



Department of
**AGRICULTURE
FISHERIES &
FORESTRY -
AUSTRALIA**



30 August 2002

Ms Mary Ayling
Prior Notice Working Group
Mail Code HFS-032
Food and Drug Administration
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD 20740

Dear Ms Ayling

I refer to the advice issued on 17 July 2002 by the Food and Drug Administration (FDA) on the *Bioterrorism Act* in which comments were requested on some aspects of the new requirements.

I am writing to you in relation to the new requirements for prior notification of imported food shipments of certain food and inedible products for sale in the United States domestic market, specified in Section 307 (Prior Notice of Imported Food Shipments) of the *Bioterrorism Act*.

Section 307 requires that prior notice of food shipments be given to FDA. The notice must include a description of the article, the manufacturer and shipper, the grower (if known), the country of origin, the country from which the article is shipped, and the anticipated port of entry.

Agricultural and food exports from Australia are regulated when governments of importing countries require government-to-government certification and inspection or auditing of processing premises. The Australian Quarantine and Inspection Service (AQIS), one of several operational units of the Commonwealth (ie federal) Department of Agriculture, Fisheries and Forestry, is responsible for inspection and certification of these regulated agri-food exports.

The AQIS export inspection program operates primarily within the statutory powers of the *Export Control Act 1982*. The Act is supported by regulations, the Export Control (Orders) Regulations and specific commodity Orders.

The following commodities are both regulated by FDA and "prescribed" under the *Export Control Act 1982*: milk and dairy products, fish and shellfish, game meat, meat from species not classed 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.

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AQIS issues an export/health certificate for all export shipments of these commodities to the United States in line with the known and negotiated requirements of US authorities. At this stage the AQIS electronic export documentation system (EXDOC) produces a paper certificate which is then presented to US import authorities.

All edible fresh and processed meat whether subject to FDA or FSIS jurisdiction are certified for export to the USA using certificates produced with EXDOC. AQIS will shortly commence sending a report to FSIS and FDA of all edible meat shipments it has authorised for export to the USA.

Australia (and also New Zealand and Canada) and the United States have agreed to commence electronic (paperless) certification for meat trade by April 2003. The new system will provide the capability of electronic certification for meat, dairy, seafood, horticulture and grain products in the near future.

Therefore, for these commodities AQIS will be in a position to send electronically certification that will contain all the information about a shipment required in Section 307 (Prior Notice of Imported Food Shipments) of the *Bioterrorism Act* and there will be no need to send a separate prior notice.

However, certain highly refined products (eg gelatin), pharmaceutical raw materials derived from animals and inedible products of animal origin which are subject to FDA jurisdiction, are currently issued with manual certificates. Until such time as EXDOC extends to the range of products currently issued with manual certificates, AQIS and Australian exporters of these products will need to determine how best to comply with the requirement for prior notification of import.

In order that AQIS may finalise details of any future arrangement to comply with the requirements of the *Bioterrorism Act*, we would appreciate clarification of the commodities and food products affected by the Act.

The export inspection and certification system is subject to regular audits by government authorities in countries importing Australian food products, for example by the European Commission and authorities in Korea, Chile, Brazil, Japan and Peru.

The Australian export fish inspection and certification system was reviewed by FDA in September 1998. Several Australian establishments processing dairy products for export to the United States were also inspected in 2001 and AQIS and FDA are now organising another review in August 2003.

Through various international fora and bilateral meetings between representatives of the United States and Australia we understand that the USA is fully committed to its WTO obligations, including Article 4 of the Sanitary and Phytosanitary Agreement which provides for consideration of equivalency between regulatory measures in importing and exporting countries.

The proposal outlined above, to meet the provision of Section 307 of the *Bioterrorism Act* through AQIS export certification of shipments of agri-food exports to the United States, would be fully in line with Article 4 of the SPS Agreement and would provide relevant assurances to US consumers and government authorities about the safety of Australian agri-food exports.

We trust FDA will consider the proposal favourably.

Yours sincerely



Steve Bailey
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AQIS Exports

CC Dr Phil Corrigan, Veterinary Counsellor, Australian Embassy, Washington
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