



April 2, 2003

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

Re: Comments of the Animal Nutrition Association of Canada on the Food and Drug Administration (FDA) proposed rules under the [U.S.] *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, as published in the *Federal Register* of February 3, 2003.

**Prior Notice of Imported Food Shipments - Docket No. 02N-0278
Registration of Food Facilities - Docket No. 02N-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 proposed regulations for prior notice of imported food and registration of food facilities.

1. Prior Notice of Imported Food Shipments - Docket No. 02N-0278

A) Trade of Canadian feed products to the U.S.:

The majority of trade of Canadian feed products involves cross border shipments to the United States that are delivered primarily by truck. As is the case with many other sectors, feed manufacturing companies employ the services of U.S. Customs brokers to handle U.S. Customs and FDA requirements (i.e. U.S. Customs and FDA entry numbers, etc.) for all shipments at point of border crossing. As many of these companies have been involved in trade of feed products for a number of years, transactions are regular, e.g. daily, weekly, monthly, and consist, for the most part, of the same products. It is our understanding that many Canadian feed exporters have been participating in existing bilateral Customs initiatives for low risk products (e.g. C-TPAT, FAST, SMART Border Plan) that are designed to address the risks associated with bioterrorism.

02N-0278

1

C183

We wish to stress that Canadian feed exporters have made significant investments and efforts to ensure they meet the requirements of U.S. regulatory authorities and the needs of their U.S. customers, and that any delays or disruptions of shipments at the border resulting from redundant paperwork will have serious consequences both for the Canadian exporters and their U.S. customers.

The concerns of Canadian feed exporters arising from the proposed rule can best be illustrated with the following example of procedures (e.g. in the dairy industry) that are typical for most transactions:

- The U.S. customer, i.e. producer, places the order by phone directly with the Canadian feed supplier.
- Most orders are given on short notice, i.e. within 4 to 24 hours before delivery, due primarily to limited bin storage capacity on the farm and the difficulty of predicting, within hours, when the producer will run out of feed. As shortage of feed can result in immediate effects on production, quick and timely delivery of products is very critical to the competitiveness of the U.S. customer.
- Once the feed is manufactured the feed mill must coordinate shipments to maximize truck capacity. To do this, trucks are loaded with shipments that will be delivered to several farms.
- The approximate quantity (within 0.5 to 1 ton) of each load in the truck can be estimated at the time the order is placed at the feed mill by the producer. The exact quantity of feed in the shipment is determined at the time of loading of the truck, which is usually 1-2 hours before the truck reaches the border.
- Time of arrival at the border and time of delivery at the farm is variable and largely dependent on weather conditions, road conditions, road closures, mechanical problems, waiting time at the border, etc.

B) Who submits the Prior Notice:

As demonstrated in the above example, although the U.S. customer, i.e. producer, places the order directly with the feed supplier, the customer has no first hand knowledge of the final contents of the truck containing his, and possibly other customers' orders. (It is our understanding that many producers, e.g. dairy customers, are not equipped with faxes or Internet service and thus are not able to submit the prior notice to FDA). It is the Canadian exporter, and the company's U.S. Customs broker, that can provide the most accurate and timely information on the shipment prior to its arrival at the border. To restrict submission of the notice, as per the current proposal, to the resident U.S. purchaser, importer or a U.S. agent acting on behalf of the U.S. purchaser or importer, will result in additional expenses for the U.S. customer and delays and inaccuracies in the transfer of the information. ***We therefore would like to recommend that the Canadian exporter and/or the exporters U.S. Customs broker be permitted to submit the prior notice.***

C) When the Prior Notice can be submitted:

The minimum time of "noon of the calendar day before the day the shipment will arrive at the U.S. border crossing or at port-of-entry" for submission of the prior notice is not flexible enough and does not take into account the operational/logistical realities of feed transactions. As indicated in the above example, a significant number of transactions occur on short notice, i.e. same day delivery, and given the effect on livestock and poultry production that additional delays in delivery would entail, compliance to the proposed minimum notice time would be very difficult to achieve without serious financial repercussions both for the Canadian exporter and the U.S. customer. To address these situations ***we recommend that a minimum time of 4 hours for submission of prior notice be permitted for transactions that are not logistically possible beyond a same day delivery time frame.***

D) Amendments to Prior Notice:

i) Quantity of shipment: As outlined in the above example, the exact quantity of feed in the shipment can only be determined at time of loading of the truck, which is usually 1-2 hours before the truck reaches the border. As this information would not be available at the time of initial submission of the prior notice, virtually all prior notices would have to indicate an amendment for the quantity in the shipment in order to be compliant with the current proposal. As this will undoubtedly result in increased administrative and data processing costs for FDA and increased risk of delays at the border, ***we recommend that either approximate quantities (e.g. within a 1 ton range of actual weight for bulk shipments) be acceptable in the initial submission of prior notice, or that a quantity amendment not be required.***

ii) Arrival time of shipment: The current proposal requiring that an update to the original prior notice be submitted to FDA up to 2 hours prior to arrival, if a shipment is expected to arrive more than one hour prior or more than 3 hours later than the time initially notified, is too restrictive. As mentioned in the above example, arrival time of the truck at the border is largely dependant on factors such as weather and road conditions, road closures, mechanical problems, rerouting due to limited border crossing points, waiting time at the border, etc. These situations are, for the most part, unpredictable and beyond the control of the exporter. (It should also be noted that when problems occur, information flow between the driver and the exporter is not always immediate, thereby making it more difficult to provide FDA with updates within the proposed time frames). Here again, while it is doubtful the intent is to create more congestion at the border and more delays in processing of the submissions, this will be unavoidable unless the requirements are made more flexible. As such ***we recommend that an approximate time of arrival at the border (e.g. indication of a.m. or p.m.) be acceptable in the original prior notice, and that updates to time of arrival be acceptable up to 2 hours prior to arrival.*** As the border crossing point of the shipment can also be subject to change due to the situations outlined above, we would appreciate clarification on the following points: will the number of border crossing points be limited and will border

crossing points be operational 24 hours a day, i.e. outside of normal business hours?

E) What information must be submitted with the Prior Notice:

As mentioned in section A) of this submission, shipments of Canadian feed products to the U.S. are regular and consistent and Canadian feed exporters are currently required to submit detailed information to U.S. Customs Services and FDA authorities for all shipments at point of border crossing. To avoid complications and inaccuracies **we recommend that FDA consider making the information required in the prior notice as consistent and as compatible as possible with the entry line level of data required by U.S. Customs Service.** We would also like to point out that Customs entry numbers are not available to the exporter until the truck arrives at the border and therefore it is not possible to provide this information in the prior notice, as per the current proposal. As such **we recommend that the Customs entry number not be required to be submitted in the prior notice.**

2. Registration of Food Facilities - Docket No. 02N-0276

A) FDA establishment registration and inspection of Canadian manufacturing facilities that export medicated feeds to the United States:

Canadian feed manufacturers who export medicated feeds to the U.S. are currently subject to an annual registration and facility inspection by the FDA. The information required by the FDA for the facility registration is very detailed and, through the annual inspections, FDA officials acquire first hand knowledge of the manufacturing facilities. In an effort to harmonize information transfer, avoid duplication and streamline FDA activities and resources **we would like to recommend that the FDA consider exempting Canadian feed manufacturing facilities currently subject to annual FDA facility registration and inspection for export of medicated feeds, from registration under the proposed regulations.**

B) Which facilities must be registered:

We would appreciate clarification on a few points relating to exemption criteria for foreign facilities. If a registered Canadian feed mill receives an order from a U.S. customer and, due to exceptional circumstances, the feed cannot be manufactured at the site where the order was placed, but can be manufactured, packaged and shipped from another mill owned and operated by the same company, is the second mill required to be registered? Has the FDA considered how amendments to the prior notice can be made in a timely manner when these exceptional situations occur?

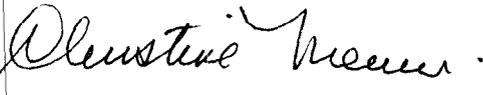
C) Future Amendments for Facility Registration and Prior Notice

Canadian and U.S. authorities already cooperate on a number of unique bilateral Customs initiatives such as C-TPAT, FAST, and SMART Border Plan that focus specifically on food safety, biosecurity and countering bioterrorism and the

effectiveness of these programs has already been established. ***We strongly recommend that FDA ensure appropriate mechanisms are in place to allow more flexibility for facility registration and prior notice requirements for Canadian exporters who participate in these programs.***

The Animal Nutrition Association of Canada appreciates the opportunity to share the concerns, comments and recommendations of member firms on the proposed regulations. 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 issues outlined in this submission and we look forward to receiving clarification on the points raised.

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