

# Facsimile Message

To: FDA Dockets Clerk  
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SUBJECT: Australian Comments.

To the Dockets Clerk,

Please find attached a signed copy of the Australian government response on the two rules for the Bioterrorism Act (Docket Nos. ~~2002N-0276~~ and 2002N-0278) that was re-opened for comment.

Please note that these comments were submitted electronically before the closing date of 31 March 2004.

Regards,

Dr Andrew Cupit.



02N-0276

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**Australian Government**  
**Australian Quarantine and Inspection Service**

31 March 2004

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

**RE: Docket No. 02N - 0276**

**Registration of Food Facilities Under the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* – re-opened comments**

I refer to the Federal Register Notice, Docket No. 02N-0276 re-opening comments on the interim final rule for the registration of food facilities published 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 provide additional comment on the registration provisions. Australia's specific comments on the Docket No. 02N-0276 are attached.

Yours sincerely

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cc Andrew Burst, Agricultural Counsellor, US Embassy, Canberra  
 Andrew Cupit, Veterinary Counsellor, Australian Embassy, Washington

ENCL 1

***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**

**Re-opened comments March 2004**

The Australian Government submitted in December 2003 comments on the Notice of Interim Final Rule on Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

Australia is still concerned that the US 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 the existing controls.

The US FDA re-opened on 1 March 2004 a comment period for 30 days to investigate initial experiences with the new requirements. We wish to provide the following comments:

- Australian exporters experienced difficulties in identifying and locating a US agent required to organise registration of their premises.
- Australian exporters also have had to carry additional administrative costs resulting from this new requirement.
- We are aware that the number of registered premises under the new requirement is not as high as originally expected by the USFDA and we assume that exporters in other countries are experiencing similar problems mentioned above.
- Whilst export shipments appear to be currently cleared with no delays caused by the requirement for Registration, this may be because the USFDA is initially taking a flexible approach to the compliance with new requirement. We expect that Australian exporters may start experiencing difficulties when the USFDA enforces fully the new requirement. We therefore believe that the comment period should be re-opened by USFDA when the new requirement for Registration is fully enforced, especially in relation to how well the system will work when USFDA needs to contact the US agenda

or Australian emergency contact in emergencies. This would allow Australia and other countries to make more considered comments on the practical/real impact of the rule.



**Australian Government**  
**Australian Quarantine and Inspection Service**

31 March 2004

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Rockville, MD 20852  
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**RE: Docket No. 02N - 0278**

***Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 – re-opened comments***

I refer to the Federal Register Notice, Docket No. 02N-0278 re-opening comments on the interim final rule for prior notice of imported food published 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 provide additional comment on the registration provisions. Australia's specific comments on the Docket No. 02N-0278 are attached.

Yours sincerely

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cc Andrew Burst, Agricultural Counsellor, US Embassy, Canberra  
Andrew Cupit, Veterinary Counsellor, Australian Embassy, Washington

ENCL 1

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**DEPARTMENT OF AGRICULTURE, FISHERIES AND FORESTRY**

***Comments of the Government of Australia  
on Interim Final Rule; request for comments  
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**

The Australian Government submitted in December 2003 comments on the Notice of Interim Final Rule on Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

Australia is still concerned that the US 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 the existing controls.

The US FDA re-opened on 1 March 2004 a comment period for 30 days to investigate initial experiences with the new requirements. We wish to provide the following comments:

- Australian exporters have had to carry additional administrative costs resulting from this new requirement.
- Whilst export shipments appear to be currently cleared with no delays caused by the requirement for Prior Notice, this may be because the USFDA is initially taking a flexible approach to the compliance with new requirement. We expect that Australian exporters may start experiencing difficulties when the USFDA enforces fully the new requirement. We therefore believe that the comment period should be re-opened by USFDA when the new requirement for Prior Notice is fully enforced. This would allow Australia and other countries to make more considered comments on the practical/real impact of the rule.