

KEDUTAAN BESAR REPUBLIK INDONESIA
EMBASSY OF THE REPUBLIC OF INDONESIA
WASHINGTON, D.C. 20036



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Washington, D.C., April 3, 2003

BY FACSIMILE

Mr. Stuart Shapiro
FDA Desk Officer
Office of Information and Regulatory Affairs
Office of Management and Budget
New Executive Office Building
725 17th St., N.W.,
Room # 10235
Washington, D.C., 20503

BY FIRST CLASS MAIL

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852
ATTN: Docket No. 02N-0276 & Docket No. 02N-0278

**Re: Additional Comments on the Proposed Rules for Section 305 and Section 307
of the Public Health Security and Bioterrorism Preparedness and Response
Act of 2002**

I would like to take this opportunity to forward to you additional comments on the proposed rules of Section 305 (Registration of Food Facilities) and Section 307 (Prior Notice of Imported Food Shipments) under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Act). These comments are additional to the comments put forward by the Embassy of the Republic of Indonesia to your office on April 1st, 2003

Proposed Rule of Section 305 (Docket No. 02N-0276)

- FDA is proposing to define a "facility" as "any establishment, structure, or structures under one management at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States." In this regard, Indonesia requests that in

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addition to extending the definition to include several contiguous structures at one general physical location, such a definition should treat as a single facility any "integrated facility" consisting of two or more buildings or structures at one general physical location that perform a combination of two or more activities of manufacturing/processing, packing and holding.

Proposed Rule of Section 307 (Docket No. 02N-0278)

- Indonesia is aware that provisions to be developed under Section 307 of the Act are for the U.S. importers to comply by providing prior notice to FDA of imported food shipments. While pieces of information and data elements to be collected are still debatable, Indonesia is concerned on how the U.S. Administration could better integrate the prior notice requirements under Section 307 with other regulations being proposed or implemented to secure the entry of imported goods to the U.S. It is Indonesia's views that while they target different entities, the prior notice requirements of Section 307 and other U.S. regulations intended to ensure the safety and security of importation of goods to the U.S. are designed for the same basic reason. In this regard, various Ministries in Indonesia are still studying the Container Security Initiative (CSI) program and related regulations administered by the U.S. Custom Service, and the introduction of prior notice requirement under Section 307 of the Act at this point may only add to the burdens of trying to comply with U.S. regulations. It is in the best interest of U.S. importers as well as Indonesian exporters to see that the U.S. could meet the need for securing imported food articles while at the same time does not discourage U.S. importers and Indonesian exporters to expand their business.

I further have the honor to forward for your consideration a letter from Indonesia's Minister of Industry and Trade to the United States Trade Representative outlining Indonesia's views on the implementing regulations of the Act.

Thank you for your kind attention and consideration.

Respectfully submitted,



IMAN PAMBAGYO
Industry and Trade Attache

//Attachment



Minister of Industry and Trade of the Republic of Indonesia

Jakarta, 31 March 2003

Our Ref. : 258/MPP/III/2003

**H.E. Ambassador Robert B. Zoellick
U.S. Trade Representative
Executive Office of the President
600, 17th Street, N.W.
Washington D.C. 20508**

**Re : Comment on Public Health Security and Bio Terrorism Preparedness
Response Act 2002 : Implementing Legislation.**

Dear Ambassador Zoellick,

On behalf of the Government of Indonesia, I would like to draw your attention to one particular issue of importance to Indonesia as well as to the U.S. As you aware, the Food and Drug Administration (FDA) is developing implementing regulations of the Public Health Security and Bioterrorism Preparedness and Response Act 2002 (the Act) enacted by President George W. Bush in June 2002. The FDA is seeking public comment on the proposed rules for Section 305 (Registration of Food Facilities) and Section 307 (Prior Notice of Imported Food Shipment) of the Act. The GOI fully understands the importance of the Act to the US for ensuring the security of food supplies. The U.S. Embassy in Jakarta has provided background information on the issues to GOI, together with an invitation to submit written comment to the US-FDA.

In my capacity as Minister of Industry and Trade, I am pleased to inform you that GOI will submit detailed comments to the FDA on April 4, 2003, especially pertaining to the impact of Section 305. However, in the spirit of maintaining our respective commitments to open and fair global trade while addressing the need for a more secure world food supply, I would like to share with you some initial views from the Indonesian perspective.

Being one of the victims of recent terrorist attacks, we believe you would agree that Indonesia fully recognizes the need to secure food supply chains. It is also in our own best interests to ensure that the implementation of the Act, particularly but not limited to Section 305, does not nullify the benefits extended under the WTO Agreements. Any dilution of WTO benefits would adversely impact not only food exporters in Indonesia but also in other countries. It is therefore important for the U.S. to ensure that the Act will not create unnecessary barriers to trade at

the same time as we continue to work together to advance the Doha Development Agenda.

As you may appreciate, the food industry in Indonesia employs some millions of workers, extending throughout the production and distribution chains. In particular, the livelihood of the Indonesian rural community depends on cultivation, harvesting and marketing of foodstuffs. In this respect, while a reasonably high percentage of Indonesian food production is consumed directly, a significant proportion is exported to countries including the U.S. We believe full implementation of the Act, especially the registration requirements included in Section 305, and the deadline for registration for food additives, will create difficulties for many countries such as Indonesia in fully complying with the required procedures.

Should implementation of the Act impact negatively on the flow of food exports from Indonesia to the U.S., we anticipate that labor retrenchments will be inevitable. This in turn will increase already high poverty in both urban and rural areas and may contribute to social unrest and extremism.

In this regard, I would like to seek your assurance that GOI can rely upon your continuing cooperation and communication to better address issues arising from the implementation of the Act for the benefit of our two countries.

Thank you for your kind attention to this matter,

Sincerely yours,



RINI M. SUMARNO SOEWANDI
Minister of Industry and Trade

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1. H.E. U.S. Ambassador to Indonesia
2. U.S. Commissioner Food and Drug