



July 8, 2003

To the US Food and Drug Administration,

**RE: Establishment and Maintenance of Records (Docket Number 02N-0277)  
Administrative Detention (Docket Number 02N-0275)**

We wish to submit our comments with regard to the regulations which address Section 306, Establishment and Maintenance of Records, as well as Section 303, Administrative Detention, proposed by the Department of Health and Human Services' Food and Drug Administration (FDA) under the [U.S.] Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act).

The Canadian Pork Council recognizes the importance of the Act and its regulations; however, we feel there is still consideration and clarification required before these regulations are finalized and put in place.

Our largest area of concern for both of these regulations deals with live food animals. In the case of the Canadian hog industry, weanlings (2-3 weeks old), feeder hogs (weighing 20 to 25 kg) and 'market' hogs (fully grown) are regularly sent south of the border. There, weanlings and feeder hogs are grown to adult or 'market' size (called 'finishing') and subsequently slaughtered and processed, while already-grown market hogs are sent solely for slaughter and processing.

As the proposed regulation on Establishment and Maintenance of Records has been presented, exempt will be:

"Farms; restaurants; non-profit operations that prepare food for, *or serve food directly to, consumers*; fishing vessels not engaged in processing; and persons regulated exclusively by the U.S. Department of Agriculture under various statutes..."

It has been made clear to stakeholder groups by the USFDA that the purpose of these proposed regulations is two-fold. They will serve to protect Americans and their food supply from perceived threats of bioterrorism, and as well, help to address food safety issues. The records kept by 'transporters' and 'non-transporters' in order to fulfil the requirements of this regulation are expected to allow the USFDA to do a complete and timely trace-back or trace-forward of any questionable food shipments to the U.S.

There has been no clarification from the USFDA whether producers who ship *live food animals* to the U.S. will be required to keep records on their farm operations, as their products will be 'finished' in another country, may have been raised on more than one farm, and may not be

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considered as going directly to the consumer for consumption. We would strongly urge the USFDA to not require farmers shipping live animals to the U.S. to incur the additional cost, time, and work involved in maintaining records, beyond those which are currently being maintained for their operations, solely for the purpose of this regulation. This requirement would heavily impact not only Canadian hog farmers, but all sectors that export live food animals to that country.

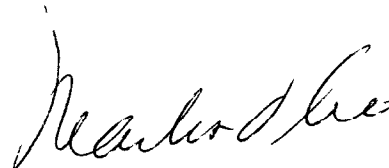
As the proposed regulation for Administrative Detention has been presented,

“The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act or the Act) authorizes FDA to detain an article of food for which there is credible evidence or information indicating such article presents a threat of serious adverse health consequences or death to humans or animals...The detention period cannot exceed 30 days...FDA has issued a proposed rule that includes these expedited procedures for perishable foods as well as procedures describing how FDA will detain an article of food and the process for appealing a detention order...FDA is proposing to define *perishable food* as food that is not heat-treated, not frozen, and not otherwise preserved in a manner so as to prevent the quality of the food from being adversely affected if held longer than 7 days under normal shipping and storage conditions.”

There has been no clarification from the USFDA on how *live food animals* are to be regarded under this regulation. Under the proposed regulation, the issues surrounding what happens in the case of the detention of live food animals urgently needs to be addressed. In the draft regulation, there are currently no specific provisions for live food animals under the definition of ‘perishable food’. Questions regarding which parties would be responsible for feeding, watering, providing adequate housing and medical care to animals during a detention also need to be considered.

The Canadian Pork Council thanks the USFDA for the opportunity to submit its feedback on these proposed regulations, and respectfully requests its incorporation into the final draft. More specifically, we ask the USFDA to provide clarification that farmers with operations raising live food animals are excluded from both of these regulations.

Sincerely,



Martin T. Rice  
Executive Director

cc: Ian Thompson, Agriculture and Agri-Food Canada  
Phil Calvert, Department of Foreign Affairs and International Trade