



MINISTRY OF TRADE

THE SOCIALIST REPUBLIC OF VIETNAM

Hanoi, 26 June 2003

Comments by the Ministry of Trade of the Socialist Republic of Vietnam on Title III of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PL 107-188)

Through the American Embassy in Vietnam and the web page of the US Food and Drug Administration (FDA) we have learned that FDA will issue regulations on the implementation of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PL 107-188), which was signed by the US President on June 12, 2002.

Since the new regulations may have a great impact on the international trade of food as well as the exports of food products from Vietnam to the United States, it is our Ministry's responsibility to learn the draft regulations thoroughly and provide the comments on them for FDA's consideration before publishing the proposed regulations.

Subtitle A- Protection of Food Supply

Sec. 305 Registration of Food Facility

Part 1- General Enforcement Regulations

Sec. 1.227 What definitions apply to this subpart?

FDA's definition of foreign facility as a facility other than a domestic facility that manufactures/processes, packs or holds food for consumption in the United States is too inclusive. We, therefore, suggest that only foreign manufacturers and exporters be subject to the registration requirement, and then these manufacturers and exporters must keep the records of their partners such as packing facilities and holding facilities.

Sec. 306 Maintenance and Inspection of Records for Foods

Part 1- General Enforcement Regulations

Sec. 1361 What are the record availability requirements?

According to this Sec., the records and other information must be made available within 4 hours of a request if the request is made between 8 a.m. and 6 p.m., Monday

through Friday, or within 8 hours of a request if made at any other time. While we believe that these requirements are applied exclusively for the US domestic facilities and do not cause any problem, we would like to ask FDA to add the availability requirements in respect to the foreign facilities. Since the foreign government acts on Vietnamese territory constitute a violation of sovereignty and, therefore, FDA's access to records of Vietnamese facilities would require the assistance by Vietnamese authorities.

Sec. 307 Prior Notice of Imported Food Shipments

Part 1- General Enforcement Regulations

Sec. 1288 What information must be submitted in the prior notice?

Since the food products are usually made with raw materials from various growers, we suggest that the growers' information not be included in the prior notice as a mandatory requirement. Instead, we propose that the growers' information be submitted on an optional basis.

Concerning the practical implementation of the prior notice requirement, we are afraid that the procedures would create unnecessary delays of the importation of food and, therefore, greatly affect importers as well as exporters.

Sec. 303 Administrative Detention

Since the exporter of food products is the side to be affected most by the detention order of its products, we suggest that FDA should immediately inform of the detention order of the products to the exporters through an appropriate system.

We suggest that FDA supplement to the draft regulation the provision that enough compensation for the detention should be paid when the detention is found unjust.

The Ministry of Trade of Vietnam would like to thank FDA for giving opportunity to giving comments on FDA's proposed regulations on the implementation of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PL 107-188), and would like to ask FDA to give due consideration to its comments.

Yours sincerely,



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