8 July 2003

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

Administrative Detention of Food for Human or Animal Consumption

1. General comments

The European Communities would like to thank the Food and Drug Administration (FDA) for the opportunity to provide comments on the Administrative Detention under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 notified to the SPS Committee under **G/SPS/N/USA/704.**

The European Communities fully shares 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 considers that it will prove counter-productive to the objective of the measures if they are unduly bureaucratic and burdensome. The European Communities also notes 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 has 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 texts notified in the framework of the SPS Agreement under references G/SPS/N/USA/690, G/SPS/N/USA/691, G/SPS/N/USA/703 - forms only part of the rules to be adopted under BTA. 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 first 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. 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 is it based on 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 explained by the US in accordance with international obligations.

At the same time, the European Communities would like to express its disappointment that the comments previously forwarded in August 2002 and April 2003 never received a direct response. The EC looks forward to receiving a written response to these comments.

No objective justification, i.e. a risk assessment, has been put forward for the implementing measures as required under WTO rules. In the absence of such risk assessment, it is impossible to assess whether the measures effectively and proportionately address the perceived risk.

The FDA has stated that a risk assessment for all implementing rules will be made available when 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 considers 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.

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.

Administrative Detention

1. CLARITY NEEDED ON USE OF GENERAL POWERS OF DETENTION OF IMPORTS

Section §303 of the BTA provides powers of administrative detention over food items. However, the EC understands from FDA (page 25243, 3rd column) that recourse to this provision for imports is expected to be minimal since FDA and US Customs currently have alternative detention authority over imported food products.

The EC requests the US authorities to provide clarity concerning which rules will be applied, and under what circumstances.

The US should undertake not to detain imported product on the basis of the BTA in circumstances where similar domestic food would not be detained.

2. DIVERGENT TRIGGER CRITERIA FOR DETENTION OF PRODUCT

It appears that the general powers to detain imports and the specific power envisaged under §303 have differing triggers:

– under the general import authority is the "appearance of adulteration";

– BTA applies the higher standard of "credible evidence or information indicating that such an article presents a threat of serious adverse health consequences or death to humans or animals."

FDA needs to explain better how detention powers will be applied to imports and how different agencies will be co-ordinated.

Discrimination between the detention rules applied to imported and domestic products under the BTA causes should be avoided. Thus the criteria used to detain imports for problems envisaged by the BTA should be "credible evidence or information indicating that such an article presents a threat of serious adverse health consequences or death to humans or animals."

3. DISCRIMINATION OF APPEAL PROCEDURES

Detention authority under §303 includes deadlines for appeal procedures, whereas the import detention authority under §801(a) of the Food, Drug and Cosmetics Act, does not.

Procedures for redress and appeal available to importers of detained food items must be no less effective than those available to holders of detained domestic food items.

4. DISCRIMINATION OF DETENTION RULES UNDER THE "24 HOUR-HOLD" PROVISION

Section §303 (c) of BTA includes a provision authorising temporary holds at ports of entry where there is (a) credible evidence of a threat, but (b) the FDA is unable to inspect immediately, the food may be held for 24 hours at a Port of Entry.

This only applies to imports. FDA has not yet developed rules on this power.

Use of this power for fresh and time-sensitive produce could cause deterioration of product or other loss of value.

If the "24 hour hold" rule is necessary, the EC questions the logic of not applying it to domestic product. The US authorities need to ensure action is taken on the basis of risk and rules are drafted and implemented in a manner that does not lead to discrimination against imported product.

The EC suggests this power should either be applied to both domestic and imported products, or not applied at all. Discriminatory treatment should be avoided. FDA must ensure that resources are not diverted away from imports to domestic alerts, relying on the 24-hour hold.

The US should avoid the position where imported food items are potentially subject to an over-lapping array of detention orders (§303(a)/BTA; §801/FDC; and 24-hour hold under §303(c)/BTA), which may be applied consecutively to the same product, while domestic product is only subject to one procedure (§303(a)/BTA).

5. CLARIFICATION OF DEFINITIONS

Serious adverse health consequences

The FDA does not give any clarifications concerning the meaning of "*serious adverse health consequences (or death to humans or animals)*" (§303(a)/BTA; §1.378/rules; and page 25245). It is necessary to clarify what is meant by this phrase.

EU industry sources believe that some sort of reference to a risk to a large part of the population should be included. This should cover the extent and severity of the risk.

Credible evidence

FDA also explicitly declines to define "*credible evidence or information*" (§303(a)/BTA; §1.378/rules; and page 25245) indicating that an article presents a threat. Rather it points out such a vague definition is common practice in US law making, implying a lack of concern that the rule should be applied in a consistent manner. This increases uncertainty for traders.

In addition, FDA may order a detention on the basis of confidential or classified information. Given that the potential damage to a company of a wrongly ordered detention will usually be considerable, FDA's ability to detain food shipments must be clearly delimited by a more precise definition.

Perishable food

FDA clarifies the meanings of "food" and "perishable food" by listing examples (page 25245). However, the definition of a perishable food only refers to products whose physical or biological properties may be affected by detention. It does not take into account the perishable nature of a product by virtue of the way it is marketed.

For example, *"nouveau"* wines or any otherwise "durable" product may be released for marketing or consumption on a specific date or season of short duration. If such a product were detained, it would not qualify as a perishable product according to the FDA proposed definition. Nevertheless, it would be severely affected by such detention because, if such a product is not actually available for sale at the optimum date, it may lose its annual sales, which are completed within a brief two or three week period.

It is therefore necessary that the FDA take into account the specific vulnerability of such a product in order that it is not effectively prohibited access to the US market.

6. CONDITIONS OF DETENTION AND EXPEDITED APPEALS

EC industry is concerned that even small detention periods or inappropriate detention conditions (e.g. heat) will lead to losses of perishable products and other products sensitive to storage conditions.

Some products deteriorate very quickly and even 24 hours (such as provided in the power under §303(c)) could lead to losses. Therefore, appropriate storage conditions should be envisaged. In addition, FDA should upon request of the owner provide the records of these conditions during detention.

7. DETENTION PERIOD AND EXPEDITED APPEALS

The rules do not contain criteria to determine the detention period, which may be of 20-30 days (§303(a)/BTA; §1.379(a)/rules; and page 25246). It seems to depend on the FDA discretion and workload at the time.

In its final rule, the FDA should clarify that it will order the detention of articles of food for only so much time as is reasonable. EU industry sources believe that, for non-perishable or time-sensitive products, 10 calendar days constitutes a working maximum.

In case of perishable products, such as fruit and vegetables and fresh fishery products FDA should develop a system which determines within 24 hours if the detention continues to be necessary or not. In addition, an expedited appeals

procedure will need to be set up. With regard to the nature of the perishable product, EU industry point out that fresh fruit should be kept in detention only for a few hours and the detention of peppers and citrus fruits should not exceed 24 hours.

8. ISSUING OF A DETENTION ORDER

Under §1.392(a) (see also page 25248) FDA will only notify the detention to the owner of the place or the owner of the vehicle where the goods are seized. However, these persons may not have a vested interest in the detained product. FDA must assume the responsibility to contact the importer or owner of the goods as soon as possible.

9. CONTENT OF DETENTION NOTICE

Proposed §1.393(b)(6) provides that detention orders must specify "[a] brief, general statement of the reasons for the detention". As noted in the preamble, the purpose of the detention order is to serve notice of the detention and of the right to an informal hearing to appeal the detention.

EU industry sources are concerned that the detention order may lack sufficient detail in order to enable an importer to prepare for an appeal. FDA should undertake, wherever possible, to include a statement of the evidence or information upon which its order is based.

EU industry would also urge FDA to use internationally recognised methods in case of laboratory analyses as well as to provide counter-samples to the owner.

10. DETENTIONS WHICH TURN OUT TO BE NON-VIOLATIVE

FDA states that it cannot confidently estimate the percentage of times that it will order the administrative detention of an article of food which turns out to be non-violative. The agency does acknowledge, however, that during the first nine months of 2002, it released 48% (page 25253) of the import shipments of human and animal food that it detained. FDA claims that this represents the upper limit of the non-violative detentions. FDA points out also that the rate of detentions for food which turns out to be non-violative will be lower under BTA Administrative Detention. This underlines the potential for discriminatory action against imports.

FDA should consider paying damages to the operators with a view to compensating lost profit, in particular for the perishable goods, but also for some seasonal products, in cases of non justified detention.

11. DETENTION OF PARTIAL SHIPMENTS

If a lot is detained because it is considered as potentially dangerous, the whole container may be detained. FDA should provide that only the food articles which the "credible evidence or information" concerns should be detained, while the rest should proceed into commerce as usual.

This is particularly important for large consignments in shipping commerce, compared with road and airfreight. However, the same principle should apply to imports of diverse lots by any means.

12. COSTS OF DETENTION

According to FDA, an administrative detention may impose numerous costs, including those associated with transportation, storage, security, loss of product, loss of product value, and appeals. While the agency estimates that the average cost for small entities would be $20,000 to $330,000 per detention (page 25265), the actual potential costs for a single detention could be much larger.

Such costs represent a considerable economic burden to EU industry and a potential disincentive to US importers. FDA should take all necessary steps to avoid unwarranted detention of food articles.

(End of comments)