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OVERVIEW OF IMPORT DATA PROVISION/DECISION PROCESS FOR THE ANIMAL AND PLANT HEALTH INSPECTION SERVICE IN THE U.S. DEPARTMENT OF AGRICULTURE

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This paper summarizes the process undertaken by the Animal and Plant Health Inspection Service (APHIS) for reviewing import requests and establishing import requirements - a process which differs between the animal and plant health sides.

Plant-Related Commodities

1. APHIS receives request from importers and/or foreign governments in writing with the following initial information:

- the name of the commodity (scientific and common)
- country of origin
- name and address of importer, including phone number

2. Initial determination results in one of the following potential outcomes:

(a) Product is listed under the regulations as enterable. Permit, listing import conditions or requirements, is issued to the importer.

(b) Regulations prohibit the commodity in question. APHIS informs requester that item is prohibited. Discussions could ensue regarding options, such as provision of information by foreign government which suggests a new risk assessment be undertaken.

(c) If regulation prohibits entry, but no risk assessment or recent assessment has been conducted, a determination is made whether to reexamine the issue and conduct a new assessment. Foreign government may provide information which suggests that circumstances have changed or that the previous pest concern is no longer an issue. APHIS determines whether new circumstances warrant a new risk assessment.

3. If request is from an importer, APHIS requests initial information, including quantity intended for export and locality of production, by form letter. Response will aid in determining whether this is a serious request before APHIS commits significant resources to conduct a risk assessment. Importer may, in turn, seek out information from foreign government.

4. If request is from foreign government, APHIS communicates its intent to conduct a risk assessment. While no information or data is required immediately from the foreign government, it

is helpful for the foreign government to provide data up-front which it believes may facilitate the risk assessment.

5. Risk assessment process is activated on the commodity in question, taking into account the following factors:

(a) Potential harmful pests associated with plant/commodity and capability of economic damage to U.S. agriculture.

(b) Probability of pest(s) being introduced and becoming established if import allowed.

(c) Mitigating measures (e.g., treatment, inspection, packaging conditions, etc.) which may reduce or alter the risk of the commodity in question.

6. APHIS takes into account the Pest Risk Assessment Standard (PRA) ratified by the United States, Mexico, and Canada under the auspices of the North American Plant Protection Organization (NAPPO).

7. If information needs emerge during the risk assessment process, APHIS may request specific or additional data or information from the foreign government to help complete the risk assessment.

8. Determination made on whether to allow entry of commodity and under what conditions.

(a) Results of risk assessments are shared with foreign government.

(b) APHIS identifies the necessary treatments for entry.

(c) APHIS and foreign government may enter into discussions if foreign government seeks consideration of alternative treatment or entry measures.

9. Procedures for regulatory changes, if any, are initiated.

(a) Regulatory changes require publication in the Federal Register as a proposed rule or rule change. This public notification must specify the risks and the requirements which will be imposed to address the risks.

(b) After public comments are received and reviewed a final rule is published.

(c) Once final rule goes into effect APHIS can issue import permits.

Responding to Pest Free Area Requests

10. APHIS uses the NAPPO Pest Free Area (PFA) standard for responding to pest free zone requests. This standard has been presented to the IPPC and is now being reviewed by members as a potential global PFA standard. Foreign governments may request a copy of the NAPPO standard.

11. A country requesting recognition of a pest free zone may submit basic supporting data as indicated in the Code of Federal Regulations (7 CFR 319.56-2(e)).

12. 7 CFR 319.56-2(e) describes the process and data requirements for establishing a pest free zone relative to fruit and vegetables. No standards or guidelines regarding pest free or disease free zones for grains, nursery stock, or lumber currently exist. However, the NAPPO PFA standard would be used to help evaluate a pest free zone for these other commodities.

13. According to 7 CFR 319.56-2(e):

> *"… fruit or vegetables may be … issued permits … if the U.S. Department of Agriculture, after reviewing evidence presented to it, is satisfied that the fruit or vegetable …:*
>
> > *(3) Is imported from a definite area or district in the country of origin that is free from all injurious insects that attack the fruit or vegetable, its importation can be authorized without risk, and its importation is in compliance with the criteria of paragraph (f) of this section; or*
> >
> > *(4) Is imported from a definite area or district of the country of origin that is free from certain injurious insects that attack the fruit or vegetable, its importation can be authorized without risk, and the criteria of paragraph (f) of this section are met with regard to those certain insects, provided that all other injurious insects that attack the fruit or vegetable in the area or district of the country of origin have been eliminated from the fruit or vegetable by treatment or any other procedures that may be prescribed by the APHIS Administrator*
>
> *(f) Before the Administrator may authorize importation of a fruit or vegetable under 319-56(e) (3) or (4), he or she must determine that the following criteria have been met:*
>
> > *(1) Within the past 12 months, the plant protection service of the country of origin has established the absence of infestations of injurious insects known to attack fruit or vegetables in the definite area or district based on surveys (developed by foreign government and reviewed and approved by APHIS) performed in accordance with requirements approved by the Administrator as adequate to detect these infestations;*
> >
> > *(2) The country of origin has adopted and is enforcing requirements to prevent the introduction of injurious insects known to attack fruits and vegetables into the definite area or district of the country of origin that are deemed by the Administrator to be at least equivalent to those requirements imposed under this chapter to prevent the introduction into the United States and interstate spread of injurious insects; and*
> >
> > *(3) The plant protection service of the country of origin has submitted to the Administrator written detailed procedures for the conduct of surveys and the enforcement of requirements under this paragraph to prevent the introduction of injurious insects…"*

14. While the 7 CFR 319.56-2(e) describes some of the data requirements, new questions usually emerge as the risk assessment proceeds (e.g., trapping and surveillance methodologies, monitoring, etc.). Therefore, APHIS relies on a continuing dialogue through bilateral discussions and/or correspondence with plant health officials of the other country to obtain information as needed.

15. With the exception of exotic fruit fly surveys, protocols for surveying other pests (used to demonstrate area pest freedom or prevalence levels) are developed by the foreign government and reviewed and approved by APHIS. Protocols for surveying the presence of exotic fruit flies must be requested from APHIS.

Animal-Related Commodities

16. The process is described separately for live animals and animal products.

Live Animal Imports

17. APHIS receives request from importers and/or foreign governments in writing, providing the following initial information:

- identity of the animal species
- country of origin
- quantity
- name and address of exporter, including phone number
- name and address of importer and location in the United States where the animals are destined.

18. Determination is made with one of the following outcomes:

(a) If animal (ruminants) originates from country or area where foot-and-mouth (FMD) or hog cholera (HC) is known to exist, the animal is required to be quarantined at a high security quarantine facility (e.g., Harry S. Truman Animal Import Center in Florida).

If foreign government seeks alternative to the high security quarantine, it could seek APHIS recognition of its country or area (see process described under paragraphs 25 and 26) as FMD-free. This process requires a risk assessment (data needs described under paragraphs 25 and 26) and subsequent proposal, in the Federal Register, to recognize the foreign country or area as free of FMD or rinderpest.

(b) If livestock originates in FMD or rinderpest free country or area, APHIS can provide the requesting country a draft copy of a protocol being used elsewhere for trade in the same commodity under similar risk conditions or draft a new protocol for the prospective country. This protocol (based on an assessment of the risks) may be accepted or serve as the basis for negotiating certain modifications tailored to the specific conditions in the exporting country. Rulemaking in the Federal Register is not required.

(c) For livestock originating in countries with other exotic animal diseases (e.g., African Horse Sickness, African Swine fever) of concern to APHIS, the Code of Federal Regulations (CFR) would have to be consulted to determine the specific entry conditions. A proposal by the foreign government to export live animals under alternative conditions would require a risk assessment and subsequent proposal in the Federal Register.

19. Finalized protocols are shared with foreign animal health officials of the exporting country. To some extent protocols can be renegotiated if the exporting country can demonstrate that alternative testing or regulatory measures would reduce the risks to the level of protection acceptable to APHIS.

20. Once the import protocols or requirements are completed APHIS issues an import permit to the importer or exporter. The permit outlines the conditions of entry.

Animal Product Imports

21. APHIS receives request from importers and/or foreign governments in writing, providing the following initial information:

- expected or intended use of product in the United States
- shipment size
- country of origin
- quantity
- name and address of exporter, including phone number
- name and address of importer and where the animals or products are destined in the United States.

22. Determination is made with one of the following outcomes:

(a) Meat and products from countries affected with FMD, HC, or swine vesicular disease (SVD) must be further processed to qualify for entry into the United States. Part of the processing requirements are outlined in the CFR. APHIS will cite the CFR requirements once the above information is provided by the importer or foreign government.

(b) For alternative processing methods not described in the CFR, the foreign government must enter into discussions with APHIS veterinary specialists concerning alternative processing methods and their effect on eliminating the FMD risk. If new processing methods are being proposed, scientific evidence would need to demonstrate that the proposed method would meet risk concerns. A subsequent regulation change in the Federal Register would also be necessary.

(c) If animal product originates in a country or area free of FMD, HC, or SVD, APHIS may provide the requesting country a draft copy of a protocol being used elsewhere for trade in the same commodity under similar risk conditions or draft a new protocol for the prospective country. This protocol may be accepted or serve as the basis for negotiating certain modifications to tailor the protocol to the specific conditions in the exporting country. Rulemaking in the Federal Register is not required in these circumstances.

23. Finalized protocols are shared with foreign animal health officials of the exporting country. To some extent protocols can be renegotiated if the exporting country can demonstrate that alternative testing or regulatory measures would reduce the risks to a level of protection acceptable to APHIS.

24. Once the import protocols or requirements are completed APHIS issues an import permit to the importer or exporter. The permit outlines the conditions of entry and use of product.

Responding to Disease Free Area Requests

25. APHIS will soon be publishing in the Federal Register a general framework for conducting risk assessments associated with regionalization requests. This framework will identify the critical risk factors which will be essential for conducting the necessary risk assessments.

26. Besides providing a public and transparent list of criteria for assessing the animal health status of a particular country or area, this general framework will be the basis for a questionnaire which will

be available to foreign governments seeking APHIS review of a disease-free area. A summary of the general data requirements includes:

(a) Source Area risk factors:

- Prevalence of a disease in the area exporting the animals or products
- Geographic location and environment
- Status of the adjoining or neighbouring areas
- Trading partners and practices
- Infrastructure (The basic objective is to evaluate the entire structure of the livestock industry, including the physical and legal infrastructure—one of the most difficult parts of any evaluation.)
- Existence and type of surveillance systems (Knowledge about the occurrence and prevalence of disease agent(s) is dependent upon the existence of an adequate surveillance system, including its laboratory capabilities in the exporting area.).

(b) Commodity risk factors:

- The type of commodity traded may alter the risk assessment for any disease agent(s).

(c) Destination risk factors:

- Availability and susceptibility of reservoirs
- Availability and competence of vectors for an imported disease agent
- Environmental risks that may occur if it is necessary to destroy all or part of a population of animals because of introduction of a disease agent
- Benefit/cost analysis for the imports.

(d) APHIS is, by law, required to publish these criteria in the Federal Register. This process involves publishing a proposed rule, taking public comments (including foreign views), and publishing a final rule.