The attached document was given to USDA/FAS in Canberra during the U.S.-Australia FTA negotiations. It is one set of Australia's comments on the proposed U.S. regulations for registration and prior notice under the Bioterrorism Act. The USDA/FAS representative had originally understood that Australia's comments were being sent electronically, to the docket, and that the attached hard copy of the comments was a courtesy copy for the U.S. Enquiry Point. As a result, the hard copy comments were kept in USDA/FAS/Enquiry Point files. Later, the USDA/FAS rep learned that Australia had not sent the hard copy comments electronially, but had sent other comments electronically. Upon learning that, FAS rep tranmitted the hard copy comments to FDA, and FDA asked that they be sent to the docket, per this message, attached below.

Comments of the Government of Australia on rules proposed by the Department of Health and Human Services Food and Drug Administration (FDA) under the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (the *Bioterrorism Act*) and notified in

WTO Notification G/SPS/N/USA/691 of 6 February 2003

The Government of Australia welcomes the opportunity to provide comments on the United States of America Government's proposed framework for registration of domestic and foreign food manufacturing facilities. Australia has a direct interest in the USA food safety system, as an exporter of substantial quantities of food and feedstuffs.

Introduction

Australia has limited its comments to the underlying principles of international standards and equivalency we believe should be followed in the establishment of any registration system for foreign food manufacturing. We have the following comments in relation to registration of premises processing and preparing certain food and inedible products for sale on the United States domestic market, specified in Section 305 (Registration of Food Facilities) of the *Bioterrorism Act*.

Australia understands that the proposed framework is intended to limit risks to the US population by providing information to enable FDA to respond quickly to a threatened or actual bioterrorist attack on the US food supply or other food-related emergency. Australia supports these objectives, but urges the US to implement these measures under this legislation in a manner that will minimise disruption to trade while addressing identified risks.

International obligations

Australia believes that the US gives a high priority to compliance with its WTO obligations. As such we would encourage the US government to ensure that measures implemented under the *Bioterrorism Act* comply fully with the WTO SPS Agreement as well as, where relevant, the TBT Agreement. Such measures would

- Be based on a risk assessment
- Be not more trade restrictive than necessary to meet its objective/s
- Allow for equivalent measures to achieve its objective/s
- Avoid arbitrary or unjustifiable differences in the level of protection applied in different situations.

Australia is particularly concerned that the *Bioterrorism Act* does not allow for equivalence determinations.

Equivalence

Australia remains committed to a food safety system that delivers high quality food. Australia's food regulatory system has as its primary objective the protection of public health and safety, while imposing minimal regulatory burden on the food industry. It has a through-chain focus, with inclusion of primary production standards in the *Food Standards Code*, and with responsibility shared between Health and Agriculture departments.

Many of the products covered by the proposed measures under Section 305 are already subject to strict regulatory and certification requirements as 'prescribed goods' under Australian legislation (the *Export Control Act 1982*)[1]. Controls applying to establishments producing these goods for export to the United States include regular audits by US authorities (FDA and FSIS). Australia therefore believes that the provisions of Section 305 of the *Bioterrorism Act* could be met through recognition of AQIS registering premises under the Export Control Act and our provision to FDA of a list of export-registered establishments on a regular basis.

As the *Bioterrorism Act* applies only to products regulated by the FDA, it can be inferred that the US considers the current regulatory arrangements for poultry and meat of livestock other than game species (which fall outside FDA jurisdiction) already provide the appropriate level of protection. These products are regulated by AQIS as prescribed goods under the Export Control Act, subject to regular US audits. Australia considers that corresponding arrangements for FDA-regulated products that are also prescribed under the Export Control Act would be a practical, cost-effective and WTO-consistent way of meeting the US objectives under Section 305. Linking the US system to the existing Australian system would provide an additional level of assurance to the US on the management of risk; the proposed registration requirements, involving direct dealing between US authorities and commercial operators, bypass that opportunity.

Conclusion

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 US 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.

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[1] Prescribed Goods under the *Export Control Act 1982* include: 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.