



4 April 2003

0002 '03 APR -4 P12:10

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
rm. 1061
Rockville, MD 20852
United States of America

RE: Docket No. 02N - 0278

Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

I refer to the Federal Register Notice, Docket No. 02N-0278 inviting comments on the rules proposed by the Food and Drug Administration (FDA), Department of Health and Human Services, under the *Public Health Security and Bioterrorism Preparedness and Response Act 2002 (Bioterrorism Act)*.

The Government of Australia welcomes the opportunity to comment on the proposed Prior Notice provisions. Australia's specific comments on the Docket No. 02N-0278 are attached.

Yours sincerely



for Dr Ann McDonald
General Manager
Market Maintenance Group
Exports
Australian Quarantine and Inspection Service
Ph 61 2 6272 5254
Fax 61 2 6271 6522
E-mail ann.mcdonald@affa.gov.au

Cc Mary Ayling, Center for Food Safety and Applied Nutrition (HFS-32),
Food and Drug Administration, 5100 Paint Branch Pkwy, College Park, MD 20740

ENCL 1

02N-0278

C198

***Comments of the Government of Australia
on Notice of proposed rulemaking
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

RIN 0910 – AC41

Overall comments

The Government of Australia welcomes the opportunity to comment on the United States of America Government's proposed Prior Notice provisions, as published in the Notice of proposed rulemaking on Prior Notice of Imported Food Under the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*. Australia as an exporter of substantial quantities of food and agricultural products to the USA has a direct interest in the USA requirements for the importation of these products. Australia is committed to a food safety system that delivers high quality food produced at facilities registered by the Australian Quarantine and Inspection Service (AQIS).

The Government of Australia understands and supports the initiatives of the Government of the USA to establish controls and countermeasures for bioterrorism and thus enhance the security of the US food supply.

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

- are based on a risk assessment
- are not more trade restrictive than necessary to meet its objective/s
- focus on outcomes rather than prescribing specific measures to achieve them, and allow for the application of equivalence in achieving its objective/s
- avoid arbitrary or unjustifiable differences in the level of protection applied in different situations.

Trade impact of proposed measures

Australia seeks the United States' assurance that the proposed measures will meet the latter's SPS and/or TBT obligations. Australia is particularly concerned that the *Bioterrorism Act* :

- does not allow for equivalence determinations
- focuses on prescribing specific measures
- may lead to more restrictive measures applied to imports than to food and agricultural products produced in the USA 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 existing controls.

The FDA in its analysis of economic impacts of proposed new requirements assumed that 16% of manufacturers exporting 10 or fewer line entries to the United States would stop exporting rather than incur the expense of registering, hiring a US agent and providing prior notice. Although the

Bioterrorism Act is not designed to discriminate against foreign exporters, unless it can be substantially simplified, the assumed reduction in exports to the USA may be an unintended consequence since exporters of 10 or fewer line entries may find the expense of prior notification prohibitive.

Australian exporters have also observed a proliferation of initiatives to meet the objectives of the *Bioterrorism Act*, for example the Container Security Initiative and the Customs Trade Partnership Against Terrorism (C-TPAT), all of which add another layer of potentially repeated information and therefore increased costs to exporters and their US importers. We believe that, in line with a risk-based approach, companies participating in C-TPAT should receive lower priority from FDA, consistent with the US Customs commitment to give companies covered by C-TPAT expedited processing at US ports of entry.

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

Furthermore, the Prior Notice requirements are likely to have significant implications for exports of short shelf life or fresh products transported by air-freight. They may also affect ambient food products which are consolidated in containers with other products, not necessarily food products. The products of smaller company exporters in particular could be consolidated in containers which can be topped up virtually at the last minute before loading, and this practice could contravene the notice requirements. The presence of non-compliant product in a consolidated container could cause delays, even the impounding of containers, and additional costs or loss of sales for exporters with compliant products in the same containers.

The Government of Australia therefore 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 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.

Current exports from Australia

Many of the products covered by the proposed measures under Section 307 are already subject to strict regulatory and certification requirements as 'prescribed goods' under Australian legislation (the *Export Control Act 1982*). These are: milk and dairy products, fish and shellfish, game meat, meat from species not classified as livestock under Section 301.2(qq) of Chapter 9 of the Code of Federal Regulations, and animal food and products thereof, including low acid canned foods and pharmaceutical raw materials derived from animals.

Controls applying to establishments producing these goods for export to the United States include regular audits by US authorities. Australia therefore believes that the provisions of Section 307 of the *Bioterrorism Act* could be met through an equivalence-based approach, recognising the Australian export inspection and certification system.

Australia understands that the US intends to build into the Prior Notice system provisions to utilise Customs information. We welcome that initiative, which will substantially reduce duplication and the burden of compliance. We are, however, disappointed that provision has not so far been made for incorporation of EXDOC (electronic certification for certain products exported from Australia)

certification. This electronic certification system has been added to the agenda of the 2002/03 Food Safety Quadrilateral meetings between the USA, Australia, New Zealand and Canada. Australia and New Zealand have been charged with developing the system which is currently being trialled. Canada expects to come “on-line” in the next few months.

We consider that Section 307 (Prior Notice of Imported Food Shipments) is potentially the most restrictive and costly measure under the *Bioterrorism Act*. The measures proposed under the *Bioterrorism Act* 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.

Australia therefore urges the USA to apply its risk mitigation measures under this Act in a manner that minimises regulatory impact on industry and has regard to existing food regulation and export certification systems in Australia, as well as to the overall WTO rights and obligations of Australia and the USA. The additional confidence provided to the USA in relation to food export businesses by the certifying authority of the exporting country, in this case AQIS, should be an important factor in the consideration of mitigatory measures.

Specific comments

Following comments reflect the format of the Federal Register Notice of proposed rulemaking.

C.1. Who is authorised to submit the Prior Notice?

It is proposed that the Prior Notice may only be submitted (electronically) by a purchaser, importer of an article of food, or an agent acting on behalf of the US purchaser, who reside or maintain business in the United States. This is presumably to facilitate FDA’s ability to conduct audits, investigations and inspections. Although it is understood that FDA can only regulate residents, this requirements does not appreciate that both FDA and FSIS audit Australian companies.

The Australian Quarantine and Inspection Service (AQIS) issues export/health certificates for the majority of export shipments of the products controlled by FDA to the USA in line with current US requirements. AQIS is presently moving to a system of electronic certification (EXDOC). 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. As noted in the general comments, Australia and the US (and also New Zealand and Canada) have agreed to commence electronic certification for meat trade in the next few months. The new system will provide the capability of electronic certification for meat, dairy, seafood, horticultural products and grain.

For those commodities prescribed under the *Export Control Act*, 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. Only certain highly refined products, eg gelatin, pharmaceutical raw materials derived from animals and inedible products of animal origin that are subject to FDA jurisdiction, will continue to require manual certificates after the full implementation of EXDOC.

We are not aware of any intentions by FDA to remove the existing requirements for export/health government-to-government certificates. FDA will, therefore handle at least two documents for each shipment of Australian products covered by AQIS – Prior Notice and export/health certificate, both containing similar information.

In addition, if access to the FDA website is the determining factor in lodging the Prior Notice, we believe that exporters or their agents in most countries exporting food products to the USA would have access to the internet and should also be able to access the USFDA website to electronically lodge the Prior Notice for themselves rather than requiring a US agent to do so on their behalf.

In conclusion, the Government of Australia believes that the requirements that only residents of the USA may lodge the Prior Notice will limit normal business practices and does not reflect existing practices. We offer the following suggestions:

- Government-to-government export/health certification that is required for imports of certain products to the USA and contains most of the information required for the Prior Notice, and that can be transmitted electronically, should be accepted as an electronically lodged Prior Notice.
- Overseas exporters or their agents should also be able to access the USFDA website to electronically lodge the Prior Notice.

C.2. When must the Prior Notice be submitted?

Section 307 requires a Prior Notice of a shipment to be lodged no later than by noon of the calendar day prior to the “day of crossing” and no earlier than 5 days before the anticipated date of arrival.

The Government of Australia believes that the above proposal would lead to unnecessary additional costs to companies handling exports to the USA because: -

- It does not reflect existing business practices (that reflect US government requirements) and
- It does not reflect the variable and unpredictable nature of transport, 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. Whilst we understand arguments about FDA resource constraints, we recommend the following modification of the proposed time frame:

- in order to accommodate transport by ship, FDA should allow lodgement of the Prior Notice earlier than 5 days before the anticipated date of arrival (“date of crossing”); and
- in order to accommodate transport by air FDA should allow lodgement of the Prior Notice later than by noon of the calendar day prior to the “day of crossing”.

C.3. How must be the Prior Notice submitted?

FDA is proposing that the Prior Notice, amendments and updates must be submitted electronically to FDA through the FDA’s web-based Prior Notice System that is now under development. The US Customs electronic lodgement system will not be modified before 2005 to accommodate requirements of FDA.

In the event of software problems, Australian exporters to the USA will be forced to repeatedly submit information to two different authorities of the one government for at least two years, in addition to providing the previously mentioned AQIS export/health certificate also required by FDA and FSIS/USDA.

Several Australian export industries have expressed their concern as to whether FDA will have the resources and capability to handle and effectively scrutinise a constant flood of thousands of initial, amended or updated Prior Notices. If the FDA’s web-based Prior Notice System will only be able to accept Prior Notices and issue automatic approvals, then it could be argued that such a system

will not provide any additional security to US consumers over and above the existing US Customs system that handles similar information about import shipments.

Australian exporters are also concerned that the above resource constraints may lead to trade disruptions such as delays in clearing shipments.

C.4. What information must be submitted in a Prior Notice?

FDA admits in the Federal Register Notice of proposed ruling that most of the information required for the US Customs entry system is identical to that required by FDA Prior Notice. The following table summarises information which exporters are required to supply to US authorities:

Information	AQIS health certificate	US Customs notification	FDA Prior Notice
The submitter		x	x
The US Customs entry type		x	x
The US Customs entry line number of identification number		x *	x
The location where the food is held if refused entry		x	x
The product identity	x	x	x
The complete FDA product code			x
The common or usual market name	x	x	x
The trade or brand name	x	x	x
The quantity	x	x	x
The lot or code number or other identifier	x	x	x
The manufacturer	x		x
The growers if known			x
The originating country	x	x	x
The shipper	x	x	x
The country of shipping	x	x	x
The anticipated port of entry	x	x	x
The anticipated date of arrival			x
The anticipated time of arrival			x
The port where entry is made for US Customs purposes		x	x
The anticipated date of US Customs entry		x	x
The importer, owner, consignee	x	x	x
The carrier			x
Container numbers	x	x	
Container seal numbers	x	x	
Value		x	

* harmonised tariff schedule

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 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 proposed rulemaking 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*.

It can be argued that information provided to FDA under existing export/health certification requirements and to the US Customs by either exporters of products to the USA or their importers

in the USA already covers all the information sufficient to facilitate real-time tracing of food products imported into the USA and hence to 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.

It can be further argued that the quantity and type of information required for the Prior Notice will fundamentally change business practices for exporters of food to the USA, 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 USA for the domestic market, contrary to SPS and TBT principles.

Therefore, as previously mentioned, the Government of Australia 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.

We also note that the proposed rule allows for an exemption from the Prior Notice for facilities that are under the control of another agency within the USDA. Currently, meat, poultry and egg products are controlled by the USDA's Food Safety and Inspection Service (FSIS) 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 USA. Thus, Australia believes that, to maintain consistency, the FDA could consider exempting shipments of products covered by FDA and controlled by AQIS.

C.5. What changes are allowed to a Prior Notice after it has been submitted?

C.6. Under what circumstances must you submit a product identity amendment to your Prior Notice after you have submitted it to FDA?

C.7. What is the deadline for product identity amendments?

C.8. How do you submit a product identity amendment or an arrival update to a Prior Notice?

C.9. What are the consequences if you do not submit a product identity amendment to your Prior Notice?

Australia welcomes the fact that the proposed system will have sufficient flexibility to accept changes to initial Prior Notices. However, we are concerned that this flexibility may ultimately overload the system, and at the same time increase the possibility of errors in Prior Notice information and disrupt trade due to backlog of Prior Notices not approved by FDA. Trade disruptions may range from delays in clearance to a loss of shipments of perishable products.

On behalf of Australia's export industries we wish to raise the following questions and concerns:

Food samples are exported with the intended end use of analysis, experimentation and/or subsequent destruction within approved company premises. Such samples generally do not enter commercial trade, and may be carried into the USA as personal baggage of company representatives or sent unaccompanied. It is noted that the FDA have proposed to exempt food carried in personal baggage only if it is for "personal enjoyment/use". Australia seeks clarification on how samples that do not enter commercial trade are to be treated under the proposed rule for the Prior Notice.

Will a shipment be held as a result of an error on the Prior Notice from eg misspelling of a brand name. If yes, we suggest FDA consider issuing a Notice to rectify the error but allow the release of a product.

Will there be a penalty for cancelling a Notice and lodging a new Notice (where details of a new shipment are significantly different and therefore the original Prior Notice cannot be amended)?

Does prior intent to amend need to be evident on the initial Prior Notice, or can an amendment be made to product identity and arrival information as long as it is within the minimum two hour requirement?

It is unclear what the impact of the proposals would be on containers bound for destinations beyond the US which are on ships that visit US ports on the way to those destinations, such as the Eastern route to Europe via the Panama Canal. If such containers are affected, the regulations could adversely effect trade to markets other than the USA. Products for which the Prior Notice was not provided could even be impounded while the ship was in a US port. Companies may seek to avoid the potential cost and disruption by diverting freight to other routes with implications for the volume of traffic and freight rates on routes via the USA.