comments to the Food and Drug Administration (FDA) on the Interim Final Rule, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), 69 Fed. Reg. 19763 (April 14, 2004) (Prior Notice Interim Final Rule).

Robin Hood Multifoods Corporation is a largely recognized Canadian wheat flour miller and manufacturer of condiment products for domestic and international supply. RHMC as a Canadian manufacturer of food products also assumes the role of non-resident importer of record for goods entered into the United States. Annual export volumes into the United States represent approximately 7,000 import entry transactions

with a significant portion originating from its Southern Ontario facilities situated within close proximity to the US border.

RHMC is encouraged by FDA's efforts to actively engage comments from all stakeholders to create a workable scheme for the provision of notice prior to import food articles. The compromises affected, although time consuming and costly, have allowed food to continue to flow into the United States while providing FDA with the information it needs to ensure the safety of the food supply. We recognize that the agency has worked especially hard in its outreach and educational efforts. FDA's commitment to a smooth implementation of the new requirements is clearly demonstrated by the graduated enforcement policy over enforcement at the outset.

With the Prior Notice Interim Final Rule now in effect, RHMC in partnership with its customs broker, have had the benefit of several months of working with the new Prior Notice System (PN System). It is that experience that forms the basis for the comments offered herein. Primary concerns focus on inadequate interface connectivity between the Bureau of Customs and Border Protection (CBP) Automated Broker Interface (ABI) and the FDA PN System that inherently transfers the submission of Prior Notice from ABI to the FDA PN System. We urge FDA to consider these comments below and incorporate recommendations into the final prior notice rule.

Among the changes RHMC would like to see FDA implement in the final prior notice rule:

- Exemption for trade samples imported for research/development purposes and laboratory analysis not intended for domestic distribution or consumption by humans or animals;

- Resolution of PN/ABI system problems so that PN can be obtained without filing a CBP entry. (example Sub-agent broker)
- Resolution for PN/ABI system problems to obtain a PN number for IT or T&E Bond entries.
- Improvement of the capacity of the FDA Prior Notice Internet System Interface.
- Better FDA communication to, and involvement with, the importing community.
- 7/24 hour port coverage at high volume border crossings to facilitate formal FDA release.

Furthermore, new regulations issued by CBP governing the Required Advance Electronic Presentation and Cargo Information which are being gradually phased in by mode has a significant bearing on CBP/FDA joint integration and coordination of Prior Notice timeframes. In particular, no final rule has been published for truck traffic giving way to particular concern for that industry as a primary mode of transportation for the movement of food articles into the United States. RHMC recommends that prior to publication of final rules for food imports a further comment period is made available for consideration. Only after a period of active FDA/CBP enforcement and surveillance, will the food import community become better positioned to offer informed comments to FDA on the PN System. FDA will also be in a better position to evaluate the degree to which the PN System is achieving its stated goals and any problems that have arisen.

Finally, RHMC would like to reply to the specific questions raised in FDA's *Federal Register* regarding CTPAT/FAST.

1. **Exemption for trade samples imported for research/development purposes and laboratory analysis not intended for domestic distribution or consumption by humans or animals.**

The issue of prior notice for trade samples has become a serious problem by imposing significant burdens without measurably improving food security. In general, samples are not intended for human or animal consumption. Samples are sent in limited quantities intended for a specific purpose. For example, in the commercial flour industry, a sample may be provided for a baking test whereby the flour is evaluated based on its finished product results. The amounts provided are too small for commercialization or resale. The test baking conducted often consumes the entire sample. If there is any leftover material, it is usually discarded.

Unlike personal and homemade food articles which are typically consumed in its entirety by recipient(s), the trade sample would be consumed in very small quantities as part of the analysis procedure. Human consumption is minor and again is contained within a controlled environment such as a test kitchen or a laboratory setting.

FDA has already provided exemptions from the prior notice for certain categories of food it deems to present a very low risk to public health. Exemptions include food carried by or otherwise accompanying an individual arriving in the United States for that individual's personal use, and food that was made by an individual in his/her personal residence and sent by that individual as a personal gift to an individual in the United States. The lack of risk to public health that justifies exempting personal use and homemade foods from prior notice requirements applies, indeed even more persuasively,

to trade samples. For these reasons, FDA should exempt from prior notice requirements any samples imported for laboratory analysis, testing, evaluation, research and development purposes.

2. **Resolution of PN/ABI system problems so that PN can be obtained without filing a CBP (example Sub-agent broker)**
3. **Resolution for PN/ABi system problems to obtain a PN number for IT or T&E Bond entries.**
4. **Improvement of the capacity of the FDA Prior Notice Internet System Interface**

Joint administration and enforcement of Prior Notice by CBP/FDA is geared towards submission through ABI or ACS which will eventually be replaced by ACE in the future. FDA has provided two options to obtain Prior Notice; via ABI or through FDA's Prior Notice Internet System (PNSI). This web-based system was not intended for high volume usage as FDA indicated should only take 20% of the prior notifications anticipated for food articles entered into the US. RHMC has received numerous reports that CBP/FDA's computer systems still contain "glitches" that forces the over-usage of the PNSI. Specifically this impacts the filing of a PN through ABI when dealing with sub-agents at out port locations. Local FDA port offices have advised that these fixes will not be resolved until such time as ACE is implemented which are not expected until 2005 at the earliest. RHMC strongly urges FDA to increase volume handling capacity of

PNSI to accommodate the overflow until such time as systems improvements or replacements can be made.

RHMC would also like to note that currently CBP is unable to accept IT or T&E bond entries via ABI due to computer programming issues. Once again this adds further burden to FDA's PNSI.

RHMC urges FDA to harmonize their efforts with respect to the prior notification of food articles. As a business, it is more practical to make the necessary changes to accommodate the requirements of both agencies through one single portal and avoid the duplication of efforts as much as possible. RHMC urges FDA to take this into consideration when working with CBP to integrate its joint administration and enforcement of prior notice for both CBP and FDA.

5. Better FDA communication to, and involvement with, the importing community.

On April 2, 2004 FDA published a Compliance Summary Information that 50% of prior notices filed were incomplete or inaccurate. Deficiencies were noted in the findings however no specific information describing the errors was contained within the document. To date, RHMC is not aware of any communication received by the company, its broker, or its carriers regarding deficiencies with prior notice tendered to FDA. Currently, a filer is receiving only the FDA/CBP confirmation that the transmission was received and that the fields have data. No error message is sent if data is incomplete or inaccurate. While this is reassuring, as a filer there is no way to substantiate that the prior notice is correct or if indeed there are any problems. As a

company, RHMC is very concerned with its compliance record and would urge FDA to communicate the more detailed findings on FDA's website so that brokers and importers can proactively identify potential issues and make the necessary corrections before FDA refuses an article of food for inaccurate prior notice

6. 7/24 hour port coverage for at high volume border crossings to facility formal FDA release.

In order to maintain the flow of trade across the border while providing both FDA/CBP with ample information and timeframes to ensure the safety of all food articles entering the US, RHMC would strongly urge FDA to increase their coverage at all high volume entry ports to include weekend coverage.

There are two main reasons for this;

- New hours of service for highway drivers are making it extremely difficult to manage shipments into a five day work schedule that corresponds to FDA's hours of operation.
- The importance of securing a formal release from FDA is imperative to retain customer confidence and to maintain a level playing field for Canadian goods entering the US market as participants to the North American Free Trade Agreement.

Importers have experienced some disruption associated with shipments crossing the border after FDA's normal hours of operation. In general a shipment crossing over on the weekend where a paper review is requested and no further actions are required such as sampling, can take up to 7 days before an official "may proceed" is issued.

RHMC firmly believes that these delays could substantially improve with additional weekend coverage thereby increasing consumer confidence with Canadian trading partners and improving FDA's overall effectiveness through a timely, complete, formal release.

C-TPAT/FAST Questions FDA Poses in the Federal Register Notice

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 to be accomplished?

Yes, RHMC believes that C-TPAT and FAST participants should be eligible for the expedited processing and information transmission benefits of these programs. RHMC believes that it would be useful for purposes of risk assessment and is consistent with food safety protocols. Participants in these programs, as FDA knows, undergo auditing and supply chain assessment. In this respect, from information gathered through the FDA prior notice will clearly identify the C-TPAT importer and FAST carrier. Integration with CBP/FDA will confirm the FAST driver providing the agency with the affirmation it needs in order to focus its scarce resources on imports likely to be considered at higher risk.

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?

RHMC supports FAST participants being eligible for shorter prior notice periods. As stated above, FAST participants must demonstrate control over their supply chain and delivery systems. Streamlining and harmonizing requirements between FDA and CBP will allow FDA to concentrate its needed risk assessment and inspection resources where they are most needed.

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?

RHMC believes there is no need to modify food and animal feed shipments regulated by FDA as C-TPAT processes are more than adequate to handle both food and animal feed.

Flexible Alternative Questions

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

RHMC believes there are sound practical reasons for streamlining and shortening the prior notice required for FAST and C-TPAT participants who have demonstrated supply and delivery chain integrity. RHMC does not believe further accommodation is necessary. The system of import surveillance and inspection will benefit all stakeholders

if the FDA and CBP requirements are harmonized to the extent possible. FDA should be consistent with CBP requirements and timeframes wherever possible and need not to exceed CBP.

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?

As stated above, RHMC does not believe it is desirable or necessary for FDA to provide flexible alternatives that exceed what CBP is already implementing. RHMC believes that consistency of requirements between the two agencies facilitates trade more effectively and moreover, RHMC believes it is not an efficient use of FDA's scarce inspection resources to duplicate the security audit and screening CBP has already undertaken as part of its C-TPAT and FAST programs.

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?

As discussed above, RHMC does not believe it is desirable or necessary for FDA to provide flexible alternatives that exceed or augment CBP's existing programs. With respect to registration, the statute and regulations are clear; prior notice must contain accurate registration information, where required. We believe nothing further need be required.

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?

As discussed, RHMC does not believe FDA needs to provide alternatives that are more flexible than those of CBP's C-TPAT and FAST programs. RHMC does not believe that FDA should seek to repeat the inspection and auditing CBP has already undertaken and considers this a duplication of efforts and ineffective use of FDA's scarce resources. CBP operating under the auspices of The Department of Homeland Security is viewed as the expert in this area and FDA can rely upon the auditing undertaken by the CBP anti-terrorist programs.

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?

RHMC does not believe such distinctions are necessary and view creating further distinctions as unwarranted and will only serve to complicate the process.

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?

Yes RHMC believes the import system is strengthened by consistency between FDA and CBP. It is viewed as more cost efficient and easier way to manage the number of changes to existing import practices.

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?

RHMC strongly supports training for the entire import community.

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This concludes Robin Hood Multifoods Corporation comments and would like to thank FDA for the opportunity to participate in the process.

Sincerely,

John Holliday,
VP Supply Chain