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Dockets Management Branch
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

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Room 52C
Washington, D.C. 20229

Dear Sir/Madam:

The National Coalition of Food Importing Associations (NCFIA) 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).

NCFIA is a coalition of trade associations that represent different segments of the food importing community. Members of NCFIA include the following associations: American Spice Trade Association, Cheese Importers Association of America, Association of Food Industries, The Cocoa Merchants' Association of America, and the National Fisheries Institute. Companies belonging to NCFIA members annually import over $13.5 billion in food products.

NCFIA is encouraged by FDA's efforts since the passage of the Bioterrorism Act to craft a workable scheme for the provision of notice prior to importation of food articles. The compromises affected have, with some notable exceptions, allowed food to continue to flow into the United States while also arming FDA with the information it needs to protect the American food supply. We recognize that the agency has worked especially hard in its outreach and educational efforts. The graduated enforcement policy, which has emphasized education and information over enforcement at the outset, has aided in a smoother implementation of these new requirements.

With the Prior Notice Interim Final Rule now in effect, our members have had the benefit of several months of working with the new Prior Notice System (PN System). That experience informs the comment we offer here. As is to be expected, NCFIA members have experienced "glitches" in the interface between the Bureau of Customs and Border Protection (CBP) Automated Broker Interface (ABI) and the FDA PN System. In some instances, while the effects upon industry have been severe and disrupting, we believe the solutions are relatively simple operational "fixes" that must be achieved at the computer interface level. Other issues our members have confronted are far more substantive or are reflective of systemic weaknesses in the PN System. We urge FDA to consider our comments below and incorporate NCFIA's recommendations into the final prior notice rule.

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

• Exemption for pre-purchase and trade samples imported for research/development purposes and laboratory and/or organoleptic analysis;

• Resolution of PN/ABI system problems so that CBP entry and prior notice need not be made at the same time. Resolution of this timing problem is especially critical because for many foods, prior notice must be submitted before entry can be made (e.g., for quota class merchandise subject to CBP "live entry" requirements) and current system configurations can make it impossible to comply with both CBP and prior notice requirements.

• Resolution of PN/ABI system problems so that CBP entry can be made for articles of food that are already in the United States;

• Provision for FDA to communicate refusals and rejections to the importer, and to the ultimate consignee, if different, and to the electronic filer, if different, as well as the carrier;

• Establishment of a system for swift resolution of technical and operational problems;

• Establishment of a system that validates data and resolves conflicts between CBP and FDA databases;

• Resolution of the problem of duplicate prior notice filings;

• Provision for correction of errors in prior notice submissions, so long as corrections are made prior to passage of the 2, 4 or 8-hour deadline;

• Improvement of the capacity of the FDA Prior Notice Internet System Interface; and

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

Before FDA begins enforcing the prior notice requirements, industry would also wish to learn from FDA now of the mistakes the agency is observing in filed prior notices. NCFIA suggests that FDA inform the filer electronically of the nature of any deficiencies in a filed prior notice. Alternatively, the agency could post on its website a description of the types of errors most commonly observed in prior notice filings.

Furthermore, NCFIA recommends that after full enforcement has been in place for at least 6 months, that FDA then re-open the comment period for an additional 60 days. With the benefit of a period of active FDA/CBP enforcement and surveillance, the food import community will be better able 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. Only after this period of full enforcement and additional comment would FDA then issue a final rule covering prior notice of imported food shipments.

Last, we comment on the specific questions raised in FDA's Federal Register notice announcing the re-opening of the comment period.

Exemption for Pre-Purchase and Trade Samples – Exemption for pre-purchase and trade samples imported for research/development purposes and laboratory and/or organoleptic analysis

As NCFIA has assisted its members with implementation of the Prior Notice Interim Final Rule, the issue of prior notice for pre-purchase and trade samples has become a serious problem. Members of the food industry, routinely receive samples from customers, suppliers, and affiliates for qualitative testing, organoleptic analysis, research, and evaluation. Filing prior notices for these pre-purchase and trade samples imposed significant burdens without improving food security.

There are many reasons for the steady flow of samples into the U.S. In the case of spices and other agricultural products, for instance, a supplier may want their U.S. customer to examine a sample of a particular lot or crop to monitor fluctuations in quality, flavor, or cleanliness that often occur with these types of raw agricultural products. In the spice, flavor, and extract businesses, a foreign customer of a U.S. company may send samples of other commercial products and ask their U.S. supplier to analyze the sample and offer a competitive product. In the cheese industry, a supplier may send a wheel, log or other form to a potential customer for evaluation of quality, flavor, and other organoleptic testing.

Samples received in this manner are not intended for commercial distribution and usually are not intended for human or animal consumption. In some instances, with ingredients such as flavors, extracts, gums, or food ingredient chemicals, the article could not be consumed unless it is processed and manufactured into a food. The amounts provided are too small for commercialization or resale. With spices, the sample size is usually five pounds or less. In the case of other foods, such as a wheel of cheese or package of frozen fish sent for organoleptic testing, the sample is typically only one unit of the food product and, therefore, too small for commercial distribution. The analysis conducted often consumes the entire sample. If there is any leftover material, it is usually discarded.

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 pre-purchase and trade samples. The sample will not be in commercial distribution. Unlike the personal and homemade foods exemptions, frequently, a human or animal will not even consume imported samples. Where the sample is consumed, such as for organoleptic sampling, the quantities are very small and sampling is conducted in highly controlled environments – often in a company's own laboratory or test kitchen. For these reasons, FDA should exempt from prior notice requirements any samples imported for laboratory analysis, organoleptic evaluation, and research and development purposes.

In the interim final rule, FDA poses that prior notice covers trade samples because:

[T]rade samples are imported or offered for import to generate sales, which is a commercial, not personal, use. Thus, there is a "shipper" when these samples are brought to the United States.

68 Fed. Reg. at 58992. However, we note that in the case of pre-purchase and trade samples sent for laboratory analysis, these samples are not imported to generate sales. The trade samples are offered for the purposes of research, testing, and analysis. The results of such testing may ultimately lead to future sales of further articles, which would, of course, be subject to prior notice requirements. However, the purpose of the importation of laboratory samples is not the sale of the sample; the importation is for analysis of the sample.

We note that the U.S. Department of Agriculture (USDA) has addressed the issue of samples and defined a class of products that are exempt from certain tariff-rate quota requirements:

Licenses are not required if . . . [t]he article imported will not enter the commerce of the United States and is imported as a sample for taking orders, for exhibition, for display or sampling at a trade fair, for research, for testing of equipment; or for use by embassies of foreign governments.

7 C.F.R. § 6.22(b)(3). In defining the scope of this proposed exemption, we urge FDA to look to the definition ad exemptions USDA already has in place.

NCFIA suggests the following parameters for a pre-purchase and trade sample exemption.

• Only pre-purchase and trade samples intended for research and development and/or laboratory or organoleptic analysis would be exempt from the prior notice requirement.

• The sample must be plainly marked: SAMPLE – FOR ANALYSIS AND EVALUATION PURPOSES ONLY – RESALE PROHIBITED."

• The paperwork accompanying the shipment should include a reference to the final prior notice regulation as the authority for the exemption from prior notice.

• FDA should create an exemption code -- a separate affirmation of compliance code – to be affixed to documentation and entered into the PN System, to plainly signal that the sample is exempt from prior notice requirements.

NCFIA urges FDA to exempt pre-purchase and trade samples imported for laboratory analysis, organoleptic evaluation, and research/development purposes from the prior notice requirements. Public health will not be endangered by the creation of this narrow exemption.

Timing and Coordination of Entries – Resolution of PN/ABI system problems so that CBP entry and prior notice need not be made at the same time

In the final prior notice rule, FDA should work with CBP to cure serious timing issues and better coordinate the PN System with CBP entry requirements. The problems arise because CBP entry of certain foods cannot be made until after the prior notice deadline has passed. This dilemma is particularly acute with CBP "live" entry requirements for quota class merchandise (i.e., most dairy products, sugar, sugar-containing products and peanuts). For quota class merchandise, CBP entry cannot be made until the goods arrive at port. In addition, for articles of food arriving by air, CBP entry may not be made until "wheels up."

From points within the Americas, flight time will often be less than four hours in duration. Thus, with foods such as quota class merchandise and articles arriving via a flight of less than four hours in duration, prior notice must be made before CBP entry can be made or the article will be refused.

However, numerous problems have arisen for filers using the ABI when they try to file prior notice for an article of food for which they cannot yet make entry. Most fundamentally, the ABI does not allow the filer to file the prior notice, and concurrently, generate, but not make, CBP entry. The ABI requires the two filings be made concurrently and the filer receives an error message if it attempts to either file prior notice without entry, or file entry without prior notice.

Filers have attempted to resolve the problem by filing prior notices for all quota class merchandise and articles arriving via a flight of less than four hours through the FDA's own Prior Notice Internet System Interface (FDA PNSI), rather than via the ABI. However, the FDA PNSI does not have the capacity to handle so many prior notice filings and the process is very burdensome and time-consuming for the filing brokers. Moreover, even if the prior notice is completed through the PNSI, significant problems have arisen when the broker has tried to make CBP entry later. The experience of our members has shown that if the filer first makes the prior notice submission through the FDA PNSI, and then later attempts to make CBP entry through the ABI, the CBP system rejects the prior notice.

Brokers face a system that makes legal compliance impossible. The ABI/PN systems as currently configured are creating perverse incentives and encouraging inappropriate conduct. Filers could wait until the merchandise arrives at port and then file the prior notice at the same time entry is made. However, this approach assures refusal of the food and delays while FDA processes the now untimely prior notice. This approach also invites FDA to bring an enforcement action – an outcome every responsible importer wishes to avoid.

For these instances, where prior notice must be made before entry can be made, CBP and FDA need a procedure in the ABI that allows the CBP entry to be generated, but not filed, at the time prior notice is submitted. Several technology and computer-interface solutions are possible, including unlinking the two systems or allowing information to be submitted at the same time to CBP and to FDA, even if some of that information (as in the case of live entries, for instance) is processed later.

Similarly, NCFIA asks that FDA consider allowing the submission of prior notice through the ABI even when that prior notice will not be timely. This would avoid brokers having to use the very difficult and slow PNSI, thereby, potentially, delaying late-filed prior notices even further. As the accepted for review message the filing broker receives is plainly not affirmation that a filed notice is timely or adequate, it does not seem that there is any prejudice to, or problems for, FDA and CBP if the ABI can used for filing untimely prior notices.

Timing and Coordination of Entries – Resolution of PN/ABI system problems so that CBP entry can be made for articles of food that are already in the United States

Brokers have learned that currently the ABI cannot accept a new entry if the article of food has already arrived in the United States. The situation arises persistently with imports where important CBP information and entry requirements can rapidly change, even from the

time that prior notice and entry are filed. For instance, with quota class merchandise, by the time the food arrives in the United States, the importer may have exceeded its tariff rate quota (TRQ) license allotment or in the case of TRQs administered by CBP on a first-come, first-served basis, the shipment may exceed the remaining TRQ quantity. In these circumstances, the ABI will reject the entry and the importer must quickly locate and identify another importer to purchase and then enter the food. Or, in the case of non-licensed TRQs, the importer will need to make a new consumption entry for the opened amount and make an in-bond entry for the balance. However, when the importer seeks to make the new, corrected CBP entry, the ABI system rejects the entry for lack of prior notice, even though the food had already arrived in the United States and was already subject to an adequate and timely prior notice.

Brokers have sought to resolve this problem by filing a new prior notice for food already in the United States that was already subject to a previously filed prior notice. Plainly, this is not an adequate solution. These types of rejections and re-filings of CBP entries are common in the imported food industry. Importers run the risk of FDA enforcement if it appears that they are repeatedly disregarding prior notice requirements. Moreover, the food must sit at the port until FDA reviews the re-filed prior notice and, eventually, releases the food.

NCFIA urges FDA and CBP to address this issue. Where an article of imported food was already subject to an adequate and timely prior notice, there should be no requirement that the filer submit a second notice. The notice prior to importation applies to foods that are not yet in the U.S. In the case where the foods are already in the U.S., but the CBP entry has had to be cancelled and re-submitted, it should not be necessary to repeat the prior notice filing; filing entry should be sufficient. It will be necessary for FDA and CBP to accommodate this situation by modifying the interface between the two computer systems. Ideally, when the second entry is made, CBP will allow for submission of the previous PN number the system generated.

Communication of Rejections of Prior Notice Filings and Refusals of Articles of Food – Provision for FDA to communicate rejections and refusals to the importer, ultimate consignee, and filer, if different, as well as the carrier

The Prior Notice Interim Final Rule provides that the carrier is the point of contact if an article of food is refused. The problem with this requirement is that the carrier is not in a position to resolve the problem with the article of food refused. Burdening truck drivers, railway operators, airlines, and other cargo shippers with a duty to report a product refusal to the importer or other concerned party is, in our view, likely to lead to delays, confusion, and ports clogged with refused food.

The Prior Notice Interim Final Rule provides communication of refusal to a party without the resources or incentive to resolve the refusal. In the case of a rejected notice, the importer or ultimate consignee, if different, and the filer, if different, are the persons in the best position to address the agency's concerns regarding the refused articles and to correct any prior notice deficiencies or other problems. In the case of refused food, the carrier merely has temporary possession of the article; the importer or ultimate consignee, if different, has an ownership interest in the refused food and a strong economic incentive to resolve the refusal swiftly. The importer, the ultimate consignee, and the filer are also in the best position to export or destroy the refused food if the prior notice defects cannot be corrected. Delaying the notification to the importer, ultimate consignee, and filer, unduly hinders resolution and increases the likelihood of crowding ports of entry with refused food.

Involvement of the importer in prior notice refusals will result in an important benefit to FDA in terms of its improving risk assessment capabilities, which, in turn, will improve enforcement. Years of experience has taught NCFIA that unscrupulous importers who are potentially trafficking in unlawful food most often disappear when FDA notifies them of a refusal under Section 801(a) of the Act. In contrast, a responsive importer who cooperates with FDA could demonstrate itself to pose less risk to food security concerns. Being able to judge the importer's response will prove to be very valuable to the agency in targeting unlawful activity and assessing the risk an importer poses. The importer's response, or lack thereof, allows the agency to refine its risk assessment tools and analysis.

For these reasons, NCFIA strongly urges FDA to include the importer, or the ultimate consignee, if different, and the filer, if different, in the notification chain. Effecting this change will not cause any additional burden since FDA knows from the prior notice filing the importer's identity and contact information. Thus, the agency has the ability to swiftly communicate with the importer via email.

Technical Assistance from FDA – Establishment of a system for swift resolution of technical and operational problems

FDA has been of tremendous assistance to industry members with the implementation of the PN System. Industry is grateful to FDA for its educational outreach. FDA has undertaken sincere and extensive efforts to explain the legal and regulatory requirements of the Prior Notice Interim Final Rule.

Unfortunately, the experience among some industry members with FDA responsiveness to technical and operational problems has been uneven. Questions directed to the Help Desk, to the general email address, and even to FDA District Office personnel have not been answered in a timely way. When some members have received responses, in many cases, the answers have been, on further study, simply incorrect. Or, the Help Desk refers the caller to the regulations, and then when the regulations do not provide the answer (as, for example with the timing/interface problem discussed above), the Help Desk refers callers to CBP. Questions to CBP are directed back to FDA, leaving the caller in a limbo of uncertainty. Urgent requests to FDA headquarters for assistance with severely disrupting operational problems have gone unanswered, even after repeated but polite queries.

We recognize that some "growing pains" are to be expected. Prior notice is a new and complex requirement. Promulgation of all the Bioterrorism Act rules has been a very, very large undertaking for FDA and resources are stretched thin.

Yet, to make this system as error-free as possible, there needs to be a more systematic method for addressing technical and operational problems, such as the timing issues we described above. We note that these are not legal or regulatory questions. Rather, these are specific problems that are preventing smooth implementation of the PN System. While perhaps of relatively minor importance to the agency, in that these particular problems may only affect one company or a group of companies, a particular product, or a particular transaction, for the participants to the transaction the problem is severe with serious economic consequences and business disruption. The Help Desk, and other methods now established for resolution of these operational issues simply are not yielding a workable "fix" to the "kinks" in the new PN/ABI system.

We suggest the following to specifically address operational (as opposed to legal or regulatory) issues, such as computer interface, data entry, coding, database, and other technical problems:

• Establishment of a CBP and FDA agency-industry working group;

• Creation of an exclusive Help Line staffed with individuals with the requisite technical expertise and the ability to resolve operational problems as they arise; and

• Creation of dedicated email boxes within FDA to whom specific questions can be addressed, such as timing problems, code rejection, transmission problems, and other categories of problems. Email capability would also allow industry and FDA to create and document an audit trail of potential systemic, technical problems.

We understand that FDA has now established a continuously staffed toll free number solely for the resolution of technical issues. If this call center is operational and has staff with the knowledge and authority to resolve problems such as ABI/PN System interface problems, we believe this will be a valuable resource. We thank FDA for taking such constructive measures.

Looking to these types of solutions, FDA can monitor where problems are arising in the PN System. We believe that dedicating resources specifically to deal with the interface/system aspects of the Prior Notice/CBP systems will be of immeasurable use to industry, the government, and to the smooth flow of safe and lawful food into the United States.

Communication to Trade – FDA Provision of feedback to industry regarding errors in filed prior notices

NCFIA members have been concerned with the lack of information so far from FDA regarding where the agency is observing prior notice problems and deficiencies. 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 reassuring, filers do not know if what they are doing is substantively correct; they are ignorant of problems with their filings, or indeed, if there are any problems. As a consequence, industry filers are looking with concern toward the future when FDA begins enforcing prior notice requirements because they do not yet know what errors they are making, and they may not know until FDA refuses an article of food.

We note with concern that the April 2, 2004 Compliance Summary Information FDA published indicates that 50% of prior notices filed were incomplete or inaccurate. For brokers, importers, and other filers working very hard with FDA to establish a viable and efficient PN System, this compliance rate is disheartening and disquieting. Members of the import community are eager to know whether they, individually, are complying.

NCFIA recommends that FDA establish a notification system to alert the transmitter and submitter when there are errors in a filing. We urge FDA to do this before the “grace period” of the enforcement policy elapses. That notification could be in the form of individual responses to filers describing deficiencies in a prior notice. We also request that FDA publish deficiency information on its website that lists the most common problems seen in submitted prior notices. In this way, filers can correct errors they are now making

unknowingly, and articles of food can continue to be imported lawfully and without interruption. Such an exercise would be useful for FDA as well, to identify systemic problems in the PN System and where further educational outreach is needed.

Validation System – Establishment of a system that validates data and resolves conflicts between CBP and FDA databases

NCFIA has previously raised its concern that the PN System provides for little validation of data transmitted. In particular, NCFIA members are reporting problems with the lack of interface between two separate databases of information – the FDA database of manufacturer facility registration numbers and the CBP Manufacturer ID (MID) database. Filers use the MID database for information such as the manufacturer's name and address when they complete the prior notice. Unfortunately, the MID database is over 15-years old and has become corrupted with erroneous information that CBP has provided no means to correct. When the transmitter/submitter files the prior notice, there is no way to compare the manufacturer's information from the MID database to the facility information for the same manufacturer on file with FDA in the PN System. Additionally, the system used to construct the CBP MID codes has generated multiple manufacturers with the same code. These kinds of mismatches are causing rejection of the prior notice.

NCFIA suggests that there be an interface between the MID codes and the facility registration numbers on file with FDA. In this way, when a broker completes the prior notice and enters the manufacturer's facility number, and the city and country it obtains from the MID, there will be a notification to the filer if the information from the MID does not match the facility registration information on file with FDA. This will give the broker the opportunity to correct the likely incorrect MID information. NCFIA urges FDA to coordinate an interface with CBP that allows for validation and coordination of data between these two systems.

Duplicate Entries – Resolution of the problem of duplicate entries

Among importers, a significant operational problem that has arisen does not concern the failure to file prior notice. Rather, brokers are finding that a single article of food is being subject to multiple prior notices! Several parties within the importing chain are all trying to file prior notice for a single article of food. It would be useful if the PN System, in its validation processes, could include a check to see if other notices are already on file for the same article.

Correction of Errors – Provision for correction of errors in prior notice filings up to time of the 2,4, or 8-hour deadline

The PN System does not allow for any corrections once the notice is filed. Either changed information does not need to be corrected (i.e., arrival time, quantity), or the prior notice must be cancelled and resubmitted. The PN System locks the filer out, even though the required period for prior notice has not yet elapsed. We urge FDA to allow in the final rule for filers to re-enter the PN System to correct errors, so long as changes are made before the applicable 8-hour, 4-hour or 2-hour prior notice deadline has elapsed.

Flexibility to correct errors is particularly important because the system requires so many alphanumeric entries. Innocent errors, such as transposing of numbers, are and will be

constantly occurring. In the case of processed foods, it is not uncommon that the identity of the plant where an article was produced is initially inaccurately reported to the filer and, consequently, must be corrected. FDA must be cognizant of the fact that in developed countries the production of food products involves a vast and highly complex supply, production and distribution network. Therefore, errors concerning such important information as identification of the production facility are not uncommon.

The efficiency, indeed the efficacy, of the FDA PN System is not served if filers must cancel and refile notices for simple errors and changes in information. Canceling and refiling notices is also costly and time-consuming for importers and their Customs brokers. The PN System should be flexible enough to allow filers to correct these mistakes, so long as the changes are made before the prior notice deadline (2, 4, or 8 hours prior to arrival, depending on mode of transportation).

Accessing the FDA PNSI – Improvement of the capacity of the FDA PNSI

NCFIA members report tremendous difficulty in accessing the FDA's PNSI during normal business hours. Access is slow and uncertain; the portal cannot handle the data submitted. The lags and problems are, of course, particularly critical for prior notices submitted for articles of food arriving by truck, rail, and air. The web portal was not designed to handle the data demands filers are placing upon the system. FDA must make more capacity available if it is to handle the prior notice submissions it is receiving through its Internet Interface.

In addition, the Customs brokers report that inputting information through the PNSI website is overly and unnecessarily time-consuming. On average, it is taking thirty minutes to input all of the required prior notice information. We, therefore, urge FDA to develop and implement a simplified format that facilitates faster input. For example, the requirement of supplying the address of a registered food facility is unnecessary and a waste of valuable manpower.

Involving Industry – FDA should more actively engage the importing community

A theme recurs in many of the issues we raise above – better communication between FDA and the importing community. Most fundamentally, food importers wish to work with FDA to assure the flow of safe, wholesome, lawful food into the United States. We share in FDA's desire to protect American consumers and to identify and apprehend those who would do our nation harm. Consumers are jeopardized and the entire importing community injured if a single unscrupulous importer succeeds. NCFIA members wish to have a productive and useful partnership with the agency.

Brokers and importers are now using the PN System thousands of times a day. They are in a position to offer feedback to the agency on the technical and operational problems. Where FDA is contemplating changes and improvements, it is imperative that the agency follow the excellent example set by CBP and engage regulated industry early and frequently. Importers need time to reconfigure operations and computer systems to respond to FDA changes. If there is an active and ongoing dialogue, importers and brokers can bring their observations to the agency as problems arise, which, in turn, fosters FDA's ability to develop and implement corrective measures.

NCFIA notes that these operational and technical issues do not relate to the requirements of the regulations. These are not concerns raised by those looking for clarification as to the

scope of the regulations or advice on what information must be in a prior notice. The parties who wish to engage FDA more actively are those who are actually making the prior notice filings daily on a very fundamental, operational level. These individuals and entities very much share the same goals as FDA – they want the PN System to operate seamlessly and efficiently and they profoundly want to do their utmost to insure the safety of our nation's food supply. NCFIA looks forward to participating in an ongoing conversation with FDA about the PN System.

Reopen Comment Period – FDA should reopen the comment period after a period of full enforcement before issuing the final rule

As mentioned above, NCFIA recommends that FDA reopen the prior notice rule comment period for an additional 60 days after full enforcement has been in place for at least 6 months. Both the government and industry need the benefit of experience with active and full enforcement before fine- tuning the prior notice regulations for the final time. The food import community and FDA will be able to offer more informed comments with the benefit of a period of real-world enforcement to evaluate. NCFIA recommends that FDA issue a final prior notice rule only after there has been a period of full enforcement and additional comment.

Questions FDA Poses In the Federal Register Notice

FDA asks a series of questions regarding the PN System, timeframes for the submission of prior notice, importations by government agencies (such as the Department of Defense), and consistency with other CBP programs, including Required Advance Electronic Presentation of Cargo Information, the Customs-Trade Partnership Against Terrorism (C-TPAT), and the Free and Secure Trade (FAST) program. Generally, it is our view that participants in C-TPAT and FAST programs are not the types of imports on which FDA should be expending its scarce inspection resources. The point of these programs is, in part, to aid the U.S. government's inspection mission and risk assessment. We encourage FDA to look to any program another government agency has undertaken where doing so may aid FDA in better identifying risks to the food supply and better deployment of its inspection resources.

We address the questions FDA poses in turn.

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?

NCFIA believes that C-TPAT and FAST participants should be eligible for the expedited processing and information transmission benefits of these programs. In the view of NCFIA, it would be useful for purposes of risk assessment if FDA knew from the PN Notice if any of the parties to the import transaction are participants in C-TPAT and/or FAST. Participants in these programs, as FDA knows, have had to undergo auditing and supply chain assessment. If FDA were aware of which articles of food C-TPAT participants were importing and which were using FAST drivers, the agency would be able to focus its scarce resources on imports likely to pose a 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?

NCFIA would support 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?

NCFIA believes that the C-TPAT processes are more than adequate to handle human and animal food imports and need not be modified.

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?

As discussed above, NCFIA believes there are sound practical reasons for streamlining and shortening the prior notice required for FAST and C-TPAT participants. Shortening the prior notice timeframes and allowing expedited processing are appropriate allowances for companies who have demonstrated supply and delivery chain integrity. NCFIA does not believe further accommodation is necessary. The system of import surveillance and inspection benefits if the FDA and CBP requirements are harmonized to the greatest extent possible. FDA should be consistent with CBP requirements and timeframes wherever possible; FDA need not exceed CBP.

Accommodation can and should be made for those who have demonstrated supply and delivery chain integrity through C-TPAT and FAST. Creating an additional system of flexible alternatives on top of those already in existence is not warranted. In NCFIA's view, creation of additional exemptions and certifications could undermine the integrity of the prior notice and CBP entry system.

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, NCFIA does not believe it is desirable or necessary for FDA to provide flexible alternatives that exceed what CBP is already implementing. Consistency of requirements between the two agencies is very useful to NCFIA members. NCFIA firmly believes, moreover, that 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, NCFIA does not believe it is desirable or necessary for FDA to provide flexible alternatives that exceed or augment CBP's existing programs. Insofar as registration specifically is concerned, the statute and regulations require that all food facilities register and update that registration as appropriate; prior notice must contain accurate registration information, where required. We believe nothing further need be required. NCFIA would prefer to see FDA's resources devoted to a sound, risk-based assessment of the prior notices submitted.

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, NCFIA does not believe FDA needs to provide alternatives that are more flexible even than those CBP's C-TPAT and FAST programs afford. If FDA believes that it must implement alternatives, NCFIA does not believe that FDA should seek to repeat the inspection and auditing CBP has already undertaken. FDA would duplicate the work CBP has already done if it undertakes the considerable task of inspecting companies in an importer's supply chain and evaluating other security measures. Either FDA can rely upon the auditing undertaken in the CBP anti-terrorist programs, or it cannot. Second-guessing another agency's determinations and duplicating another agency's efforts is not an efficient use of FDA's recourses.

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?

NCFIA does not believe such distinctions are warranted. As stated above, creating further distinctions and exceptions risks opening holes in the food security net.

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?

NCFIA believes the import system is strengthened by consistency between FDA and CBP. It is more cost efficient and comprehensible to minimize the number of changes to existing import practices. A coordinated phase-in of CBP and FDA requirements means an easier and smoother implementation for import businesses.

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?

NCIFA strongly supports such training for the import community.

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To conclude, NCFIA sincerely thanks FDA for its efforts to create a workable Prior Notice System that balances food security needs and commercial realities. The final rule needs refinement to make it an effective enforcement tool that still allows for the smooth and rapid importation of lawful articles of food. We are available to meet with you to discuss our hopes for the final rule and our anticipated resolution of these issues.

Very truly yours,
Richard H. Koby
Coalition Coordinator