AQIS
AUSTRALIAN QUARANTINE AND INSPECTION SERVICE

Department of AGRICULTURE FISHERIES & FORESTRY - AUSTRALIA

ABN 24 113 085 695

4 July 2003

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

RE: Docket No. 02N - 0277

Establishment and Maintenance of Records Under the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*

I refer to the Federal Register Notice, Docket No. 02N-0277 inviting comments on the rules proposed 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 comment on the proposed Record Keeping provisions. Australia's specific comments on the Docket No. 02N-0277 are attached.

Yours sincerely

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ENCL 1

02N-0277

EMC 138

COMMENTS OF THE GOVERNMENT OF AUSTRALIA
on Notice of Proposed Rulemaking
ESTABLISHMENT AND MAINTENANCE OF RECORDS
under the
PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS
AND RESPONSE ACT OF 2002

Federal Register Docket No. 02N-0277

RIN 0910 – AC39

Overall comments

The Government of Australia welcomes the opportunity to provide comments on the United States of America Government's proposed requirements for record keeping by domestic and foreign food manufacturing facilities, as published in the Notice of proposed rulemaking on Establishment and Maintenance of Records Under the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*. Australia, as an exporter of substantial quantities of food and agricultural products to the United States of America (USA), has a direct interest in the USA requirements for the importation of these products. Australia is committed to a food safety system that delivers high quality food produced at Australian Quarantine and Inspection Service (AQIS) registered facilities.

The Government of Australia understands and supports the initiatives of the Government of the USA to establish controls and counter-measures 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 USA, through its *Bioterrorism Act*, proposes to introduce four new rules to enforce/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.

The Government of Australia 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 assessment 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 application of equivalence in achieving its objective/s; and
- avoid arbitrary or unjustifiable differences in the level of protection applied in different situations.

Trade impact of proposed rules for the US Bioterrorism Act

Australia seeks the United States' assurance that all of the proposed measures under the US *Bioterrorism Act* will meet the latter's SPS and/or TBT obligations. Australia is particularly concerned that the proposed rules:

- do not allow for equivalence determinations;
- in some instances, focus 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;
- appear to be more trade restrictive than necessary;
- in some instances, may lead to duplication of some measures; and
- do not consider whether the stated objectives are already achieved through the existing controls.

As stated previously, Australia supports initiatives to establish controls and counter-measures for bioterrorism. We note, that "***C Highlights of the Proposed Rule***" of the record keeping proposed rule states that the "*FDA will comply fully with its international trade obligations, including the applicable World Trade Organisation (WTO) agreements.*" The Food and Drug Administration (FDA) should therefore ensure that the proposed rule for record keeping requirements is not more trade restrictive than necessary to meet the objectives of the US *Bioterrorism Act*, and thus, does not impose unnecessary obstacles, barriers or requirements for international trade. The FDA should also ensure that the proposed rule's requirements are flexible, and that such flexibility should include the principle of equivalence as expressed in Article 4 of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement). Australia would welcome such approaches by the USA. The Government of Australia acknowledges and welcomes the USA's efforts to limit the prescriptive nature of the proposed rule on record keeping and the flexibility it has built into the timeframe for full compliance with the ruling. These gestures will be well-received by all food manufacturers, both domestic and international traders.

Summary of Australia's concerns and comments

Australian legislation – Australia seeks recognition of equivalence for 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. This recognition of equivalence 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.

Risk assessment – Australia concurs with the FDA risk assessment on food for animals and food from foreign facilities as it is presented in the Federal Register Notice of Proposed Rulemaking Establishment and Maintenance of Records under the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*. Therefore, Australia seeks risk mitigation measures to be instituted in the final rule making on record keeping to reflect the lower level of risk represented by foreign facilities and foods for animals.

Registration/prior notice proposed rules – The FDA cost benefit analysis for the proposed rule on record keeping indicates that food for animals, both food producing and non food

producing, and imported food present lower levels of risk to the US human and animal populations. Given this FDA assessment, and the Australian Government request for risk mitigation measures to be instituted in the final rule making on record keeping to reflect the lower level of risk represented by foreign facilities and foods for animals, Australia also requests that the USA reconsider its proposed rulemaking for facility registration and prior notice of imported food to allow similar risk mitigation measures to be instituted to reflect the lower levels of risk presented by animal and imported food.

Australia's favourable BSE health status – Given Australia's favourable BSE animal health status, Australia urges the USA to consider, under Article 4 of the World Trade Organisation (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) official recognition of Australia's equivalence of 21CFR589.2000, the US BSE rule.

Attached are Australia's justifications for its requests for recognition of equivalence and adjustments to the measures proposed by the USA to implement the *Bioterrorism Act* in light of the FDA's own risk assessment. All clarification requests on the proposed rule are included in the final section of this document.

ATTACHMENT

Animal food – Risk assessment

Australia concurs with the FDA risk assessment that the consequences of a potential terrorist attack or food-related emergency are of greater concern for the human food chain than for animal food. Australia also concurs with the FDA risk assessment that the consequences of a potential terrorist attack or food-related emergency is of greater concern for food for food-producing animals than for food for non-food producing animals (i.e. pet food[1]). Given the lower risks of potential bioterrorism or food-related emergencies associated with food for food-producing animals and for pet food, the applied measures to protect human and animal health should be lower or different to those measures applied to protect food intended for human consumption.

The FDA requested comments on four questions relating to the risk assessment and treatment of animal food[2] and pet food. Australia provides the following responses:

Q1 and Q2. *Should we exempt all types of animal food entities from all or part of this proposed rule? Should we exempt all pet food entities from all or part of this proposed rule?*

The FDA provides only one reference in the Federal Notice of proposed rulemaking discussing bacterial contamination of animal feeds and its relationship to human foodborne illness and cites a couple of examples of animal/pet food contamination. These cited examples occurred in 1996 and 2002.

There is some potential risk of contaminated animal/pet food affecting humans, although the potential impact on humans would be of a more limited nature in comparison to contamination occurring in human food.

Transfer of bacteria from contaminated animal or pet food to humans would largely be the result of poor hygiene practices of the people handling the animal/pet food products. Such bacterial contamination, and subsequent illness, could also result from poor hygiene practices when handling the animals themselves rather than their food *per se*. For example, parents visiting petting zoos or agricultural shows with their children need to encourage hand washing and cleanliness to prevent potential bacterial contamination and illness resulting from handling the animals. Similarly, reptile owners must rely on good animal handling practices to avoid episodes of salmonellosis, as reptiles are known to carry *Salmonella*.

Poor handling of contaminated animal/pet foods could result in direct contamination of the animal/pet food handler or in unintentional cross-contamination of cooking surfaces or utensils. However, such contamination would tend to be sporadic in occurrence. In contrast, human illness arising from contaminated human food potentially could affect many more people and thus appear more explosive in nature.

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[1] As per the FDA definition quoted in the proposed rule, pet food is for non-food producing animals such as dogs, cats, horses, zoo and circus animals etc.

[2] Animal food in this document refers to food intended for food-producing animals.

Terrorist attack on the animal food chain seems to be a much lower risk compared to potential attacks on the human food chain. This risk would be even lower for pet food. Thus, the FDA should give serious consideration to adjusting the requirements of this proposed rule as they apply to animal and pet food suppliers and transporters. Consideration should be given to limiting the proposed rule requirements to retaining all current business records, including those given to animal/pet food businesses as well as those generated by the businesses themselves, without the added burden of supplying more information (i.e. re-designing forms), and without imposing access time limits. Such considerations and adjustments to record keeping requirements would reflect the lower levels of risk to human health represented by animal food and pet food contamination.

Given these lower levels of risk for animal/pet foods, the FDA should also consider revising the requirements as they apply to foreign establishments to reflect the different levels of risk posed by these commodities. The FDA should consider limiting the requirements for the proposed rule for the establishment and maintenance of records to only the final establishment handling the product prior to its arrival in the USA.

The proposed rule, as it stands, does not require transport companies in foreign countries to establish and maintain records of any food transportation, irrespective of whether it is intended for human or animal use within the USA. Given this appropriate level of protection (ALOP) assessment and requirement by the USA, Australia cannot see the reasoning for expecting all establishments producing and manufacturing food (for human and animal consumption) in the food chain to establish and maintain records over and above current business and Australian regulatory requirements.

Australia acknowledges that the USA only foresaw a limited number of foreign establishments having to comply with the proposed rules ensuring compliance with the *Bioterrorism Act*, namely the last establishment to manufacture/process the food and any facility conducting only de minimis activities, such as applying a label. Unfortunately, as explained in the Government of Australia's comments on registration submitted to the FDA by 4 April 2003, many more businesses will need to be registered with the FDA to ensure that shipments are not detained at port of entry due to registration issues. The Government of Australia stated in its submission that: "*Effectively for Australian businesses, this requirement* (facility registration) *would necessitate that all Australian facilities register with the FDA just in case their product is exported to the USA to avoid any US port of entry problems with detained shipments because of lack of registration issues. This scenario means that many more facilities need to be registered under the Bioterrorism Act than the FDA anticipated.*"

Thus, in view of the large number of foreign facilities that require registration, and the FDA acknowledged lower level of risk presented by animal food and pet food, Australia urges the USA to consider limiting the requirements of this rule, the establishment and maintenance of records, to only the final establishment handling the product prior to its arrival in the USA. Current business and foreign country (Australian?) regulatory requirements should be able to supply adequate information on prior handlers of the animal or pet food should any traceback investigation be required.

Q3 and Q4. *Should we treat pet food the same as other types of animal food by requiring all pet food entities to meet the record keeping requirements under this regulation, not just those subject to the BSE rule? Should we use criteria other than the scope of the BSE rule to determine which pet food entities should be exempt?*

Australian responses to these two questions are limited to only a consideration of Australian exports.

Australia currently enjoys a highly favourable animal health status in general, and in particular for transmissible spongiform encephalopathies (TSEs), including bovine spongiform encephalopathy (BSE). This status is widely recognised in many jurisdictions, and has been accorded the most favourable geographical BSE risk (GBR) rating of Level 1 by the Scientific Steering Committee of the European Commission. Australia maintains its favourable status by undertaking measures to protect this status. Such measures follow the OIE guidelines for BSE, and includes ruminant feeding bans.

Australia's current ruminant feeding ban exceeds OIE recommendations for countries recognised as being 'BSE free'. Australia's current legislation bans the feeding of ruminants with products derived from vertebrate animals, with the exception of milk, tallow and gelatine. This ruminant feed ban also exceeds current US legislative requirements which allow the feeding of equine or porcine proteins to ruminants (see 21 CFR 589.2000, otherwise known as the BSE rule). The Government of Australia endorses health certificates for Australian processed animal products being exported to the USA with the following endorsement:

"*This product:*

(1) was derived from animals that have never been in;

(2) *did not originate in and was never stored, rendered or otherwise processed in;*

(3) *was not otherwise physically associated with a facility located in; and*

(4) *has not been otherwise physically associated with or exposed to, or commingled with ruminant material from;*

any region listed in Title 9, Code of Federal Regulations part 94.18(a)."

Title 9, Code of Federal Regulations part 94.18(a) lists those regions (countries) where meat and edible products have restrictions placed on their importation to the USA due to BSE concerns in the nominated countries. Processed animal products covered by this endorsement include meat and bone meal (MBM), fish meal, poultry meal, inedible offal, tankage, unprocessed ruminant fat and tallow etc., and any other product containing such materials, including processed pet food. Furthermore, the FDA requires the following cautionary statement to appear on an accompanying documentation (such as invoice or bill of lading) for Australian ruminant derived protein exported to the USA: "*Do not feed to cattle or other ruminants*".

Therefore, given Australia's favourable BSE animal health status, Australia urges the USA to consider, under Article 4 of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) official recognition of Australia's equivalence of 21CFR589.2000, the US BSE rule, thus exempting Australia from maintaining the specified records under the BSE rule.

Human food – Risk assessment

Australia concurs with the concept that it is important to be able to track food distribution, both one step forward and one step backward, arising from a detection of adulterated food or other food-related emergency. Tracing forward is an important tool for the prevention of further consumption of adulterated food still circulating in the market place, or in people's homes thereby protecting people's lives and limiting the negative impacts of adulterated food. Tracing back will allow regulatory authorities and businesses to effect measures to prevent further occurrences of adulterated food. Current AQIS export registration processes already fulfil this product tracing requirement without the need for FDA to duplicate the process. Such duplication could present a burdensome compliance requirement on Australian industries exporting to the USA.

Australia questions the benefits to the USA human and animal populations of the FDA's need and ability to trace adulterated product back to its original source within a foreign country, where the demonstrated risk is so low. Australia feels that in the situation where our products present such a low level of risk, our being able to determine which exporter is implicated in supplying the adulterated products should be sufficient to provide protection to the USA human and/or animal populations. The FDA acknowledges that the final holders may be the most accessible foreign facility to contact in the event of an FDA traceback.

Surely it is the domain and legal right of foreign (i.e. exporting) country authorities to determine the extent of product tracing and conduct product tracing investigations on their own national soil, and thus set its own requirements for record keeping and time frames for access to documents according to its own country statutory legislation rather than to a USA Government Departmental authority's specifications. It is questionable what international legislative action the FDA can take against foreign companies that do not comply with the proposed regulations under the *Bioterrorism Act*, for example where a foreign company does not update its registration details as required by Section 305, or does not establish and maintain the records as specified under Section 306.

Australia acknowledges that it will be in the interests of both foreign (i.e. exporting country) regulatory authorities and businesses to promptly ascertain the source and reason for any adulterated food detected in the USA, be it human or animal food, and to take the necessary steps and regulatory action to rectify the situation. Such prompt corrective and regulatory action will assure the USA that adequate measures have been taken to protect not only the health of US citizens and/or its animal population, but also the health of the foreign country's citizens and/or its animal population. Such prompt action will ensure continuing good relations and food trade with the USA.

Australia concurs with the FDA risk assessment that: "*...imported food accounts for a small percentage of total domestic food consumption...*" (Source: ***III Analysis of Economic Impact,*** *B. Initial Regulatory Flexibility Analysis, Option 10, same as option 4 except the foreign coverage is the same as for the registration proposed rule*). The FDA assesses that the amount of food consumed within the USA and sourced from foreign facilities will be less than the amount of food that originates from US facilities. The FDA acknowledges that a reduction in the number of foreign facilities that have to comply with the proposed rulemaking will only result in a much smaller impact on the relative benefits obtained by the rule. Conversely, the FDA believes that excluding domestic facilities, eg intrastate facilities will have a much greater reduction in benefits obtained by the rule. In fact, the FDA, in discussion of Option 11, states: "*..the*

proportionally smaller importance of imported foods in the domestic food supply implies that the exemption (i.e. the option where the rule only applies to facilities that are final holders before export) *should have relatively little effect in benefits.*" Australia urges the USA to abide by its WTO obligations by considering the FDA risk assessment and modify its rule requirements for foreign animal and human food facilities to reflect their lower level of risk to the US human and animal populations compared with domestically sourced human and animal food.

Australia feels that the ranking applied in Table 38 – "*Ranking of Effectiveness of each Mechanism under each Option*" does truly reflect the lower level of risk represented by food from foreign facilities. The ranking of the intrastate facility exemption should be lower than the options with reducing numbers of foreign facilities (i.e. options 10 – 12), as the relative detrimental impact and loss of benefits from the intrastate exemption would be greater than from the options 10 – 12.

Trade restrictive issues of the proposed rule

Foreign Facilities During the cost benefit analysis process, the FDA's sensitivity analysis, maintained consistency with the proposed rule on facility registration, by estimating that 16% of manufacturers exporting 10 or fewer line entries to the USA would stop exporting rather than incur costs imposed by the burden of complying with the proposed record keeping rule. There are four proposed regulations for compliance with the *Bioterrorism Act* – facility registration, prior notice for imported food, record keeping and administrative detention –each with their own associated costs for compliance. The proposed rule for record keeping has indicated that businesses will potentially have increased costs for learning about the regulation, re-designing forms, and record storage and access. These costs will be in addition to the increase in costs arising from compliance with facility registration and prior notice on imported food regulations.

The FDA has not shown in its sensitivity analysis the cumulative cost increases that all the regulations for the *Bioterrorism Act* will have on foreign exporters. Such accumulated costs may lead to a greater than expected decrease in foreign exporters participating in trade with the USA (i.e. greater than a 16% drop in exporters accessing the USA market). Although the US *Bioterrorism Act* is not designed to discriminate against foreign exporters, unless it can be substantially simplified, the assumed and potentially underestimated reduction in exports to the USA may be an unintended consequence. This unintended consequence could be considered discriminatory and not consistent with WTO/SPS principles.

Lot Coding The recording of lot codes and batch numbers as a mandatory field in the required records under the proposed rule for the establishment and maintenance of records could potentially be trade restrictive depending on the business practices currently used by food manufacturers and transport companies. It is plausible that some companies may have in place technology that will easily allow or already records such lot code/batch number information. An example of such technology is bar coding[3]. The use of this technology would facilitate precise recalls of only the affected product without involving unaffected product in the recall action.

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[3] Bar coding – Provides industry, transport and retail businesses with an automated method of identifying and describing its products and the bar coding language can be recognised globally, thus facilitating trade. Such globally recognised languages provide regulatory authorities and businesses with the ability to limit the negative impact of food product recalls by focussing on recalling only the affected product. EAN/UCC is a globally recognised bar coding language.

For those businesses that do not have access to or use of bar coding technology the imposition of recording lot codes/batch numbers could potentially and drastically change current businesses practices and culture. The impact and costs of such technological changes were not factored into the FDA cost benefit analysis. It may take businesses a lot longer than FDA anticipated to introduce and take up new and potentially innovative bar coding technology that would make their business compliant with the FDA proposed rule on record keeping.

Australia believes that the requirement for lot code/batch number information should be made optional. This would allow flexibility in the rulemaking to accommodate the various types of business practices and cultures involved in the food and transport industries, thus limiting trade restrictive measures.

Record Retrieval Australia believes that the FDA should introduce flexibility into the proposed timeframes for companies and businesses to retrieve records. Such timeframes (4 hours and 8 hours) may not be feasible or reasonable depending on the volume of records required by FDA and the timing of the request being lodged with a company. For example, a request for one or two records being presented to a company in the morning, say 10 am, could possibly be easily accommodated within the specified 4 hour time limit, whereas an FDA request for several weeks or months worth of records being lodged with a company at 5.30 pm may possibly not be met within the regulatory 4 hour time limit. The FDA must consider the reasonableness of specifying a "one-size fits all" time limit. A more flexible approach could be for the FDA to negotiate with the company when the records would be available or for the FDA determine a reasonable time limit on a case-by-case basis.

Exports from Australia

Many of the products covered by the proposed measures under Section 305 (Registration) of the *Bioterrorism Act* are already subject to strict regulatory and certification requirements as 'prescribed goods' under Australian export legislation (the *Export Control Act 1982*). These are: 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.

In the Government of Australia's comments on Facility Registration, Australia sought consideration of equivalence (as per Article 4 of the SPS Agreement) in the assessment and registration of export food manufacturing facilities. This request was based on the strong rationale to utilise the existing Australian export registration requirements which are already accepted by the USDA's Food Safety and Inspection Service (FSIS). The FSIS accepts AQIS registration of export facilities exporting FSIS controlled products (meat and ratite products) to the USA.

Such recognition of equivalence of the Australian export registration process, which would be consistent with current US (FSIS) practices, can also facilitate any product tracing required by the FDA. AQIS is well positioned to conduct necessary product tracing arising from the detection of adulterated food originating from Australian 'prescribed goods' sources.

Nevertheless, Australia concurs with the FDA's assessment that the registration (Section 305 of the *Bioterrorism Act*) and record keeping (Section 307) regulations would work cooperatively to identify and track possible sources of an outbreak. The FDA can contact the facility involved

directly from the information gathered in the registration process and the prior notice of imports to follow up any food related emergency or adulterated food.

As raised in the previous discussion on *Animal food – Risk assessment*, Australia believes that FDA should further analyse the potential risk presented by food from foreign facilities. This further analysis should include both food for animals and food for human consumption. As ably demonstrated by the current FDA cost benefit analysis in the Federal Register Notice for the proposed rule on record keeping, there is very little loss of benefits gained by the proposed rule from excluding certain categories of foreign facilities. Australia urges the FDA to reconsider which foreign facilities are required to comply with the regulations enforcing the US *Bioterrorism Act* in light of the relative risks presented by imported food compared to domestically produced food, and the potential underestimation of the number of foreign facilities obliged to comply with the registration requirements of Section 305. As stated previously, Australia urges the USA to consider limiting the requirements of this record keeping rule to only final foreign holders handling animal and human food prior to its arrival in the USA.

Australia believes that the regulations under the *Bioterrorism Act* are potentially trade restrictive and are costly measures, particularly Sections 305 (Registration of Food Facilities), 306 (Establishment and Maintenance of Records) and 307 (Prior Notice of Imported Food). These measures proposed under the *Bioterrorism Act* will impose a substantial burden of compliance on industries exporting to the USA, and may limit opportunity for smaller operators to continue to participate in this trade.

Australia therefore urges the USA 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 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, as well the US FDA's own risk assessment that animal foods, pet foods, and food from foreign establishments present a lower level risk to US human and animal populations and that foreign establishments only represent a marginal change in the level of benefits gained from their inclusion in the proposed regulations of the Act.

Specific questions and comments on the Federal Register Notice of proposed rulemaking requiring clarification

1. Australia seeks clarification on whether foreign transporters are expected to comply with the new rule. The language in the proposed rule is conflicting. In some instances it does not require foreign transporters to comply with the record keeping rule, as they are not entities that are obliged to comply with the regulation on facility registration. On the other hand, in the cost benefit analysis, FDA claims that the burden of record keeping will be shared by "two covered entities, including transporters". In fact, the FDA states: "*FDA treats foreign facilities already subject to a similar record keeping regulation as already in compliance, and assumes that the burden of additional records maintenance will be shared among an average of two covered entities, including transporters, for an average of 15 minutes per week per facility or 13 hours per year per facility.*" How can the FDA claim on one hand that foreign transporters are not included in the new rule but during the cost benefit analysis assume that foreign transporters will

share the burden and costs of compliance for foreign facilities by keeping the extra record data that is required by other businesses, the non-transporters?

2. The proposed section 1.361 states that when the FDA has a reasonable belief that article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, any records or other information is accessible to the FDA and available for inspection and photocopying or other means of reproduction. Will the written notice presented by FDA requesting access to company records provide procedural fairness information explaining the reasonable grounds that FDA are using to gaining access to records?

3. What assurances can FDA give to ensure that information stored on records will not be subject to unauthorised disclosure?

4. Australia seeks clarification on whether the staggered time frames (6 months, 12 months, and 18 months) for full compliance with the proposed rule on establishment and maintenance of records will also apply to foreign businesses of varying sizes?

5. We seek clarification on the method utilised by the FDA to determine business sizes for deciding the timeframe for compliance. This information is particularly relevant for businesses operating in separate locations but come under the one umbrella of a single parent company. Is size worked out using all employees of the parent company as a whole or according to each individual enterprise/location?

6. How does this proposed rule affect long shelf life product that was prepared before the introduction of the new rule, and is still in storage when full compliance is required? Is the rule retrospective or does it apply to food manufacture from the date of full compliance?

7. In the FDA's cost benefit analysis for Option 10, *Require all components of option 4, but only cover foreign facilities covered by the proposed registration regulation*, it reduced the number of "other facility types" to zero whilst creating a new category solely for de minimis processors/packagers. The FDA claims that the "other facility types" is a large and uncertain category whose exclusion under Option 10, the FDA's preferred option, has a significant impact on all cost estimates. By reducing the foreign facility categories to "final holders", manufacturers", and "de minimis processors/packagers" there does not appear to be any option for including food contact packaging manufacturers. Under the facility registration proposed rule's definition of "food", the FDA proposes to include "substances that migrate into food from food packaging and other articles that contact food". We seek clarification on the impact of this definition of food. Commercial food packaging is not supposed to have migratory substances otherwise it would not be suitable for food. Food contact materials are supposed to be non toxic. Australia does not see the relevance of including *"substances that migrate into food from food packaging and other articles that contact food"* in the definition of food. Australia again seeks clarification on whether foreign manufacturers of food contact packaging are required to be covered by the proposed regulations under the *Bioterrorism Act*. Namely, are these packaging manufacturers expected to register with the FDA, and establish and maintain the required record information specified by the proposed record keeping rule?

8. Food samples are exported with the intended end use of analysis, experimentation and/or subsequent destruction within approved company premises. Such samples do not enter commerce, and may be carried into the USA as personal baggage of company representatives or sent unaccompanied. It is noted in the proposed rule making on facility registration that the FDA have proposed to exempt food carried in personal baggage only if it is for "personal enjoyment/use". Australia seeks clarification on how samples that do not enter commerce are to

be treated by the proposed rules under the Bioterrorism Act, namely registration of food facilities, prior notice of imports and record keeping requirements.

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This document has previously been submitted by E-mail.

With the Compliments

of

Embassy of Australia

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