Washington, D.C. April 4th, 2003

Joseph Levitt
Director, Center For Food Safety and Applied Nutrition
Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Comments of the Secretaria de Agricultura, Ganaderia, Desarrollo Rural, Pesca Y Alimentacion ("SAGARPA") On the Notice of Proposed Rule to Implement Provisions of the Bioterrorism Act of 2002 - - Prior Notice of Imported Food Shipments (Section 307) - - **Docket No. 02N-0278**

Dear Mr. Levitt:

On behalf of the Secretaria de Agricultura, Ganaderia, Desarrollo Rural, Pesca Y Alimentacion ("SAGARPA"), the Agriculture Department of the Government of Mexico, we are submitting these comments on the above captioned proposed rule addressing prior notice of food shipments to the United States promulgated pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act of 2002"). 68 Fed. Reg. 5428 (2003). As a threshold issue and as a good neighbor sharing a 2,000 mile border, SAGARPA understands the desire of the United States --or indeed any country-- to ensure the safety of its citizens and the security of its food supply. SAGARPA would be pleased to work with you to reach this goal in a reasonable and realistic manner so as not to unnecessarily disrupt trade and economic integration.

For the calendar year 2002, total exports of food from Mexico to the United States were $6.3 billion dollars. Mexican exports of fresh produce to the United States were roughly 7 billion pounds valued at more than $2.4 billion. Mexico is proud of the increase in trade and economic integration between the United States and Mexico, especially since the implementation of the North American Free Trade Agreement.

We would ask that the U.S. Government recognize the uniqueness of trade in food products between Mexico and the United States. Mexico has spent significant time and resources working to harmonize practices on importing and exporting with U.S. government agencies, especially the U.S. Customs Service. We believe that a system of harmonization that has taken decades to develop is now in jeopardy. Our concern is that the implementation of the prior notification provisions of the Bioterrorism Act, if not done carefully and with full recognition of the uniqueness of Mexico's trade in food products with the United States, is likely to set this agenda back and disrupt the mutually beneficial trade in food products, particularly produce.

We would like to bring to your attention that the demand for fresh produce by U.S. consumers is increasing as the health benefits of fresh produce become well-known. Mexico supplies many varieties of produce that are not grown in the United States during many months of the year. Our request is that you keep this trade and U.S. consumers demand for these Mexican products in mind as you implement this regulation.

In summary, after carefully reviewing the proposed regulation, SAGARPA believes that the regulation fails in any way to take account the uniqueness of the Mexico-U.S. trade relationship; imposes an excessive burden on trade that is at times duplicative and unnecessary; and that the security benefits do not come close to offsetting the burdens imposed by this regulation. This is particularly true with regard to fresh produce.

I. The Bioterrorism Act Authorizes a Unique Solution for Mexico

SAGARPA believes that the regulations ultimately promulgated by the FDA to implement this provision must take into account the special circumstances of Mexican exports of food products to the United States. Unlike almost all other countries (with the exception of Canada), the overwhelming majority of products Mexico exports to the United States arrive at U.S. ports of entries by truck or train, not by ship or airplane. The majority of Mexican facilities exporting food products to the United States are within eight hours of the U.S. border - - and many are within a few miles of the border. These circumstances must be taken into consideration by the FDA when drafting its final rule.

The intention of Congress on prior notice is that FDA take into account the situation of each exportation so as not to impose any unnecessary burdens. The statute permits FDA to take into account the locations of ports of entry, modes of transportation, and the type of food imported. The statute is clear that a "one size fits all" solution is not the intent of Congress. Section 307(a) adds a new subsection (m)(2)(A) to Section 801 of the Federal Food Drug and Cosmetic Act, which states: with respect to the prior notification request imposed by new Subsection (m)(1):

In determining the specified period of time required under this subparagraph, the Secretary may consider, but is not limited to consideration of, ***the effect on commerce of such period of time, the locations of the various ports of entry into the United States, the various modes of transportation, the types of food imported into the United States, and any other such consideration***. (Emphasis added.)

This language clearly envisions that the FDA, when implementing this statute, will promulgate different rules to account for different circumstances. The proposed rule does not do this, at least with regard to food product from Mexico.

II. For Mexico, FDA Already has the Information it Needs for Prior Notice and the Proposed Rule is Unnecessary

A. For Mexico, the OASIS database is adequate to meet the prior notice requirement of bioterrorism statute

Agreements between the U.S. and Mexican governments will require in the next months that the U.S. Customs entry identification number be presented to Mexican Customs before any shipment is allowed to proceed to the U.S. inspection facility. This means that for all land crossings from Mexico there will be electronically submitted information available to FDA through its Operations and Administrative System for Import Support ("OASIS") database prior to all shipments physically arriving at the border. Separately, due to Customs requirements on ocean freight, FDA through Customs may obtain this information electronically well in advance of physical arrival to the United States through OASIS for ocean freight.

Thus, for Mexico the existing OASIS system is meeting the statutory requirement for prior notice.

For Mexico, the information that Customs already requires (with much of it forwarded to FDA through the OASIS system) meets all statutory requirements listed in the Bioterrorism Act of 2002. Section 307(a) of the act specifically requests "the identity of each of the following: The article, the manufacturer and shipper of the article; if known within the specified period of time the notice is required to be provided, the grower of the article; the country from which the article originates; the country from which the article is shipped; and the anticipated port of entry for the article." OASIS provides this information.

Any additional information not submitted to Customs that FDA may deem useful is readily available from other agencies working at the ports of entry. For instance, the U.S. Department of Transportation has specific contact information for the carriers as requested in the proposed rule, even though this information is not required by the statute.

III. For Mexico, the Proposed Regulation Imposes an Excessive Burden on Trade

A. Prior notice timeframe of noon the day before is unworkable for Mexico

FDA's proposed prior notice timeframe of noon the day before the product is to be physically entered in the United States imposes an excessive burden on trade -and SAGARPA strongly opposes this proposed timeframe insofar as it will be applied to food products shipped from Mexico. For the majority of Mexico's exports of fresh produce, it is not possible to provide prior notification until the produce is harvested and in order to ensure quality and availability the produce is harvested in a timeframe shorter than the noon the day before notification requirement would allow.

In addition, given the location of the growers and the process, it is typical now for products to be presented to Customs at the border in the evening. In these many cases the noon the day before requirement will add another 17 to 20 hours. This additional time is significant, particularly for fresh produce. Following is a chart illustrating this point (typical operation of a produce export company in Sonora state--6 hours away from the U.S. border):

TIME	ACTION
DAY 1	
05:00	Distributor in Nogales starts offering products to wholesalers and retailers
08:00	Grower start harvesting
12:00	Product arrive to the packing house
14:00	Product is packed
16:00	Distributor inform the grower the amount of produce to be shipped to the U.S.
17:00	Grower request transportation service
19:00	Truck arrives to the packing house for loading
20:00	The grower provides the Mexican custom agent with the information of the product, amount, truck information and ETA.
21:00	Truck depart to Nogales, Mexico
DAY 2	
02:00	Truck arrives to Nogales, Mexico
07:00	Mexican custom agent fills the information in the Automatic Notification system. U.S. customs is informed immediately.
08:00	Truck is put in line to cross U.S. border
09:00-14:00	Truck crosses the border depending on the work load, level of inspection of the product and/or any contingency upon the border (demonstrations, traffic, threats).

As you can see, for this reason, the production from the states of Baja California, Baja California Sur, Sonora, Chihuahua, Coahuila, Nuevo Leon and Tamaulipas, which are at 8 or less hours away from the border will be greatly disadvantaged by the timeframe provided in the proposed rule. **We request that the timeframe for prior notice for Mexican products be reduce to 2 HOURS based on the efficiency, communication and coordination of the Customs agencies of both countries.**

This prior notice timeframe will significantly hinder food exports from Mexico to the United States, particularly fresh fruits and vegetables. According to our producers and exporters using land transportation (about 80% of produce shipments), the proposed prior notice period would seriously disrupt trade. This is because the most common harvesting and shipping practices for fresh produce is that product is harvested in the morning and then packed and/or cooled in packing or cooling facilities that same afternoon, with shipment to the border later that day or evening. This practice of harvesting and shipping in the same day will no longer be possible under the proposed timeframe. The majority of fresh produce from Mexico originates within a production and shipping zone close to the U.S. border. Under the proposed rule, produce will have to arrive before noon on the day before crossing the border. For example, products that are ready for loading at 12:01pm that would be ready for inspection when FDA opens the following morning at the border will now be forced to wait another day and be subject to a 31 hour and 59 minute waiting period.

SAGARPA would like to clarify that U.S. importers do not know in advance the orders for specified products and usually do not know the detailed contents of a shipment before that

shipment is harvested. The vast majority of fresh produce from Mexico is sent to a U.S. agent acting as a sales representative on behalf of the Mexican exporter -- direct sales are very limited. Thus, it is the Mexican exporter that has the information required for prior notification and he has this information only upon harvest of the product - - which often occurs the morning of the day the product is shipped.

In addition, the FDA has enforced sampling, testing, and trace back protocols with Mexico that have transformed the industry practice regarding information currently being sent to the FDA. The information now transmitted to FDA with respect to shipments of Mexican food products are extremely detailed and absolutely unavailable until a trailer has been loaded. For example, fresh tomatoes commonly have four to six individual entry lines representing boxes containing different sizes of tomatoes on the same conveyance, even though all the products are fresh tomatoes and all are packed in the same size carton.

B. Chaos at the border

SAGARPA is concerned about the impact of the requirement set out in the proposed rule that data be submitted to FDA and then separately to an unlinked database at the Department of Homeland Security ("DHS"). The effect of this requirement is that every truck that approaches a land port of entry at the U.S-Mexico border and presents documentation will have to enter the secondary inspection areas if they are a food product.

This will hinder Customs goal (obtained after years of effort) to limit unnecessary activity in inspection areas. The ability to target higher risk shipments will be hindered and the physical infrastructure at most high traffic land ports-of-entry with Mexico will be overwhelmed.

C. Additional, confusing and overlapping agency paperwork requirements

In the proposed rule, FDA requires that the Customs entry identification number be included in the prior notice submission. We see several problems with this approach:

The entry number is commonly assigned only when the specific entry is ultimately made. Given that Customs does not permit electronic amendments on its system, FDA would be forcing U.S. filers to provide inaccurate, incomplete, and false information to Customs.

U.S. filers will incur the expense of resubmitting the final and correct information to FDA.

There will be significant differences in the prior notice database and the Operations and Administrative System for Import Support (OASIS) database, requiring more resources to reconcile the databases.

IV. Prior notification could <u>increase</u> risks of bioterrorism to U.S. food supply

It is undeniable that the prior notice requirements in the proposed rule will significantly hinder trade between the United States and Mexico. On the other hand, the countervailing benefit is not clear or well-considered. We understand the U.S. goal to increase security, but we respectfully do not believe that the prior notice requirement in the regulation accomplishes that goal.

It is our understanding that the new requirements will increase storage and holding areas at the packing sheds near the border. We believe that the larger holding and storage areas at the packing houses are more likely to be target for bioterrorism than any point in the current distribution system. Another unintended outcome is that more trucks will be sitting unsecured on highways leading to the borders waiting for the prior notice period to expire.

V. The Prior Notice Rules Increase the Likelihood of Food Contamination

According to Mexico's food safety experts, delaying shipments from the time of harvest to the time of importation, and ultimate consumption will increase the likelihood of bacterial contamination. The increased waiting periods will especially harm perishable products. The waiting period will allow what were previously low levels of bacterial contamination to significantly multiply.

VI. FDA's Cost Estimate for Mexico is Flawed

Meeting the prior notification requirements as set out in the proposed rule will be very expensive for Mexican producers and exporters and so for U.S. consumers. According to Mexico' producers and exporters, FDA's cost estimates underestimate the costs for Mexican producers and exporters. The main areas contributing to the cost underestimate for Mexico are assumptions about the number of transmissions, the percentage of product degraded, and the wholesale and retail values of fresh produce from Mexico.

In the proposed rule, FDA has asked that each lot be separately identified and be reported as a separate and individual prior notice. Given that the majority of the Mexican industry uses pallet tags to individually track product, there will be approximately 18 submissions per trailer, much higher than the two to three estimated by the FDA.

Differences in the maximum weight regulations and their enforcement in Mexico and the United States for over-the-road trucks and trailers mean that the exact contents of a trailer are not known until product arrives at staging areas close to the border.. Thus, the final contents of the truck and the exact carrier that will cross the trailer is not known by noon the day before the product is crossed, resulting in significant delays to fresh produce.

It is necessary to submit amendments every time a trailer is outside the timeframe allowed by the proposed rule. Many trucks will be forced to sit idly on the side of the road waiting for their proper window when FDA will allow entry. If there has already been the amendment for changes to the carrier and box count, then the process will have to start over again resulting in additional two day delays for product to cross the border.

The FDA analysis regarding the losses due to the perishable nature of Mexican produce is flawed. on several counts. The FDA failed to recognize that the notification to USDA consists only of the intent to ship a certain product and to confirm a location for inspection; however, there is no detail regarding the many data fields requested by the FDA in the proposed rule.

FDA underestimates the wholesale-retail spread significantly. Even under the most optimistic assumptions used by the FDA of only a 1.2 percent reduction in value, the industry will lose $37 million in value.

VII. The Prior Notification Regulation Raises Apparent WTO and NAFTA [1]Inconsistencies

A. Technical Barriers to Trade Issues

On February 13th, 2003 the Secretariat of the Committee on Technical Barriers to Trade (CTBT) of the World Trade Organization (WTO), delivered the notification G/TBT/N/USA/32 in which United States presented the Bioterrorisem Act. On February 6th, 2003 the Committee on Sanitary and Phytosanitary Measures of the WTO under notification G/SPS/N/USA/690, was notified about the Bioterrorism Act. However, the Bioterrorism Act was not notified under the Technical Barriers to Trade ("TBT") Agreement, which Mexico maintains is inconsistent with WTO/TBT requirements.

With regard to the TBT, Mexico makes the following points and requests:

Mexico requests that the United States, according to articles 2.5 and 2.9.3 of the TBT, explain in detail its justification of the prior notice measure. According to the 2.9.4 of the TBT Agreement, Mexico requests that the United States maintain communication on the development of the final regulation.

Assuming that the regulations does go into effect, Mexico requests that the United States provide technical assistance to assist Mexican exporters to accomplish the necesssary corresponding legal norms and compliance methods, considering the complexity, including new concepts, requirements, prerequisites, prescriptions and features being established.

Pursuant to article 12.3 of the TBT, Mexico requests that the United States explain the steps being taken to ensure that this new measure will not create an unnecessary obstacle to trade.

According to Article 2.9 of the TBT Agreement, Members are required to: i) announce to the members through a notice , in an early stage, its intention to adopt the regulation ii) notify, also in an early stage, the objective, reason and products affected by the regulation, to allow the Members to formulate comments iii) provide details about the contents of the technical regulation project and indicate their differences regarding applicable international standards and norms iv) provide a schedule, in a reasonable timeframe, for the formulation of observations, to maintain dialogue and

[1] The discussion refers to the WTO but in most instances there is a parallel or identical provision of the NAFTA.

consider such observations and conversations. The United States failed to meet these transparency requirements.

Under the TBT, Article 2.2, technical regulations must have a legitimate objective (which would include national security). However, eve if there is a legitimate objective, the measure must be more trade restrictive than necessary to fulfill the legitimate objective. Otherwise, the measure is an unnecessary obstacle to international trade. In Mexico's view, while national security is a legitimate objective, the measure taken on prior notice does not meet this objective and at the same time is very burdensome to trade. Mexico requests that FDA again review alternative measures for protecting national security with regard to food imports from Mexico. The United States should put forth alternate measures (there is flexibility in the Bioterrorism Act to do this, as discussed above) and analyze these measures and show why the approach taken in the proposed rule is the least trade restrictive for obtaining the objective. In this context, the United States should also consider, as set out in Article 2.7 of the TBT, the possibility of accepting equivalent measures taken in Mexico if these measures will meet the objective.

Mexico would also like to point out in this context that the legitimate objective of protection against a national security is a very low level of threat for Mexico. FDA should take this into account in developing the appropriate least trade restrictive measure for Mexico. Mexico is the second largest trading partner of the United States and there is no basis to suspect a bioterrorism attack from Mexico. On this basis, the FDA should tailor the measure to this circumstance, in other words because the threat from Mexico is low the measure must be accordingly least trade restrictive in light of the low risk of a threat to national security from Mexico. Due to the geographic proximity of Mexico and the high level of trade, there is a uniquely well-developed system already in place of ensuring security.

B. National Treatment Issues

It appears to Mexico that some aspects of the proposed regulation would violate the national treatment provisions of the WTO (paragraph 2, article III of the General Agreement of Trade Tariff (GATT of 1994) and Article 2.1 of the TBT Agreement).
The prior notice regulation applies to importer and not to domestic producers. For some products, particularly perishable products, the burden of compliance is not justified by the benefit.

Importers face an additional obstacle that it is not required for U.S. producers and sellers. There is no justification for the different treatment as it is just a likely for the U.S. domestic food supply to be a target as for imports.

For transparency, Mexico requests that United States provide norms and source documents for the design and elaboration of the regulation; and, in addition, the name of the companies, organizations and institutions which participated in the development, or, the name of the institutions consulted for that proposed.

C. GATT 1994 Article XI Restrictions

Article XI of GATT 1994 disallows any restrictions that are not duties, taxes or charges (including quotas, import or export licenses or other measures) unless they meet certain exceptions of Article XI. The prior notice requirement does not meet any of the exceptions of Article XI.

D. Sanitary and Phytosanitary Agreement

The prior notice regulation also is inconsistent with the Sanitary and Phytosanitary Agreement of the WTO ("SPS"). Under Article 2.1 and 2.2 of the SPS, any measure taken to protect human or plant health must have a scientific basis. Mexico does not believe that the Bioterrorism Act and the prior notice regulations have a scientific basis in the sense contemplated by the SPS. The Act and regulations were put forward very quickly in response to a national terrorism attack and no scientific analysis of the likelihood of risk to human or plant health was conducted.

Article 2.3 prohibits measures that are a disguised restriction on trade. Mexico questions the validity of the prior notice regulation because the United States and Mexico already have extensive inspection agreements that address the issues of food safety and contamination. Mexico fears that this new regulations will undo years of progress on these joint inspection programs and could lead to a higher likelihood of food contamination.

Annex C of Article 8 of the SPS sets out the requirements for implementing procedures for SPS measures. The Annex requires that the procedures do not cause undue delay and that the procedures are not tougher on imports than domestic products. The Annex requires that procedures do not require more information than necessary. Mexico believes that it already supplies the information necessary for prior notice and that the new requirements are unnecessary. The Annex requires that the confidentiality of data is guaranteed to the same extent as for domestic procedures and Mexico would like assurances from the United States that this will be the case.

E. Agreement on Import Licensing Procedures

The prior notice regulation is an import license in that it is an administrative procedure requiring the submission of an application or other documentation (other than that required for customs purposes) to the relevant administrative body as a prior condition of importation. The effective requirement of the prior notice regulation is that a U.S. agent will have to attest on behalf of the producer to the contents of the shipment in a manner more detailed than ever before required. However, the U.S. agent will not always be able to be as accurate as the prior notice is requiring (product by product notification). As a result shipments will be rejected for minor variations in value or quantity, which is a violation of Article 1.8 of the Licensing Agreement.

VIII. Mexico Proposes the Following Alternatives

Assuming that the United States, in spite of the commentaries made, imposes these measures, the Government of Mexico proposes the following: (which does not imply in any way recognition from Mexico about the validity of the possible measures adopted by the United States --and consequently

Mexico reserves without prejudice the ability to exercise its rights within the framework of the WTO and the NAFTA):

?? ***Inspections at the point of origin***. The U.S. Department of Agriculture conducts programs of food safety verification at the point of origin for the export of fresh fruits and vegetables. The production process of packing, certification and export is monitored 100% by USDA personnel, in the same way, we suggest that FDA could take advantage of this mechanism.

?? ***Use of the Customs registers of importers and exporters in Mexico and the United States***. FDA should make use of the information already collected by Customs in the U.S. and Mexico.

?? ***Consideration recognition of process in Mexico.*** The regulations and data collection already taking place in Mexico for food safety should be relied on.

?? ***Additional cooperation***. FDA could notify to the regulating Mexican authorities instances of products rejected by Customs to be able to take pertinent action and to avoid entry of non-regulated products.

?? ***Guarantee of confidentiality***: Mexico asks the United States to guarantee that the information the companies present will be kept strictly confidential, and that information will be handled in a way so as to avoid any risks.

?? ***Avoiding obstacles to trade***. Coordinated efforts between the Customs authorities of both countries should be made, for which Mexicos's General Administration of Customs has initiated contact with the Customs Service of the United States to obtain its point of view and support in specific areas of operation.

?? ***Guarantee electronic system***: Guarantees of functionality of the electronic system must be made in order to avoid delays and involuntary omissions to the regulation.

IX. Chart of Specific Issues

Section	Proposed regulation	Mexico comments
IIIA, pp 5429	The notice must be submitted electronically through the Prior Notice System unless the FDA system is not functioning...	It is necessary that the FDA establishes "ab initio' an alternating mechanism in the case that the system does not work properly.
IIIB1, pp 5430	FDA is proposing to exempt from the requirements of this regulation imported foods that, at the time of importation, are subject to USDA´s exclusive jurisdiction...	It is proposed that the vegetable products included in CFR(Q37) must be exempted as well.

Section	Proposed regulation	Mexico comments
IIIB2c pp 5430	FDA is requesting comment on wether this term [country from which the article of food was shipped] should include the countries of intermediate destination	It could be included as a reference; however, If it is in transit or in bond, the FDA should not ask for documents to verify the transit in an intermediate country.
IIIB2f pp 5431	FDA request comments on the proposed definition of "port of entry"	Port of entry: entering point of a country where the merchandise is checked by official authorities and in compliance with the existing regulations will issue the authorization to enter the country
IIIB2g, pp 5431	FDA is proposing to define "you" in proposed 1.227(f) as the "purchaser or importer of an article of food who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States acting on the behalf of the U.S. purchaser or importer"...	FDA is proposing to define "you" in proposed 1.227(f) as the "purchaser or importer of an article of food who resides or maintains a place of business in the United States, or abroad or an agent who resides or maintains a place of business in the United States if it is the case acting on the behalf of the U.S. purchaser or importer"...
IIIB3, pp 5431	...the food shall be refused admission under section 801(m) of the act. Examples of indequacy are untimely, inaccurate, or incomplete prior notice. As set out in section...	the food shall be refused admission under section 801(m) of the act. Examples of indequacy are untimely, inaccurate, or incomplete prior notice. Nevertheless, FDA should consider changes in the information concerning the anticipated arrival after the article is ordered due to unforseen traffic or mechanical failures, or car accidents, given that those potential changes are not intended. As set out in section...
IIIB3, pp 5431	As described previously, U.S. Customs has identified a well-established network of storage facilities that are secure.	And that will have to be near to the consigment point, so that the integrity of the products won't be affected. It is proposed the construction of private warehouses, or the use of alternating facilities in Mexican territory, with the possibility that FDA verifies the conditions in which these are operating.
IIIB3, pp 5432	Therefore delivery will not be allowed under a basic importation or entry bond	Define "basic importation"
IIIB3, pp 5432	FDA believes that importers, owners and consignees of food that has been refused under 801(m) of the act can make arrangements for food to be held: these arrangements can be made without taking possession of the food.	As long as the FDA decision is not ratified in a period of 72 hours.
IIIB3, pp 5432	FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States.	It is required that FDA determines if this measure is applied only at the entrance point of the United States, or to any employee that has antecedents of this nature and that collaborates with the import company in its facilities. In addition to this, it is proposed to ask the FDA a consultation area, to know the names of the people who have this type of antecedents.

Section	Proposed regulation	Mexico comments
IIIB3, pp 5432	Finally, the Bioterrorism Act does not provide specific procedures for the disposition of food refused admission under section 801(m) when no subsequent adequate notice is submitted.	The procedure to be followed in order to return the merchandise must be a decision of each country .
IIIB3, pp 5432	Typically, after 6 months, unentered merchandise is deemed unclaimed and abandoned and can be disposed of by the United States. Before this 6 month period runs, however, such merchandise can be reexported...	It is necessary that the FDA clarifies what is going to happen in these cases, to avoid the food re-export that the agency determines as prejudicial for the health of the population. Or even, to avoid the entrance of those products into our country.
IIIB3, pp 5432	FDA and U.S. Customs plan to develop additional guidance to explain how the agencies will handle food when it must be placed in general order warehouses due to refusal under section 801(m) of the act.	To require an application deadline of this regulation and to submit it to the opinion of the exporting countries. In case that it has been identified some irregularity in the prior notice or fulfillment of the indicated time of arrival by diverse situations, it sets out that the FDA recognizes additional official documents emitted by the corresponding authorities such as: fito or zoosanitary certificates, food safety certificates, analysis of laboratory, others of official character, that could allow the FDA to evaluate the possibility of allowing the entrance of the merchandise. It would be convenient to emphasize that the FDA should accept the official documents that explain the reason for the irregularity in the fulfillment of the prior notice and in that way to avoid incurring in a prohibited act.
IIIC1, pp 5432	FDA is proposing that a purchaser or importer of an article of food who resides or maintains a place of business in the United States is authorized to submit prior notice. FDA is also proposing that an agent who resides ...	FDA is proposing that a purchaser or importer of an article of food who resides or maintains a place of business in the United States or abroad is authorized to submit prior notice. FDA is also proposing, without being mandatory that an agent who resides ... It is proposed that FDA recognizes the exporter for prior notice of shipments. If the exporter considers that his agent or importer in the United States, must be the one that sends him the copy of the prior notice, once he has carried it out. Considering that the FDA establishes that the agent, importer, owner or consignatary should give the prior notice, it's reasonable the last part of the SAGARPA proposal, so that the Mexican exporter has certainty that the notice occurred and not to run risks of product detention (this makes evident the importance that the contracts will have between the individuals).
IIIC2, pp 5433	...FDA is proposing that the prior notice must be submitted to FDA no later than noon of the calendar day before the day article of food will arrive at the border crossing in the port of entry.	Despite the reasoning and practical thinking that the FDA gives, the period that it is anticipating to impose through the Regulation it is more restrictive than the existed one in the Law, which legally is unacceptable because it harms the individual .

Section	Proposed regulation	Mexico comments
IIIC2, pp 5433	Section 801 (m)(1) of the act makes clear that a primary purpose of prior notice is to enable inspections or other FDA action upon arrival of food in the United States to protect consumers in the U.S. from food imports that may be at risk of intentional adulteration or that may pose other risks.	The procedures of inspection and sampling would be the same that the FDA has established until now. It is necessary that FDA defines specifically how will act.
IIIC2, pp 5433	FDA believes that this timeframe will give it the minimum time it needs to conduct its assessments and provide the information to its field offices so they can allocate their inspectional resources on a daily basis and plan any necessary travel.	In case that the demand exceeds the capacity of the FDA to carry out the inspections, it sets out that the permanent personnel of the border (USDA) should be the one who reviews the information and authorizes the entrance of the merchandise.
IIIC2, pp 5433	FDA believes that this proposed deadline will have the most impact on those who import food by truck and rail over the land borders	Because most of the exports of our country are by land, our country would be affected by this disposition, mainly by the time of arrival and the time limit for the prior notice.
IIIC2, pp 5434	FDA also recognizes that information concerning the anticipated arrival may change after the article is ordered due to unforseen traffic or weather issues and has accomodated those potential changes by requiring updates information	Even though the time of arrival can be corrected, the time limit for the notification could cause problems mainly for the transportation by land. If a correction to the notification has been made to complete the information about the identity of the product, it would be impossible to correct it a second time because of problems related to the arrival hour caused by climate or traffic factors. It would be convenient that the FDA would provide lists of the ports with the schedules that apply for each one.
IIIC3, pp 5434 - 5435	Because most of the persons responsible for submitting the prior notice must reside or maintain a place of business in the United States the FDAPrior Notice System will be in English.	The system will have to be in English, French and in Spanish and will have to be required in any of these three languages, in order to avoid errors in the filling of the notice.
IIIC3, pp 5435	FDA anticipates the system will date and time stamp an electronic confirmation of the system´s receipt of each prior notice, amendment, and update, which the system will send to the submitter automatically	To establish the maximum time of confirmation of the prior notice if the transmission is successful, if it is not the case, to make another attempt, or to send it via fax or in person.

Section	Proposed regulation	Mexico comments
IIIC3, pp 5435	In proposed 1.278 FDA is proposing that if its prior notice system is unable to recive prior notice electronically, the prior notice amendments, and updates must be submitted using a printed version of the prior notice screen delivered in person, by fax, or by e-mail to the FDA field office with responsability over the geographical area in which the anticipated port of entry is located.	It is also set out that the FDA establishes an emergency program in case that the system falls or the system is saturated. It is necessary that the FDA determines the moment at which these amendments or updates will take effect for them and through what mechanism, in case it's not clarified, it could have negative consequences for the exporter and the importer.
IIIC4d, pp 5435	Additionally FDA is proposing to require the date that the article will arrive at the location where it will be held as well as the identification of a contact at that location	It is recommended that every time the shipment is held because of the prior notice of shipment was not filled adequately, the importer could recover his merchandise to return it to his country, or, could ask again the FDA the prior notice properly required.
IIIC4e.iv, pp 5437	FDA request comments on wether changes in quantity will occur after the deadline for prior notice and, if so, how commonly changes occur and how significants the changes usually are.	In the case of foods that can gain or lose weight by hydration, it is necessary the establishment of a period of time that allows the evaluation of these variations, therefore it is suggested the establishment of product categories.

In summary, SAGARPA requests that FDA carefully tailor its prior notice requirement to fully take into consideration unique circumstances of trade with Mexico—and to avoid unnecessary disruption of this trade for little if any overall enhancement of food security. For Mexico, the OASIS database already supplies FDA with prior notice adequate to meet the requirements of the Bioterrorism Act. FDA should rely on this existing information. In any case, the prior notice requirement of noon the day before is unworkable for and would impose an excessive burden on trade and bring chaos to the border. Moreover, the procedures envisioned in the proposed rule will pose security and health risks, at least with respect to products from Mexico, which will exceed any enhancements in security provided by these regulations. Finally, Mexico respectfully submits that FDA should carefully consider U.S. obligations under international trade agreements as it finalizes its regulation.

We would be please to discuss any of these points with you at the appropriate time.

Sincerely,

Enrique Lobo
Minister
Agricultural Office
Embassy of Mexico