



International Food Coalition

*Working to Make It Better*

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

*via federal express*

**FDA Proposed Food Regulations  
Dockets Number 02N-0276 and 02N-0278**

Dear Sirs:

The International Food Coalition (IFC) is a coalition of businesses involved in the international food industry, including Customs brokers, food importers of a wide variety of food products and domestic food purchasers dependent upon foreign food products to meet customer demands. Members of the IFC believe that the proposed FDA food regulations threaten the entire international food industry and respectfully submit these comments in the hopes that the FDA will reconsider the methods by which it elected to implement the BioTerrorism Preparedness Act of 2002.

IFC members depend upon the safety and integrity of imported food products. Accordingly, upon passage of the Bioterrorism Preparedness Act of 2002, IFC applauded and looked forward to implementing rules meeting the Act's mandate of improved information systems and increased port inspections. Confident that Congress intended only to protect the American consumer from unsafe food items, IFC understood and appreciated the need for comprehensive rulemaking that would coordinate inter-agency review of food imports and its members expected more streamlined inspections at the port of entry.

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However, the proposed rulemaking will aggravate rather than improve coordination between federal agencies, and even more disturbingly, jeopardizes the entire future of the international food industry. Accordingly, IFC submits these comments as a plea for the Agency to reconsider the impact of its proposals on both the American consuming public and the legitimate international food business.

**1. Rising Costs of Imports**

**A. Verification of Information will Increase Personnel and Systems Requirements**

The information that the importer, purchaser or Customs Broker will be required to transmit to the FDA prior to arrival of any food item will necessarily force U.S. brokers to raise the costs of importing food into this country to unforeseeable and unmanageable levels. These businesses, as the likely submitters of the Prior Notice, will be responsible not only for timely transmission of information provided to them by customers, but also for the accuracy of that information. This additional verification responsibility will necessarily require additional time, expense and manpower unforeseen by the FDA's own burden and cost analysis.

Customs brokers and importers have no current systems in place to verify that all downstream participants in the supply chain have complied with their relevant responsibilities to the FDA. Customs brokers generally are knowledgeable only about the logistics and regulatory requirements for shipments, not the substantial information regarding production, packing and characteristics of the products being shipped. Most brokers, shippers and importers are small or medium-sized businesses that have no research departments charged with the responsibility of checking and doublechecking the minutia of registration numbers, whether or not each foreign manufacturer or warehouse has duly appointed a U.S. agent, the variety of growers that may be relevant to an import of processed and mixed foods and/or whether or not a downstream facility has timely recorded addresses changes with the FDA. Moreover, most of the affected businesses do not have the personnel to man the ports 24 hours a day to determine whether a Prior Notice must be updated due to unforeseen shipment delays or carrier changes; they do not have the software systems capable of tracking the required information that must now be known to any entity submitting a Prior Notice.

The necessary costs to improve existing in-house systems, to increase the in-house staff and personnel and to restructure current business operations will either drive small brokers and importers out of business and/or will make the costs of imported food so



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expensive as to eliminate consumer demand for these products entirely. The result will be a frozen economy bereft of the benefits provided by a free and open global marketplace through which American consumers should be provided with more and not less genuine products. And, in the midst of all of this upheaval, the onerous rules will not effectively attack the real need to guarantee the American public a safer food supply.

## **2. Duplicative Efforts**

### **A. Require Information That Can Be Transmitted Via Existing Systems**

FDA has elected to propose regulations which broaden the requirements set forth by Congress in the Bioterrorism Preparedness Act of 2002 in connection with both the content of the Prior Notice and the facility registration rules. As a result, it is impossible to utilize existing information systems to meet the regulatory burdens and, instead, international food businesses must avail themselves of a newly created, untested Internet-based system linked directly and only to the FDA. This is true even though much of the information to be supplied through this new system will duplicate that data already required to be submitted through ACS and OASIS.

The original seven requirements set forth by Congress to be included in the Prior Notice submission are currently included within that information transmitted by Brokers/importers on the ACS system. That is, Customs currently provides FDA with information identifying the imported article, the manufacturer, the country of origin, the shipper, the country of export and the anticipated port of entry. ACS could easily be adapted to include information related to grower of the subject item as well. However, the proposed regulations inexplicably expand this list to include information that makes utilization of existing systems impossible.

FDA has proposed that the Prior Notice include all of the data suggested by Congress as well as the identification of importer, purchaser, consignee, date of arrival, time of arrival, quantity of product, port of entry, date of entry, carrier, entry number, lot or code numbers, originating country and detailed information on the submitter of the information. The proposed regulations should be modified to conform to the goal - the mandate set forth by Congress - to improve existing systems instead of bypassing those systems. It should require the information identified by Congress on the Prior Notice to be submitted through OASIS (or ACS) before arrival --- in this way, the existing information system would suffice for purposes of submission of the required information



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and the only amendment to existing operations would be the submission of this information before arrival instead of after entry.

IFC understands and appreciates that FDA intends to work with Customs to ensure that the ACE system can handle both the entry and pre-arrival submissions. However, ACE is not yet operational; accordingly, this type of promise is empty, at best, and only causes concern of future rulemaking that will require additional amendments to business operations already in upheaval as a result of the recent and anticipated Customs pre-entry notification regulations and these newly proposed FDA regulations. FDA must, instead, finalize its rulemaking not with a promise that the systems will be improved in the future to make those regulations more palatable at a later date but, rather, with evidence of its commitment to provide importers and Customs brokers with the least burdensome method of fulfilling the objectives set forth in the Bioterrorism Preparedness Act of 2002.

Congress advised what it intended the FDA to require for Prior Notice transmission --- the intended content could very easily be submitted immediately through existing information systems. The proposed rule is clearly in conflict with this intent by requiring additional information at the time of Prior Notice submission and by demanding such a large amount of additional and unnecessary data as to make utilization of existing systems impossible.

B. Allow For Submission of "Blanket" Prior Notices

There are many importers who import the same product in similar quantities at the same port of entry or arrival on or about the same day -- perhaps every week or every two weeks or perhaps monthly. These importers should be allowed to submit information to the FDA one time detailing these common and uniform arrivals. In this way, the FDA will have the information it requires to determine which of these consistent and predictable arrivals warrant inspection and can make all of the necessary personnel adjustments to so inspect. The only consequence of requiring that Prior Notices be submitted for each and every line item of these shipments each and every time they arrive at a U.S. Port of Entry when all such Prior Notices will, more or less, be identical is to, again, intentionally complicate the importation of food articles into the country so that such importation becomes unnecessarily burdensome and overly expensive. The repetitive filing for each transaction also further burdens FDA personnel and electronic systems, which could far more effectively monitor imports of food if the system evaluated shippers and importers as accounts, rather than treating each individual shipment as a separate and unique transaction requiring full investigation.



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**3. Non-disclosure of registration information**

**A. Maintaining Confidentiality of Registration Numbers Is Baseless**

There is no other FDA regulation that summarily eliminates any possibility to secure or verify the information necessary to lawfully import consumer goods into the country. Importers of low-acidified canned products can ascertain status of the registration of foreign manufacturers through the FDA; drug and device listing numbers can similarly be ascertained through an FDA FOIA request. However, for some reason, the FDA and Congress believed that any information provided to the FDA by food facilities must remain immune from disclosure --- even if such information would, in fact, benefit the public interests and would not compromise any trade or business secret or similar proprietary information. This is an incongruity that warrants further evaluation. If registration numbers are not made available to the importing public, or to those in the supply chain for a particular product, this failure to make public information necessary to guarantee lawful importation and distribution will inhibit and possibly eliminate lawful international trade.

**B. The registration number is a number necessary for importers to verify the validity of their imports**

Lawful importers must provide the FDA with the registration numbers of all supply chain participants required to be registered as a part of the Prior Notice. However, FDA has undertaken none of the responsibility for helping U.S. importers secure this information....a mere sequence of numbers linked to a registered food facility. Registration numbers relay no information as to the content of the information transmitted to the FDA by that facility and do not otherwise reveal any type of confidential information. Rather they only confirm that a particular food facility manufactures, holds, packs or stores food that is lawful to bring into this country. How, then, can it be contrary to U.S. objectives to prevent unsafe food from entering the country by denying this critical information to importers making efforts to confirm the legality of their intended transactions?



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**4. Unnecessary transmission of Registration Numbers in Prior Notice**

**A. Supply chain information should be sufficient to indicate on prior notice**

The underlying legislation and the proposed rulemaking are clearly attempts to make the importation of food products in the United States safer. Importing products only from registered food facilities is a critical element of this objective. However, verifying that such a lawful importation has occurred will not be facilitated by transmission of mere numbers that may be inaccurate or inadvertently incorrect. In contrast, providing FDA with complete information so that the Agency itself may verify the registration status of every required supply chain participant is a more effective manner to regulate food imports. In this way, mere typographical errors in transmission of registration numbers will not serve to delay food shipments and those importers committed to “beating the system” will not be able to rely upon the wrong numbers for purposes of merely completing a Prior Notice submission.

**B. Typographical Errors Cannot Be Fixed – Even if Inadvertent**

The proposed regulations provide for no correction of administratively deficient prior notices. However, it is only natural that, especially in the case of a shipment that may require hundreds of Prior Notices to be filed simultaneously, that administrative errors will inadvertently occur. To deny entry of those goods which, in all other respects, are otherwise lawful, is not only unfounded but is also unnecessary.

There is no need to require registration numbers to be shown or reported on Prior Notice documents. The issue should be importation from a registered foreign food facility--- it need not be the ability of the importer or its broker to guarantee that human error will not cause even an inadvertent error to be made in transmission of a registration number in one of over 100 documents transmitted within perhaps an hours' time.

Whether or not a particular food product is being imported from a registered facility is information the FDA should maintain in its databases. Accordingly, upon its receipt of a Prior Notice detailing the supply chain of a subject product, the FDA should have the means to verify the registration status of all foreign food facilities, thereby eliminating the need of importers or their agents to provide certain numbers to the Agency that may be misleading or inadvertently in error.



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C. Ambiguity of Existing Regulations Mandate Flexible Guidelines

The ambiguity of the proposed regulations in connection with food contact substances and holding carriers creates an impossibility of compliance for all legitimate importers.

Will the importers of packaged products be required to know the registration numbers of the plastic wrap in which the food articles are contained? Will each and every truck or ship carrying product from one destination to another have to be separately registered --- requiring separate registration numbers for each such individual carrier that may be impossible to learn prior to arrival and/or that may be impossible for international shipping lines to obtain? If the answer to either one of these questions is yes or even possibly yes, then the FDA should create a schedule of mitigation of penalties for lack of registration information on the prior notice submission. While the Agency may require certain facilities to register --- such as food contact facilities or international shippers --- it will often be impossible to determine that information prior to shipment of the food product. The importer or broker may not even hazard a guess as to every single possible facility in such an obscure supply chain that may be subject to the registration requirements and to deny entry of an article for lack of a registration number related to a facility that merely produced the plastic liner in a cereal box is an unnecessarily harsh implementation of the underlying Congressional requirements.

**5. Prescribed Time Period for Submission of Prior Notice Does Not Reflect Industry Realities**

Because many shipments leave the country of export more than 10 days prior to arrival in the U.S., it is nonsensical to require that the Prior Notice cannot be submitted until that ocean-bound shipment is already 3 days toward its destination. Similarly, especially in connection with land and air cargo, there are a wide variety of reasons why the information necessary to be included on the Prior Notice simply will not be known by noon of the calendar day before anticipated arrival. Fresh produce is picked the night before it is put on a plane or on the back of a truck. Fresh seafood is harvested sometimes hours before it reaches U.S. ports. It is, therefore, mandatory that the requirements for timely submission of the Prior Notice be flexible enough not to jeopardize the freshness of these products or their marketability as they sit on the docks for no reason other than an absolute inability to comply with FDA regulations --- despite an importer's best intentions. Agencies such as the FDA, charged with ensuring the safety of America's food product, must be cognizant of its responsibility to do everything possible to facilitate those goods reaching intended customers and consumers as quickly



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as possible, without undue delay. Insisting upon a time frame for submission of the Prior Notice not reflective of common occurrences in the actual marketplace, is to intentionally disrupt legitimate and desirous international commerce.

**6. All efforts must be undertaken to mitigate delays at the Port of Arrival**

A. Untested systems cannot be relied upon for transmission of documentation. A Phase-In Period Must be Considered.

With all due respect to the technologists on-staff at the FDA, there is no basis upon which to believe that the systems currently under development will be fully operational by December 12, 2003. In connection with the Prior Notice system, there is not even a testing phase provided so that the FDA itself will be able to learn whether or not the systems will be able to handle the influx of Prior Notice submissions on a daily basis. Nevertheless, unless that system crashes (and there is no practical method for timely providing Prior Notice in such an event), all importation of food articles will rely 100% on this untested method of submitting the pre-arrival data. This is unacceptable, at best.

The entire international food industry, businesses and tradesmen from throughout the World, cannot be held to wonder whether a newly created Internet-based system may in fact work in order to know whether their food products – including perishable products with short-shelf lives -- will be allowed off the docks. The FDA must provide a phase-in test period not only for the benefit of importers who must adjust to these newly introduced regulations, but also for its own benefit to ensure that the Agency has the ability to handle the multitude of submissions that may very easily exceed even the most liberal estimates. A transitional period is needed for the Agency to effectively police imported foods while truly facilitating lawful trade.

B. The Importer must be provided the means to correct a Prior Notice before Arrival

Due to the lack of a procedure to correct inadvertent errors in Prior Notices, importers have no assurances that shipments will not be stopped and held at the Port of Arrival even where each component in the supply chain is duly registered and the Prior Notice is timely submitted. The proposed rule should be amended to require that the FDA immediately notify the importer or other submitter of the Prior Notice whether the submission is incomplete or inaccurate so that all efforts may be immediately undertaken to correct such errors prior to arrival without risking the marketability of the products heading to the U.S. ports.

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The FDA Internet-based system will automatically assign a registration number to a food facility regardless of whether or not the FDA has inspected that facility to ensure that it is not manufacturing poisonous food or holding tampered with product. The FDA Internet-based system will automatically acknowledge receipt of a timely filed Prior Notice regardless of whether it contains an incorrect registration number or indicates a foreign manufacturer not registered with the FDA. However, at the port of entry, the FDA may deny release of any food article in connection with which the Prior Notice is deficient for any one of a broad range of inadvertent, correctible errors, such as listing a foreign manufacturer that has not updated its change of address within 30 days. This is an unacceptable method for protecting America's food supply and will only lead to unnecessary delays of imported goods.

The FDA should alert the submitter of the Prior Notice of an inconsistency or problem in its Prior Notice prior to Arrival in order to facilitate trade and mitigate delays at the Port, and to allow the correction to be made prior to arrival, or after arrival, as appropriate. The Prior Notice system must do more than merely acknowledge receipt of a document with all fields completed --- it must advise the Importer if the fields are correct or sufficient. In this way, the Importer may immediately undertake measures to correct informal or insubstantial inconsistencies and may, further, have the ability to deter its shipment back to its original exporter in the event the inaccuracies may not be timely corrected. To make the Importer wait until arrival at a Port of Entry to learn whether or not its Prior Notice is sufficient or acceptable, will deny the Importer the ability to overcome any inadvertent errors and is most certainly a cause to fear substantial port delays because of food unable to make entry as a result of unsubstantial errors in Prior Notices that may have been corrected if brought to the attention of the Importer in a timely manner.

C. Determination of Admissibility must be made Simultaneously with Determination of Acceptability of Pre-Arrival Information

The Prior Notice and registration requirements are said to be necessary to allow the FDA to determine which food importations should be inspected upon arrival. The proposed regulations make it clear that such submissions are, however, unrelated to determinations of admissibility. Will the inspections that take place as a result of information provided on the Prior Notice be sufficient to determine admissibility? That is, will a shipment inspected upon arrival as a result of the timely submission of a Prior Notice once "released" be deemed to also be admissible or is that same shipment still subject to redelivery once the entry documentation is submitted subsequently through OASIS?



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If the timely submission of a Prior Notice results in no inspection at arrival, and then upon its receipt of the entry information provided through OASIS the FDA requests sampling of that same shipment, will such a sampling be requested due to inconsistencies in the Prior Notice and the Entry documentation? Will the OASAS sampling be issued only if there is a question as to admissibility of the article itself or even if such inconsistencies are only due to insubstantial clerical errors? These ambiguities and potential duplication of efforts accomplish nothing short of chaos and fear of the finalized version of these regulations.

In its current structure, the duplication of information required in the Prior Notice submission, and then in the subsequently-required Customs' and FDA entry documentation, does nothing to protect the American food supply. Determinations as to admissibility should be based on a single submission of information to both Customs and the FDA. It is unacceptable to require two distinct submissions by importers, neither of which serves to definitively advise the lawful international trader whether or not its intended import may be legally brought into the Country. The imported goods should be subject to only one inspection and one verification of supply chain data. Otherwise, the risks of importing food articles into the country and the continued vulnerability to post-entry recalls is unacceptable and serves no purpose other than to deter international trade.

## **7. Confidentiality of Prior Notice**

Prior Notice submissions must remain confidential and not be subject to disclosure through a FOIA request or otherwise. Shippers and carriers must not be fearful of theft or other pirating as a result of inadvertent disclosure of information related to transported shipments and importers and U.S. purchasers must be assured that their business transactions will remain confidential. The Prior Notice documentation contains so much detailed information about an intended product arrival so that, if non-disclosure cannot be guaranteed, competitors may easily learn data related to brand name of the imported articles, the quantity of the imported goods, the source of those products and the intended purchaser of same, and more broadly as to marketing and distribution strategies. This possibility will diminish or eliminate legitimate competition in the United States. This is an unacceptable possibility fostered by the proposed regulations and any finalized regulations should rectify the critical omission in the proposed rulemaking of system to assure non-disclosure of Prior Notice submission.



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## **8. Additional Time Required**

Members of the IFC respectfully ask that the published food regulations not be implemented – provisionally or otherwise -- during the 2003 calendar year. There has not been sufficient time to review the impact of the proposed regulations with participants in the international food supply chain and, accordingly, there has been insufficient time in which to implement the necessary changes in-house that the regulations will mandate. While IFC appreciates that there are specific time lines provided in the BioTerrorism Preparedness Act of 2002 that require implementation by December 12, 2003, IFC also believes that the statutory deadline permits implementation to be staged, and that the regulatory provisions beyond the direct requirements of the statute are not governed by the statutory deadlines. The FDA should not promulgate rules to be implemented by year's without taking the additional time needed to work with impacted industries to make these regulations more palatable to the international food industry and more effective in securing the nation's food supply.

In addition, registration of foreign and domestic food facilities is not even possible before the middle of October 2003. Accordingly, even should an international trader do everything possible to ensure that every party in its supply chain has duly registered each and every one of its applicable facilities, it is very likely that all such registrations will not, and cannot, be accomplished in the short timespan of 60 calendar days. This is especially true in the case of foreign food facilities --- that may include food packagers and transporters --- to which notice of the finalized registration form and procedures may first have to be relayed and confirmed before registration may even be started. Accordingly, while a registration system may legitimately need to be in place by December 12, 2003, it is unreasonable to expect that all existing food facilities will be registered by that date nor is there reason to believe that Congress intended for each of the hundreds of thousands potentially effected facilities to be able to accomplish such a task within a 2 month time period.

The public outreach by FDA in developing the regulations, and as supplemented in the formal rulemaking process, is far from adequate to address the complex questions raised by imposing registration and pre-importation notice systems on the world's suppliers of food to the United States. While the FDA published certain industry trade meetings on its website quietly and without great herald prior to publishing these regulations, it in no way reached the small importers or businessmen that will be most affected by their provisions. Only now are importers and brokers and other affected tradesman becoming aware of how greatly their business operations may be impacted by these proposed rules.



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To insist upon a deadline for compliance without further consultation and outreach can only lead to adoption of procedures which will damage the efficiency and economics of US food supplies, without significantly enhancing the security of our food supply.

It is a remarkable tribute to the integrity of the international food distributors and the work of the FDA that there has been not a single incident of terrorist-related food imports since the horrific events of September 11, 2001. The existing systems of food inspection and import controls have proven sufficient to date. With that track record as a well-established fact, it is overwhelming to all of the members of the IFC that the FDA would, without further hearings and without receiving further testimony, implement a dramatic change in regulations that threaten the future of the entire food importing industry. More time is needed to draft regulations reflective of the Congressional intent of the underlying legislation and to meet the FDA's challenge to protect the American food supply without jeopardizing the international food community.

### **CONCLUSION**

The Proposed FDA Food regulations will increase the cost of importing food products into the United States so that the entire domestic economy will necessarily suffer. The duplicative efforts required of importers and Customs Brokers and the fact that the proposed regulations do not coordinate FDA's efforts with those of other U.S. agencies, promises not only less of a diverse food supply for U.S. consumers but also threatens the entire international food industry. As small brokers and importers necessarily fail and competition decreases, the larger businesses will raise prices and costs to cover their increased personnel and information system needs so that American consumers will be subject to a monopolistic marketplace, driven solely by the needs of domestic food manufacturers.

The FDA has been charged with the responsibility of protecting America's food supplies and improving its information systems to facilitate that objective. However, the proposed rules are not well-designed to secure safer food imports, and will clearly impose administrative burdens and costs on the importing community which cannot be sustained, and are not needed. Under the proposed rules, there will be no improvement in existing systems, no improvement in communication between federal agencies and no guarantee that food articles are being manufactured by safer facilities or are being imported by more reputable agencies. Accordingly, the IFC---with its members dependent upon and committed to ensuring the safety of the American food supply ---urges the FDA to reconsider its rulemaking in order to better reflect the mandate of the

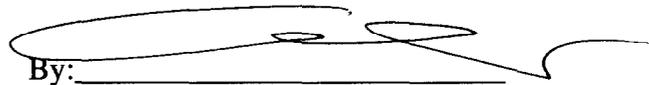


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underlying legislation and to better represent the needs of the global international trade community.

Should there be any questions or concerns regarding the IFC or its position as stated in this correspondence, please feel free to contact the undersigned or Lauren Perez of this office directly at any time.

Respectfully submitted,  
**International Food Coalition**

By: 

Gilbert Lee Sandler, Esq.  
General Counsel

cc: IFC Members