DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 94–106–8]

RIN 0579–AA71

APHIS Policy Regarding Importation of Animals and Animal Products

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The Animal and Plant Health Inspection Service is adopting a policy that recognizes regions, and levels of risk among those regions, with regard to the importation of animals and animal products. We are applying this policy to all species of animals regulated under the Code of Federal Regulations, title 9, chapter I, subchapter D, including, but not limited to, ruminants, swine, birds, poultry, and horses. We consider this policy to be consistent with and to meet the requirements of international trade agreements entered into by the United States.

ADDRESSES: You may submit comments on this statement of policy by sending an original and three copies of your comments to Docket No. 94–106–8, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road, Unit 118, Riverdale, MD 20737–1238. Please state that your comments refer to Docket No. 94–106–8. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690–2817 to facilitate entry into the reading room.

FOR FURTHER INFORMATION CONTACT: Dr. Gary Colgrove, Chief Staff Veterinarian, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20237–1231, (301) 734–8590.

SUPPLEMENTARY INFORMATION:

Purpose

In this document, the Animal and Plant Health Inspection Service (APHIS) sets forth our policy regarding the manner in which we will apply the concepts of regionalization and risk analysis to regulating the importation of animals and animal products into the United States. We are applying this policy to all species of animals regulated under the Code of Federal Regulations, title 9 (9 CFR), chapter I, subchapter D, including, but not limited to, ruminants, swine, birds, poultry, and equines.

We have traditionally viewed animal disease distribution on a country-by-country basis, with the presence or absence of a particular disease anywhere within a country's borders serving to establish, for regulatory purposes, the status of the entire country with regard to that disease. That approach has had the effect of establishing an all-or-nothing standard of risk avoidance that precludes our consideration of factors such as disease-free zones or low disease prevalence within a country when establishing restrictions on the importation into the United States of animals and animal products. Consistent with our obligations under international trade agreements, APHIS is altering its traditional country-based import restrictions by recognizing that there are identifiable and measurable gradations in the degree of disease risk presented by imported animals and animal products, and that these gradations are often tied more to climatological, geographical, and biological factors than to national political boundaries.

To help ensure that our standards for regulating imports on a regional basis and for assessing disease risk within defined regions are transparent and applied on a consistent basis, we have decided to issue this policy statement setting forth the factors we will take into account when considering future requests to export animals or animal products to the United States from distinct or definable regions that may not be national entities.

The Concept of Regionalization

Regionalization (division of areas into regions) is rooted in the concept that restrictions on the movement of animals and animal products for the purpose of disease control are biologically and ecologically most logical when applied to areas that are geographically homogenous with respect to disease distribution and livestock health infrastructures. Under this concept of regionalization, regions may be countries, parts of countries, or groups of countries.

Regionalization is used for:

- Localization and containment of existing, exotic, or newly emerging diseases.
- Recognition of distinct, definable areas of reduced risk within areas of greater risk.
- Providing a geographic basis for sanitary (animal) measures to reduce the risk of disease introduction through the movement of animals and animal products.

Contemporary international regionalization expectations are outlined in the World Trade Organization (WTO) Sanitary and Phytosanitary (SPS) Agreement that was authorized by the General Agreement on Tariffs and Trade (GATT). The WTO-SPS Agreement obliges member countries to develop transparent SPS measures based on sound scientific principles, risk assessment, and relevant international standards, and to apply them without discrimination, using the principles of equivalence and regionalization.

The United States has applied these concepts for decades in domestic programs for controlling brucellosis, tuberculosis, and pseudorabies, and for containing and eradicating outbreaks of exotic diseases such as highly pathogenic avian influenza. These concepts have also been used to facilitate exports by regionalizing the United States for bluetongue and other agents.

Recent APHIS Rulemaking

We have already applied the concept of regionalization of a region of low risk to the importation of beef from Argentina. On June 26, 1997, we published a final rule in the **Federal Register** (62 FR 34385–34394, Docket No. 94–106–5) allowing the importation of fresh, chilled or frozen beef from Argentina under certain import conditions, based on our determination that the unrestricted importation of such beef would present a low risk of introducing FMD into the United States. We have also applied the concept of regionalization in several other recent rulemaking actions. For example, on May 9, 1997, we published in the **Federal Register** a final rule (62 FR 25439–25443, Docket No. 94–106–6) to allow, under certain conditions, the importation of fresh, chilled or frozen pork from the State of Sonora, Mexico. On June 12, 1997, we published in the **Federal Register** a proposal (62 FR 32051–32053, Docket No. 97–002–1) to recognize all of Italy, except Sardinia, as an area in which African swine fever does not exist. Each of these actions was taken after we thoroughly investigated, through site visits and other data collection, the disease history, surveillance systems, animal health policies, and infrastructure of the areas in question. This document gives notice of our intent to apply such approaches to regionalization and risk analysis in future rulemaking actions.

Regionalization and Risk Assessment

The principles of the WTO–SPS Agreement are consistent with the

regulatory strategies adopted by many national veterinary services, as they have adapted to advances in animal health technology, progress in the control and eradication of major animal plagues, worldwide privatization of regulatory responsibilities, changing national boundaries, formation of trading blocks, and movement toward more transparent governmental decisionmaking.

In response to these changes, APHIS is adopting a policy of evaluating hazards presented by proposed animal and animal product importations based on the disease risk associated with the region from which they are exported, rather than on ''disease-free'' or ''not-disease-free'' statuses determined on a country-by-country basis. APHIS will analyze the disease risk involved and fashion appropriate import requirements over a wide range of variables. Thus, this policy approach will encompass the concepts of regionalization and risk assessment.

Risk assessment consists of identifying risk factors and evaluating their seriousness. The concept of assessing risk has underpinned regulatory decision-making in numerous sectors for some time. There are many risk assessment techniques. Some are very simple and others are extremely complex. APHIS has developed guidelines it has used and will use in the future in assessing the risk of disease introduction from the unrestricted importation of animals and animal products from specified regions, and in determining which conditions of importation will reduce any disease risk to a negligible level. These guidelines are discussed below.

Definition of ''Region''

With only minor exceptions, the regulations in 9 CFR, chapter I, subchapter D, are currently based on the disease status of entire countries. This document gives notice of APHIS's policy to consider, for purposes of the importation of animals and animal products, the disease status of regions. APHIS considers a region to be any defined geographic land area identifiable by geological, political, or surveyed boundaries. A region may consist of any of the following:

- A national entity (country);
- Part of a national entity (zone, county, department, municipality, parish, Province, State, etc.);
- Parts of several national entities combined into an area; or
- A group of national entities (countries) combined into a single area.

It is important to note that a region can be a national entity. Consistent with this concept, we are continuing to apply on a country-by-country basis the importation requirements currently set forth in 9 CFR, chapter I, subchapter D, for countries listed as being affected or not affected with specific diseases. We will continue to apply the current importation requirements to these countries until we receive a request to ''regionalize'' a country into regions, or to ''regionalize'' a group of countries into a region, or both. Once a request is made, we will evaluate the request and its supporting documentation to determine if the requested action is scientifically supportable, and solicit public comment on the request and its supporting data.

New Paradigms to Describe Risk

In reality, ''free'' is not the same as ''risk-free,'' and a ''not-free'' designation does not ensure that all regions so considered pose an identical risk. Under the current regulations in 9 CFR, chapter I, subchapter D, unrestricted imports (i.e., importations subject to no import conditions) from countries classified as ''free'' of a certain disease can present different levels of risk. Current §§ 94.11 and 94.13 address this risk by imposing restrictions on the importation of meat from countries that are ''free'' of certain diseases, but that present a higher disease risk due to importation practices of these countries or the geographical proximity to countries with a higher disease risk. We consider the countries listed in §§ 94.11 and 94.13 to be ''modified-free'' countries.

Levels of risk exist upon a continuum. The extremes of this continuum can be exemplified by the risk statuses of countries set forth in the current regulations. For instance, § 94.1 of the current regulations lists countries considered to be free of rinderpest and foot-and-mouth disease (FMD). The two diseases are considered to exist in all countries not included on the ''free'' list. Under APHIS policy, conditions for ''freedom'' from disease under the current regulations include the requirement that vaccination for the disease not be carried out in the country in question. Thus, certain countries might not be included on the ''free'' list, even though they have reported no case of the disease for several years, because they continue to vaccinate for the disease. At the other end of the spectrum are countries where rinderpest or FMD is known to exist. Under the current regulations, all countries listed as those in which the diseases are considered to exist are treated as if the diseases exist throughout those countries at a uniformly high prevalence.

The import conditions applied under the current regulations for animals and their products reflect the extremes of ''free'' as currently understood and ''not free.'' On the one hand, countries considered free of FMD and rinderpest may in most cases export animals to the United States with only a certificate of the animal's origin and health (subject to general inspection and quarantine at the U.S. port of arrival). At the other extreme, animals from countries where the diseases are considered to exist may not be imported into the United States, unless they have undergone pre-embarkation quarantine and testing in the country of origin and are imported through the high-security Harry S Truman Animal Import Center.

As noted above, until otherwise requested by foreign regions and approved by APHIS, we will continue to operate under the system of ''free,'' ''not-free,'' and ''modified-free'' on a country-by-country basis for those countries currently so listed in 9 CFR, chapter I, subchapter D. However, we will, in the future, evaluate the risk of importations and seek to determine the degree of risk involved to ascertain where the proposed importation would fall on the risk continuum. This will allow APHIS to address the degree of risk involved in a particular type of importation, rather than trying to fit it into one of the three categories contained in the current regulations.

Factors Considered in Assessing Risk

Factors affecting the risk levels of ''free'' regions are many and can include geographical proximity to areas where the disease exists, and importation practices that increase the risk that the disease might be introduced into the ''free'' region. Similarly, significant differences in risk can exist among regions in which a particular disease is known to exist, depending on the prevalence of the disease (the number of cases at a given time) or the infrastructure in place for identifying, containing or eradicating the disease.

In this policy statement, we are setting forth the factors we will consider in determining the risk of unrestricted importations from a region. Broadly, these factors are the following:

- The authority, organization, and infrastructure of the veterinary services organization in the region.
- The type and extent of disease surveillance in the region—e.g., is it passive and/or active; what is the quantity and quality of sampling and testing?
- Diagnostic laboratory capabilities.

• Disease status—is the disease agent known to exist in the region? If ''yes,'' at what prevalence? If ''no,'' when was the most recent diagnosis?

• The extent of an active disease control program, if any, if the agent is known to exist in the region.

• The vaccination status of the region. When was the last vaccination? What is the extent of vaccination if it is currently used, and what vaccine is being used?

• Disease status of adjacent regions.

• The degree to which the region is separated from regions of higher risk through physical or other barriers.

• The extent to which movement of animals and animal products is controlled from regions of higher risk, and the level of biosecurity regarding such movements.

• Livestock demographics and marketing practices in the region.

• Policies and infrastructure for animal disease control in the region—i.e., emergency response capacity.

Characterization of Levels of Risk

In practice, regions could have numerous possible combinations of the above factors. For instance, one region might have a low prevalence of a disease (the number of cases at a given time), but have loosely restricted borders with adjacent regions where the disease is present. Another region might have tighter border controls but a higher incidence of the disease (the number of new cases over a given period of time). Two regions with identical histories of disease incidence and disease prevalence might differ in that vaccination continues in one region, but not in the other. Two regions might theoretically share all risk characteristics, including adjacency to a region where a disease of concern is known to exist. However, in one case, the disease in the affected neighboring region might exist close to the border. In the other, it might exist two time zones away, if the neighbor is a large country that has not yet requested to be subdivided into regions. This one variable could affect the actual risk level between the two regions, and could potentially support two different sets of conditions necessary to reduce the risk of the importation of animals and animal products to a negligible level. Therefore, although each of the factors we will consider are accepted on an international level as potentially affecting the disease risk in a region, the weight each of the factors will be given will depend on the individual circumstances of the region.

Because of the number of potential variables and the vast number of possible combinations of those variables in assessing the risk of unrestricted importation of animals and animal products from a region, the precise combination of measures necessary to reduce the risk of disease introduction to a negligible level may vary from region to region depending on the commodities to be imported and the diseases of concern.

Recognizing these potential variables, we nonetheless consider it useful to provide benchmarks or ''targets'' of general risk characterization, by dividing the continuum of risk into five general categories, based on the risk factors described above. These benchmark risk categories are:

• Negligible risk;
• Slight risk;
• Low risk;
• Moderate risk;
• High risk.

In order to determine the risk category of a region, we must have or be supplied with sufficient information to evaluate the region's level of risk. Any region for which sufficient data is not available to make such an evaluation would be considered to be high risk until information became available to support an alternative determination.

As noted above, there are factors that we always look at in determining the level of risk that unrestricted importations from a region would present (veterinary infrastructure, disease status, disease status of adjacent regions, vaccination status, etc.). We have weighed these factors in our determination of a country's disease status under the current regulations, and will continue to do so in the future. The difference between the current regulations and the policy we are adopting is that, in the future, our consideration of these factors will not always result in one of the three current classifications of ''free'' ''not free,'' or ''modified free.'' In theory, and likely in practice, regions where an animal disease is not known to exist may present different levels of risk, and regions where an animal disease is known to exist may likewise present different levels of risk. We will establish import conditions appropriate to each of the regions in a transparent, scientific manner, subject to public review and comment, as discussed below. A region will be able, however, to determine how we will generally view its animal disease risk, according to the following factors and scenarios.

1. *Negligible Risk.* A region in which all of the following factors are present would generally be considered a region of *negligible risk* for a restricted disease agent:

• The restricted agent has not been diagnosed within the region for a period of time appropriate for that agent. This period of time will depend on the disease in question, but can range from 1 year for a disease such as FMD, to a longer period of time for diseases with long incubation times, such as spongiform encephalopathies and mycobacterial diseases.

• The restricted agent is not known to exist within any adjacent defined region.

• Vaccination for the restricted agent has been prohibited within the region for a period of time appropriate to the disease in question (exceptions may be made for certain diseases such as vector-transmitted diseases, or for animals specifically vaccinated to meet import requirements of other regions, and such vaccination would not increase the risk of importing the restricted agent into the United States).

• Any adjacent regions of slight risk or low risk for the restricted agent are separated by natural or man-made physical barriers or protected borders, or other movement controls and other measures and restrictions that are equivalent to those imposed in the United States for similar diseases subject to domestic control programs.

• All border access points from adjacent regions of slight risk or low risk for the restricted agent are controlled to prevent movement of susceptible animals or animal products from the adjacent regions except under conditions that achieve the same level of biosecurity as required for importations from such regions of greater risk into the United States.

• Movement of animals and animal products into the region from regions of greater than negligible risk for the restricted agent is done only under conditions that achieve the same level of biosecurity as required for importations from such regions of greater risk into the United States.

• The region maintains an adequate passive surveillance system with the demonstrated capability of detecting restricted agents in a timely fashion.

• The region maintains policies and infrastructure to respond to any occurrences of a restricted agent.

2. *Slight Risk.* In general, a particular disease agent would not be known to exist in a region of slight risk, but adjacency to or extensive trade with regions of higher risk levels would create a greater risk of disease exposure than exists in a region of negligible risk. A region in which all of the following factors are present would be considered a region of *slight risk* for a restricted disease agent:

• The restricted agent has not been known to exist in the region for a period of time appropriate for that agent.

• Vaccination for the restricted agent is prohibited within the region (exceptions may be made for certain restricted agents such as vector-transmitted diseases, or for animals specifically vaccinated to meet import requirements of other regions, and such vaccination would not increase the risk of importing restricted agents into the United States).

• Any animals previously vaccinated against the disease have been slaughtered or moved out of the region, or are under provisional quarantine (exceptions may be made for certain restricted agents such as vector-transmitted diseases, or for animals specifically vaccinated to meet import requirements of other regions, and such vaccination would not increase the risk of importing restricted agents into the United States).

• Any adjacent regions of greater than slight risk for the restricted agent are separated by natural or man-made physical barriers or protected borders, or other movement controls and other measures that are equivalent to those employed in the United States for similar diseases subject to domestic control programs.

• All border access points from regions of greater than slight risk for the restricted agent are strictly controlled to prevent movement of susceptible animals or animal products from the adjacent regions, except under conditions that achieve the same level of biosecurity as required for importations from such regions of greater risk into the United States.

• Movement of animals and animal products into the region from regions of greater than slight risk for the restricted agent is done only under conditions that achieve the same level of biosecurity as required for importation from such regions of greater risk into the United States.

• The region maintains adequate passive and/or active surveillance systems with the demonstrated capability of detecting restricted agents in a timely fashion.

• The region maintains policies and infrastructure to respond to any occurrences of a restricted agent.

3. *Low Risk*. A particular disease agent would not be known to exist in a region of low risk, but continued vaccination would create concerns about residual infection and/or masking of the agent. A region in which all of the following factors are present would be considered a region of *low risk* for a restricted disease agent.

• The restricted agent has not been diagnosed within the region during the past year, except for diseases with long incubation periods such as spongiform encephalopathies and mycobacterial diseases, and the prevalence of the restricted agent has been low over a period of time appropriate to the disease in question.

• Vaccination for the restricted agent is prohibited within the region or is limited to those herds that are at greatest risk of exposure from animals from regions of higher risk levels (exceptions may be made for certain diseases such as vector-transmitted diseases, or for animals specifically vaccinated to meet import requirements of other regions, and such vaccination would not increase the risk of importing restricted agents into the United States).

• Any adjacent regions of greater risk for the restricted agent are separated by natural or man-made physical barriers, or protected borders, or other movement controls and other measures that are equivalent to those employed in the United States for similar diseases subject to domestic control programs.

• All border access points from adjacent regions of greater risk for the restricted agent are controlled to prevent movement of susceptible animals or animal products from the adjacent regions except under conditions that achieve the same level of biosecurity as required for importations from such regions of greater risk into the United States.

• Movement of animals and animal products into the region from regions of greater risk for the restricted agent is done only under conditions that achieve the same level of biosecurity as required for importation from regions of greater risk into the United States.

• The region maintains adequate passive and active surveillance systems with the demonstrated capability of detecting restricted agents in a timely fashion.

• The region maintains policies and infrastructure to respond to any occurrences of the restricted agent.

4. *Moderate Risk*. A particular disease agent would be known to exist in a region of moderate risk, but at a low level. A region in which all of the following factors are present would be considered a region of *moderate risk* for a restricted disease agent.

• The restricted agent has been diagnosed within the region during the past year, or within a longer period of time for diseases with long incubation periods such as spongiform encephalopathies and mycobacterial disease, but the prevalence of the restricted agent has been low for a period of time appropriate for the disease agent.

• An active control program with a goal of eradication for the restricted agent is in operation in the region.

• Vaccination for the restricted agent is currently limited to those herds at greatest risk of infection (exceptions may be made for certain diseases, such as vector-transmitted diseases, or for animals specifically vaccinated to meet import requirements of other regions, and such vaccination would not increase the risk of importing restricted agents into the United States).

• Any adjacent regions of greater risk are separated by natural or man-made physical barriers or protected borders, or other movement controls and measures equivalent to those employed in the United States for similar diseases subject to domestic control programs.

• All border access points from adjacent regions of greater risk for the restricted agent are strictly controlled to prevent movement of susceptible animals or animal products from the adjacent regions except under conditions that achieve the same level of biosecurity as required for importation from such regions of greater risk into the United States.

• Movement of animals and animal products into the region from regions of greater risk is done only under conditions that achieve the same level of biosecurity as required for importation from regions of greater risk into the United States.

• The region maintains adequate passive and active surveillance systems with the demonstrated capability of detecting restricted agents in a timely fashion.

• The region maintains policies and infrastructure to eliminate any outbreaks of the restricted agent that may occur.

5. *High Risk*. A disease agent would be known to exist in a region of high risk, possibly at a high level. A region in which the following factors are present would be considered a region of *high risk* for a restricted disease agent.

• The restricted agent has been diagnosed within the region within the past year, or within a longer period of time for diseases with long incubation periods such as spongiform encephalopathies and mycobacterial disease, and the prevalence of the disease agent in the time period appropriate to the disease agent exceeds that of a moderate-risk region.

• A control program for restricted agents may be in operation in the region but does not meet the minimum standards for a region of moderate risk.

• Vaccination for the restricted agent may vary from herd to herd.

• Movement of animals and animal products into the region may not be adequately controlled from regions of moderate risk or high risk for the restricted agent.

• The region does not maintain a passive and active surveillance system for the restricted agent at a level that meets standards for a region of moderate risk.

• The region may or may not maintain policies and infrastructure to effectively control and restrict spread of any outbreaks of the restricted agent that may occur.

It should be noted that of the five general categories of risk set forth above, the categories referred to as ''negligible risk,'' ''slight risk,'' and ''high risk'' correspond to risk classifications as set forth in the current regulations. ''Negligible risk'' is comparable to our current free-without-restrictions status. ''Slight risk'' is comparable to our current modified-free status, applied to those countries where a disease is not known to exist but which, because of their proximity to countries where the disease exists or because of their importation practices, are considered to present more than a negligible risk of unrestricted importation of meat products. ''High risk'' is comparable to those countries where a disease is known to exist. To these three current classifications, the factors described above add the categories of ''low risk'' (to address regions that have reported no cases of disease over a specified period of time but that still vaccinate for the disease) and ''moderate risk'' (to address those regions where a disease may exist on a limited basis, but where it is adequately controlled and contained). Examples of regions that would fall under one of these two additional characterizations, along with an example of a high risk region, are as follows.

Example 1: A Region Considered To Present a Low Risk of FMD Introduction Through Unrestricted Importation

The example of a region characterized as presenting a low risk for FMD is one that we recently applied with regard to the importation of beef from Argentina. Because the last outbreak of FMD occurred in Argentina in 1994, we considered the disease risk in Argentina to be low, although higher than in other countries in which the disease has not occurred, due to the following factors:

(1) Vaccinations for FMD still continue in Argentina;

(2) Argentina supplements its national meat supply by importing fresh, chilled and frozen meat of ruminants and swine from countries where some prevalence of FMD occurs; and

(3) Argentina shares land borders with Brazil and Bolivia, for which we do not have enough information to establish a disease risk characterization for FMD.

For these reasons, we established import conditions on the importation of beef from Argentina that do not apply to other countries in which FMD is not known to occur. These conditions are discussed below under the heading ''Examples of Import Conditions.''

Example 2: A Region Considered to Present a Moderate Risk of FMD Introduction Through Unrestricted Importation

In this example, Region X has had an outbreak of FMD in the past year, but the prevalence of the disease in recent years has been low. Region X borders a region where FMD is known to exist. However, Region X has in place adequate passive and active surveillance systems for detection and reporting of the disease. Further, Region X has in place an active control program with the goal of eradication of FMD. Vaccination for FMD is currently limited to those herds at greatest risk of infection. Region X maintains policies and infrastructure to *eliminate* any outbreaks of the restricted agent that may occur.

Compare Region X to Region Y, which is:

Example 3: A Region Considered To Present a High Risk of FMD Introduction Through Unrestricted Importation

Region Y is identical to Region X in every way except two. First, it does not have an active control program with the goal of eradication of FMD. Second, it has in place policies only to *restrict,* rather than *eliminate,* outbreaks of FMD.

We would consider Region X to present a moderate risk of the introduction of FMD through unrestricted importation. We would consider Region Y to present a high risk.

Import Conditions Based on Risk

The risk characterizations described above are guidelines for the use of regions seeking to export animals or their products to the United States, and to provide guidance as to the factors we consider in deciding where a particular region falls on the disease risk continuum. The risk characterizations themselves do not determine whether an animal or its products may be safely imported into the United States, nor do they dictate the precise import conditions that would be appropriate to the importation of a particular commodity. But they do provide an indication as to the severity of the disease risk and the necessary restrictions that we would apply to importations to reduce the disease risk to a negligible level.

The actual decision whether to allow importations, and under what conditions, would be based on the outcome of a risk analysis conducted on a particular commodity from a particular region. In accordance with the WTO–SPS Agreement, we recognize that different import conditions might achieve equivalent results in reducing disease risk. However, the final determination of which import conditions to impose, and whether different sets of conditions are equivalent, will rest with APHIS. The WTO–SPS Agreement principles require that SPS measures be equitably applied, scientifically sound, guided by international standards, and ''transparent.'' Signatory countries must also recognize that equal levels of risk mitigation can be achieved by applying differing sanitary measures (equivalence), based on risk-assessments applied on a regional basis.

In accordance with the WTO–SPS Agreement principles, it will be our policy to establish appropriate conditions for the importation of animals and animal products based either on international standards or as the result of an individual assessment of risk of the importation of a particular type of commodity from a particular region. A document describing the Agency's internal guidelines for risk assessment is currently under development. It will be made available electronically upon completion. In general, we will process applications for regionalization according to the following procedure:

The potential exporting region must submit a request to the APHIS Administrator for approval to export a particular type of animal or animal product to the United States. Along with the request, the region must provide information addressing the areas described above in this notice, under the heading ''Factors Considered in Assessing Risk.'' This information will be made available to the public prior to our initiating any rulemaking action on the request. Additional information may be requested from the exporting region depending upon the specific commodity and the risk being evaluated.

Once we have received from a potential exporting region the information necessary to conduct a risk assessment, and have evaluated the risk, we will make a determination whether an import can be safely allowed and

under what conditions. If we believe the importation can be safely allowed, we will propose in the **Federal Register** to allow such importations, and under what conditions, along with a discussion of how we reached that decision. We will then provide a period of time during which the public may comment on our proposal. We will find most useful those comments that support their position with verifiable data or scientific information. During the comment period, the public will have access, both in hard copy and electronically, to the information upon which we based our risk analysis, as well as to our methodology in conducting the analysis. Once we have reviewed all comments received, we will make a final decision on what conditions will be necessary to allow the importation in question, and will publish that decision in the **Federal Register**.

Although the import conditions applied in each situation may vary according to the region, the disease, and the commodity involved, we anticipate, based on our experience enforcing the current regulations, that similar levels of risk will require similar conditions of importation. We have adopted, and have been applying for decades, a body of risk mitigation measures that will likely be used in some combination for each importation. These can include measures ranging from something as simple as a certificate of origin, to the requirement that animals intended for importation from regions of high risk be quarantined at APHIS's high-security Harry S Truman Animal Import Center, to outright prohibition of an importation.

The broad risk management options available for application, either individually or in combination, to animals or their products are:

- Certificate of origin of animals and animal products.
- Tests and inspection of imported animals or products.
- Tests and inspections of herds or premises of origin.
- Treatment of animals or products.
- Quarantine of imported animals.
- Restricted use or movement of imported animals or products.

Not all of the options are appropriate for every disease agent, so different strategies will be necessary for different agents. Some of the variabilities of the disease agents include:

- The incubation period.
- The duration of carrier status in animals.
- The number of potential host species that may be affected.
- The survivability of the disease agent outside the host animal.
- The effectiveness of available test procedures to detect the disease agent.
- The effectiveness of available treatment procedures to eliminate the disease agent or its vector.
- The availability of technology to eradicate the disease agent if it were introduced.
- If the disease agent were introduced, the potential costs (both economic and environmental) to eradicate it, or potential costs into perpetuity if the agent cannot be eradicated.

Application of Import Conditions

The three examples we presented earlier in this document of regions characterized as either ''low risk,'' ''moderate risk,'' or ''high risk'' for FMD can also be used to illustrate the types of mitigation measures we would consider appropriate for a disease such as FMD, which is a serious disease with significant potential costs in the event of introduction and establishment. Examples of the types of import conditions that would be appropriate are set out as follows. Please note, however, that the precise import conditions in any specific case will depend on all of the factors affecting a particular region.

Example 1: Importation of Beef From a Region Characterized as Low-Risk for FMD

As noted above, we recently made final a rule allowing the importation of beef from Argentina, which we determined to be a country that would present a low risk of FMD introduction if unrestricted imports were allowed into the United States. Because of the potentially severe consequences of FMD introduction, we considered it necessary to apply the following import conditions to any fresh, chilled or frozen beef imported from Argentina, and to cured or cooked beef from Argentina that does not meet the requirements of 9 CFR 94.4. An authorized official of Argentina must certify on a meat inspection certificate that each of the following conditions was met.

(1) The meat is beef that originated in Argentina;

(2) The beef came from bovines that were moved directly from the premises of origin to the slaughterhouse without any contact with other animals;

(3) The beef has not been in contact with beef from regions in which FMD is considered to exist;

(4) The beef came from bovines that originated from premises where FMD and rinderpest have not been present during the lifetime of any of the bovines slaughtered for export of beef;

(5) The beef is from bovines that originated from premises on which ruminants or swine have not been vaccinated with modified or attenuated live viruses for FMD at any time during the lifetime of any of the bovines slaughtered for export of beef;

(6) The beef originated from premises where no bovines have been vaccinated for rinderpest at any time during the lifetime of any of the bovines slaughtered for export of beef;

(7) All bone, blood clots, and lymphoid tissue have been removed from the beef; and

(8) The beef comes from carcasses that have been allowed to maturate at 40 to 50 °F (4 to 10 °C) for a minimum of 36 hours after slaughter, and have reached a pH of 5.8 or less in the loin muscle at the end of the maturation period. Any carcass in which the pH does not reach 5.8 or less may be allowed to maturate an additional 24 hours and be retested, and, if the carcass still does not reach a pH of 5.8 or less after 60 hours, the beef from the carcass may not be imported into the United States.

Example 2. Importation of Beef From a Region Characterized as Moderate Risk for FMD

In the examples or risk characterization we provided earlier in this document, we considered Region X to be a region of moderate risk for FMD. Although the actual conditions for the importation of beef from Region X might be established by means of a risk analysis, based on our experience enforcing the regulations, it is likely that the conditions would be similar to those for a low risk region, with the following differences due to the existence of FMD in the region and the resulting higher risk:

1. The beef would have to come from bovines that originated from premises where FMD or rinderpest has not been diagnosed within 15 statute miles (25 kilometers) within the previous 12 months; and

2. The beef would have to be held at no more than 40 °F (4 °C) for a minimum of 14 days before export, during which time the premises of origin of all animals from which the beef in the shipment came would have to remain free of FMD and rinderpest.

Example 3: Importation of Beef From a Region Characterized as High Risk for FMD.

The importation of fresh, chilled or frozen beef would be prohibited from a

region characterized as presenting a high risk for FMD.

Diseases of Concern

The current regulations specifically address a number of diseases subject to import regulations, either because they are not known to exist in the United States or because they are subject to Federal or cooperative Federal/State control or eradication programs in the United States. We will continue to regulate the importation of animals and their products with regard to these diseases. Additionally, it will be our policy to consider the risk presented by certain diseases not currently specifically listed in 9 CFR when determining whether to allow an importation and under what conditions.

With regard to ruminants and swine, the diseases we are specifically naming here have, in many cases, been of concern even under the current regulations, but have not posed a significant practical risk because the countries in which they exist have also been countries in which rinderpest or FMD exists. Accordingly, such importations were prohibited. The current regulations ban the importation into the United States of most animals and animal products from countries in which rinderpest or FMD exists. In those cases where animals or animal products are allowed to be imported from these countries, they must meet stringent quarantine or processing requirements. These prohibitions and safeguards effectively ban many animals and products affected with other diseases.

However, several factors now make it necessary to consider specific regulatory restrictions for certain diseases not currently addressed in the regulations. The first factor is the policy we are adopting of providing for regionalization and for various levels of characterization of disease risk. For example, unlike under the current regulations, the fact that FMD exists in one region of a country may not significantly restrict the importation of animals and animal products from another region of the same country, if the two regions are so separated and monitored that the risk of the disease being transferred from one region to the other is negligible. This is a departure from the current regulations, in which FMD in any part of a country determines the FMD status of the entire country.

The second factor is the progress many countries have made in eradicating, or moving toward eradication of, rinderpest and FMD in specific regions. In countries where FMD exists, an increasing number of regions have eradicated or come close to eradicating the disease. Therefore, under our policy of regionalization, import restrictions due to FMD in one part of a country can no longer be relied upon to guard against the importation of other animal diseases of concern.

In addition to FMD and rinderpest, other disease agents that are specifically addressed in current 9 CFR parts 92 and 94 are: In part 94, African swine fever virus, hog cholera (also known as classical swine fever virus), swine vesicular disease virus, exotic Newcastle disease (END) virus (also known as velogenic Newcastle disease or VVND virus), fowl pest (also known as fowl plague or highly pathogenic avian influenza), bovine spongiform encephalopathy, and salmonella enteritidis phage type 4; in part 92, contagious pleuropneumonia, scrapie, surra caused by *Trypanosoma evansi*, fever ticks and other ticks, vesicular stomatitis, dourine caused by *Trypanosoma equigenitalium*, glanders caused by *Pseudomonas mallei*, equine piroplasmosis caused by *Babesia equi* or *B. caballi*, equine infectious anemia, contagious equine metritis caused by *Taylorella equigenitalis*, African horse sickness virus, Venezuelan equine encephalitis virus, epizootic lymphangitis caused by *Histoplasma farciminosum*, and *Taenia multiceps* (also known as *Taenia coenurus*).

In addition to the diseases listed above, we will consider the following diseases when determining conditions for the importation of animals and animal products: Akabane virus, bluetongue virus, epizootic hemorrhagic disease virus, malignant catarrhal fever virus (African or wildebeest form), blue eye disease of swine (paramyxovirus), *Brucella abortus, Brucella melitensis, Brucella suis, Trypanosoma vivax*, contagious agalactiae of sheep and goats due to *Mycoplasma agalactiae, Mycobacterium bovis*, pseudorabies, sheep pox and goat pox, heartwater due to *Cowdria ruminantium*, Japanese encephalitis virus, lumpy skin disease (Neethling virus), Nairobi sheep disease (Ganjam, Dugbe) virus, peste des petits ruminants, Rift Valley fever, and theileriosis (east coast fever, corridor disease, Mediterranean fever), turkey rhinotracheitis (swollen head), goose parvovirus (Derzsy's disease), adenovirus 127 (egg drop syndrome), *salmonella pullorum*, and *salmonella gallinarium*.

In determining conditions for the importation of animals, we will also consider the presence in the region of ectoparasites of animals if the ectoparasites are not known to exist in the United States or are subject to cooperative Federal/State control programs in the United States. These ectoparasites include the following:

Ticks: Amblyomma astrion, A. cohaerens, A. gemma, A. hebraeum, A. javenese, A. lepidum, A. marmoreum, A. pomposum, A. sparsum, A. testudinarium, A. tholloni, A. variegatum, Boophilus annulatus, B. decoloratus, B. florae, B. geigyi, B. kohisi, B. microplus, Dermacentor daghestanicus, D. marginatus, D. nuttalli, D. pictus, D. reticulatus, D. silvarium, Haemaphysalis bispanosa, H. leachii, H. longicornis, H. otophila, H. punctata, H. sulcata, Hyalomma anatolicum anatolicum, H. anatolicum excavatum, H. detritum, H. dromedarii, H. marginatum marginatum, H. marginatum rufipes, H. marginatum turanicum, H. scupense, H. truncatum, Ixodes persulcatus, I. pilosus, I. ricinus, Ornithodoros erraticus, O. moubata, O. moubata porcinus, Rhipicephalus appendiculatus, R. bursa, R. capensis, R. compositus, R. evertsi evertsi, R. evertsi, mimeticus, R. glabroscutatum, R. kochi, R. lunulatus, R. pulchellus, R. simus, R. turanicus, and R. zambeziensis.

Mites: Chorioptes bovis, various subspecies of which cause mange in horses, cattle, and sheep; *Psorergates ovis*, the causative agent of sheep scabies; *Psoroptes cuniculi*, the causative agent of ear mange in goats and rabbits; and *P. ovis*, various subspecies of which cause scabies and mange in horses, cattle, sheep, and swine.

Insects: Chrysomyia bezziana (Old World screwworm), *Cochliomyia hominivorax* (*Callitrogra americana*) (New World screwworm), and *Hippobosca* spp. and *Lipoptema* spp. (louse flies).

Done in Washington, DC, this 22nd day of October 1997.

Terry L. Medley,

Administrator, Animal and Plant Health Inspection Service.

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