Comments of the Australian Government on Interim Final Rule; request for comments on Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Federal Register Docket No. 02N-0278

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The Australian Government welcomes the opportunity to provide comments on the United States of America (US) Government's Federal Register (Docket No. 02N-0278) Interim Final Rule for Prior Notice of Imported Food Under the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, published on 10 October 2003.

Executive Summary

The Australian Government believes that the objective of the *Bioterrorism Act* could be met by adopting a systems approach, based on a risk management that is tailored to reflect the existing information provided as a result of country-to-country arrangements. The system would thus link the information already provided to US authorities on food products labels, existing export/health certificates and the US Customs system.

We consider that implementation of Section 307 (Prior Notice of Imported Food Shipments) is potentially the most restrictive and costly measure under the *Bioterorrism Act.* The specified measures will impose a substantial burden of compliance on industries exporting to the US, and may limit the opportunity for smaller operators to continue to participate in that trade.

The quantity and type of information required for the Prior Notice will fundamentally change business practices for exporters of food to the US. The requirements will not pertain to domestic US food businesses, and will therefore clearly lead to more restrictive measures applied to imports than to food and agricultural products produced in the US for the domestic market.

Controls applying to establishments producing these goods for export to the US include regular audits by US authorities. The Australian Government therefore believes that the provisions of Section 307 of the *Bioterrorism Act* could be met through alternative approaches, recognising the Australian export inspection and certification system.

Due to the nature of trade and transportation, there must be greater flexibility in allowing submitters and transmitters to lodge Prior Notice. Acceptance of Prior Notice should be allowed to occur at the time of lodgement of Customs Border Protection documentation, as it would provide greater efficiencies to importers in regard to information exchange. Duplication of the provision of information is an undesirable impost upon exporters of food to the US.

The Australian Government believes that the requirement for submitters and transmitters of Prior Notices to provide separate notices for each grower where they are known is onerous and costly. We believe only one notice providing the name of the consolidator or, at the very least, one notice with the names of all the growers, should be sufficient. In the case of bulking of commodities such as cereal grain, many growers will deliver their grain to a bulking/transport point and that grain may be exported to various international markets. Although the growers identities are known, it is problematic whether any portion of their individual harvest is actually in a consignment being exported to the US and requiring Prior Notice.

General comments

The Australian Government places a high priority on a food safety system and ensures the production of high quality food at Australian Quarantine and Inspection Service (AQIS) registered facilities. Australia is an exporter of substantial quantities of food and feedstuffs to over 130 countries and therefore as a significant trading partner, has a direct interest in the United States (US) food safety system.

The Australian Government understands and supports the initiatives of the US Government to establish controls and countermeasures to help contain threats of serious adverse health consequences or death to humans or animals from accidental or deliberate contamination of food, thus enhancing the security of the US food supply. The US, through its *Bioterrorism Act*, has introduced four new rules to enforce and embody the principles contained within the *Bioterrorism Act*. These rules should be considered as a package of measures, and not necessarily in isolation from each other, as the impacts of these rules, on both domestic and foreign trade, are inter-related. The Australian Government also acknowledges and welcomes the changes made to the proposed rules on prior notice. Additionally, the Australian Government is pleased to see a phase in period of implementation where the FDA will be flexible in its interpretation of enforcement to avoid unnecessary disruptions to trade. The FDA has allowed several periods for trading partners to be able to provide specific comments on the new food provisions of the Act to again avoid trade disruption.

The Australian Government reiterates it is not opposed, in principle, to the imposition of new legislative measures for the importation of food and agricultural products to the US, provided these measures:

- are based on sound risk assessments that address real risks;
- are not more trade restrictive than necessary to meet its objective/s;
- focus on outcomes rather than prescribing specific measures to achieve them;
- allow for the recognition of alternative systems in achieving its objective/s; and
- avoid arbitrary or unjustifiable differences in the level of protection applied in different situations.

The Australian Government seeks US assurances that the final rule on prior notice will meet the latter's SPS and/or TBT obligations. The Australian Government is particularly concerned that the US *Bioterrorism Act*:

- does not allow for recognition of alternative systems;
- focuses on prescribing specific measures;
- may lead to more restrictive measures applied to imports than to food and agricultural products produced in the US for the domestic market;
- appears to be more trade restrictive than necessary;
- may lead to duplication of some measures; and
- does not consider whether the stated objectives are already achieved through the existing controls.

Submitter/transmitter of Prior Notice

AQIS is presently moving to a system of electronic certification (EXDOC) for export shipments to the US. The new system will provide the capability for electronic certification of meat, dairy, seafood, horticultural products and grain. All edible fresh and processed meat, whether subject to FDA or FSIS jurisdiction, is certified for export to the US using EXDOC certificates. AQIS will shortly commence sending a report to FSIS and FDA of all edible meat shipments authorised for export to the US. The Australian Government and the US (and also New Zealand and Canada) have agreed to commence electronic certification for meat trade during 2003.

E-cert is an electronic certification system that provides a web interface enabling importing authorities to access to EXDOC certificate data held in a secure environment in the exporting country. For these reasons it would seem appropriate to allow EXDOC system to be the *"Transmitter"* of the data and the exporter would be the applicant for the EXDOC certificate, i.e. any person with knowledge of the required information, to be the *"Submitter"*. This would fit the requirements of S1.285.

In terms of the US *Bioterrorism Act* information requirements, AQIS will be in a position to send electronic certification that will contain all the information about a particular shipment that is required by Section 307 obviating the need for a separate prior notice for these products.

We note that the interim final rule does not apply to shipments of commodities regulated exclusively by the USDA. Currently, the USDA's Food Safety and Inspection Service (FSIS) control meat, poultry and egg products and thus foreign shipments of these products are exempt from the Prior Notice requirement. The FSIS accepts AQIS controls, including registration of export facilities exporting FSIS controlled products to the US. Thus, the Australian Government believes that to maintain consistency, the FDA should consider exempting shipments of products covered by FDA and controlled by AQIS.

Format for submitting Prior Notice

AQIS issues export/health certificates electronically for all export shipments of 'prescribed goods' to meet US requirements. Prescribed goods are those as listed under the *Export Control Act 1982*: milk and dairy products, fish and shellfish, game meat, some other meats, animal food, live animal and genetic material and other products managed by AQIS.

In the case of Australian exports to the US, government-to-government certification already provides most of the information required by prior notice provisions and, therefore, there is scope for simplification of the rules.

We believe that the secure online electronic export certification (EXDOC/ E-cert) initiatives that our agencies are in the early stages of adopting could be adapted to meet USFDA requirements under the *Bioterrorism Act* without the need for duplicating systems.

Electronic export certification would provide for increased procedural efficiency, lower transaction costs, and significantly improve the security of the data and therefore credibility of government-to-government export certification.

EXDOC, for example, currently sends information to both USDA and USFDA and has the capability for electronic certification for meat, dairy, seafood, horticultural products and grain. For goods covered by the *Bioterrorism Act*, we would be prepared to add to EXDOC any additional fields of information required, and thus meet the requirements of Section 307 of the Act.

Timing of Prior Notice and transportation variables

Section 307 requires a Prior Notice of a shipment to be lodged no less than 8 hours in the case before arrival by water, no less than 4 hours in the case before arrival by air or rail, no less than 2 hours in the case before arrival by road and before the consignment is posted in the case of mail. It also states that Prior Notice may not be sent earlier than 5 days before the anticipated date of arrival.

The Australian Government believes that the above proposal again leads to unnecessary additional costs to companies handling exports to the US because: -

- It does not reflect existing business practices where governments and international trade organisations are moving to simplification and are only required to supply relevant information to an importing country once;
- It does not reflect the variable and unpredictable nature of transport. For example, it is common practice of airlines to purchase and sell cargo space and then move the cargo onto different Master Airway Bills (MAWB), which then alters the carrier, flight number, port of entry, *planned shipment information* and arrival times. It is also not inconceivable that due to the vagaries of transport economics, the consignment could be diverted through Canada (perhaps Mexico) and road/rail transport used to move the shipment into the US, therefore altering the mode of transport and producing different transport data not described on the original Prior Notice;
- These movements are currently handled efficiently under Customs Border Protection management, which is integrated into international transport systems and would logically be able to provide the conduit for FDA's information requirements, and;
- It does not prevent double handling of Prior Notices for Customs and FDA, and government-to-government export/health certificates (that are often issued on or before the date of departure of a shipment).

Potential rejection of consignments on the basis of administrative error or failure to meet prior notification timelines does not reflect a risk-based approach to potential bioterrorism threat.

Furthermore, the Customs notification must be lodged in line with the 24 hour Customs rule. This means that the Customs notification for sea freight shipments from Australia will be lodged well before FDA required Prior Notice (no more that 5 days prior to the arrival in the USA).

The Australian Government seeks clarification and confirmation that Prior Notice generated through the Customs/FDA database link will not disadvantage these types of shipments. Whilst we understand arguments about FDA resource constraints, we recommend the following modification of the proposed time frame:

- in order to accommodate 24 hour Customs rule, FDA should allow lodgement of the Prior Notice earlier than 5 days before the anticipated date of arrival. This would allow exporters to be able to complete their documentation at the same time the bill of lading and health certification is usually completed in the case of product shipped by sea. If the information can be stored on a database it should not matter how many days beforehand it is lodged prior to the product being presented at the port of entry.

Information to be supplied in Prior Notice

Certain new additional information is required in regard to the identity of the transmitter, the consolidator, the mode of transport and the Harmonised Tariff Schedule code. Again, it must be re-iterated that FDA admitted in the Federal Register Notice of interim final ruling that most of the information required for the US Customs entry system is identical to that required by FDA Prior Notice. There seems to be a duplication of the information required by both agencies and therefore it should be feasible to have the two agencies requirements linked. This would streamline the required information flow for each shipment while still providing the necessary information for both agencies.

The requirement whereby submitters of prior notices must provide separate notices for each grower in the case of consolidated shipments (if the growers are known). This is very onerous and costly for exporters of consolidated shipments of horticulture products, in particular: -

- We believe only one notice providing the name of the consolidator or at the very least, one notice with the names of all the growers should be sufficient.
- Under the proposed record keeping rules there is a requirement for relevant information to be kept through the whole chain. This should ensure that the names of the growers as required under the prior notice will be available anyway.
- The proposed record keeping rules already provide much of the information requested under the prior notice rules. We believe such duplication should be removed.

Some of the information required for the Prior Notice is already covered by registration requirements under Section 305 of the *Bioterrorism Act,* therefore FDA will already have this information. The Prior Notice could be simplified, thus reducing the possibility of errors and potential trade disruptions, by quoting the registration number and only adding information specific to a particular shipment.

It is clear that the information required for the Prior Notice is far in excess of that required in the CCFICS Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates (CAC/GL 38-2001). The information required for the Prior Notice, as specified in *Notice of interim final rule on Prior Notice,* also appears to be in excess of the information required in Section 307 of the *Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.*

Information provided to FDA under existing export/health certification requirements and to the US Customs by either exporters of products to the US or their importers in the US already covers all the information sufficient to facilitate real-time tracing of food products imported into the US, and hence, achieve the desired objective of the *Bioterrorism Act*.

Furthermore, information on food product labels required for food sold on the US market also aims to facilitate product tracing and recall.

The quantity and type of information required for the Prior Notice will fundamentally change business practices for exporters of food to the US, and not domestic US food producers. It will therefore clearly lead to more restrictive measures applied to imports than to food and agricultural products produced in the US for the domestic market, contrary to SPS and TBT principles.

Therefore, as previously mentioned, the Australian Government believes that the objective of the *Bioterrorism Act* could be met by adopting a systems approach, whereby the system is based on a

risk management approach tailored to reflect the already existing information provided as a result of country-to-country arrangements. The system would thus link the information already provided to US authorities on food products labels, existing export/health certificates and US Customs system.

Transhipment through the United States

The Interim Final Notice states; *[FDA has determined that, for purposes of section 801(m) of the FD&C Act, the phrase ``imported or offered for import into the United States'' can reasonably be interpreted to apply to articles that are brought into the United States for consumption in the United States, for transshipment through the United States and export to another country, for further processing in the United States and export, and articles of U.S. origin that are ``re-imported'' back into the United States. We have also determined that the phrase ``imported or offered for import into the United State*s" can reasonably be interpreted to exclude articles that are brought to the United States for the purpose *of being exported without ever leaving the port of arrival until export.]*

This proposal has potential to adversely affect trade. Companies may seek to avoid the potential cost and disruption by diverting freight to other routes rather than use transhipment facilities through US territory for destinations in Mexico and Canada.

Specific questions requiring clarification

On behalf of Australian export industries we wish to raise the following questions and comments specific for the Federal Register Notice of the Prior Notice of Imported Food Under the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, interim final rule.

1. International airlines use food supplies kept in storage (in US) under bond until they are loaded onto a flight for use in-flight. Similarly, unused and part used bottles of alcohol, soft drink and water are unpacked into a bonded kitchen for future intended re-use on subsequent international flights leaving the USA. All used and unused food goes to waste within the bonded kitchen. Do Prior Notice requirements apply in these circumstances where the food is stored under bond in the USA but is either consumed in-flight on international airlines or discarded in the bonded kitchen.

2. How will FDA handle the scenario where a Prior Notice is submitted but the Notice lists a manufacturing/processing facility that has previously cancelled its registration, however, at the time of production the manufacturing/processing facility was legitimately registered with the FDA?

3. What will happen to goods if they are accidentally shipped without meeting these guidelines, i.e. can they be transhipped, etc?

4. Identification of the submitter, transmitter, and manufacturer - will FDA's PN System Interface provide guidance on formatting of this information? We are concerned that FDA's PN System Interface may only accept certain formatting, without providing guidance to the submitter, and this may cause problems with FDA's PN System Interface accepting and processing prior notice.

5. We are similarly concerned about the formatting of information about the identification of the article of food.

6. The Interim Rule stated that food sent to research facilities requires Prior Notice. However, can an exemption apply to food samples that are being sent to research facilities for laboratory analysis only and are not intended for human consumption and will never enter the food chain or be consumed. For example, Australian companies, particularly those with headquarters or similar operations in the US who frequently exchange samples for quality assurance/quality control purposes. It will also be likely to affect samples sent to laboratories for analysis where the particular method of analysis is not reliably available in Australia or for inter-laboratory validation purposes.

7. The Australian Government would like to see an exemption from prior notice, in particular, for samples sent to FDA registered laboratories for the purpose of quality assurance/quality control and, in general, to non-FDA registered premises for samples imported for the purpose of quality assurance/quality control.

8. Please clarify whether the additional requirement for *planned shipment information as applicable (carrier, vessel name, voyage flight numbers and bill of lading number)* will carry an impost where those details change due to transportation arrangements outside of the control of the supplier.