

4 April 2003

**Comments sent by the European Commission
on implementing rule of US Bioterrorism Act**

Prior Notice of Imported Food

1. General comments

The European Communities would like to thank the Food and Drug Administration (FDA) for the opportunity to provide comments on the Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 notified to the SPS Committee under **G/SPS/N/USA/690**.

The European Communities fully share the US aim to provide measures to ensure an effective control of the food and feed chain, namely deriving from the terrorist threat. It is noted, also, that there is no risk assessment provided in relation to the proposed measures as requested by the SPS Agreement.

The basis put forward is that it is “a low probability, but potentially high cost event”.

The US should provide such a risk assessment as requested by the SPS Agreement both to justify the proposed measures and to ensure that any potential risks are addressed in an effective and proportionate manner.

The European Communities consider that it will prove counter-productive to the objective of the measures if they are unduly bureaucratic and burdensome. The European Communities also note that the measures have the potential to impact significantly on trade through the introduction of new regulatory requirements. These will affect in particular imported products.

2. Impact on EU Exports and WTO compatibility

The European Communities have serious concerns about the potential adverse impact on EU exporters and WTO compatibility of the above measure. Small and medium-sized enterprises are, of course, particularly concerned by the implementation of this measure and their possibility to trade could be seriously compromised.

The proposal – together with the text notified in the framework of the SPS Agreement under reference G/SPS/N/USA/691 - forms only part of the rules to be adopted under BTA, with other parts still to be notified (e.g., rules for keeping records and administrative detention). As such there are a number of general comments that can be made on the overall process that apply to most individual pieces of the jigsaw.

Based on statements by FDA since the two implementing measures were published, the FDA intends to treat comments in two broad categories: 1) those where FDA considers that it possesses flexibility to respond and 2) those where FDA considers it does not have such flexibility.

The first group includes specific comments on individual implementing measures. They highlight real life problems that the proposed rules will cause and suggest

possible solutions to improve the situation. It is the view of the European Communities that most of them could easily be taken into account in the Final Rule.

The second group involves a more fundamental set of comments that address the actual basis of the proposed rules and the foundation on how implementing measures will function, e.g., need for a defined group of traders to be registered. The message that the FDA has conveyed when asked about this second group of issues is that flexibility is not possible because they inherited specific requirements as part of the June 2002 Bioterrorism Act (BTA). The basic message has been that comments will be “considered as far as possible” but the fundamentals cannot be changed. A situation whereby measures enter into force which are both ineffective in relation to their purpose and trade distortive must be avoided.

The BTA itself was never notified to WTO nor justified by a risk assessment. Both implementing measures include the statement that the “ FDA believes that this proposed rule is not more trade restrictive than necessary to meet the objectives of the BTA.” However, the objectives of the BTA have never been justified by the US in accordance with international obligations.

At the same time, the European Communities would like to express their disappointment that the comments previously forwarded in August 2002 never received a direct response. A copy of these comments is attached. The EC look forward to receiving a written response to these comments.

No objective justification has been put forward for the two implementing measures as required under WTO rules. This in turn has a direct influence on the extent of the measures that can be applied, i.e., to maintain the principle of proportionality to the perceived risk.

The FDA has stated that a risk assessment will be made available before the final rules for “prior notice” and “registration” are published (12 October 2003). This is the inverse of the normal situation where measures follow a risk assessment and are drawn up in the light of its findings, and not vice-versa. The European Communities would like to receive a copy of the risk assessment as soon as possible.

The European Communities consider that the normal WTO obligations should be followed. These obligations are designed to limit the introduction of arbitrary and unjustifiable trade measures more restrictive than necessary. To date, the US has yet to show what specific risks its measures are supposed to address and therefore they have also not been able to make the argument that the proposed measures will eliminate these unspecified risks in a proportionate and non-discriminatory manner.

The speed at which the measures are being introduced and the apparent lack of co-ordination with similar initiatives by other US agencies greatly increases the risk that the impact on trade will be greater than is necessary. The US must co-ordinate these measures to avoid unnecessary duplication for exporters to the US.

3. Proposed rule exceed scope of Act

The BTA, title III. is limited to bioterrorist threats to the food supply (e.g. § 301). However, in drafting the implementing rules, FDA has widened the scope to “other public health emergencies that may result from imported food” (section III, paragraph 1 of the Federal Register notice, p.5429). The US SPS notification (section 6) is also wider than terrorist risk and cites “accidental” contamination.

The US must clarify that this measure is limited to countering bioterrorism incidents as intended by BTA. The proposed rules should not exceed the scope of the BTA.

4. Discriminatory nature of the measure

The US justification of the prior notice measure is that it facilitates checks and inspections to take place on foreign imports. The analysis appears to follow the line that if a terrorist risk is identified in product X or from source Y, FDA can deploy inspectors to intercept the relevant shipments. However, the analysis does not presuppose that all foreign lands are intrinsically subject to greater risk than domestic companies and plants. On the basis of the FDA analysis there is no reason why the same prior notice requirements should not apply to inter-state commerce. In the same way as is proposed for imports, FDA would be able to react and deploy resources to meet terrorist incidents within the US.

The application of such a burdensome measure only to foreign trade in the absence of any risk assessment, and in particular the absence of any evidence that foreign goods, and in particular those from the EU, are a source of greater risk than US goods, is discriminatory and not compatible with trade law.

5. Absence of any proper impact cost assessment

The US has not provided any impact cost on foreign exporters to the US. On the basis that “prior notice” will be completed by the US importer, the only cost analysis concerns the increased administrative burden on US companies. However, the issue of greater importance is the impact on foreign suppliers. Three effects must be analysed:

- The increased burden on foreign suppliers in collating and providing the data to their US importers to allow the prior notice to proceed;
- The cost of lost contracts because US buyers decline to buy from foreign sources owing to the administrative burden of prior notice; and
- The costs passed on to foreign suppliers by US importers.

In the Federal Register notice concerning registration of facilities, the FDA estimated that 16% of companies would cease to export to the US as a result of that measure. Given the far greater burdens estimated by the prior notice measure, the effect on trade in terms of cancelled orders must be expected to be far greater.

FDA must conduct a proper and thorough impact and cost analysis of the prior notice measure and take the results into account before proceeding.

6. Duplication of information

The European Communities would like to draw the attention of FDA to:

- US Customs requirement that containers departing foreign ports for the US must provide cargo manifest details 24-hours in advance of the ship's departure;
- US Customs intention to impose similar requirement for advance information in relation to air cargo but the time element applicable to air cargo will be considerably different;
- US Coast Guard has also announced a prior notification of arrival in US ports. This rule will be effective April 1, 2003.

In this context it is considered that a detailed assessment of the US Customs requirements by the FDA would be beneficial in terms of avoiding potential difficulties which could arise because of:

- (i) different time requirements for receipt of prior notification of data by FDA, US Customs and US Coast Guard,
- (ii) different definitions for, or interpretation of, similar data,
- (iii) duplication of effort and burden on trade.

It is also understood that all consignments of foods, feeds and beverages which cross the US border are covered by the proposals. Thus transshipments of goods to a final destination outside the USA are included with a consequent additional burden on this trade.

The 24-hour rule operated by US Customs already fulfils the objectives of prior notice requirement of the BTA.

Early discussions are expected between EU and US customs representatives on the integration of security checks into customs controls. These discussions on the development of an EC-US framework to improve security in maritime traffic will address matters like the definition of key information for the identification of high-risk consignments, introduction of common control standards and the collection and exchange of this information between the competent authorities.

The proposed measures appear disproportionate to the envisaged goal given the economic charges on exporters. Equally, the proposed rules are in apparent contradiction with the efforts undertaken in the framework of the Doha negotiations within the WTO aiming at facilitating trade by rationalising and simplifying customs procedures.

Data provided to US Customs, should be used also for FDA purposes. The fact that FDA does not have the necessary infrastructure to receive information from the Customs authorities does not justify the administrative expenses for European exporters.

A particular problem is likely to appear for perishable goods that are detained for administrative reasons. Even short periods of detention, particularly of chilled fresh produce, will reduce value and lead to spoilage. For these cases a damage claim system should be set up.

The trade in perishable products is very dynamic in nature, depending largely on market conditions, product availability and transportation availability. The proposed regulations will interfere with trade practice, for example by ruling out last minute substitutes of product and therefore largely reduce the flexibility in trading both for U.S. importers and foreign exporters.

7. Detail of information is excessive

This draft regulation requires the prior notice of every single food shipment, on an article by article basis. This is a most burdensome feature of the BTA.

The information required by FDA should be reduced according to the following criteria:

- Remove from the FDA list all duplicative information already supplied to US Customs, Tax and Trade Bureau (TTB) or other agencies;
- Remove from the FDA list all information not required in the BTA itself. The implementing rules should not go beyond the BTA requirements;
- Limit the prior notification system to certain categories of food, on the basis of a risk assessment, avoiding a generalisation of the system.

8. Amendments/updates of prior notice

“Updates” must be provided for every notice where the expected time of arrival is more than 1 hour earlier or 3 hrs later than that first notified. This could mean 1000’s of updates for a single ship arriving outside the predicted time, e.g. by being one and a half hours early.

The Final Rule should allow a single “update” by “the carrier” who will be in the best position to know when the ship will arrive in the US and how this differs from the previously notified time. This is more relevant and important for sea transport due to the scale involved.

“Amendments” – if “the shipper” realises after the “noon the day before deadline” that there is a mistake on the prior notice – what can they do? A system that allows quick resolution of minor problems must be set up to avoid simple and genuine mistakes from causing long delays to the processing time of shipments.

In case of insufficient or inaccurate prior notice, the “importer must bear costs of storage” – There should be rapid appeal mechanism introduced to hear cases where the importer is not at fault, in which case compensation should be available.

9. Timing inadequate

For air-freighted goods (e.g. fresh fruit, fresh fish, and vegetables and cheese) the period of notice required is too far in advance and poses a threat to this type of trade. A US importer may place an order with an EU company after 12.00 noon and expect delivery by air within 24 hours. Indeed it is common practice for orders to be filled even as the aircraft are being loaded. In these cases, prior notification would have to have been made 24 hours before the order was placed. FDA should allow notifications for air-freighted goods to be given from “wheels-up”.

10. Who may notify?

The requirement that the importer must notify may not reflect business practice in all cases, nor is any particular justification advanced by FDA. The rules should allow the foreign exporter to provide the prior notification.

11. Electronic submissions

Notifications may be submitted by an importer or US agent but, whether ‘Initial’, ‘Amended’ or ‘Updated’, they must all be submitted electronically. This may be problematic for some smaller traders.

What happens when computers fail and prior notice can only be legally accepted in electronic format ? The Final Rule should address this point and include specific procedures.

12. Identification of growers “if known”

It is unclear whether or not a notification has to be made for each article of food that comes from a different grower. The proposal states that the “if a product is sourced from more than one grower, the prior notice must provide the identification of all growers, if known”– it is not clear how the definition “if known” will be interpreted.

On the other hand, the proposal states that the requirement to notify “applies to each article of food” - whereby “each article of food” means each article of food produced by each manufacturer. The requirement to notify each article from each manufacturer is a very difficult requirement in case of the European fresh produce production structure, whereby a shipment can be composed of dozens of lots, each of them sourced from dozens of different growers.

13. Administrative burden may exceed FDA capacity

The EC is not reassured that FDA has the resources or manpower to handle all the data submissions and operate the system smoothly. An issue of concern to fresh produce exporters is the ability of the FDA to timely process all notifications it receives.

FDA should provide guarantees that the processing of notifications by the FDA and the transmission of data between FDA and US Customs and other agencies will function efficiently, especially in respect of fresh and perishable produce.

Losses due to deficiencies in US administration should be compensated.

14. Co-ordination with TTB

As far as alcoholic beverages are concerned, much of the information required in the prior notice, together with certain additional details, is already provided to the US authorities under existing regulations. TTB has to approve and register labels (including bottle sizes) for all alcoholic beverages imported into the US. The process involves the submission of substantial information relating to the company and its products.

The US Customs Service receives advance notice of a ship's arrival and of its manifest well ahead of its actual arrival. Its Container Security Initiative (CSI) requires the presentation of cargo details 24 hours before loading onto the vessel.

15. Samples

Concerning the situation of products' tests on the US market (meaning small quantities, restricted availability), access should be allowed without the prior notice requirement. Should this restriction not be lifted, it would appear as a serious barrier restricting US market access. Samples should be exempt in the same way that individual travellers' goods are exempt.

16. Parallel inspections

The FDA claims that advance information of a food shipment will allow the FDA to target inspections more effectively before products enter domestic commerce. However, the CSI involves *inter alia* the inspection of shipments destined for the US by US Customs personnel based overseas. Inspections must be co-ordinated.

17. Country of origin

The US should confirm that "EU" will be accepted as country of origin for the purposes of prior notification.

18. Review clause

The European Communities requests inclusion in the final rule of a provision for reviewing and amending the system so as to ensure that possible negative effects on trade and foreign companies are minimised in practice, in particular in the light of the experience acquired.

19. Fishery products

By its nature the fisheries sector is characterised by the perishability of its products and the large number of species involved. The Commission's dictionary of aquatic animals¹ lists 1440 species of fish, crustaceans and molluscs all of which can be food species. Many species are closely related and the requirement to list exact species names will be very onerous. Problems will arise when closely related species are used as ingredients for value-added products.

Questions arise as to which facility would be responsible for filing the prior notice and which facility would be responsible for a new prior notice should there be a change in the species composition, size of packaging or brand or a delay in the ship or plane arriving at the US port. Two cases to illustrate this point are annexed.

¹ Multilingual illustrated dictionary of aquatic animals and plants. Second Edition. European Commission/Fishing News Books, 1998.

Annex

Fisheries cases to illustrate practical difficulties:

Case 1 - Salmon.

An order is received from a US customer on Thursday morning by a Scottish producers' group located in the Western Isles and salmon is sourced from four local salmon farms during Thursday and packed for export at the group's packing station following evisceration. It is collected by the freight company late on Thursday and it taken by ferry to the mainland and then by road to Heathrow Airport where it arrives on Friday evening. The packages are stored in chilled containers at a warehouse facility at the airport overnight prior to being air-freighted to Newark Airport on Saturday.

On Saturday all flights are delayed due to freezing fog and the flight eventually takes off late on Saturday night and arrives in the US early on Sunday morning. The salmon producers group made the prior notification on Friday afternoon when they were preparing the invoices and the office closed for the weekend at 5 pm.

The customer calls the airline and quotes the airways bill on Saturday afternoon and is told there is a delay. When he eventually calls to collect the salmon he is told that they have been detained as the timing indicated in the prior notification is incorrect and that a new notification is required. A new notification is not filed until Monday and as a result the salmon miss the intended fish market on Monday morning creating difficulties for the importer and his regular customers.

Case 2 - Fish cakes with ingredients from cod and related species.

Three freezer vessels land their frozen whitefish (five species of *Gadidae* - cod family - which have been headed and gutted prior to freezing) landings at Vigo on Wednesday and the landings are taken to the secondary processing plant for further processing into fish cakes. During Friday the fish cake line uses three of the whitefish species from two of the freezer vessels.

Subsequently an order from a US client is being met from Friday's production. Is the administrative office required to make two notifications per product as the raw material has been sourced from two different freezer vessels or would one notice suffice with the names of the two suppliers indicated? Change in the nature of the food is not permitted prior to filing the prior notice. Does the office notify the three species or *Gadidae* or does it list the five species just in case there has been an error on the production line or does it simply indicate "whitefish fish cakes"?

As 12 oz packages of Brand X and Y together with 18 oz packages of Brand X and Z have been ordered, the answer to the above would need to be multiplied by five for the five different products (three brands & two package sizes) which the customer has ordered.

It is not clear how many prior notices are required all together.

Preliminary comments from the European Commission on the USA Bioterrorism Act

INTRODUCTION

The Commission thanks the FDA for the opportunity to provide “initial comments” on the Bioterrorism Act which was signed into law on June 12, 2002. However, due to the very short notice provided for comments, exacerbated by the holiday season, kindly consider the remarks presented below as preliminary. These comments are the result of limited consultation between certain Commission services and a number of Member States. Revised comprehensive comments will be forwarded to the USA authorities in due course once a more comprehensive consultation process has been carried out between the relevant Commission Services and the Member States.

Individual Member States may also submit comments directly to the USA.

The Commission shares the USA concerns deriving from the bioterrorism threat and, in principle, understands the USA aim to provide appropriate prevention measures against the potential bioterrorism menace. However, the introduction of certain measures proposed in the Act will have potentially significant consequences for existing trade patterns and in our view will not provide the desired protection.

The Commission underlines the good relationship between the EU and the USA on SPS issues, and reminds the USA of the good record of the EU in identifying potential hazards and taking the necessary measures to eliminate them. The Commission believes that the combined system of controls by Member States and the Commission provides the best possible safeguards for consumer safety and animal and plant health. As we read them, the provisions of the Bioterrorism Act do not appear to enhance those safeguards.

In particular, the EU has serious concerns over the basic requirement to register every food business which supplies the USA. While recalling that the EU shares the security objective leading to the elaboration of these measures, the EU cannot but question the practical effectiveness of this proposal in reducing the risk and serving our shared security purpose. We fail to see how such a measure, which would involve a major administrative burden and which would create serious barriers to trade, would deter or offer any additional protection against a would-be criminal or terrorist determined to spread some form of contamination, that will obviously act beyond the control of a supplier, registered or not.

The Commission would like to remind the USA of its Rapid Alert System which gives quick information about contamination of food products. This is backed up by a comprehensive control and monitoring programme. The Commission suggests that this provides the USA with excellent safeguards against accidental and deliberate contamination.

FDA is responsible for about 80% of the food supply in the USA. Most of the remaining 20% (meat products, poultry and some egg products) is under the responsibility of USDA's APHIS. We note that this consultation is being carried out by FDA alone. We would like to be informed whether other US agencies are likely to come forward with proposals resulting from the provisions of the Bioterrorism Act and if they intend to carry out a similar consultation process.

The proposed new measures affecting the importation into the US of drugs and devices also cause concerns.

Finally, the Commission considers that the provisions of the Bioterrorism Act and the fact that it has already been introduced without notification to the SPS Committee of the WTO, does not comply with the USA's international obligations nor those of the EC/USA Veterinary Agreement.

GENERAL REMARKS

1. It is understood that the Bioterrorism Act is a framework Act, which will be completed by application measures that have to be adopted before the 12 December 2003. However, it is considered that the Bioterrorism Act already has provisions that due to their nature have potentially significant consequences for existing trade patterns and, therefore, should have been notified in accordance with Article 7 of the SPS Agreement to the SPS Secretariat.
2. The EU would like to receive information about the risk assessment carried out in accordance with Article 5 of the SPS Agreement, on which the Bioterrorism Act is based.
3. The EU would like to remind the USA of the exchange of communications between the European Commission and the USA on the occasion of the adoption procedure of Commission Directive 98/51/EC². Amongst other things, the text lays down the provisions for the listing procedure of third country establishments manufacturing certain feedingstuffs, for export to EU Member States. The listing procedure envisages a transmission of the information (list of registered facilities) from the competent authority of the exporting country to the Commission.

The Commission notified the draft text (DOC. VI/5637/97 Rev. 4) to the SPS Committee (Notification G/SPS/N/EEC/58).

The USA commented on the said notification with submission G/SPS/GEN/88 on 4 September 1998. In its submission, the USA questioned the EC requirement for a list of third country establishments and made the following remarks:

- the proposed Directive could create unnecessary obstacles to trade;

² Commission Directive 98/51/EC of 9 July 1998 laying down certain measures for implementing Council Directive 95/69/EC laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector (OJ L 208, 24/07/1998 p.43)

- the list of third country establishments would create needless expense and bureaucracy and inhibit trade in feedingstuffs without creating a safer food supply.

This response from the USA seems to be inconsistent with the principles proposed by the USA in the Bioterrorism Act.

The Commission, in the interest of consistency, would like to receive the following clarification:

What are the steps that the USA intends to take in order to limit unnecessary obstacles to trade, resulting from the adoption of the Bioterrorism Act ?

How does the USA intend to proceed in order to avoid needless expense and bureaucracy and inhibition of trade in food, as a consequence of the registration procedure of all domestic and foreign facilities dealing with all types of food ?

4. Furthermore, for the record, the USA has not complied with the provisions of the Agreement between the European Community and the United States of America on sanitary measures to protect public and animal health in trade in live animals and animal products (EC/USA Agreement) (Council Decision 98/258/EC of 16 March 1998), Article 10 (2) (Information exchange). It is considered that due to the relevance of the Act a notification should have taken place between the USA and the EC contact point for the EC/USA Agreement.
5. The EU would also like to express the opinion that, for the products covered by the EC/USA Agreement, the provisions laid down by Title III, Section 305 (Registration of Food Facilities) of the Bioterrorism Act (*“the owner, operator or agent in charge of a [...] foreign facility”* must *“register with the FDA no later than December 12, 2003”*) are considered to be against the principles laid down by Annex V, Footnote 7, of the said the EC/USA Agreement (i.e., *“The list, or lists, of approved establishments, and any additions and deletion to such lists, shall be supplied to the importing Party by the exporting Party”*)

COMMENTS AND QUESTIONS ON SPECIFIC SECTIONS OF TITLE III OF THE ACT

Section 302 (Protection against adulteration of food):

In what way will the increased number of inspections at border posts on account of bioterrorism affect the importation of goods into the USA and the related costs ? Will the provisions referred to in the EC/USA Agreement, Annexes VII and VIII be taken into account when defining the increased inspection frequencies of consignments originating from EU Member States ?

How does the principle of “increased number of inspections at border posts” on account of bioterrorism relate to the principle laid down in the last paragraph of Annex VII of the EC/USA Agreement, (modulation of physical check frequency in the light of the progress towards the recognition of equivalence under the consultative process provided for in Article 7) ?

Section 303 (Administrative detention):

In the event that a regular and risk-free consignment would become unusable or lose value, due to the imposed import checking procedures, rules for indemnification and compensation respectively in accordance with the customary trade law should be foreseen.

The term “credible evidence” is considered too vague. Clearer criteria are needed to define when a consignment should be refused import on grounds of Bioterrorism. Consideration should be given by the USA authorities, in the adoption procedure of the final regulation to lay down rules for the rights of appeal against decisions by the competent authorities including urgent appeal procedures.

The specific period of detention is an important issue. Of particular concern is the impact it can have on the normal flow of trade of FDA regulated products, especially perishables. Therefore, for perishable products we would like to suggest a maximum period of detention of 24 hours.

There should be a notification procedure, whereby exporters are to be informed directly by the FDA-authorities in case of detained shipments. Some exporters do not use agents. For notification purposes, we suggest the creation of a central FDA-contact point.

The EU would like to receive information about whether the overall burden of requirements on companies exporting to the US are more or less onerous than on firms within the US producing for their domestic market.

Section 305 (Registration of Food Facilities):

Taking into account the listing procedure as laid down by Annex V, Footnote 7 of the EC/USA Agreement consideration might be given to the possibility that enterprises dealing with food of animal origin be exempted from registration.

How does the USA propose to deal with the practical aspects of the registration of the foreign facilities? For instance, how long will it take to get a registration number and are packaging firms considered to be facilities in this Act ?

Is it the case that every firm has to request registration directly ? (it seems that this is the case from the text) Should the information required only be submitted by the registering firm ?

Will the register be published and freely available ?

Section 306 (Establishment and Maintenance of Records):

It is not clear whether the “one up, one down” principle would be applied to foreign suppliers. Section 305 applies the registration requirements only to the final supplier to the EU. This suggests that the “one up, one down” principle would not apply to them, given that there is no registration requirement for the upstream suppliers.

It is considered that the provisions of Regulation (EC) N° 178/2002 of the European Parliament and of the Council of 28 January 2002 (General Food Law) fulfil the requirements of this Section.

Consideration might be given to exempt products which are clearly identifiable on the basis of the batch identification, reported in the framework of the labelling system from data registration.

Have the practical aspects of “maintenance of records” in foreign facilities been considered ? How do the USA authorities plan to access records kept by facilities in other countries to ensure compliance ?

Section 307 (Prior Notice of Imported Food Shipments):

Concerns have been expressed that the foreseen pre-notification procedure will generate administrative, logistic and economic burdens.

Regarding the practical aspects of the notification before importation of goods into the U.S., who should be notified? Can existing notification and paperwork that is sent to and through customs be used? This point is particularly important. A large amount of information is already required for entry through USA customs. Is it the intention to request all exporters to submit an additional set of documents to conform to the Bioterrorism Act in addition to documentation for existing animal health and trade legislation? Could the existing documentation be used for the additional purposes set out in the new Act?

Section 308 (Authority to mark articles refused admission into United States):

The planned marking of consignments whose entry has been refused should be limited to those batches presenting serious health risks.

Section 310 (Notices to States regarding imported food):

Do the USA authorities plan to notify also to the public health structures within the EU their findings about health threats resulting from imported food in order to allow them to take protective measures? At EU level, the European Commission could be the contact point for the USA and can carry out the necessary co-ordination in these cases, building on close communication links with the corresponding structures in the Member States.