Comments of the Government of Australia on Notice of Interim Final Rule on Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Federal Register Docket No. 02N-0276

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Overall comments

The Australian Government welcomes the opportunity to provide comments on the United States of America Government's Federal Register (Docket No. 02N-0276) interim final rule for the Registration of Food Facilities Under the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, of 10 October 2003.

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

The Australian Government understands and supports the initiatives of the Government of the USA 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 Government, 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 just in isolation from each other, as the impacts of these rules, on both domestic and foreign trade, are inter-related. Australia also acknowledges and welcomes the changes made to the proposed rules on facility registration and prior notice.

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 USA, 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, and 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.

Australia seeks the United States' assurances that the interim final rule on facility registration will meet the latter's SPS and/or TBT obligations. Australia is particularly concerned that the US *Bioterrorism Act*:

- does not allow for recognition of alternative system 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 the existing controls.

Summary of Australia's requests

Reduction in the current economic impact and trade restrictive nature of the US agent requirement arising from the interim final rule – Australia seeks further flexibility in the mandatory requirement for a US agent. Australia acknowledges that the Bioterrorism Act requires the nomination of a US agent, however, Australia requests innovation on the part of FDA in the implementation of this requirement to limit its negative and trade restrictive impact on commerce, both domestically and in foreign countries.

Recognition of alternative systems – Australia seeks recognition of the Commonwealth of Australia *Export Control Act 1982* legislation and the export inspection and certification system underpinning the operation of this legislation for commodities covered by FDA as being an alternative system producing comparable outcomes. This recognition of alternative systems will be consistent with recognition already accorded to this legislation and system by the US Food Safety and Inspection Service (FSIS) for the provision of safe and wholesome meat and ratite products to the USA for human consumption.

Introduction

As stated previously, Australia supports initiatives to establish controls and countermeasures for bioterrorism. We note however, that "***I. Background and Legal Authority***" of the interim final rule states that the "*In developing this interim final rule, FDA has complied with its international trade obligations, including the applicable World Trade Organisation (WTO) agreements and the North American Free Trade Agreement (NAFTA)*". Australia appreciates the US Food and Drug Administration (FDA) commitment to international trade obligations, and in particular the re-opening of the comment period in March 2004 to consider comments based on actual experience of complying with the regulations.

The FDA should also ensure that the rule's requirements are flexible, and that such flexibility should include the principle of equivalence as expressed in the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement). Australia would welcome such approaches by the USA.

Australia would appreciate the FDA providing a further comment period based on the full enforcement operation of the Bioterrorism Act regulations (ie re-open the comment period after the first eight months following the effect date of 12 December 2003). The FDA's Compliance Policy Guide (issued 11 December 2003) indicates that the first eight months will be a focus of educating people on the requirements of the new regulations.

Trade restrictive issues of the interim final rule – US Agent

In general, the FDA has made efforts to simplify the process of electronic registration and facilitate prompt turnaround in receiving an FDA registration on completion of the registration procedure. Electronic registration can represent cost savings to both the FDA and to facilities that need to register, and for computer literate businesses this method of registering works well. However, for both computer literate and non-literate Australian businesses the costly imposition of completing the registration procedure is the requirement for a mandatory US agent.

In the interim final rule the FDA reaffirms in section "***3. Number of Facilities Affected***" that 16% of foreign manufacturers/processors would stop exporting to the United States because of the cost of complying with the facility registration regulation. This would occur as result of the mandatory requirement for engaging and maintaining a US Agent to act as a communications and post office box link between the FDA and the foreign facility. The FDA has advised in its response to Comment 88 that day-to-day registration issues may include FDA's need for information about the facility, and arranging routine inspections. Furthermore, where the foreign facility does not optionally elect an alternative foreign emergency contact, FDA expects the US agent to facilitate inspections or communications with the foreign facility in the event of a potential bioterrorist threat or other public health emergency. Additionally, the FDA also factors into its costs in section "***IV. Analysis of Economic Impacts***" the cost of an annual mailing to registrants.

Australia agrees that there is potential for some loss of Australian export trade to the USA resulting from the registration requirement for a mandatory US agent to be nominated. The Australian Government, like FDA, is unable to provide any advice to exporters on procuring and engaging a US agent as this matter is of a commercial nature. This lack of assistance may prove problematic for those exporters with little or no contacts in the USA, and also for new exporters wanting to enter the market.

There are several types of Australian businesses and final exporters that are affected by the requirement for a US agent and may cease trading with the USA as a result of the registration regulation. As FDA expects, smaller traders, single operator businesses and those facilities without sister companies in the US will have difficulty in locating a suitable person or business to act as the US agent for registration purposes.

In addition, there could be Australian businesses that already trade with partners or business affiliates that act as agents for these businesses for facilitating their trade to the USA but these agents live and maintain a business just over the US border in either Canada or Mexico rather than in the USA proper. For these types of businesses, the impost of obtaining a US agent that resides or maintains a place of business in the USA seems trade restrictive and illogical where presently engaged commercial agents just over the border facilitate the exporters' trade with US businesses. These commercial agents live in the same time zones as the USA, and can converse easily with FDA officials, thus making the impost of another layer of bureaucracy overly burdensome and costly without yielding any additional benefits over and above the communications service that the current commercial agents could provide.

Some Australian export trade is conducted by non-packer exporters (NPEs). These are people/businesses that source product from other Australian businesses or companies, and in the terms of agreement for sale take ownership of the food product once the product is on board the vessel, aircraft or other form of transport carrier. Hence NPEs are businesses that do not physical store or handle the food product, and thus, are not required to be registered under the

Bioterrorism regulation. As a result, NPEs, the final exporter of food to USA, are obliged to source food product from facilities that are registered with the FDA.

For some NPEs, their suppliers are Australian domestic facilities that may not otherwise engage in the export trade. It is a commercial decision for such domestic suppliers whether to register for the benefit of the NPE or to forego their business. Likewise, cold stores, freight-forwarders and other storage facilities that handle little FDA jurisdictional food product (i.e. tend to handle product that comes under US Department of Agriculture [USDA] jurisdiction or products destined for non-USA markets) are in a similar position of making a commercial decision as to whether to register with the FDA and commit to all that registration entails, or to avoid commerce that would require such action. Adverse commercial decisions by businesses in the supply chain of NPEs could greatly diminish the opportunity for American importers to trade with these businesses.

The Australian Government acknowledges and welcomes FDA's move to allow foreign businesses to nominate an alternative emergency contact to the mandatory US agent. This change does introduce some flexibility in the implementation of the final regulation, while more flexibility is still required to alleviate the trade restrictive impact of this requirement. Even though the intent of the US *Bioterrorism Act* is not to discriminate against foreign exporters, unless the registration requirement for a mandatory US agent can be simplified further, the assumed reduction in exports to the USA will be a real consequence of its implementation.

The Australian Government requests that the US Government reconsiders the interpretation for the mandatory requirement for a US agent for Bioterrorism Act registration purposes. Australia acknowledges that the US *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (the "*Bioterrorism Act*") states *"... shall include with the registration the name of the United States agent for the facility*." However, this statement does not specifically state the two qualifications imposed by the FDA as being required (namely that the US agent is (1) required to reside or maintain a place of business in the United States and (2) to be physically present in the United States). The Act also does not state that the US agent nominated could not be the importer broker relevant for each particular consignment.

Australia requests that consideration be given to showing flexibility in the final rule by allowing for the nomination of the importer/consignee as listed on the relevant Prior Notice for each consignment where the registrant elects the option of nominating an alternative emergency contact. We acknowledge that this person (importer/consignee) may change between consignments, so an acceptance of a general registration entry, such as for example *'see relevant importer/consignee information on Prior Notice'* in the US agent field will be required to still meet the legal requirements of the US *Bioterrorism Act*. In cases of emergencies relating to a particular consignment, it is expected that as part of any FDA emergency investigation or follow up, the FDA would contact the importer/consignee in addition to the nominated emergency contact point for the facility as part of a one up and one down investigative approach.

Australia believes that the US requirement for a communication link between the FDA and the registered facility could be met by allowing the nominated Australian emergency contact person to be contacted electronically for all routine communications in addition to any emergency contact by telephone. This will reduce the cost imposts on Australian businesses for engaging and maintaining a mandatory US agent as well as imposts for the FDA if their annual mailing to registrants is also conducted electronically. Use of electronic communications could also potentially reduce the negative compliance impacts for smaller Australian traders, other exporters (eg NPEs) and domestic businesses, and thus facilitate continuing participation in food transactions with US businesses by these operators. Australia also notes that the FDA has stated

in the interim final rule (response to Comment 121) that it will consider contacting the facility directly in the event they cannot reach the nominated US agent, thus bypassing the US agent's involvement as a communications link completely.

Such flexibility in the option for registrants to nominate the relevant importer/consignee for consignments would also reduce potential negative impacts on US businesses through the potential loss of suppliers due to the implementation of the US *Bioterrorism Act*.

Australia questions FDA's requirement for organisations applying for registration to have a mandatory US agent to provide a communication link between FDA and the Australian facility where electronic means of communication is available at the Australian facility and whether this condition would be necessary for the protection of human or animal health. The listing of a mandatory US agent would seem to constitute a disguised restriction on trade (as per Article 2.3 of the SPS Agreement). Flexibility by the FDA in the implementation the US agent stipulation of the US *Bioterrorism Act* would alleviate any adverse trade restrictive impact of this new regulation, and be consistent with WTO/SPS principles and obligations.

US Agent – contractual obligations

In the proposed rule, the FDA recommended that a legal arrangement be entered into between the foreign facility and the mandatory US agent. However, in contrast, the interim final rule does not recommend facilities to enter such arrangements. The interim final rule does however, in its response to Comment 84, note that *"Liability issues between the facility and its US agent must be resolved between the private parties …, most likely through the terms of their contractual relationship."* In contrast, the FDA response to Comment 183 states that *"FDA does not require a legal agreement between the US agent and the foreign facility…"*. These are contradictory signals from the FDA, particularly in relation to foreign facilities and foreign governments concerns relating to the responsibilities and liabilities of US agents and how FDA will handle such issues.

The FDA requested comments on aspects relating to the US agent and the impact of this requirement on domestic (US) businesses. Australia provides the following responses:

Request for comments: *FDA requests comments on the distribution of cost between submitting registrations and other services offered by the US agent.*

Australia assumes that the fees stated for US agent services are limited to the FDA stipulated duties to be undertaken by US agents, namely the provision of routine communications between FDA and the foreign facility, and optional emergency contact support and authorisation to register the foreign facility. Many firms such as US law firms, which are generally not considered as part of the usual import trade process in clearing consignments, are offering their services to act as US agents for foreign facilities, thus it can be assumed that, in general these quoted fees will be for US agent duties only.

If a foreign facility nominates a US agent that is presently acting in another capacity for the facility (eg as an import broker) then the US agent duties will be in addition to current import broker duties. These additional (US agent) duties could possibly incur further business expense for the foreign facility depending on the contractual arrangement the facility has with the import

broker. Hence, Australia assumes that US agent fees will be in addition to any fee for service arrangements currently in progress between facilities and business agents for expediting port of entry clearance for consignments.

Request for comments: *FDA requests comments on the overall cost of hiring and retaining a US agent and the assumptions underlying FDA's estimates of these costs.*

FDA acknowledges that its costing for foreign facilities includes the activities of finding and hiring a US agent for registration purposes. However, it is does not appear clear that this costing estimate allows for legal costs incurred by a foreign facility in reaching a contractual arrangement between the two parties (ie facility and US agent). FDA's costs appear to focus on the fees a potential agent will charge for services. There is no indication whether these fees cover comprehensive services such as registering the foreign facility, updating registration details as required, acting as communications link for routine exchanges and providing emergency contact support, or whether the fees only cover minimal routine communications support.

The ease of finding a suitable US agent, then engaging and retaining this agent is quite variable for foreign facilities. For small to medium enterprises, and those Australian domestic businesses that need to comply with US Bioterrorism Act regulations to allow their clients to continue to trade with the USA, locating possible agents in the first instance is proving problematic. Overcoming this hurdle could take Australian exporters longer to find a US agent than the FDA originally anticipated it would take foreign firms to accomplish, thus incurring greater administrative costs in completing the registration process and also incurring costs associated with the temporary inability to trade with US importers who would also incur costs from not being able to supply product to their US customers. This would also result in a slow uptake in the registration of foreign facilities due to the time involved in locating a US agent.

Australia believes that FDA's cost analysis for US agent fees underestimates the true cost to foreign facilities for locating, engaging and retaining a US agent. Australia acknowledges that global trade does involve language barriers, and that steps must be taken to surmount these obstacles for the continuation of trade. However, where language does not present an obstacle, FDA flexibility in allowing for the option of routine communications to occur electronically directly with the foreign facility, in conjunction with the nomination of "see relevant import broker for consignment" for the mandatory US agent registration data field would be greatly appreciated. Such action would alleviate the trade restrictive aspect of the registration regulation and be consistent with WTO obligations.

Request for comments on: *Effects on domestic (US) small businesses, if any, of some foreign facilities cease exporting to the United States due to the US agent requirement for registration.*

It is reasonable to assume that US domestic businesses and consumers will be affected by loss of foreign trade resulting from the US agent requirement for registration. Potential market forces that may affect US domestic businesses could include:

- the need to source new suppliers of food product;

- inability to supply items to an existing customer base;
- possible increase in cost of goods due to a contraction in supply of goods (eg US beef prices increased in 2003 when Canadian beef could no longer be obtained); and
- cost increases could be passed on to the US consumer.

Recognition of Alternative Systems

The Australian Government welcomes FDA's commitment to continue to look for ways to minimise duplicative registrations in the future as stated in the interim final rule. Australia requests that consideration be given to Australia's *Export Control Act 1982* and the export registration, inspection and certification systems underpinning the legislation being recognised as an alternative system. Many of the products covered by the registration regulation are already subject to strict regulatory and certification requirements as 'prescribed goods' under this legislation. Registration for export purposes requires an official assessment of acceptability of the application, including conducting 'fit and proper persons' reviews on all people listed in the application prior to granting export registration.

Australia believes 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 FDA 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 is a system operating between US, Canada, Australia and New Zealand and could be used to advantage and has the capability for electronic certification for meat, dairy, seafood, horticultural products and grain.

Currently the US agency, the Food Safety and Inspection Service (FSIS), within the US Department of Agriculture recognises Australia's export systems as being an acceptable alternative system. The Australian Government requests that FDA give consideration for the recognition of our export systems as being an acceptable alternative system.

Australia therefore urges the US Government to consider mechanisms that minimise regulatory impact on industry whilst still protecting US human and animal health, 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 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 *Registration of Food Facilities Under the Public Health Security and Bioterrorism preparedness and Response Act of 2002*, interim final rule.

1. What are the obligations for facilities such as Australian export meat establishments that register with the FDA in case their food products are consumed in the USA by animals? The FDA recommends this type of action for producers of vintage wine in the interim final rule response to comment 22.

2. FDA states that it will use the food category information to target communications, particularly in the event of a food related emergency. How will it differentiate edible meat facilities that register just in case their product is consumed in the USA by animals from those animal food facilities that are required to register?

3. What happens to consignments of food that arrive in the USA, but the last manufacturing facility has changed ownership, and hence cancelled its registration, since production of the food? The registration number of the facility was current at the time of production, however this number is cancelled prior to the food arriving in the USA.

4. Clarification is sought on the difference between the registration and prior notice rules. Namely, all foreign facilities the supply food to the US, including all States and Territories of the USA, and to the District of Columbia, or the Commonwealth of Puerto Rico are required to register with the FDA. However, prior notice to import is only required for food shipments exported to US States, the District of Columbia, and the Commonwealth of Puerto Rico. Thus, prior notices are not required for food shipments to the Territories of the USA.

5. Clarification is sought on which products are under the joint jurisdiction of FDA and the US Department of Agriculture (USDA), and thus will be obliged to comply with the new regulations. For example, processed meats, sausages, or other ready to eat meat based products may contain some degree of binder, marinade etc. Are these products under joint USDA / FDA jurisdiction?

6. The response to comment 63 discusses processing aids. Do foreign establishments producing processing aids have to register under the requirements of the Bioterrorism Act if they supply these aids to another foreign facility for use in the food that the subsequent manufacturer produces? What are the registration responsibilities for processing aid manufacturers that supply the aids to establishments under the exclusive jurisdiction of the USDA?

7. FDA response to comment 83 indicates that warehouses holding food for sale in duty free shops are not required to be registered, as the food is not consumed in the USA. Given this scenario, are bonded airline kitchens and stores required to be registered given that the food stored in these premises is also not consumed within the USA, but is consumed in international air space during flight? And does food going to these bonded kitchens/stores require prior notice to import notifications?

8. Clarification is sought on when the interim final rules for record keeping and administrative detention will be released and on whether the FDA plans to contact each registered facility with these new rule requirements.

9. Would a person who is conducting a direct marketing business (via the internet) from their own private residence be exempt from the registration requirements under the private residence exemption? Such direct marketers could be supplying US consumers directly and to some US food distributors. Would direct marketers working from their own private residence be exempt from registration requirements despite the fact that they supply mainly US food distributors?

10. Does the registration regulation apply to fishing vessels that catch seafood (eg prawns), sort them in grades, etc, and then pack the prawns into cartons ready for freezing on board the vessel? It can be assumed that this product is then off-loaded at the dock into a storage facility ready for distribution and being further packed into containers/pellets ready for export.

11. With international mail, do the individual post offices have to be registered ? (as they will be potentially holding food items).

12. Food samples that are consumed in the USA are required to be sourced from registered facilities. (see response to comment 67) In light of this requirement, does this mean that commercially prepared food, purchased from a retail outlet and thus exempt from registration under the retail exemption, needs to be originally sourced from registered manufacturing facilities to allow entry to the USA? It is anticipated such products would be posted to the USA

13. Clarification is sought on how the Act will be applied to artificial and/or natural casings. For example, are natural casings exclusively covered by USDA FSIS and thus are exempt from the Act's requirements?