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

RE: Docket 02N-0278, RIN 0910-AC41 – Prior Notice of Imported Food

Dear sir or madam:

I am writing on behalf of the Canadian Trucking Alliance (CTA) in response to the request for comments on the above-noted interim final rule, which was published in the Federal Register on October 10, 2003.

By way of background, the CTA is a federation of Canada's regional and provincial trucking associations formed to represent the views of the industry on national and international policy issues. CTA member associations include:

- Atlantic Provinces Trucking Association
- Quebec Trucking Association
- Ontario Trucking Association
- Manitoba Trucking Association
- Saskatchewan Trucking Association
- Alberta Motor Transport Association
- British Columbia Trucking Association

The associations comprising the CTA federation collectively represent some 4,000 companies across Canada. The Canadian trucking industry as a whole generates over $50 billion per year in freight revenue, and in 2002 carried about two-thirds (by value) of Canada's $564 billion trade with the United States, including most of the food shipped across the border. Further information on the CTA, and the importance of Canada-US trade, can be found at www.cantruck.com.

It is clear that the interim final rule on prior notice published on October 10, 2003, addresses a number of significant issues brought forward by CTA and other interested parties in response to the proposed rule published earlier this year. In particular, we note that FDA has chosen to work with US Customs and Border Protection (CBP) to use their Automated Commercial System (ACS) as a conduit or pipeline for information to the FDA's OASIS system. We note that time frames for prior notice have been brought closer to those required by CBP under rules published pursuant to the *Trade Act*. Finally, the introduction of a fairly lengthy period of educational enforcement should help all parties in the trade chain to adjust business processes and practices to meet the new requirements without fear of fines or significant disruptions at the border. We view each of these measures as essential, but they are only a first step.

Despite the positive developments noted above, CTA believes that additional refinements are necessary to the interim final rule in order to further align its requirements with those of other programs and measures, particularly those of CBP. It is our view that changes designed to streamline requirements and reduce the potential for problems at the border can be accomplished without compromising the essential goals of the *Bioterrorism Act,* to protect the US food supply. At this point we have had just over a week to assess the impact of the interim final rule on operations, and to be frank, with such limited experience and less than full enforcement it is difficult to draw too many conclusions. For this reason CTA expects to make an additional submission when the comment period is re-opened in March, 2004. However, we do believe we have sufficient knowledge at this point to make the following observations and suggestions.

1. As noted above, some progress has been made in bridging the gap between CBP and FDA. The use of ABI/ACS to supply FDA with prior notice information is a step forward, but it must be recognized that fundamental differences remain between FDA's prior notice rules and the advance cargo information rules published by CBP under the *Trade Act*. These discrepancies are bound to cause confusion.

From a practical standpoint, what this means is that trucking companies will have to abide by two different sets of rules depending on the commodities carried in a particular truck. If a truckload carrier is moving electronic components to the US from Canada, CBP advance cargo information rules will apply. If the same truckload carrier is moving canned apple juice, FDA's prior notice rules will come into effect. If it happens to be a less than truckload carrier with both electronic components and apple juice in the same trailer, the carrier will have to be able to comply with both.
CBP Commissioner Bonner, at a trade symposium in Washington in late November, indicated that the two agencies were continuing to work together to iron out differences between FDA prior notice requirements and CBP's advance cargo information rules. CTA would strongly encourage this process. We see no practical advantage from a security standpoint in having industry comply with two sets of advance notification rules. We would further suggest that a common set of rules will lead to better compliance rates and fewer disruptions at the border, goals shared by CTA and FDA alike.

2. In a similar vein, CTA wishes to note that the two hour advance notice period is a bit deceiving, since it doesn't take into account the time a broker may require to submit prior notice information and receive an acknowledgement back from FDA. Carriers have been telling CTA that brokers are advising clients to build additional time into the process, in some cases two or three hours. This may not be a problem for all shipments, but it will cause difficulties in many instances. A simple example is bulk flour shipments, which are timed to meet bakery schedules in the US. Currently a truck is dispatched as soon as the order arrives and can cross the border from Canada and reach the bakery in a couple of hours. If a four to five hour period is now required, this type of operation will have to be re-structured. Yet it is not clear what security benefits will accrue by having the truck sit and wait.

Therefore, as part of the effort to eliminate discrepancies between the two rules, and to help address situations such as the one described above, CTA would suggest that the shorter time periods outlined in CBP's advance cargo information final rule should prevail.

3. CTA is deeply concerned that FDA will no longer confer low-risk status on certain pre-qualified importers, carriers and shippers, and in return grant these companies expedited treatment at the border.

The most obvious example of this type of thinking is FDA's decision to eliminate food products from BRASS. The irony is that at the same time, CBP and its Canadian counterpart, the Canada Border Services Agency, have been vigorously promoting risk management approaches for both people and goods through the NEXUS and FAST programs respectively. It is difficult to argue with the rationale behind these programs. They allow expedited treatment at the border for pre-screened, low risk parties, and free up enforcement resources to concentrate on people and goods of unknown or higher risk. They are prime examples of how security and efficiency can co-exist at the border. As cross border traffic grows between Canada and the United States, programs such as FAST and NEXUS will be absolutely vital to ensuring that border crossings do not become choke points and stifle the economies of both nations.

Unfortunately the decision to eliminate food products from BRASS eligibility suggests that FDA has no faith in these sorts of risk management programs, even though other agencies of the US government, with an equal stake in border protection and national security, are vigorously marketing them. While it is acknowledged that food has never been eligible for expedited treatment under FAST, CTA is aware that the Canadian government is currently looking at ways to increase the range of qualifying products. CTA would strongly encourage FDA to work with CBP and relevant Canadian agencies to examine how a program such as FAST could include food. Particular attention will have to be paid to ensuring buy-in from importers, so as not to make eligibility so onerous as to drive them from the program. We are confident that a close examination of FAST, which is predicated on security throughout the supply chain, could be implemented without compromising the safety of the US food supply.

4. It is not clear to CTA to what extent FDA and CBP have worked with the Canada Border Services Agency and the bridge authorities to address issues surrounding refusal of entry due to missing or incomplete prior notice information. CTA is aware that local staff at busy border crossings such as the Peace Bridge and Ambassador Bridge have indicated that trucks will be turned back for missing/incomplete prior notice if secure storage cannot be arranged. Given the scope of operations and limited space available at these locations, this is understandable from a logistical standpoint.

Canadian government officials have told CTA that they are examining this issue. One proposal would be to have CBP stamp a shipping document (such as the bill of lading) "Refused – BTA". It is also understood that CBP has procedures in place for refused trucks which pre-date the BTA. Regardless of what method is adopted, the essential point is that the relevant agencies on both sides of the border should have a plan in place to deal with the inevitable problems posed by larger volumes of returning trucks so that busy border crossings do not become a no man's land.

5. Many concerns have been expressed regarding the fact that prior notice confirmation numbers will be sent to the filer (usually a broker), but a mechanism doesn't exist to get this number to the carrier. It is CTA's understanding that since implementation on December 12th, many carriers have been demanding that a shipper present the PN confirmation number(s) to them before a shipment will be picked up. At the same time one has to be realistic and expect that PN numbers may be missing for a certain percentage of shipments due to incomplete or inaccurate information, and that carriers will not want to turn down business if it appears that only one or two PN's are missing from a truck that may require dozens or even hundreds. In addition, time constraints in certain industries (e.g., fresh seafood) will demand that a truck be dispatched to the border *before the PN confirmation number has been issued*.

In both instances described above, the truck will be traveling “blind” to the border on the expectation that a prior notice confirmation number will be issued before the crossing is reached. However, the truck driver, under the current rule, is two steps removed from receiving the notice, as it will go first to the filer (likely a broker), and from there to the broker’s client (the Canadian shipper or US importer). Various solutions have been discussed for addressing this problem, including e-mail messages to the carrier identified in the prior notice information. CTA would encourage FDA and CBP to work out a protocol on how this could be accomplished.

6. Discussions between CTA, brokers and officials from CBP and FDA suggest there is likely to be a problem with so-called "dual mode filers", or brokers who must present paper copies of required documents to FDA before a truck is allowed to leave the customs compound. Though it is not clear at this stage the extent to which this problem exits, it is apparent that at certain busy border crossings such as Buffalo, N.Y./Fort Erie, Ontario, some brokers are required to submit paper copies of required documents to FDA after the release has been obtained from CBP.

In practical terms this means is that even if a load is cleared using the Pre-Arrival Processing System (PAPS), and a prior notice confirmation number has been issued by OASIS, the driver will still have to “walk the paperwork” to FDA before leaving the border crossing. An additional complication stems from the fact that a customs officer in the primary inspection booth will not be given any indication of the broker’s status. Therefore, it is entirely possible that a driver will be given a "may proceed" message by CBP, when in fact he should be reporting to FDA so that paperwork can be verified.

This situation will no doubt lead to compliance problems and may expose carriers and drivers to unwarranted penalties. As well, considering that many food shipments were cleared with BRASS prior to December 12th, 2003, a significant number of drivers and carriers are now having to adapt to a completely new way of dealing with border crossings. The desired outcome is to have as many trucks as possible clear at the primary line so that secondary parking areas do not become backlogged with trucks reporting to FDA.

It is suggested that during the current period of educational enforcement, FDA and CBP examine the impact of dual-mode filers on BTA compliance, and make whatever adjustments are necessary to border processing procedures to ensure carriers are given clear direction at primary inspection. This should reduce the possibility that a truck will leave the port of entry without proper FDA release. Fines, penalties and delays should likewise be reduced. As well, CTA suggests that the OASIS status of brokers be made available to carriers upon request from FDA at each US port of entry, so that carriers can plan ahead and educate their customers, drivers and operational staff on this issue.

7. The sheer volume of prior notice confirmation numbers is bound to cause problems as we move forward into implementation. As noted above, because PN’s are attached to individual “articles of food”, it is entirely possible that dozens or hundreds will be required for a single truck, particularly in the less-than-truckload environment. A carrier could achieve compliance of 99+ percent – for example, 199 out of 200 PN’s properly submitted for a given truck – but the truck could still end up re-routed to secure storage in the US, or turned back to Canada, if the 200th is missing or incomplete.

A possible solution to this problem would be to relate the prior notice to all food products on a single bill of lading rather than assigning one to each and every article of food. Under this scenario FDA would still receive prior notice on all food products, but would, in effect, “clear” the entire shipment from a single shipper to a single consignee, carried on the same truck. No doubt this solution would have to be examined carefully – for example, what mechanism would there be for advising the shipper and carrier that a single product in a shipment raised concerns for FDA? Nevertheless, CTA believes it would be worth exploring in greater detail.

8. In closing, CTA would like to place the FDA prior notice rule within the broader context of security, trade and the border. The prior notice interim final rule is just one of the myriad of new programs, rules and requirements that the trade community is currently adapting to in order to meet the US security agenda. CTA does not question the importance of this agenda, and the carriers we represent, drawn from both sides of the border, have so far been willing to do their utmost to adapt to

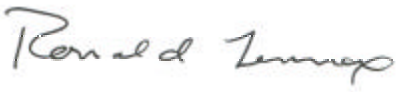
the new reality. Yet we note that at the same time carriers have been gearing up for prior notice implementation they have also been:

- Registering, as required, under FDA's food facility registration rule
- Developing strategies to comply with advance cargo information rules published on December 5, 2003, by CBP
- Signing up, in the hundreds, for C-TPAT and FAST
- Registering drivers, in the thousands, for FAST
- Complying with vastly increased VACIS scans at the border
- Preparing for implementation of *Patriot Act* requirements for security screening of drivers moving hazardous materials
- Complying with new Department of Transportation security requirements for the transportation of explosives
- Responding to requirements for enhanced security imposed by individual seaports in both the US and Canada
- Ensuring landed immigrant truck drivers have the appropriate visas to ensure continued access to the United States
- Monitoring the potential impact on the truck driver population of the Transportation Worker Identity Credential, or TWIC, which is currently being developed by the Transportation Security Administration; and the US Visit program, which Homeland Security plans to implement on the land border in a little over a year
- Preparing for the CBP's Automated Commercial Environment and Canada's Advance Commercial Information, both of which will contain an advance cargo reporting component

Each and every initiative identified above is intended to enhance the security of the United States. Yet at some point one has to stand back and look at the "big picture." Have we reached the point of diminishing marginal returns? Can trade continue to function in a more or less efficient manner if we continue to layer new and sometimes conflicting or incompatible security programs on top of those already in existence? And finally, is the situation at the border becoming so complicated that carriers and drivers are no longer confident that they even know *how to comply*? CTA accepts that these are not questions for FDA alone, and would only request that in considering changes to the interim final rule, that these "big picture" issues be taken into consideration.

CTA appreciates the opportunity to comment on this interim final rule. As previously noted we would expect to file further comments next March once the industry has had more experience working with FDA prior notice requirements.

Sincerely,



Ronald Lennox
Vice President, Regulatory Affairs