

FOREIGN SERVICE OF THE PHILIPPINES



Embassy of the Philippines  
**Office of the Agricultural Attaché**  
1600 Massachusetts Avenue, N.W.  
Washington, D.C. 20036  
Tel: (202) 467-9422  
Tel: (202) 467-9423  
Fax: (202) 467-9421

19 September 2002

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Sirs:

In connection with the issuance of the implementing regulations of the Bioterrorism Act of 2002, enclosed are the comments, in two (2) copies, submitted by the Bureau of Animal Industry (BAI) of the Department of Agriculture of the Philippines.

Very truly yours,

A handwritten signature in black ink, appearing to read "Lucio C. Manghinang, Jr.", written over a horizontal line.

LUCIO C. MANGHINANG, JR.  
Assistant Agriculture Attache

Enclosures:

As stated.

02N-0278

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**Comments: Re US Bioterrorism Act**

Inflicts terroristic act thru the use of biological warfare such as Anthrax found in mails and sarin gas/other poisonous substances.

As far as the BAI is concerned, the need to protect and promote the general welfare of its clientele especially on importation and governing the flow of livestock and poultry, animal and each by-products and other services—the production of feeds/feed ingredients, vaccines, pharmaceutical and biologics, a close supervision, monitoring of products/merchandise coming from other countries with trade regulation from the Philippines to be vigilant on inspection (port of entry/embarkation) regulation in the final destination of the products/goods so that biological or other substances that maybe included in the shipment which may cause harmful effects to the end user/consumer must be looked into rigidly.

**Section 303 -**

The time frame for release of food test should be indicated in the proposed Act. For how many months should the food/commodity be detained?. Does USA has developed bio-security and sophisticated device to test and control on dangerous biological agents and toxins including those that present a threat to plant or animal? Did they developed new methods to detect contaminated foods, work with state food safety regulators, and to protect crops and livestock?.

**Section 305-**

The FDA should issue final regulation before registration of food facilities. FDA should not exempt farms, restaurants, other retail food establishments, non-profit food establishments in the registration in which food is prepared and served directly to the consumers for the reason that the people engaging in that business can connive with the terrorist. The USDA must improve linkages with other federal regulatory agencies that share responsibility for food safety and detection of intentional adulteration of foods.

**Section 306-**

It is necessary that the FDA should maintain records of food establishments for future reference in case a problem arises and for monitoring purposes. However, registration should be made after regulations were finalized. Farms and restaurants must be included in the record of FDA. US should increase participation in pulsenet, food borne diseases active surveillance network and other networks to enhance federal, state and local food safety efforts.

**Section 307-**

It must have proper /approved regulations before laws and policies be implemented. In this case, the FDA is enforcing law without basis. However, the necessary data needed by FDA should be accomplished. In the last sentence, that the regulations to be issued by December 2003, and if such regulations are not issued the importers still required to submit notice to FDA no less than eight (8) hours and no more than 5 days until the regulations take effect is clearly imposition of an unclear policy regarding importation.