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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/EC[1]. 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;

   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.

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1 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 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.