Facsimile Message

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SUBJECT: **Australian Questions.**

To the Dockets Clerk and
Louis J Carson.

Please find attached the Australian government and industry questions for consideration during the satellite downlink public meeting on the two interim final rules for the Bioterrorism Act to be held on Tuesday, 28 October 2003.

Docket Nos: 2002N-0276 and 2002N-0278.

Regards, Dr Andrew Cupit.

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Australian Government

Department of Agriculture, Fisheries and Forestry

Questions for consideration during the satellite downlink public meeting on the two interim final rules for the Bioterrorism Act to be held on Tuesday, 28 October 2003.

FACILITY REGISTRATION

- The interim rule for Facility Registration indicates on page 16 that the FDA will hold international outreach activities for US trading partners. What international outreach activities are being planned?

- Comment/response 17 (pages 28-9) indicates that the manufacturer/processor needs to register, along with every facility that subsequently engages in packing or holding 'the beans', and any facility the subsequently engages in "de minimis" manufacturing/processing. In addition, FDA's comment/response 26 (page 32-3), states that de minimis activity does not involve the direct manipulation of food. However the FDA's response to comment 10 (page 25), states that the interim final rule requires only the last manufacturer/processor, including those that package food, to register. Surely facilities that package foods in a non de minimis manner are the "last" manufacturer/processor, thus any previous manufacturer/processors of the beans need not register. We seek clarification on this issue.

- We request further clarification of de minimis activity. Could you provide examples of de minimis activity?

- We seek clarification on whether quarantine/customs bond stores and inspection facilities are required to register.

- Are facilities that store food that is being trans-shipped through Australia required to be registered with the FDA?

- Airlines receive goods (including food) destined for export to the USA into their cargo terminals. These goods may be pre-packed (eg into cargo load devices (ULDs) or on pallets), or may be loose and require packing into ULDs. Is it necessary that each cargo terminal be registered?

- To what extent is the Australian exporter liable for penalties if its US agent is negligent in performance of its duty as a communication link (including for emergency purposes) between the FDA and the exporter?

- Can the US FDA provide a list of whom it considers to be suitable US agents for the purposes of meeting the requirements of the US Bioterrorism Act Facility Registration Regulation?

- Does FDA have any contingency plans in place to avoid trade disruptions occurring on or after 12 December 2003 in case the electronic registration system is not as efficient as expected?

- Does FDA have any contingency plans for handling a greater than anticipated number of facility registrations? (ie where FDA greatly under-estimates the number of foreign facilities being required to register.)

- Non-packer exporters, whilst owning food, do not store food in a facility. The non-packer exporter takes ownership of a food consignment once it is stored on board the carrier (eg ship) that conveys the food to the USA. As facility registration only applies to facilities we seek confirmation that non-packer exporters do not have to register with the FDA under the Bioterrorism Act, as they do not have (own) facilities to store food consignments.

PRIOR NOTICE

- Assuming non-packer exporters do not register with the FDA, what are the Prior Notice obligations for this type of food trader?

- The interim final rule for Prior Notice to Import states that postal items containing food which do not have evidence of Prior Notice will be refused admission into the USA. What will be the disposition of mail without Prior Notice? Would it be the responsibility of the US postal service?

- International airlines use food supplies kept in storage (in USA) 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.

- 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?

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

- The starting date for the new requirements - when exactly do the new requirements commence? For example, is it 00:01am on 12 December 2003 in the Eastern USA and therefore late 11 December in the Western USA, or 00:01am on 12 December in the Eastern USA and then, few hours later, 00:01am on 12 December in the Western USA?

- If Australian exporters anticipate arrival of the shipments in the US before 12 December, but flights/sea voyages are delayed, will FDA be able to process last minute prior notices without affecting these shipments?

- 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.

- We are similarly concerned about the identification of the article of food.

- Scope of the ruling - who should submit the Prior Notice?
  We seek further clarification of products covered by the new requirements - which if any products, normally subject to the jurisdiction of the USDA under the Federal Meat Inspection Act/the Poultry Products Inspection Act or the Egg Products Inspection Act, will be also covered by the new requirements for plant registration and prior notice?

OTHER RULES

- Given that the implementation date for all the rules under the Act is 12 December 2003 when are the interim final rules for maintenance of records and administrative detention expected to be published?