8 July 2003

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

Establishment and Maintenance of Records

1. GENERAL COMMENTS

The European Communities would like to thank the Food and Drug Administration (FDA) for the opportunity to provide comments on the Establishment and Maintenance of Records under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 notified to the SPS Committee under **G/SPS/N/USA/703.**

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 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 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/704 - 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 their 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 two 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.

3. SCOPE OF THE BIOTERRORISM ACT LIMITS "RECORDKEEPING" TO DOMESTIC ENTERPRISES

3.1. Implementing rule is *ultra vires*

The US Bioterrorism Act §306 applies to "…each person (excluding farms or restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports… food. "

Under normal legal interpretation, §306 only applies to domestic facilities, not to foreign. Explicit text is needed to extend the reach outside the US. The word "importer" at the end of the list supports this construction. The BTA is explicit when it has extraterritorial effect (e.g. §305 on registration and identification of "foreign facilities"; in the converse example, §303 on administrative detention does not make explicit that it is "only domestic", but clearly it does not apply to foreign jurisdictions).

If the text of BTA is read contrary to normal interpretation to apply to foreign facilities, the lack of any qualifier, such as *"food for consumption in the US"*, would lead to the absurd result that BTA record-keeping applies to the entire world's food supply ("any location") whether or not it is consumed in the US ("each person who manufactures, etc."). Clearly this is not the intent of BTA.

Therefore, there is no authority in BTA to apply the second sentence (extension to foreign facilities) of §1.326 of the implementing rules, which is *ultra vires*.

FDA's claim (page 25191, 2nd col.) that it believes that the measures should be extended to cover not just imports, but foreign countries internal arrangements, is not supported by the parent act.

3.2. Proposed rule is too burdensome

The European Communities has received many observations and comments on the detailed application of the proposed rules. Many of these serve to highlight the impracticability of the extension of record-keeping to foreign countries and the burdensome nature of the proposals.

Notwithstanding the EC's view that there is no authority for the FDA to give extraterritorial effect to record-keeping rules, the EC is pleased to pass on the detailed observations for consideration by the US authorities. These are **annexed**.

3.3. Proposed co-operation to make use of existing record-keeping systems

According to implementing rule §1.337, the source of every ingredient must be recorded ("one up") and according to §1.345 recipient of every food must be recorded ("one down").

The EC has in place measures, which include the same requirement, which is the basis of traceability systems. There is no need to supplant EC traceability and food safety systems with a US system covering the same ground. This will create

confusion for operators. However, the EC is ready to discuss further with the US how existing and future systems for traceability, on both sides, can be utilised to enable the necessary action to be taken, should it be necessary and thereby reassure health authorities in both jurisdictions.

The EC legislative framework for traceability includes:

- general food law (Regulation 178/2002/EC): general requirement for traceability systems to be put in place for all food and feed, covering all parts of the food chain from and including primary production to distribution to the final consumer. (to be implemented from 1 January 2005);
- mandatory indication of lot numbers (Directive 89/396/EEC);
- hygiene rules (Directive 93/43/EEC);
- beef labelling and traceability rules (Regulation 760/2000/EC);
- fish labelling and traceability rules (Regulation 104/2000/EC);
- wines and spirits rules (Regulation 1493/99/EC);
- Rapid Alert System.

The EC looks forward to being able to explore the extent to which these measures meet the objectives of the US proposals via bilateral discussions.

4. SANCTIONS

According to §1.363, failure to keep records as specified is a "prohibited act" under s.301 FDC Act. This can result in a fine of $1000 or $10.000 or imprisonment for 1-3 years (§303 FDC Act).

The FDA has confirmed orally that it does not intend to apply the rules in respect of enterprises in the EU. Outside the US territory, the rules on record keeping are not enforceable.

Any legal proceedings taken on the ground of a breach of record keeping in a foreign country which could result in confiscation of assets held in the US or action against executives visiting US territory, would be considered by the EC to be a very grave step. This would be unworkable in practice and problematic in terms of bilateral relations.

FDA should make clear that no enforcement action would follow in respect of record keeping by facilities situated in the EC.

5. CONCLUSION

The EC considers that the extension of record-keeping requirements, powers or inspections, and sanctions to foreign facilities to be *ultra vires* under the BTA and not an acceptable application of extraterritorial effect of domestic law.

Nevertheless, the EC proposes to enter into discussions with the US in order to determine mutual co-operation procedures to reassure authorities in both jurisdictions.

Without prejudice to the above, the EC is pleased to communicate the **annexed** detailed observations.

Annex

Detailed comments on Record Keeping

1. TIMING FOR NOTICE TO PRODUCE RECORDS

The FDA requires records to be accessible within a time frame of not more than 4 to 8 hours, depending on the day and time (page 25199). This time frame appears unrealistic in the case of records held in the EC. Local time should be taken into consideration, e.g. a request made at 2 p.m. EST is received at 8.00 p.m. CET when no one may be present at a facility. A delay of 24 hours has been estimated by EU industry.

If the request takes place during a weekend, the response would require 72 hours.

Records, particularly older ones, may be stored 'off site'. In such circumstances, more than 24-hours would be needed in order to retrieve such records. The provision of 24-hour cover to assist with emergency access to records, whether on or off site, would be extremely costly to businesses.

2. FDA INSPECTORS CANNOT OPERATE IN THE EU WITHOUT AUTHORISATION FROM EU AUTHORITIES

There are no powers for FDA inspectors to operate in foreign countries. Thus, the rules on record keeping cannot be enforced outside the US territory. The EC notes (page 25191, 2nd col.) *"FDA plans to take the appropriate steps and work closely with foreign governments to obtain access to the needed records if a threat of serious adverse health consequences or death to humans or animals from adulterated food necessitates inspection of records in foreign countries."* The EC is ready to enter into discussions to achieve this. Any arrangements should be under an agreement covering also reciprocal arrangements for EC traceability inspections in the US.

Note also that §303 of the Act applies "Administrative detention" powers to any covered food that is found during an inspection (via. "304(h)(1)(A) of FDC Act). By extending FDA's powers in relation to record-keeping to foreign facilities, the FDA has inadvertently applied US administrative detention powers in the EU. Evidently this is not possible.

3. "*DE MINIMIS*" REQUIRES FURTHER DEFINITION

According to the implementing rule § 1.326 (a) foreign facilities that manufacture/ process, pack, or hold food for human or animal consumption in the United States are subject to these regulations.

Foreign facilities are excluded from the implementing rule if the food goes through further process, unless the further process is "*de minimis*" nature. The definition "*de minimis*" should be clarified precisely.

4. DUPLICATION OF INFORMATION

From a general point of view, there is a substantial risk that implementation of the FDA implementing rule could lead to additional burdens upon EU exporters. To minimize this, it is of particular importance that no new records should be required by FDA.

The proposed rule, §1.330,states that the existing records can be used if they contain the information required provided they have been laid down by Federal, State or local (presumably 'local' in the US) authorities. No reference is made to record keeping required by foreign rules.

Duplication of existing systems for record keeping and registration should be avoided. Existing systems that contain all of the information, whether or not it is in a format or language preferred by FDA, required by this Act should be accepted.

Records to be maintained must include:

(1) firm name, responsible individual and contact information (address, phone number, and, if available, fax number and email address) of the non-transporter immediate previous source or subsequent recipient (whether domestic or foreign);

(2) Adequate description of the type of food received or released, including brand name and specific variety;

(3) Quantity and information on how the food is packaged;

(4) Dates of receipt or shipment;

(5) Firm name, responsible individual and contact information (address, phone number, and, if available, fax number and email address) of the transporter who delivered the food to the non-transporter or transported the food to another non-transporter;

(6) Lot or code number or other identifier (to the extent it exists).

Most of this information (points (1) to (4)) is contained in Bills of Lading; point (5) will be available from order papers.

5. RESPONSIBILITY FOR TRANSPORTER'S DETAILS SHOULD BE HELD BY THE PARTY ORDERING THE TRANSPORT

It should be made explicitly clear that only the party ordering the transport is obliged to maintain the records containing the information in question. In a usual

transaction, it is either the sender or the recipient of the food item who orders the transport. The information required about the transporter is only reasonably available to the ordering party.

Where—as is typically the case—the sender orders the transport, it would be an additional burden for the recipient to check the identity of the transporter of every shipment received and create appropriate records. This applies, vice versa, to cases where the recipient orders the transport, as is becoming more and more commonplace in Europe. The burden would be seriously increased because the transporter used by each sender or recipient may vary from shipment to shipment.

6. ALCOHOLIC BEVERAGES

6.1. Duplication of records with TBT requirements

Alcoholic beverages are subject to overall regulation under the Alcohol and Tobacco Tax and Trade Bureau (TTB) in accordance with Title 27 of the Code of Federal Regulations (CFR). The particular regulations for the maintenance of records of imported spirits, wine and beer are contained in 27 CFR Part 251, Subpart I. The importer's records enable a product to be traced from the point of importation on to its destination as well as back to the producer/supplier.

These record-keeping provisions should be utilised for FDA requirements.

6.2. Retention of records

The FDA proposes that records should be retained for a period of 2 years (page 25198).

From the point of view of *alcoholic beverage* production and distilled spirits in particular, retention of records for a period of only 2 years would be inadequate to trace a matured product right back to source. This suggests reliance should be placed upon alcoholic beverage producers' own record systems to enable traceability.

6.3. Traceability

The import of alcoholic beverages is prohibited unless the importer holds a Federal Basic Permit to import and an alcoholic beverage cannot be imported for sale in the US domestic market without first having obtained a Certification/Exemption of Label/Bottle Approval (COLA) from the TTB. Substantial information about a product imported legally into the US is therefore already held in the TTB database.

In any event, EU spirits producers hold comprehensive records that enable full traceability for all components of their products, as well as records for tracing key 'dry material' components, such as bottles, capsules etc. In addition, EU legislation requires the inclusion of lot codes on the labels for the purpose of traceability; US regulations require tamper-proof closures on spirits and wine products; and containers are security sealed.

The traceability and security of EU spirits and wine products is already provided for under EU and, in some cases, national legislation and also in standard industry practice.

The EC urges the FDA to utilise existing systems, currently managed by competent and experienced professionals in other US Departments such as TTB, and to work with the Commission to establish the necessary communications and co-operation, thereby tapping into existing and future EC systems.

7. FOOD RECIPES

Section §306/BTA / §414(d)(4)/FDC states that record keeping requirements "shall not be construed … to extend to recipes for food, financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales)."

At page 25195, FDA states that proposed §1.328 defines 'recipe' as the quantitative formula used in the manufacturing of the food product, but not the identity of the individual ingredients of the food. If finalised as proposed, FDA would have access to the records containing the ingredients used in a food product, but would not have access to the quantities of the ingredients used to make a product. The act currently requires manufacturers to disclose to the public the ingredients they use on the labels of their food products. It is critical to a tracing investigation that the ingredients and the sources of the ingredients are identified."

7.1. Ultra vires

The BTA is clear that recipes should not be disclosed. In its ordinary meaning a 'recipe' includes three elements: the ingredients, the quantities, and the procedure. However, the fundamental element, and the one which in most cases is the most commercially sensitive, in the ingredient list.

It is not reasonable to define 'recipe' in a perverse way, excluding the list of ingredients, in order to escape the interdiction in the BTA to disclose the said list. This rule (§1.337(a) and §1.328 in so far as they refer to 'ingredients' and 'recipe') is *ultra vires* the BTA.

7.2. Ingredients are not required on all food products

The act referred to in the quote from page 25195 above is presumably the Food, Drug and Cosmetic Act, which requires labelling on a range of products. However, current US rules do not require labelling of ingredients for alcoholic beverages, for example. Therefore the statement by FDA is misleading since there are currently no labelling requirements for a range of products but the new rules will require the recipe of these products to be available to FDA.

FDA should keep to the original intentions of wording of the BTA and not require ingredients to be listed.

7.3. Risk of disclosure of commercially sensitive information

The FDA bases its definition of a 'recipe' as the notification of the actual quantity of each ingredient used in the manufacture of a product and, accordingly, assumes that it is not requesting 'recipe' information because it does not require to know the relative individual quantities. However, EU industry is very concerned by the risk of disclosure of sensitive commercial information ("trade secrets") through having to provide a 'one-up' source nontransporter record for each of the ingredients in a product.

FDA must clarify that such sensitive information will not be, nor required to be, disclosed to any other person or company.

7.4. "Reasonably available" unclear

Part IV, proposed § 1.337 (a) would require disclosure of information reasonably available to identify the specific source of each ingredient that was used to make every lot of finished product. Further clarification is needed relating what is the meaning and extent of "*reasonably available*".

7.5. Processing aids and transformed additives

FDA must clarify whether processing aids and additives that are transformed (i.e. they are not present in the final product) are also covered by the term "ingredients". With many foods and beverages, the production process can substantially change the character and chemical composition of the raw materials and some of them may even be absent from the final product.

7.6. Ingredient requirement excessively burdensome

EU spirit drink producers have underlined the extreme difficulties of listing all ingredients and processing aids. For example, in the case of blended scotch whisky, which may contain as many as 50 individual Scotch malt and Scotch grain whiskies, listing each would be extremely burdensome and would reveal brand-sensitive information.

Furthermore, EU industry sources are concerned that an importer will have to make available records on the life history of the goods from production to arrival in the US including transport records, before putting the product on the market. This is likely to affect the cost of the product very seriously and even, in certain cases, to prevent its access to the American market.

8. TRANSPORTATION

The U.S. importer has to record and retain the name, address, and phone number of the transporter who transports the food to the U.S.

In some international shipments, there are several transporters. Depending on how the freight is booked, the U.S. importer doesn't always have access to this information. FDA should clarify that only the transporter who delivered the good to US shores need be identified.

9. SAMPLES

The record-keeping requirement should not apply to commercial samples. New exporters cannot be expected to engage in record-keeping requirement concerning exports prior to testing marketing opportunities.

10. COMPLIANCE PERIOD

A longer time-scale for compliance with the proposed regulation should be permitted for companies with 10-500 employees and for those with up to 10 employees.

11. COSTS

Although current records (*e.g*. bills of lading, purchase orders or invoices) can be used in part to meet requirements, modifications are required; thus new costs will be involved. FDA claims that the learning curve for the registration and record keeping components of these regulations overlap, reducing implementation costs, however the initial implementation costs and ongoing costs for compliance remain high. FDA estimates that ”learning” costs (interpreting how to adopt the regulations by the company) alone will exceed US $201 million for foreign operations. This is in addition to the FDA estimated costs to redesign records for compliance which is in the range of US $4,000-12,000 per firm (page 25207) with an estimated time commitment industry wide of over 11 million hours. While the FDA-estimated (page 25204) full-cost per hour of roughly $25 for administrative employees is reasonable, the time commitments do not appear to be realistic.

As with the Registration requirements, FDA also predicts that at least 16% of the foreign firms will be driven out of export business by this regulatory burden.

12. RISK ASSESSMENT

A measure having such an effect, in the absence of a specific risk analysis, is difficult to justify in trade law. In these circumstances, the EC suggests providing a risk assessment to qualify the effects of the measure.

13. LANGUAGE PROBLEM

Taking into consideration the level of the information required, it would not always be possible to provide the information in English. Please define the language in which the information should be provided.

(end of comments)