

April 4, 2003

Comments of the Canadian Produce Marketing Association (CPMA) on rules 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)*.

JUL 18 03 APR 7 10:30

Docket No.'s 02N-0278 02N-0277

The CPMA welcomes the opportunity to provide comments on the above-referenced notices of proposed rulemaking as published by the Food and Drug Administration (FDA), Department of Health and Human Services, in the *Federal Register* of February 3, 2003.

While we appreciate that the normal course would be to submit comments separately, and we understand that both are key elements of the proposed USFDA strategies. In our review of both notices, it is our view that the requirements of the registration process, and the reporting components of the information required, and how some of that information may be required on the daily notification, also makes the notification process more difficult and onerous. The final conclusions on the registration, will likely dictate the information required on the daily notices to some effect.

Consequently, whatever the final decision on an appropriate time for the Notice Process, the level of the date required in such notices in itself may also impose significant difficulties and obstacles

Having said that, we will try to respect making specific reporting under each docket #.

The CPMA

The CPMA is a voluntary not-for-profit trade association whose members have an interest in the health and economic success of the fresh fruit and vegetable market in Canada and represents over 90% of all fresh fruits and vegetables sold in Canada. It is a vertically integrated association with members from the production side right up through to retail and foodservice in Canada; including import and export. We also have members who supply service to the trade and a large international membership, with upwards of 40% of our members from outside Canada. This stands to reason given that approximately \$3 out of every \$4 sold at retail or at foodservice in Canada is imported. Our single largest supply country is the United States; representing approximately 75% of all fresh fruits and vegetables imported into Canada. Consequently, we have over 170 U.S. companies or commodity organizations as members, or, approximately 85% of our international membership. The balance of our international membership is from ten other countries.

CPMA's input is generally targeted to the Canadian legislative or regulatory processes; however, periodically the CPMA provides input into the U.S. legislative and regulatory

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process. This latter input is based upon two objectives. The first is to provide input to U.S. authorities on proposed, or actual legislation and/or regulations which may have a negative affect upon our members who export fresh fruit and vegetables to the United States. The second is to provide input to the U.S. authorities on U.S. legislation and/or regulations, that if emulated or replicated by the Canadian government, would potentially have a negative impact upon trade into Canada, and as a consequence damage our Canadian import members and foreign suppliers to Canada.

In this case, our reason for commenting is based upon both. However, we are focusing upon the proposed USFDA regulations and commercial practices of fresh fruit and vegetable exporters, as we have received more comments from this sector. As an aside, we have asked importers in Canada to equally assess the implications of such regulations were they applied on imports into Canada. On this latter point, there is serious concern that such regulations would create cost, and indeed create problems upon trade into Canada. The reality is, of course, we received little substantive importer feed back, as indeed most organizations have nothing concrete (i.e. Canadian regulations) at this point to consider. All of the parties understand the importance of the U.S. Bioterrorism Law.

While we have many U.S. members, we want to emphasize that we did not receive feedback as clearly the proposed regulations do not affect them as they operate within the United States. We do not wish to leave any impression to USFDA, nor our valued U.S. members that this input reflects their views. That is neither our mandate nor desire. We fully understand that the U.S. government has extensive dialogue internally to obtain input from their constituents.

Docket No. 02N-0278

Prior Notice of Imported Food

The CPMA is pleased to have the opportunity to provide comments on the *Bioterrorism Act of 2002*. We sincerely hope that the Secretary of Health and Human Services will have the necessary regulatory authority to implement the prior notice provisions in a way which achieves the objectives of the provisions, while at the same time taking account of the unique circumstances of produce commerce across the Canada-United States border and the highly integrated nature of this industry in both countries.

When Must Prior Notice be Submitted?

The single most significant time sensitive mode is truck – for our sector. It is the most impacted. As we understand it, the largest threat to the U.S. is from offshore, yet the regulations severely impact Canada. The proposed “one size fits all” minimum time for prior notice is not flexible enough for Canadian fresh fruit and vegetable exporters, a significant percentage of which live within 1 –2 hours from the U.S. border; and for a sector that exports almost 100% of its products via truck carrier. This sector alone is also one of the most complex of all to deal with, given the closeness of many to the border – less than ½ hour for some, the multiple product nature of some shipments, the multiple

growers on some shipments, the vast array of products, the extreme perishability of many products, the very tight just in time delivery time frames, and the large number of players exporting products. As you can appreciate, for fresh fruits and vegetables, the problem is significant. Relative to registration of facilities and Canadian farms; shippers at times combine product from various growers on any particular load, how this will work could be problematic – there is no doubt that this will create administrative burden. It is not yet clear to us to how USFDA may require this information on each notification, and how far back it goes to farms supplying the shipper.

We have also just been advised that any product (e.g. packaging) that touches the product needs to be registered also. If this is the case, fresh fruit and vegetable exporters will need to know how the registration and reporting process works; including on the notification process. This could include plastic wraps, paper cartons, or also paper containers. This could also be potentially extremely problematic.

As we understand it, if notice is provided by noon, it can move at 12:01 midnight (next day). If notice is given at 1 minute after noon, it cannot move into the USA until 12:01 midnight the following day – in essence 36 hours. Either is a huge problem – many Canadian loads are ordered and shipped in the afternoon of the day before the load is required at the U.S. destination city, and within 1/2 hour of loading, some loads can be and are at the border. How the proposed USFDA time frames proposed could be seen to be workable is somewhat beyond our comprehension; at least not without huge changes in commercial practices; which likely will discourage U.S. buyers.

We understand there could be a proposal that FDA draw a representative sample of the enormous volume of trucks (and train) from Canada as part of their efforts to underpin the minimum notice time frame – we highly agree – we also think the sampling needs to be examined between sectors as well. In conclusion, four hours would certainly be preferable to the current proposal. This will be useful to some in our export sector, most easily acceptable by those firms four hours from the border, but again those close to the border will find it problematic. Equally, if no amendments are permitted, this too will be problematic.

Even a four hour proposal – which as we understand USFDA had earlier rejected – is problematic for many of our exporters. A further caveat of a proposed two hour period for amendments before arrival is also problematic- particularly for multiple commodity exports. Amendments to the final notice can occur at time of loading, which can be less than one half hour before arrival at the border.

Quantity Changes Before Arrival - We would also ask that FDA allow for the update of product quantities prior to two hours of arrival time. We have been advised that in the sensitivity analysis which was conducted, the estimated cost of the proposed rule is most sensitive to the assumed fraction of prior notices that will need to be changed. We have been advised that a greater volume of 20% of the notifications of all perishable product shipments will need to be amended due to quantity changes and not identity changes. We believe this is higher for produce – given the extreme time sensitive commercial reality,

the reality of mixed loads (multiple commodities, and/or varying pack sizes for one commodity), and greater susceptibility for substitution due to production vagaries, product sizing, etc. This will increase costs and errors caused through increased amendments. It is understood that amendments to the quantity of product arriving will impact sample sizes, however, we do not think it should be a factor in decisions on whether to interdict a shipment for bioterrorism-related reasons based on the prior notice.

We firmly believe Canadian fresh fruits and vegetables represent very, very low risk, and commercial trade is of a daily and highly repetitive nature and we sincerely hope this is considered in the final development of solutions.

Information that Must Be Submitted - For each prior notice, we understand the FDA is proposing to require much more information than Congress intended and we would hope this is reconsidered. In particular, multiple notices will be needed for essentially the same product from the same exporter 365 days a year. i.e. unlike customs documents which allow for 1 document for an entire load. The FDA level of detail should be as compatible as possible with the entry line level of detail required to be submitted to the U.S. Customs Service. For example, it is not clear how requiring a notice for different sizes of containers for the same product will substantially aid the FDA in targeting shipments.

Use of FDA Codes - USFDA refers to a code – it is now clear this is an additional code for this sector. We believe this will also create more confusion, administration and potential for inaccuracy. We would recommend that USFDA accept the HS codes that are already provided to U.S customs. We believe the more that gets added, the greater the potential for meaningless information and mistakes – and we would add potential for manipulation. Not knowing the nature of USFDA codes, if they are tied to a commodity by commodity basis, then the potential for confusion will grow, particularly on multiple commodity loads.

Relative to the need for data – which includes codes, product identification, etc.; there may be some validity for the U.S. to look at a comparable form to the Canadian Confirmation of Sale (C.O.S.) form for this sector, as a means for them to obtain much of the information they are seeking. The C.O.S. is the primary customs document for produce shipped into Canada and includes the necessary data elements required by Canada Customs and Revenue Agency, Agriculture and Agri-Food Canada, Statistics Canada and the Canadian Food Inspection Agency and therefore to both customs/security, plant health and human health. Indeed the document clearly has specific reference to the importer (and exporter) meeting Canadian plant and human health regulations. A C.O.S. must accompany every load at the time the goods enter Canada. Having said that, amendments are permissible importation to allow for importers to correct the C.,O.S. for many of the minor adjustments for quantity, value adjustments required due to product value deterioration from quality change, etc. Why not a bilateral or even trilateral C.O.S.? While this doesn't deal with the notification time problems, it may provide other key important data, which when linked back to a "licensing" system, would potentially provide far more security.

In addition, it is important for the FDA to clearly define the circumstances under which updates or amendments or re submissions of notices must be made due to changes in the nature of the shipment after a notice is submitted.

We feel that for Canadian exports by truck (our major concern), rail or aircraft, the FDA should establish times that reflect these modes and the commercial transactions involved. This approach is being promoted by the U.S. Customs Service. We think it is important for the Canada-United States border that the minimum time allowed for notice strikes the right balance between the FDA's needs and the huge volumes shipped by truck and rail. We also feel it is also important that the requirements of the two agencies (USFDA and US Customs) be as consistent as possible to avoid costly duplications and unnecessary disruptions at the Canada-United States border. It would also eliminate potential for inaccuracies.

Docket No. 02N-0277

Who Can Submit a Notice

We will focus our principal attention in this area, as we feel it is here where we might see the most effective solution. Indeed it might well eliminate many of the foreseen administrative problems for industry – and we think U.SFDA and U.S. Customs.

Our initial view is it may be more effective for the two governments would be more effective, for this sector (and potentially others), to develop mutually agreed upon criteria that their respective exporters must meet, maintain a registry that is mutually accessible to each government, and is plugged electronically into each other's customs systems. Failure to be on this list negates ability to move product into each other's country. This puts the onus for clearance effectively back at the greatest point of potential threat. This would have to be examined as well relative to third party movement through both countries. Equally carriers might follow a similar type registry; certainly their views would be required.

We think this may reduce the pressures at the border, provided the exporter and carrier have a so called "clean bill of health". It might eliminate or reduce the need of many of the administrative requirements which will be burdensome to non-problematic or non-threatening industry in both countries, and which in the end may not offer any real or significant guarantee of protection to U.S. or Canadian citizens.

For the fresh fruit and vegetable sector, there already exists – in both countries – a system of licensing or registration for many of the firms that already export to each other (and Mexico is coming along). Perhaps this is a suggested good first start – possibly building upon the ones that already exist. For our sector, the PACA, DRC and the CFIA. We appreciate these registration systems do not fall under USFDA (or whatever the Canadian security counterpart might be), but the fact remains that our two governments already have a well defined and long standing system of identification for firms that trade into

each other's country. Having said that, we only offer this in the context of an option that may well warrant examination by the two governments and industry.

It also would mean each country would have to develop mutually agreed upon criteria as to the information needed to reassure each other of the minimization of potential threat; and also have a system for reviewing "registrants". If indeed the regulations are critical to meet U.S. and Canadian food security objectives, this alternative may replace for the majority of commerce and majority of legitimate traders, administrative obstacles which would find them unable to trade, or in a constant situation of being in violation, and consequently subject to criminal action.

This would be our preference.

USFDA Proposal - The proposed rule, under Section 1.285, would require the prior notice to be submitted by a purchaser or importer who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States, acting on behalf of the U.S. purchaser or importer. We think this proposal will detract from FDA receiving the most accurate and timely information in prior notices and will cause serious adverse and unnecessary commercial consequences for Canadian exporters and their U.S. customers.

Almost 100% of fresh fruit and vegetable imports from Canada at the land border are sold on the basis of the Canadian exporter taking responsibility for the entire U.S. Customs and FDA transaction at the border. The Canadian exporter is the actual owner of the produce until delivered to the U.S. customer. The invoice price to the U.S. customer will normally be inclusive of all U.S. customs or other U.S. border agency charges. The Canadian exporter normally hires and pays a U.S. Customs broker to act as its agent at the border, including all liabilities for duties or fees, including, for example, any redelivery to FDA and Customs (or liquidated damages) of any food shipments found to be non-compliant upon sampling and testing by FDA. It is the Canadian exporter, for legal purposes, that is the U.S. importer of record.

If only resident U.S. parties or their agents are permitted to submit the notice, we think the FDA will be creating obstacles to its objectives.

The resident U.S. customer would need to provide information third hand in the notice as obtained from the Canadian exporter. In transactions involving perishables or just in time deliveries or transactions involving companies located near to each other across the border, this could introduce errors and make it more difficult to comply with the minimum time for advance notice. It is the Canadian exporter that will know the soonest, and with the highest degree of accuracy, precisely what is being shipped in an order.

In any case where the shipment may be the subject of an inadequate notice, it is the Canadian exporter that normally owns the products at the border that would be held or sent to a secure facility. However, under the proposal the FDA will be requiring the resident U.S. customer which does not have a financial interest in the product to bear

responsibility for complying or disposal of the product. The inclination may be to simply abandon the shipment and cease to do business with the Canadian exporter.

From an operational standpoint, FDA is requiring detailed and extensive information for the prior notice. The level of detail is consistent with the information normally submitted by U.S. Customs brokers acting as agents for importers of record. As noted above, it is the Canadian exporter that hires such a customs broker and provides this information to the broker acting as the exporter's legal agent. The proposed rule would result in this information continuing to be submitted by Canadian exporters and their U.S. customs brokers for Customs Service purposes yet, at the same time, requiring for the same transaction the submission of essentially the same data by a resident U.S. party (hiring the same or different broker) solely to comply with the FDA prior notice requirement. This will inevitably introduce complications, delays and inaccuracies for the FDA.

From a commercial standpoint, if resident U.S. customers have to hire a U.S. customs broker, incur additional expenses for submitting the notice, and incur liabilities for holding products at the border, solely for purposes of the proposed rule, then a distinct competitive disadvantage will be newly introduced for Canadian exporters.

While we prefer the CFIA/DRC/PACA type registration option articulated earlier in this section, if this ultimately is not an acceptable alternative, then we would hope FDA amends the rule to include food exporters in the requirements for who must submit the notice. We understand that Congress did not specify which parties must submit the notice. We think these circumstances are unique to the Canada-United States border. We would re emphasize that this will be a more effective and accurate information flow and in the most timely way consistent with FDA's objectives.

We also think the time frame provided for registration should be expanded beyond the 8 week period this fall. Given the number of commercial exporters, and dependent on the level of information required, we think USFDA may be very challenged administratively. This would mean that many firms might be left out through no fault of their own. On the other hand it could well be that adequate registration review staff are in place.

General Comments

1/ Canada – Mexico Trade – and Offshore Movement into Canada through the USA, and through Canada into the USA.

We would mention that we have not yet examined how the new regulations will affect movement between Canada and Mexico – almost all exports into Mexico, or imports into Canada from Mexico, moves through the USA via truck. Re offshore (and notably ships), but also some air through the USA to Canada, much of the imports into Canada are first landed in the USA; e.g. Chilean grapes through eastern seaboard, New Zealand kiwi through Los Angeles, S. African citrus through New York, etc., it is not clear to us at this point how this will be handled by either government. We will be seeking input over the next few months.

To a far lesser degree, Canada moves product similarly, and this will need to be addressed, although, it will be governed by the USFDA regulations and this will also have to be assessed.

2/ Filing by electronic means. Certainly if this were a requirement for many Canadian importers (in a situation where Canada adopted this approach) we would eliminate many importers at this point. Having said that, most Canadian exporters could use these means. We would be concerned re computer "crashes" and potential delays, however, we are sure this has also been addressed.

Also unique for Canada-United States transactions is the Customs-Trade Partnership Against Terrorism (C-TPAT) and the Free and Secure Trade (FAST) bilateral arrangements which are available for low risk imports. They flow from the Smart Border Plan directed by Department of Homeland Security Secretary-designate Ridge and Deputy Prime Minister Manley. The USFDA should be building on these Customs initiatives which share the FDA's counter-bioterrorism objectives. Canadian exporters enrolled in these programs have invested heavily in preventative measures which clearly result in reduced bioterrorism risks from an FDA perspective. The proposal therefore needs to take this into account through reduced prior notice times or otherwise acknowledging the reduced risk.

For exporters, we have heard that this is a time consuming and expensive process, and one which to date has not been extensively pursued by this sector. While in concept it might be a useful solution, it will require much more time and cost to industry and likely government as well.

3/ Border facilities - There are already delays at the border. These new requirements will add further delays. Even if an exporter works to meet these, what happens if the delays are caused by U.S. Customs or border lineups. If the product deteriorates, the U.S. buyer might reject the load; or if delayed too much cancel the order. And where does this product go? We see this as even a bigger challenge at the Windsor /Vancouver ports, albeit it will occur elsewhere. The increase in border line ups might also provide even more potential for tampering.

One suggestion to address the potential for line-ups at the border and attendant possibility for increases in time spent waiting to get through the border (and potentially adding to the four hour allotted window to arrive at and cross the border) is a registration-type mechanism. In this scenario, a vehicle arriving at the border could register as arriving at the border at a certain time, then if unusual delays led to waits for processing over the four hours allotted, there would be proof that they had indeed arrived in necessary time. While this would add another level of administration to the border proceedings, it would never-the-less provide a vehicle to ensure carrier efforts to adhere to the 4 hour window would be verified and subsequently ensure the recognition that they had made every effort to comply with the required processes.

For perishables, it the need for proper facilities to handle product is critical, otherwise product could be damage in physical handling – or submitting produce including temperature extremes. In our own context, we have worked with both the Canadian Food Inspection Agency and Canada Customs and Revenue Agency to develop within this sector alone criteria for perishability, but also as it relates to any potential Canadian import customs inspections when temperature extremes can ruin a product. We think this too may be useful for U.S. customs where and when product may require some inspection, particularly if this need will increase with the implementation of the new regulations.

Outreach

The CPMA appreciates that FDA officials will inform affected parties and to fully consider all comments. With the creation of these new rules, extensive new information requirements and the creation of new electronic supporting systems, it will be even more important for FDA to continue these outreach efforts as implementation proceeds. It will be equally important for FDA to ensure that administrative systems are fully operational and maintained to avoid any need to revert to a paper system. Even temporary shut downs will result in unmanageable congestion at the Canada-United States border.

Whatever the final decision, we also sincerely look to consistency of application across the various U.S. Customs zones.

Future Amendments

If we could make but one recommendation, it would be to emphasize the importance and the absolute need for engagement of bilateral efforts to develop and fine tune or assess the commercial implications of the regulations. We feel it is critical that this include USDA, US Commerce– and their Canadian counterparts – under the Smart Border Initiative. We would go further and suggest that, at some key point, Mexico be included; the largest commerce remains between our three countries – we also share the borders (and therefore the potential threat).

From our side, we will recommend that our government form a specific consultation group with the CPMA to address the fresh fruit and vegetable sector issues, from an export and import perspective.

Summary:

This is an important initiative by USFDA to address what is sadly a reality of the times; consequently, the U.S. should be applauded for their commitment to protect their citizens from any food security threat. Notwithstanding, the regulations as proposed, if implemented, will be highly disruptive to the two countries' trade, which we fully understand was never the intent. We understand that security requires new thinking and solutions.

We sincerely hope the FDA will build into the final rule, the capability to amend either regulatory requirement – registration or notification - notably in respect of imports from any country for which the FDA has reached an arrangement that would serve as the basis for having different (e.g., more efficient or effective) registration or prior notice requirements. Such a provision would be important for the FDA to adjust procedures quickly and efficiently to reflect actual reductions in risks through such arrangements.

Again, notwithstanding the final evolution of USFDA regulations, we would ask that the above points be addressed in the Smart Borders dialogue. We would again highlight the issue related to trade with Mexico and how it will be impacted, as well as how offshore movement to Canada through the USA will be impacted.

We appreciate the opportunity to provide our comments, and hope they are of some value in assessing the application of the proposed regulatory requirements on fresh fruit and vegetable exporters from Canada; and possible suggestions for the development of the regulations. We sincerely hope that once the U.S. has completed their review, which we would hope includes U.S. Customs and USDA, that there will be further bilateral discussions prior to implementation to assist the effective implementation of a system that meets U.S. needs without negating or damaging what has been an outstanding volume of non threatening trade into the U.S. from Canada.

We would be pleased to play any role we can to assist in the efforts to develop necessary bio security controls, while maintaining a smooth of fresh fruits and vegetables between both countries.

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