Animal Nutrition Association of Canada

ANAC

Association de nutrition animale du Canada

December 19, 2003

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

Re: Comments from the Animal Nutrition Association of Canada on the Food and Drug Administration's (FDA) interim final rules under the [U.S.] *Public Health Security and Bioterrorism Preparedness and Response Act of 2002,* as published in the *Federal Register* on October 10, 2003.

1) Prior Notice of Imported Food Shipments - Docket No. 2002N-0278
2) Registration of Food Facilities - Docket No. 2002N-0276

The Animal Nutrition Association of Canada (ANAC) is the national trade association representing livestock and poultry feed manufacturers and suppliers of grains, oilseed meals, micro-ingredients and other commodity and related services to the industry. ANAC members currently represent approximately 90% of the animal nutrition products commercially manufactured in Canada. We are pleased to have the opportunity to convey the concerns, comments and recommendations of member firms engaged in the trade of feed products to the U.S., relating to the interim final rules for prior notice of imported food and registration of food facilities.

To begin, the interim final rules incorporated many of the concerns raised with the proposed rules, and we would like to commend FDA their responsiveness to the submitted comments.

1. Prior Notice of Imported Food Shipments - Docket No. 2002N-0278

Foreign Quality Assurance Samples Destined for Laboratory Analysis:

It is our understanding that the interim final rule requires prior notice for ingredient/feed quality assurance samples that are exported to U.S. laboratories for *in vitro* analysis (e.g. chemical testing for amino acid or vitamin content, heavy metals levels, etc.). The facilities that manufactured these samples, including farms, are required to obtain a Facility Registration Number unless the sample is of "a food in its natural state".

A) Non-food uses: While ANAC agrees with the requirement that samples destined for test marketing purposes are subject to prior notice, we do not agree with the requirement for samples destined for laboratory analysis (QA samples) since QA samples are clearly not destined for consumption. We support this comment with a reference to the FDA document "Guidance for Industry, Prior Notice of Imported Food, Questions and Answers", where the answer to questions #9 and #10 state that articles are only considered to be "food" for prior notice purposes "if any of the persons involved in importing or offering the product for import reasonably believes that the substance is reasonably expected to be directed to a food use". ***ANAC recommends that QA samples that are not directed to a food use be excluded from the requirement to provide prior notice.***

625-325 rue Dalhousie St., Ottawa, ON K1N 7G2 Canada ☎(613) 241-6421 (613) 241-7970 info@anac-anac.ca

If the FDA does not implement the above suggestion in the final rule, we would like to recommend the following:

B) One Container – One Prior Notice: In the interim final rule a prior notice is required for each "article" of food (i.e. the same complete FDA product code, the same package size and the same manufacturer/grower). One shipment of QA samples from a feed mill to a U.S. lab could conceivably contain several different ingredients and feeds from the feed mill, plus QA samples from various farms if they are being handled by the feed mill as a service to their customers. Such a shipment would require multiple prior notices, possibly one prior notice for each sample bag. The typical weight for one ingredient/feed sample is less than a pound. Once the lab analysis is complete the samples may be stored at the lab for a period of time (in the event re-testing is required), but are ultimately destroyed or disposed of as garbage. Samples are typically sent via couriers. Courier companies have increased their fees as a result of this rule, for example one company has increased their standard charge by $5, plus $4 per prior notice with a minimum charge of $12. The requirement to provide prior notice for "each article of food" in a shipment of QA samples is expensive and onerous. ***ANAC recommends that all QA samples in one shipment be included under one prior notice, similar to the allowance for "comingled articles of food"***.

2. Registration of Food Facilities - Docket No. 2002N-0276

U. S. Agents:

During FDA's satellite broadcast on November 4, 2003, FDA officials asked in particular for information on the costs to secure a U.S. agent. ANAC members have been approached by various companies offering their services as U.S. agents, and the current quotes range from $280 to $800 per site.

The Animal Nutrition Association of Canada appreciates the opportunity to share the concerns, comments and recommendations of member firms on the interim final rules. We invite you to contact the undersigned at the Association national office in Ottawa if you require clarification or additional information on any of the comments contained in this submission.

Sincerely,

Christine Mercier, agr.
General Manager
Animal Nutrition Association of Canada
325 Dalhousie, Suite 625
Ottawa, Ontario
K1N 7G2
Tel. (613) 241-6421, fax (613) 241-7970, email: cmercier@anac-anac.ca