



March 3, 2003

Mr Stuart Shapiro
Desk Officer for the Food and Drug Administration
Office of Information and Regulatory Affairs
Office of Management and Budget
New Executive Office Building
725 17th St, NW Room 10235
Washington DC 20503

Re: **Docket No 02N-0278**
Comments to Proposed Prior Notice of Imported Food Rule

Dear Mr Shapiro:

This letter represents the comments of Northland Cranberries, Inc. ("Northland") relating to economics and information collection in response to the proposed rules for the Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

Northland is a vertically integrated grower, handler, processor and marketer of cranberries and value-added cranberry products. Northland sells its own brand of 100% juice cranberry blends and fresh cranberries, as well as *Seneca* brand juice products, through retail supermarkets and other distribution channels nationwide. Northland also co-packs other branded juice products and markets to various industrial customers who manufacture juice products. Northland believes it has been proactive in ensuring our products are safe and secure. We believe that food chain security is only as strong as its weakest link. We also believe in a level playing field for security because issues in other segments of the beverage industry directly affect Northland. Northland purchases both domestic and foreign juice concentrates, from all continents. Our questions and comments are listed by section.

Section 801(m) of the Act states that if adequate notice is not provided, the food shall be refused admission to the USA. In Section III.C.2 of the regulation commentary FDA states it believes 20,000 import notices will be filed each day. If the web based Prior Notice System (PNS) goes down, Northland believes the fax/email/letter backup system will quickly become overloaded and fail. Is FDA willing to shut down all food imports if the PNS goes down? This is a crucial question to Northland, who is currently importing juice concentrates on a "just in time" basis. If there is a realistic chance that our foreign supply will be disrupted, we would need to increase our inventory significantly to prevent

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disruptions of sales and loss of customers. Adding a month's inventory would cost Northland a million dollars. Many other companies are in the same situation. Media reports on INS's new SEVIS web based foreign student tracking system indicate it is not as efficient as initially envisioned. Also note the weeks it took for freight through the west coast to return to normal after its recent disruption.

Who is Authorized 1.285: Northland believes that Customs House Brokers who currently file data into Customs will be the primary organizations that will interact with the Prior Notification System (PNS). They are closest to having the software in place to interact with PNS. These organizations must be allowed to act as the agent.

Anticipated Arrival Info 1.288.a: The proposed timing is restricted to a four hour window to allow FDA inspectors to be able to go to the port and inspect the product without any undue interruption. What specifically is meant by "time of arrival"? Many juice concentrates are shipped by boat, which takes a day or two to unload. Does "time of arrival" mean when the boat arrives at the pier, when the container is off loaded, or when it is available for FDA inspection? No one wants FDA Inspectors waiting for two days for a container to be unloaded, but no one can be expected to know in what order a ship will be unloaded. The issue is different for truck shipments. There should be different windows based on the mode of transportation. The window for arrival time on ships can not be less than one day.

Originating Country 1.288.h: Apple concentrate presented for import into the US could be from apples grown in Poland, processed into concentrate in Germany, and blended in Switzerland with Italian apple concentrate. If we are to follow the fish example, then it becomes a blend of Poland and Italy. Will the form allow for multiple originating countries? Does one simply pick the predominant country that the fruit was grown in, even though the info to FDA is not complete? Or does originating country refer to where the fruit was processed?

Grower 1.288.o: Individual lots of juice concentrate can now be 100,000 gal. Single strength fruit juices are stored in million gallon tanks. The number of growers represented by these quantities in the best case would be 6 - 10. On the other hand, Chinese and European apple processors may accept a few bushels from each of hundreds of families with relatively few apple trees. Does FDA expect this level of detail? If so, the time needed to enter this data will go up dramatically. Being in the juice business, we have had recent experience in obtaining legally required HACCP plans from foreign juice processors and know that this takes much more time than anticipated. Juice exporters are not accustomed to forwarding this information.

Owner 1.288.o: Which owner is required to be listed? There are many owners affected by each prior notice submission, including growers, trucking firms, manufacturers, warehouses, brokers, Customs brokers, and consignees. Assuming it is the owner of the food product, is it the owner at the time the food enters into the US?

Updates 1.290: Currently, only arrival and grower information are allowed to be updated. There is other information that may not be available before a ship departs, hence delaying shipments while waiting for information to arrive. This data includes the carriers, especially foreign ones, lot numbers, and exact lot size. Consignees may even change while the ship is on the water as well. If more items can not be updated, many notices will be canceled, tying up the PNS, costing everyone time and money.

Crucial to the economics is how fast the information can be gathered. Data entry into PNS will be easy in comparison. There would be at least 125 fields and as many as 250 fields to fill in for PNS. Getting names and addresses of 10+ growers, and 2+ overseas trucking company names will be very difficult at first, and require much more time. We assume that the time to do this would be 100 minutes of administrative time plus 20 minutes of manager time. This is twice FDA's assumption made in Table 3, doubling this cost. The PNS must allow fields to be populated automatically (from prior entries) on a user by user basis or allow automatic data entry from other software. This would reduce the time spent to closer to FDA's 60 minute estimate.

FDA solicits comments about how the prior notice will affect business practices. While it is true that some products are ordered with deliveries spread out over weeks or months, more and more is being ordered with very little time built into the system other than the time that is required for actual shipping. FDA indicates that 75% of the time OASIS information was available a day prior to entering info. Northland estimates that under these proposed regulations it will take several days for the manufacturer to assemble all of current and new data, submit it to the US Broker, who forwards it to the Customs House Broker, who provides the Notice. This will force finished goods to wait overseas until the information is assembled. As an example of how this information consolidation slows down commerce, the new Customs 24 hour advanced manifest regs are adding 3-4 days on to "immediate" boat shipments - product that is packaged and ready to move.

Northland intends to comply with these regulations fully, but several sections of the proposed regulations raise numerous questions and could be revised to reduce the cost of compliance. Thank you for your consideration of our comments. Please feel free to contact me if you have any questions or we can provide additional information.

Sincerely,



Steve Cockram
Director of Technical Services
Northland Cranberries, Inc.

cc: Ricke Kress
Ken Iwinski