

4 April 2003

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

Registration of Food Facilities

1. General comments

The European Communities would like to thank the Food and Drug Administration (FDA) for the opportunity to provide comments on the Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 notified under the TBT Agreement as **G/TBT/N/USA/32** and to the SPS Committee under **G/SPS/N/USA/691**.

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/690 - 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. Definition of food

A **better definition of Food** is needed as this would clarify the scope of application of the measure. Currently there are general groups of products and a statement that these proposals apply to all food not under the exclusive responsibility of USDA without defining what that specifically is. Clarification on this basic point is necessary.

4. Justification for registration measure unclear

The notified measure requires foreign facilities that manufacture, process, pack or hold food for human or animal consumption in the United States to register with the FDA by 12 December 2003.

The said measure, laid down in the framework of the Bioterrorism Act, aims at monitoring closely and instantaneously any bioterrorist action in the food sector by enabling, through an enhanced traceability of the contaminated product, to trace back the origin of such action.

The European Communities have serious concerns over the requirement for any facility involved in trade with the United States to be registered. It is also very difficult to conclude that such a measure, implying a significant administrative burden and, hence hindering trade, might be effective in meeting its aims.

5. Practical difficulties with registration as proposed

Several problems arise in relation to the registration requirement for each foreign facility which holds food for export to the US:

- In many sectors it is common practice for a food producer to sell through traders before the product is exported to the US. This is particularly the case in sectors characterised by a highly developed commercial infrastructure, such as the fruit and vegetable sector and the wine sector (registration may be less burdensome for vertically-integrated large corporations which have agents in the US). In such cases, the producer or packer may not even know that his/her product is being exported by a subsequent trader in the chain to the US. In the wine industry, exporters frequently buy wines from small private wineries. FDA underestimates costs faced by these producers. FDA should clarify that only those facilities that hold products for direct export to the US need to register.
- For reasons of commercial confidentiality, traders may not wish to reveal the identity of the packer or producer to the importer. In these cases, the BTA rules could seriously interfere with commercial confidentiality.

Under the text of the proposed rule, it is not absolutely clear to whom the requirement to register applies. The requirement should only apply to the last holder of the goods and not to entities further down in the chain (packing stations; warehouse facilities; transporters). It is not feasible to propose that the whole supply chain will be able to

have a contract with a US agent. This may not be difficult for large-scale operators, but impossible for smaller entities.

Difficulties will be encountered at “collection points” (e.g. a distribution facility of a company or an auction), which receive products from a very large number of suppliers. Shipments from these “collection points” are generally composed of an assortment of products from various suppliers. If a company (exporter, packing station) receives products of such a “collection point” (which means receiving products from various production facilities), only the last holder of the goods (exporter, shipper, distribution centre) should be required to register.

It is also not clear whether facilities which export solely to their own subsidiaries in the US must also register.

In many cases, foreign (i.e. non-US) companies send finished or semi-finished goods or even raw materials only to their own subsidiaries in the US, where these products undergo a more than minimal further processing. The US subsidiary is therefore ultimately responsible for bringing these products into the food chain in the US. Hence, their foreign parent company should not have to register with the FDA.

In some cases, the foreign facility only packs raw materials previously bought (some on international markets) in order to send them to its US subsidiary for final processing. Under the proposed provision, not only this facility, but also all of its suppliers would have to register with the FDA. Again, this should not be necessary as the US subsidiary’s registration should suffice. Also, the consequences of a failure to register for one of the suppliers, i.e. a product detention at the port of entry, would possibly be borne by the foreign facility sending the packed products. Thus the sending facility would have to make sure that all of its suppliers are registered with the FDA. This would be an extreme administrative burden as some of these suppliers may be located in another third country, and may not be held responsible for not registering under the respective legal systems of the countries in question.

The measure regarding registration to the FDA of any facility exporting foodstuffs or animal feed to the United States proves quite burdensome for small and medium-sized enterprises (SMEs), which produce and pack directly on the spot of production (olive oil, wine, cheese, products registered as protected designations of origin or protected geographical indications). Such producers are unable to determine the effective final destination of their products when selling their production to wholesalers/operators. In practice, since small exporters and/or SMEs will be most affected by such measure, the European Communities ask the US authorities to examine, for this category of exporters, whether it would be sufficient only to supply the relevant commercial documents.

6. Do trans-shippers have to be registered ?

Concerning product in trans-shipment through the US, it is not clear if facilities involved in the production of these products should also be registered.

7. Duplication of information supplied to other US departments

The US has already decided to exempt from registration facilities that produce products regulated by USDA on the basis that the necessary information is supplied to the US authorities. It must be noted that the information supplied to USDA is not in the same format as that being proposed for submission to the FDA.

The same principle should be extended to information supplied to the USA in the framework of the EC/US Veterinary Agreement¹ and to other US departments, such as US Customs and Tax and Trade Bureau (TTB):

- In the case of spirit importers, a large amount of information is already supplied to TTB;
- In the case of wines, TTB receives EC documentation for all shipments detailing the origin and provenance of the wine.

The duplication of information supply should be addressed in terms of communication between US departments themselves, before passing the burden of double notification to trade. A failure to address duplication of information cannot be described as the less trade-restrictive measure.

FDA may argue that the BTA requires the information to be supplied expressly to FDA and that information to US Customs does not achieve this objective. However, this can easily be addressed by widening the destination of existing information declarations to embrace FDA. Thus data can be supplied “to US Customs and FDA” or “to TTB and FDA”.

8. Overlap with importers’ licence (alcoholic beverages)

Foreign producers can only import alcoholic beverages through an entity that holds the Federal Basic Importer’s Permit. Moreover, the importer is required to produce letters from the foreign supplier about the product as part of the application process. The US should require TTB to share this information with FDA before imposing this duplicative burden to suppliers. Requirements for the unnecessary submission of duplicative information is incompatible with the obligation to adopt the less trade-restrictive measure.

9. Samples

The registration requirements should not apply to commercial samples. New exporters cannot be expected to engage an agent and register exports prior to testing marketing opportunities.

¹ 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

10. Registration period

The registration of facilities will place an enormous burden on FDA and in particular on its computer systems. It will be essential to ensure that businesses are not affected by delays in processing.

The proposed rule allows for paper registration. It will not be possible to apply until after the Final Rule is published, i.e., 12 October 2003 and must be completed by 12 December 2003.

What happens to correctly completed applications made on e.g. 13 October but not responded to by 12 December? FDA has stated that it may take months to respond to applications in writing and therefore mandatory deadlines may not be met.

Moreover, registration will take place at the end of the year, which is a peak supply period for example for the alcoholic beverage industry. Thus, any significant delay in the registration process could impact adversely on many producers.

In order to get the system operational step-by-step and not disrupt trade flows, a period of exemption from prosecution should be foreseen for operators who do not register correctly (or not at all) in time. A longer lead-in period is needed before registration becomes obligatory for all trades to the US.

11. Cost and discriminatory trade impact

FDA has identified that a disproportionate cost of compliance with the registration measure falls on foreign suppliers (Table 42, "Total cost of options..."). The costs are in the order of 30 times greater for foreign facilities than for US facilities.

Furthermore, FDA acknowledges that as a result of the registration measure, up to 16% of exporters to the US (those who export fewer than 10 trades a year) will cease trading to the US (section 9, paragraph b). FDA recognises that for these small exporters, the 'trade distorting impact' will be total. Despite this, there is no analysis to show that there is a particular or increased risk of bioterrorist threat on the product of small companies, nor is there any analysis of the level of impact. Indeed the only comment by FDA is that American consumers will suffer since they will no longer have access to certain foreign niche products, the implication being that the US consumer will substitute a US product. A measure having such a discriminatory effect, in the absence of a specific risk analysis, is difficult to justify in trade law. In these circumstances, the EC suggests that the onus is on the US authorities to devise a system which enables trade to proceed. Various options can be considered, such as a *de minimis* exception from registration and/or allowance of *post-hoc* registration. Waiver of the requirement to engage a US agent is also important for this type of enterprise.

12. Requirement for an Agent

Clarification within the text of the obligation to have an established agent in the United States is needed. As the text stands now, it does not seem compulsory.

However, FDA has stated that any exporting facility is bound to have such an agent established in the United States. The European Communities consider that such an obligation would create a burdensome expense, in particular for small and medium-sized enterprises. Moreover, if the registration is operated through such an agent, clear indication as to the extent of legal liability of the said agent should be stipulated in the text.

The requirement for a US-based agent presents several difficulties:

- FDA is wrong to assume that importers or business partners will act as agents with their foreign partners, except in the case of multinational companies working through their subsidiaries or parent companies. Many business relations are not “one-to-one”: foreign companies frequently deal with different customers and most US importers will import from different suppliers.
- Designation of only one agent may not correspond to business practice, as a producer can operate with an importer for a specific product, and another importer for another product or brand, or two different importers, each of them acting in a specified geographical area.
- The functions of the agents and their level of exposure to potential liability are not clear or understood. The implication that the agent will bear or share responsibility if a terrorist incident occurs is outside normal commercial arrangements.

The requirement to have an agent in the US for the purposes of registration will impose difficulties and burdens for enterprises which have to be registered. US individuals and companies who are currently offering their services as agents appear to be offering no more than a US postal address in exchange for a fee. They are likely to have no relations with the foreign company other than being cited in the registration form. It is difficult to ascertain any added value to FDA of these “paper agents”.

The requirement for an agent may impede trade, interfere with private commercial relations, while at the same time offer no apparent increase in security. No justification is advanced explaining why a US-based agent is required, nor why it is inadequate for facilities to register directly with FDA without the need to engage a US-based agent.

The US should examine alternatives or simpler procedures to the agency requirement as currently proposed.

A “US agent” is defined as “ a person residing or maintaining a place of business in the US whom a foreign facility designates as its agent”.

However, FDA has stated that it is thinking of expanding this definition to include some kind of legal responsibility. Traders will not be able to designate an agent until agents know what their function/responsibilities will be. This will only be known on 13 October 2003, which allows only 2 months for all registered traders to designate an agent and any formalities required under the Final Rule. This is not a reasonable period as required under WTO rules and strengthens the case that agents should not be obligatory.

The proposal to only require the final facility to register would also help avoid the associated problem with the current proposal that all registered premises need an agent in the US. Do 1.8 million wine producers need to pay \$1,200 per year for an agent? This price may prove to be too high and effectively exclude a large number of small producers from the possibility of being eligible to export to the US.

13. Cost of an agent

According to FDA analysis the costs are \$1,200 /year, but EU industry sources say that the costs are underestimated by a factor of 5 to 10.

There should be a review clause built into the Final Rule to monitor the consequences of having to designate agents. This review should be based on an assessment of whether the system is working as predicted and on whether the average costs of agents being borne by foreign exporters are justifiable.

The problems of cost and necessity of an agent are also significant.

14. Review clause

The European Communities would like to request FDA to include in the final rule 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.

15. Fishery products

Exports of fishery products to the US already require a health certificate under FDA rules and registration of establishments is also required. The question arises whether it would not be more prudent for the US authorities to build on the existing requirements for the fisheries products sector, in the effort to prevent intentional adulteration of food. The new rules as currently drafted would add significantly to the administrative burden on exporters, most of which are SMEs.

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.