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Dockets Management Branch (HFA-305)
Food and Drug Administration
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USA

Bioterrorism Act - Proposed Regulations on the Administrative Detention of Food for Human or Animal Consumption (Section 303) and on the Establishment and Maintenance of Records (Section 306) – Comments by the Swiss Government

Dear Sir or Madam

With reference to the WTO notifications G/SPS/N/USA/703, G/SPS/N/USA/704 and to the publication of the proposed rules on Sections 303 and 306 of the Bioterrorism Act Switzerland would like to seize the opportunity to submit comments to the competent US authorities. The present remarks complement the Swiss preliminary comments (dated August 30, 2002) as well as the Swiss comments to the proposed provisions on Sections 305 and 307 (dated April 04, 2003) of the Public Health Security and Bioterrorism Preparedness and Response Act.

General Comments

Switzerland comprehends the U.S. concerns about possible bioterrorist threats and thus understands the U.S. objective in formulating a strategy to enhance the security so as to protect its citizens from the threat of bioterrorism or related emergencies. We are, however, concerned that the proposed U.S. measures, including "establishment and maintenance of records" would considerably impede international trade in food while not significantly contributing to the level of protection targeted by the U.S.

Switzerland agrees with the U.S. that a potential strike on the food supply, though having a very low probability, could trigger very high costs. It is thus understandable that the U.S. government desires to dispose of effective tools with a view to deterring a possible outbreak and to limiting the consequences of such an outbreak. However, Switzerland is not convinced that the proposed measures in general and the prior notice requirement

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Specific Comments - Section 303 (Administrative Detention)

§ 1.337 Definitions

The definition of food is in our view too broad for the purposes of the Bioterrorism Act. In particular the inclusion of feed and pet food seems to be excessive. We therefore request FDA to limit the scope of the proposed regulations to food and food products which are intended for direct human consumption without further processing.

§ 1.378 What criteria does FDA use to order a detention?

This paragraph indicates that an officer or qualified employee of FDA may order the detention of any article of food if he has credible evidence or information indicating that the article presents a threat of serious adverse health consequences. However we are unable to find satisfactory explanations on the criteria for the determination on whether information or evidence is credible. It is being outlined that the decision on whether a piece of information is credible will be made on a "case-by-case basis". While we understand the practicability of this approach, we would be most interested in the factors considered within the decision process. There is little information on this issue (reference is made to a non-exhaustive list of factors such as reliability, reasonableness, the totality of the facts and circumstances) included in the draft provisions. As long as the factors on which a decision process is based are not known, there is no possibility to assess and evaluate the legitimacy of the decision. Thus we consider the rule contrary to the fundamental principle of legal certainty.

Switzerland, therefore, urges FDA to adequately address the issue by publishing further guidance on how the decision must be taken (e.g. name all sources of information that may be considered "reliable", describe the requirements with respect to accuracy of the information etc.).

§ 1.379 How long may FDA detain an article of food?

It is indicated that FDA may detain an article of food for a "reasonable period" of time. This period may not exceed 20 days. However there is no other indication on what the criteria are to determine the "reasonableness" of the detention period. How does FDA ensure that the detention periods ordered will not be standardized on the maximum period?

§ 1.381 May a detained article of food be delivered to another entity or transferred to another location?

Does FDA ensure fast procedures with respect to requests for the limited conditional release of the detained article?

§ 1.380 Where and under what conditions must the detained article of food be held?

This paragraph provides FDA with the competence to direct articles of food be moved to a secure facility and, if necessary, be moved from refrigerated storage to freezer (§ 1.381). However, such an action is usually not neutral for the quality and integrity of the food, given that frozen food may then no more be marketed as "fresh" food. In other words, this action will change the intrinsic nature of the food. Thus, such actions are likely to generate additional costs or depreciate the value of the articles of food. In addition, a detention of "perishable food" will shorten their shelf live period and, consequently, impair the future ability to distribute or market them when the detention order is terminated.

Switzerland is of the opinion that FDA must foresee compensation for any consequential losses in value that such FDA action generates.

§ 1.393 What information must FDA include in the detention order?

Due to reasons of national security interests FDA may refrain from disclosing information on the reasons why a shipment has been detained. In our view it is a basic right of the defendant to obtain information on the rationale for the detention. How else could in an appeal process the defendant put forward comprehensive counter-evidence if the evidence or credible information on which the detention order is based, is unknown?

§ 1.405 (f)

Proposed § 1.405 (f) states that confirmation of a detention order by the presiding officer is considered a final agency action for purposes of section 702 of title 5, the United States Code (5 U.S.C. 702). Does this mean that there is no possibility to further appeal a decision on the detention?

Specific Comments - Section 306 (Documentation Requirement)

Introductory remarks

FDA recognizes that the system to facilitate recordkeeping would involve significant financial costs with annual effect on the economy estimated of about US\$ 100 million. Thus, it is highly questionable that record maintenance is no more trade-restrictive than necessary to meet the objectives of the Bioterrorism Act as stated in the proposed rulemaking

In addition, the proposed rulemaking indicates that to understand the possible costs of an intentional attack on the food supply, FDA examined five outbreaks resulting from accidental and deliberate contamination, and from domestic and imported foods. However, the described examples of foodborne outbreaks appear to have no relation with deliberate bioterrorist attacks. Thus, FDA should affirmatively state its intention to limit its new authority of Section 306 to action in the context of deliberate contaminations (bioterrorist threats) only.

In its explanations FDA invites comments on whether final rules should include additional provisions, such as a model form that can be used to record all the required information. Switzerland indeed believes that such a model form could be helpful to those who have to comply with the documentation requirement. As FDA is willing to accept electronic record-keeping, Switzerland would appreciate if FDA could develop and provide respective freeware (download from the FDA web-site or possibility to order a CD) well in advance of the entry into force of the provisions.

§ 1.326 Who is subject to the regulations

FDA requests comments on whether the level of risk to human and animal health from potential contamination of outer packaging is high enough to warrant inclusion of outer packaging in the final regulation. Switzerland agrees with FDA on the conclusion that the risk to human and animal health from contamination of outer food packaging is relatively small compared to the risk of the immediate packaging that comes in direct contact with the food. We are, therefore, of the view that the inclusion of outer packaging material in the scope of the regulations would be disproportionate and therefore request to exempt outer packaging from the record-keeping requirement.

Within the section that analyses the economic costs of additional record-keeping (FR, p. 25208) the sources do not distinguish between facilities that produce packaging for food and packaging for other products. We would like to emphasise that there are a number of facilities that produce packaging for

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non-food products only. These facilities do not fall within the scope of the Bioterrorism Act and must thus be exempt from the regulations

§ 1.328 Definitions

The proposed definition of “nontransporter” reads as follows: “*Nontransporter means a person who owns food or who holds, processes, packs...*” (emphasis added). The same reference to a “person” is included in the definitions of “nontransporter immediate previous source” and “nontransporter immediate subsequent recipient”. We assume that the proposed rules apply rather to firms and enterprises (and other legal entities) than to “physical persons”. Any other solution would in our view neither be appropriate nor practicable.

§ 1.330 Can existing records satisfy the requirements of this subpart?

This proposed paragraph indicates that the regulations of section 306 do not require duplication of existing records if those records contain all of the information required.

With respect to acceptance of existing records we would like to note that the concept of “equivalence” included in the SPS Agreement does not require “identity” of measures but does recognize that measures different from those proposed can be considered “equivalent” if the importing member’s appropriate level of sanitary protection can be achieved. In conducting a determination of equivalence not only the record keeping measures must be taken into account but also the other relevant measures within the food safety system.

What is the strategy of the U.S. authorities with a view to accepting as “equivalent” other foreign food safety systems? What is the appropriate level of sanitary protection invoked by the U.S. (necessary basis to conduct a determination of equivalence)?

§ 1.337 What information is required and

§ 1.351 Requirements to Establish and Maintain Records to Trace the Transportation of all Food

The proposed rules require records on the immediate previous source (nontransporter) as well as on the transporter who has delivered the food. While we understand the concern that tampering with food may occur during transportation, Switzerland is of the view that the inclusion of the transport sector is not proportional to the risk and impractical. We thus request FDA to limit the record-keeping requirement to food producing / processing establishments.

§ 1.361 What are the record availability requirements?

According to Swiss penal law, government acts, such as enforcement of access to documentation, performed by foreign government agencies, are prohibited¹. Government Acts may be performed by Swiss authorities only. Therefore, if FDA requests access to records kept by a Swiss enterprise it would have to seek administrative or judicial assistance by Swiss authorities. The procedures with a view to such cooperation would need to be established before the entry into force of the final provisions.

Notwithstanding the lacking competence of U.S. authorities to require Swiss enterprises to provide access to documentation, the proposed rules require that documents must be available for inspection within 4 hours (or 8 hours respectively) of a FDA request. While these response periods may be workable for cases within the U.S. we do not believe, that the same rules may apply for foreign enterprises underlying the documentation requirement. What are the procedures proposed by FDA to implement the respective provision on territories outside the U.S. jurisdiction?

§ 1.362 What records are excluded?

Section 306 imposes that the records would have to identify the immediate non-transporter previous source, whether foreign or domestic, of all foods received, including the name of the firm and the responsible individual. Although names of firms supplying food may not be considered as confidential data by FDA, such information might conflict with foreign confidentiality rules of law. Thus, it should be also ensured that Section 306 prevents FDA from disclosing to the public or to other agencies information that FDA is authorized to receive.

We appreciate that the proposal excludes recipes and other sensitive data from the record availability requirement and would like to emphasise the importance of this provision. It must be noted that FDA does not have the right to quantitative data, as this data would reflect recipes

¹ Art 271 Actes exécutés sans droit pour un Etat étranger

1 Celui qui, sans y être autorisé, aura procédé sur le territoire suisse pour un Etat étranger à des actes qui relèvent des pouvoirs publics, celui qui aura procédé à de tels actes pour un parti étranger ou une autre organisation de l'étranger, celui qui aura favorisé de tels actes, sera puni de l'emprisonnement et, dans les cas graves de la réclusion

2 Celui qui, en usant de violence, ruse ou menace, aura entraîné une personne à l'étranger pour la livrer à une autorité, à un parti ou à une autre organisation de l'étranger, ou pour mettre sa vie ou son intégrité corporelle en danger sera puni de la réclusion

3 Celui qui aura préparé un tel enlèvement sera puni de la réclusion ou de l'emprisonnement

Art 273 Service de renseignements économiques

Celui qui aura cherché à découvrir un secret de fabrication ou d'affaires pour le rendre accessible à un organisme officiel ou privé étranger, ou à une entreprise privée étrangère, ou à leurs agents celui qui aura rendu accessible un secret de fabrication ou d'affaires à un organisme officiel ou privé étranger, ou à une entreprise privée étrangère, ou à leurs agents, sera puni de l'emprisonnement ou dans les cas graves de la réclusion. Le juge pourra en outre prononcer l'amende

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§ 1.368 What are the compliance dates for this subpart

According to the proposed rules the regulations shall be effective 6 months after the date of publication of the final rule in the Federal Register (with exceptions for small and very small businesses). Taking into account the necessary operational adjustments of the production process (establishment and implementation of documentation system) we consider the transition period to be too short. Although we respect that establishment of compliance with the proposed regulation may be a special challenge to small and very small businesses we would like to note that the food production process and thus the establishment of a detailed record-keeping system is very complex. A minimum transition period of 1 year should thus be granted to all those affected by the rule, irrelevant of the size of the business.

Additionally, Switzerland would like to express its dissent on the implementation of the final rules without prior agreement between the U.S. authorities and their counterparts in the exporting countries on their cooperation with respect to access to records, which are not under U.S. jurisdiction

We thank you for taking into account these concerns while drafting the final provisions and look forward to a written response to the questions raised. As these comments are in response to WTO notifications as well as to the publication in the U.S. federal register, Switzerland will provide the USTR, U.S. Permanent Mission to the WTO, with a copy of our comments. We furthermore reserve the right of discussing this issue further in the respective WTO fora.

Sincerely yours,

State Secretariat for Economic Affairs

A handwritten signature in black ink, appearing to read 'Oscar Zosso', is written over a horizontal line. The signature is fluid and cursive.

Oscar Zosso
Ambassador

copy. - USTR, Permanent Mission of the United States to the WTO
 - U.S. Embassy in Bern
 - Swiss Embassy in Washington

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