

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



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THE AMBASSADOR

Washington, D.C., July 7, 2003

BY FACSIMILE

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

Fax # 202 395-6974

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-0275 & Docket No. 02N-0277

Re: Comments on the Proposed Rules for Section 303 and Section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

On behalf of the Government of the Republic of Indonesia, I have the honor to submit the comments from Indonesian Ministry of Agriculture on the FDA's notice of proposed rules of Section 303 (Administrative Detention) and Section 306 (Establishment and Maintenance of Records) under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Act) as attached.

02N-0277

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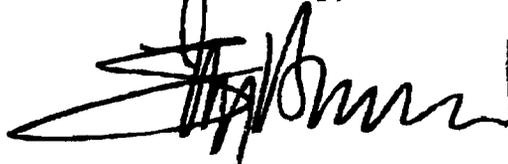
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In addition to the comments from the concerned Ministry, I would also like to draw your kind attention to some particular issues in regard with Section 305 and Section 306 of the Act, as the following:

- It is indicated that small and very small businesses will be given 12 months and 18 months respectively from the date the final regulations under Section 306 are published to fully comply with the regulation. However, the criteria used in Section 306 to determine small and very small businesses is the number of employees, while in other countries, especially the developing ones, other criteria such as the value of investment or total asset value is used to better reflect the factual nature of the business. Therefore, Indonesia would like to ask that the value of investment and value of the assets can be considered as other criteria in determining whether a business meets the definition of a small or very small business in order to be allowed extended time to comply with the regulations.
- It is not really clear how the implementing regulations of Section 303 and Section 306 will address the trans-shipped foods. Relative to trans-shipment through other countries, what will happen when an Indonesian exporter has the food repackaged in other countries and once the food reaches the U.S., authorized personnel at the port of entry orders the detention of the food based on "credible" evidence or information that the food poses a threat of serious adverse health consequences or death? Who should be held responsible? How is the Indonesian exporter expected to keep records of third parties in other countries? Who should bear the financial and administrative burdens of having the shipment delayed at the port of entry? And, equally important, how will the interface between the Container Security Initiative and the Bioterrorism Act work relative to administrative detention (under Section 303) in such a case?
- Indonesia would also like to ask for clarification as to whether all the facilities under one parent company have the file (under Section 305) and keep records (under Section 306)? If a cooperative collects nutmeg from different small growers prior to export to the U.S., do all the growers have to be listed and to keep records?

The Indonesian Government conveys its sincere thank to OMB and FDA for the opportunity to comment on the proposed of Section 303 and Section 306 regulation. It is our sincere wish that Indonesia's comments can be considered favorably in the context of developing free, fair and yet secured trade in food which is mutually benefited both to the U.S. and to Indonesia.

Sincerely,



SOEMADI D.M. BROTODININGRAT
AMBASSADOR

Cc:

The Honorable Mark B. Mc Clellan, M.D. Ph.D.
Commissioner of Food and Drug
560 Fisher Lane, Room #HFA-305
Rockville, MD 20857

//Attachment



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MENTERI PERTANIAN
REPUBLIK INDONESIA

COMMENTS ON THE BIOTERRORISM ACT 2002

The Ministry of Agriculture (MOA) understands the important of the Bioterrorism Act 2002 signed by President G.W. Bush in June 2002. In response to the Act, which will effectively be implemented on December 12, 2003, the MOA has held meetings and dialogs with Indonesia business society/ exporters of farm products and food. In general they committed to follow the regulation. The Act, however, may have serious implication on Indonesian food exports to the United States. The following aspects under Sections 303 and 306 of the Act need to be taken into account.

I. Section 303 (Administrative Detention)

- a. I understand that any article of imported-foods is subject to inspection, examination, or investigation. However there is a need to ensure that this regulation does not create additional cost (e.g., costs for inspection, storage during temporary detention, and to appeal the detention order) to exporters.
- b. The maximum detention periods for perishable and non-perishable foods are 20 and 30 days. These maximum periods should be in accordance with the type of the products to minimize unnecessary additional cost for the exporters.
- c. The written notice of detention should include the basis for detention, handling dispute and resolutions, appeal right and other information required by the exporters.
- d. The criteria of 'credible evidence and information indicating a threat of health or death to humans and animals' should be clearly defined.
- e. In case of suspected products, the FDA or other US appointed parties should assure foreign exporters that the quality of their products will be maintained during detention period.

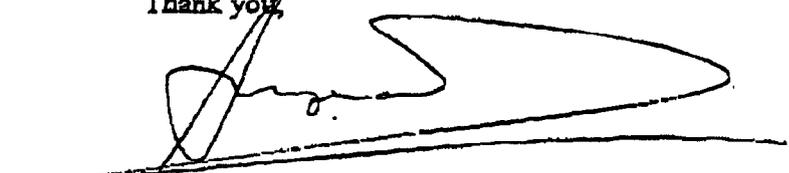
II. Section 306 (Establishment and Maintenance of Records)

- a. The terms of *adulterated and threatened food to humans or animals* need to be clearly defined.
- b. The required time of 4 hours to respond and submit records of foods will be a problem for exporters especially those who have not representatives in the US.

Special treatment is needed to enable small-scale enterprises that do not have any representative in the US.

Finally, I do hope that in the future the trade relation between the US and Indonesia can be strengthened for mutual benefit. Therefore, complicated process that may discourage US traders to import Indonesian farm products or food need to be avoided.

Thank you



Prof. Dr. Bungaran Saragih
Minister of Agriculture, Republic of Indonesia