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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 92 and 98

[Docket No. 94-085-3]

Importation of Sheep and Goats and Germ Plasm From Sheep and Goats

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the animal importation regulations to revise who may issue health certificates for ruminants offered for importation. This amendment will make the regulations more consistent with regard to different animals and countries and will provide an alternative method of issuing health certificates.

We are also amending the animal importation regulations to revise the conditions for importing sheep and goats. We are similarly amending the animal germ plasm regulations to revise the conditions for importing germ plasm from sheep and goats. These changes appear necessary to prevent the importation of sheep and goats, and germ plasm from sheep and goats, that may be affected with scrapie.

We are also amending the animal importation regulations to allow imported goats to be quarantined in privately operated quarantine facilities that meet the requirements that now apply to privately operated quarantine facilities for sheep. This amendment will provide uniform rules for the quarantine of animals which pose a similar disease risk.

In addition, we are removing from the regulations health certificate requirements that apply specifically to the importation of sheep from New Zealand. Since sheep from New Zealand pose no greater disease risk than sheep

from other countries, there is no longer a need to retain separate health certification requirements for sheep imported from New Zealand.

Lastly, we are adopting as a final rule, without change, an interim rule that amended the regulations for importing sheep and goats from Canada and Mexico. The rule requires that, with the exception of sheep and goats imported through land border ports for immediate slaughter, and wethers imported through land border ports, all sheep and goats imported into the United States from Canada and Mexico be accompanied by an import permit. This requirement is necessary to prevent the importation of sheep and goats that may be affected with scrapie.

EFFECTIVE DATE: May 20, 1996.

FOR FURTHER INFORMATION CONTACT: Dr. Joyce Bowling or Dr. Roger Perkins, Staff Veterinarian, Import Animals Program, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737-1228, (301) 734-8170.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 92 govern the importation into the United States of live animals, including sheep and goats, which are regulated in part to prevent those infected with scrapie from transmitting the disease to livestock in the United States. The regulations in 9 CFR part 98 govern the importation into the United States of germ plasm (semen and embryos), including germ plasm from sheep and goats.

Scrapie is a progressive degenerative disease of the central nervous system of sheep and goats. Scrapie occurs more often in certain flocks and certain bloodlines, indicating that these animals may be genetically predisposed to become infected with or develop the disease. Scrapie may be transmitted through contact with the placenta or bodily fluids of infected animals which have just given birth.

The disease develops slowly, with an incubation period lasting up to 5 years. The signs which then become manifest may include nervousness, incoordination, slight muscular tremors, visible weight loss, lack of luster in the animals' wool, and itching. Affected animals become debilitated and die. There is no diagnostic test for confirming the presence of the disease

in a live animal or in germ plasm. Therefore, presence of the disease cannot be detected until an animal becomes clinically ill. There is no known treatment for the disease. The impact of the disease in the United States could increase if spread of the disease is not controlled, or if incidence of the disease increases. For these reasons, our regulations are intended to prevent the importation of animals and germ plasm that could transmit scrapie, while controlling spread of the disease as it exists in the United States and eliminating foci of infection.

The regulations in 9 CFR parts 92 and 98 are designed, in part, to prevent the importation of scrapie-infected animals and germ plasm into the United States. Other regulations concerning scrapie are contained in 9 CFR parts 54 and 79. The regulations in part 54 deal with controlling scrapie in the United States, and include, among other things, the Voluntary Scrapie Flock Certification Program. The regulations in part 79 concern identification of sheep and goats in the United States that are or may be affected with scrapie, and restrict the interstate movement of sheep and goats so as to prevent the interstate spread of scrapie.

In an interim rule effective and published in the Federal Register on March 15, 1995 (60 FR 13898-13900, Docket No. 94-085-1), we amended the regulations in part 92 to require that, with the exception of sheep and goats imported through land border ports for immediate slaughter, and wethers imported through land border ports, all sheep and goats imported into the United States from Canada and Mexico be accompanied by an import permit. This action was necessary to prevent the importation of sheep and goats that may be affected with scrapie.

We solicited comments concerning the interim rule for 60 days ending May 15, 1995. We received 4 comments by that date. They were from one foreign government, and from industry representatives and businesses.

On May 11, 1995, we published in the Federal Register (60 FR 25151-25162, Docket No. 94-085-2) a proposal to amend the regulations in parts 92 and 98 by: (1) Revising who may issue health certificates for ruminants offered for importation; (2) revising the conditions for importing sheep and goats; (3) revising the conditions for

importing germ plasm from sheep and goats; (4) allowing imported goats to be quarantined in privately operated quarantine facilities that meet the requirements that now apply to privately operated quarantine facilities for sheep; and (5) removing health certificate requirements that apply specifically to the importation of sheep from New Zealand.

We solicited comments concerning the proposed rule for 60 days ending July 10, 1995. We received 15 comments by that date. They were from foreign governments, Federal and State government agencies, industry representatives, livestock producers, and private individuals.

Of the comments received in response to the interim rule, one addressed issues which were not contained in the interim rule, but which were contained in the proposed rule. Although we did not count this comment as being received in response to the proposed rule, we did consider suggestions made in the comment when we determined changes necessary in the proposed rule.

Two comments received in response to the interim rule failed to address any issue raised by either the interim rule or the proposed rule. One commenter discussed the importation of washed and frozen embryos, a topic not relevant to either the interim rule or the proposed rule. The other comment contained the results of an industry association member survey concerning the importation of animal genetics. However, the survey, as described in the comment, did not appear to have addressed the specific provisions of either the interim or the proposed rule. For these reasons, we did not consider either of these comments when determining changes necessary in the interim and proposed rules.

We have carefully considered all of the relevant comments we received in response to both the interim rule and the proposed rule. Issues raised by the comments are discussed below by topic. In our discussion, we refer to the regulations in both parts 92 and 98 as "the regulations."

Scientific Basis of Regulations

Two commenters objected to our statement, in the background of both the interim rule and the proposed rule, that scrapie is transmitted by breeding. The commenters are correct—breeding, itself, does not appear to transmit scrapie. Scrapie is also not a hereditary disease. However, it does appear that scrapie can be transmitted through contact with the placenta or bodily fluids of infected animals which have just given birth. In addition, there is a

tendency to develop the disease which appears to follow bloodlines. Therefore, we have amended the background information in this document concerning scrapie transmission so that it more accurately reflects current scientific knowledge about this disease.

One commenter objected to proposed § 92.405(b)(2), which would have required the certificate accompanying imported sheep or goats to state that none of the female sheep or goats in the flock or herd from which the sheep or goats will be imported was impregnated, during the 5 years immediately preceding shipment of the sheep or goats to the United States, with embryos or semen from another country other than the United States or from a flock or herd of unknown scrapie status. The commenter maintained that it is scientifically unjustified to restrict the importation of sheep and goats from flock or herds in which females have been impregnated with germ plasm from Australia or New Zealand. We agree with this comment, and we have made two changes to this provision, as discussed below.

Our proposed rule and this document allow the importation of sheep from countries other than Australia, Canada, or New Zealand, provided such sheep enter a flock participating in the Voluntary Scrapie Flock Certification Program (VSFCP). It was never our intention to be more restrictive with regard to sheep from flocks in which any female has been impregnated with germ plasm from (1) a country other than the United States or (2) a flock of unknown scrapie status, provided such sheep enter a flock participating in the VSFCP. Any risk of scrapie presented by such sheep would be mitigated by placing them in a flock participating in the VSFCP. Therefore, we are removing the requirement that the certificate state that none of the female sheep in the flock from which the sheep will be imported has been impregnated with germ plasm from a country other than the United States or from a flock of unknown scrapie status.

Additionally, sheep imported from Australia, Canada, and New Zealand will be required to enter a flock participating in the VSFCP if any of the females in the flock from which the sheep will be imported has been impregnated, during the 5 years immediately preceding shipment of the sheep to the United States, with germ plasm from a country other than Australia, Canada, New Zealand, or the United States. Any risk of scrapie presented by such sheep would be mitigated by placing them in a flock participating in the VSFCP. As the

commenter indicated, Australia and New Zealand are free of scrapie. Germ plasm from sheep in Australia and New Zealand can therefore be used to impregnate animals without fear of transmitting scrapie. Although Canada is not free of scrapie, Canada employs reporting and surveillance requirements equivalent to those of the United States. Germ plasm from sheep in Canada can likewise be utilized under the conditions set forth above without fear of transmitting scrapie into the United States.

We are not making any specific changes on this issue with regard to goats. This is because, as explained elsewhere in this document, we are amending § 92.405 to exempt goats under certain circumstances from many of the requirements of this section. Together, we believe these amendments impose the fewest restrictions on importers while still protecting U.S. livestock from the importation of scrapie.

We are also amending § 92.405 to clarify that sheep and goats must be accompanied by a certificate stating that none of the female sheep or goats in the flock or herd from which the sheep or goats will be imported has been impregnated, during the 5 years immediately preceding shipment of the sheep or goats to the United States, with germ plasm from a flock or herd known to be infected with scrapie. This requirement, along with restrictions on progeny of scrapie-infected animals, is designed to prohibit importation into the United States of animals most likely to be infected with scrapie. This requirement was implied in our proposed regulations. However, as we are completely revising § 92.405 in this final rule, we are taking this opportunity to include a clear statement of this requirement.

Compliance With International Agreements

One commenter stated that requiring a permit for sheep and goats imported from Canada is "contrary to the domestic regulatory position currently in effect and, therefore, not consistent with the principles of the Treaty of the World Trade Organization [WTO]." The commenter did not explain how our proposal is "inconsistent." The same commenter also stated that imposing a permit requirement would be "counterproductive to our mutual commitment under the North American Free Trade Agreement [NAFTA] Animal Health Technical Working Group to facilitate trade through shared risk assessments and common import policies." Again, the commenter did not

explain how our proposal is "counterproductive."

We do not agree with either assertion. If the comment is interpreted literally, no WTO signatory country would be permitted to substantively amend its regulations, because substantive amendments would always be "contrary to the domestic regulatory position currently in effect." This is clearly not the intention of the WTO. The WTO clearly maintains, in Article 2, the right of countries to take any sanitary (animal) and phytosanitary (plant) measure necessary to protect human, animal, and plant life and health. Furthermore, the WTO requires, in Article 5, that signatory countries base their SPS, that is, sanitary and phytosanitary requirements, on an assessment of the risks. If, according to this assessment, the level of risk changes, a country may adjust its requirements. We agree with the commenter that NAFTA obligates Canada, Mexico and the United States to work towards common import policies. However, that commitment is secondary to each country's biosecurity needs.

In the case of Canada, there has been an increase in the level of risk of transmitting scrapie into the United States. Until 1994, Canada did not generally import animals or germ plasm from countries where scrapie exists. The few importations that did occur were rare and easily traced. However, this is no longer true. Canada now frequently imports germ plasm from countries where the United States believes scrapie exists. For example, germ plasm from France and the United Kingdom has recently been imported into Canada. This has increased the risk that scrapie will be transmitted into the United States by animals and germ plasm from Canada. Our proposal to require that animals and germ plasm from Canada be accompanied by an import permit is a response to the increase in disease risk brought about by this change in Canadian imports.

One commenter stated that we should, to fulfill the "rights and obligations of the United States as a signatory to the Sanitary/Phyto-Sanitary (SPS) Chapter of the World Trade Organization, * * * recognize the use of [germ plasm] from sources which provide equivalent assurances to those achieved under the Voluntary Scrapie Flock Certification Program." Implementation of this SPS concept (i.e., equivalency), depends, to a large extent, on an official recognition of the exporting country's procedures or systems as being equivalent. We believe our proposed regulations recognize the use of germ plasm from equivalent

sources. Sections 92.435, 98.10a, and 98.37 of the regulations specifically provide for importation of sheep, goats, and sheep germ plasm in programs determined by the Administrator of the Animal and Plant Health Inspection Service (APHIS) to be equivalent to the VSFCP. Countries must make an official request for U.S. recognition of equivalency in these matters. If the Administrator determines that a country's programs are equivalent, animals from that country will then be allowed to be imported into the United States into a flock or herd that participates in the VSFCP, and will be required to remain in such a flock or herd until they reach Certified status. However, the time required for them to reach Certified status will take into account the time spent by them in an equivalent program in the country of origin.

Classification of Countries

One commenter suggested that the Republic of South Africa be classified as scrapie-free. We are not making any changes based on this comment at this time. Currently, Australia and New Zealand are recognized by the United States and the World Health Organization as scrapie-free countries. However, we are constantly reevaluating the disease status of countries. If we determine that the status of any country should be changed, we will publish a proposal for public comment in the Federal Register.

Imports From Canada

One commenter stated that the disease situation in Canada has not changed, and there is therefore no justification to require permits for animals imported from Canada. Two commenters stated that import permits for sheep and goats and germ plasm from sheep and goats from Canada are unnecessary.

We have not made any changes based on this comment. As explained above, until 1994, Canada did not generally import animals or germ plasm from countries where scrapie exists. The few importations that did occur were rare and easily traced. However, this is no longer true. Canada now frequently imports germ plasm from countries where the United States believes scrapie exists. To ensure that there is no risk of transmitting scrapie to livestock in the United States, we need to be able to trace the movements of this germ plasm and animals resulting from the germ plasm. To obtain the information needed to make tracing possible, we are requiring that animals and germ plasm

from Canada be accompanied by an import permit.

Several commenters stated that sheep and goats imported from Canada should be handled differently under the regulations (i.e., be subject to more stringent requirements) than sheep and goats imported from Australia and New Zealand. Commenters also suggested that Canada could serve as a "back door" into the United States for sheep and goats from third countries.

We had proposed to exempt sheep and goats and germ plasm of sheep and goats from Canada, Australia and New Zealand from proposed §§ 92.435, 98.10a, and 98.37, which would require such animals and germ plasm to enter a flock or herd in the United States that participates in the VSFCP. It is true that Australia and New Zealand are free of scrapie, while Canada is not. However, the Canadian government has an effective system to report, trace, and destroy infected animals. Canada employs reporting and surveillance requirements equivalent to the United States. Such requirements include, but are not limited to: (1) Reporting incidence of scrapie; (2) restriction of animal movement within the country because of scrapie; (3) identification of flocks or herds with scrapie; and (4) depopulation mechanisms for scrapie (i.e., removal of high-risk animals). Canadian regulations are distinctly designed to control the spread of scrapie within that country. Furthermore, APHIS and Canadian animal health authorities closely coordinate scrapie control efforts. For these reasons, we consider the risk of scrapie from animals and germ plasm from Canada to be negligible, provided that certain requirements are met. As explained above, we are requiring that importers obtain an import permit for sheep, goats, and germ plasm from Canada. The permit application process is designed to provide us with the information we need to ensure that animals and germ plasm to be imported meet our requirements and that they are not exposed or infected with any disease or pest of concern. This includes not only scrapie, but other diseases and pests. The permit requirement applies to animals and germ plasm from all countries, including Australia and New Zealand.

As to whether Canada could serve as a "back door" for infected animals or germ plasm to enter the United States, we believe the permit requirements imposed by our interim rule should close the "back door" that now exists. With these requirements in place, animals and germ plasm from Canada may enter the United States only when

APHIS has been alerted to their health history. The application for an import permit gives us specific information on the scrapie status of animals and germ plasm to be imported, including the genetic history of germ plasm donors. These requirements, along with certificate requirements we proposed (see §§ 92.405, 98.5, and 98.35 in this final rule), will help ensure that animals and germ plasm are imported into this country only under conditions designed to prevent the importation and spread of scrapie. For example, pregnant sheep imported from Canada will be required to enter VSFCP flocks if they have been impregnated with germ plasm from any country other than Australia, Canada, New Zealand or the United States.

One commenter also stated that it is "unfair" to treat subsequent generations of animals differently, depending on whether they were born in the United States or in Canada. We have carefully considered this comment and we are not making any changes based on this comment. We believe the commenter attempts to compare two dissimilar issues: The treatment of animals to be imported into the United States and the treatment of animals already in the United States. We believe these issues require different approaches. Our intention in both the interim rule and the proposed rule was to protect livestock in the United States from being exposed to scrapie through imported animals and germ plasm. The regulations in part 92 and 98 were not designed to reduce the spread of scrapie within the United States. To accomplish that goal we have established the VSFCP (see 9 CFR part 54). That program is designed to encourage sheep and goats owners to eliminate scrapie within their herds and flocks and thereby help prevent spread of the disease within the United States. We believe the final regulations contained in this document will encourage participation in the VSFCP.

Exemptions From Permit Requirement

Commenters suggested that certain animals or germ plasm be exempted from the permit requirements contained in the interim rule. Suggestions were made to exempt feeder lambs imported into the United States from Canada and sheep and goats imported into the United States from Canada for temporary exhibition. A suggestion was also made that sheep and goats from flocks or herds in Canada where the only genetic material imported into the flock or herd was semen or embryos should not be subject to permit "restrictions."

We have carefully considered the suggestion that we exempt from the permit requirement sheep and goats imported from Canada for temporary exhibition in the United States. We need to know where these animals are located and when and where they are moved after they enter the United States. This information is necessary to help ensure that these animals do not come into contact with livestock in the United States under circumstances where they could transmit scrapie. We obtain this information through the import permit process and therefore cannot exempt these animals from this requirement.

We have also carefully considered the suggestion that we exempt feeder lambs from Canada from the permit requirement. We agree that feeder lambs are generally kept in confinement. However, we do not agree that they pose no greater risk of transmitting scrapie than do slaughter animals simply because they are normally kept in confinement. On the contrary, we believe feeder lambs pose considerable risk. Feeder lambs are usually shipped in mixed loads of ewe lambs and wether lambs. At the time they cross into the United States, they have entered U.S. commerce. Unlike wethers, which have no value other than slaughter, and which in any case are unlikely to transmit scrapie, feeder ewes are bought and sold for other purposes. Many are sold directly from feedlots for use as breeding ewes. It is not illegal to sell and buy feeder lambs for this purpose. Under these circumstances, we do not believe that exempting feeder lambs from Canada from the permit requirement is appropriate. We are therefore making no changes based on this comment.

The comment requesting that permit "restrictions" not be placed on animals from flocks or herds in Canada where the only genetic material imported into the flock or herd was semen or embryos was also carefully considered. It has been theorized that scrapie is not transmitted through germ plasm. However, at this time there is insufficient data or research to support this theory. While the topic is under study, we believe the most prudent course is to monitor through the VSFCP importation of animals from Canada that are from flocks where semen or embryos have been imported into the flock from a country other than Australia, Canada, New Zealand, or the United States. Therefore, we are making no changes based on this comment.

Who May Issue Health Certificates

One commenter suggested that we simplify the proposed regulations to

allow licensed veterinarians to certify source flocks as free of scrapie. We are not making any changes based on this comment. We require government certification to ensure that the information on certificates is reliable. If we allowed any licensed veterinarian to certify animals, we would have no means of ensuring that the information was accurate, and no recourse if it were not.

Additional Restrictions

Commenters also suggested that certain animals or germ plasm be placed under greater restrictions than provided in the interim and proposed requirements. The suggestions were to: (1) Prohibit importation of live animals born in the same flock during the same lambing or kidding season as progeny of scrapie-positive dams; (2) require that sheep or goats remain for a minimum of 5 years in a flock or herd participating in a disease prevention program; (3) restrict movement of animals located in zoos in the United States; (4) require identification of certain progeny; and (5) require necropsy of certain imported animals that die before they have been in the United States for 5 years.

We have determined that no changes are needed in response to the suggestion that we prohibit importation of live animals born in the same flock during the same lambing or kidding season as progeny of scrapie-positive dams. These animals would be prohibited importation under § 92.405. That section requires that, with limited exceptions, all ruminants intended for importation be accompanied by certificates. The certificates for sheep and goats (except for those animals from Australia, Canada, or New Zealand) must, in addition, specifically state that the animals have not been in any flock or herd nor had contact with sheep or goats which have been in any flock or herd where scrapie has been diagnosed or suspected during the 5 years immediately prior to shipment. Also under § 92.405(a), ruminants, including sheep or goats, would have to be accompanied by a certificate stating that the animals are not in quarantine in the country of origin. This is a new requirement in this final rule and is discussed below under "Animals in quarantine in New Zealand." These requirements would have the practical effect of prohibiting the importation of live animals born in the same flock during the same lambing or kidding season as progeny of scrapie-positive dams.

We have carefully considered the comment that we should require sheep and goats to participate in a scrapie

control program for a minimum of 5 years. We have determined that no changes are necessary in response to this comment. Except for limited exemptions discussed elsewhere in this document, our requirements will allow the unrestricted importation of sheep and goats and sheep germ plasm only from countries which are free of scrapie or, in the case of Canada, which employ reporting and surveillance requirements equivalent to the United States and have regulations distinctly designed to control the spread of scrapie within the country. All imported sheep and goats and germ plasm of sheep and goats must be accompanied by a certificate. With the exception of sheep and goats from Australia, Canada, and New Zealand, the certificate accompanying animals must specifically state that the sheep and goats have not been in contact with other sheep and goats, during the 5 years previous to importation, such that they could have been exposed to scrapie (see § 92.405). The certificate accompanying germ plasm must specifically state that, in the case of embryos, the donor animals, and in the case of semen, the donor sire, have not been in contact with other sheep and goats, during the 5 years previous to collection of the germ plasm, such that they could have been exposed to scrapie (see §§ 98.5(b)(1) and 98.35(e)(1)). Except as explained later in this document (see the discussion below headed "Goats"), sheep, goats, and sheep germ plasm from countries other than Canada, Australia, and New Zealand may enter the United States only into a flock or herd participating in the VSFCP (see §§ 92.435, 98.10a and 98.37).¹ These imported animals and all first generation progeny resulting from the imported germ plasm must remain in a participating flock or herd until the flock or herd qualifies as "Certified." If the flock or herd is a level "C" flock or herd when the animals or germ plasm enter it, the process of attaining "Certified" status takes a minimum of 5 years. Animals and germ plasm may qualify to enter a flock or herd of higher status if they have been imported from a source flock or herd participating in a program which the Administrator has determined is equivalent to the APHIS VSFCP. In that situation, the animals

and any first generation progeny resulting from the imported germ plasm may have to remain in a participating flock or herd for fewer than 5 years. However, the animals (or donor animals, in the case of imported germ plasm) would have been in a participating flock or herd, or in an equivalent flock or herd in the country of origin, for at least 5 years.

We are also not making any changes in response to the comment that we place additional restrictions on the movement of animals from zoos in the United States. Very few animals are imported to zoos, and those which are imported are mainly from other zoos. Most zoo animals are captive-bred and rarely moved from their home zoo. Under these circumstances, we believe the disease risk presented by zoo animals to be very slight. Under our current regulations, animals moving from a zoo in the United States must be accompanied by a permit. The information provided as part of the permit process—when and where and under what conditions the animal is being moved—is sufficient to allow us to trace the animal and ensure that it does not come into contact with livestock under circumstances where it could transmit scrapie. We believe these requirements are adequate to prevent the spread of scrapie.

We have carefully considered the comment that we require progeny of imported sheep and goats to be permanently identified, and that we require a necropsy on animals which die less than 5 years after importation. The "Uniform Methods and Rules—Voluntary Scrapie Flock Certification" (UM&R), governs the VSFCP. The UM&R requires all animals in the flock or herd, including animals born into the flock or herd, to be permanently identified. The UM&R also requires that a necropsy be performed on any animals that die under suspicious circumstances. Sheep and goats imported into the United States under this final rule, with certain exceptions, will be required to enter a participating flock or herd. They would therefore be required to be permanently identified. They would also have to be necropsied should they die under suspicious circumstances. We believe these requirements are adequate to prevent the spread of disease, should it occur. The only sheep and goats imported into the United States not subject to these requirements would be animals which are exempt from entering a participating herd because they present no risk of disease. Each category of exempt animals is explained elsewhere in this document, or in the proposed rule.

Goats

Several commenters suggested that sheep and goats should be treated differently under the regulations, as scrapie rarely occurs in goats.

We have carefully reviewed these comments and have determined that some changes in the regulations with regard to goats are warranted. It is true that goats are susceptible to scrapie. However, since 1947 in the United States there have been only 5 reported cases of scrapie in goats. All occurred in goats which had been in contact with scrapie-infected sheep. As goats are not normally kept in contact with sheep, and as the incubation period for scrapie can last up to 5 years, we believe goats that have had no contact with sheep for a period of at least 5 years would pose an insignificant risk of scrapie. Therefore, under this final rule, goats will not be subject to § 92.435 if they are certified as having had no contact with sheep for at least the previous 5 years. Further, goats from Australia, Canada, and New Zealand would not be subject to § 92.435 even if they have had contact with sheep. Australia and New Zealand are free of scrapie. Contact with sheep in New Zealand and Australia would therefore not result in potential exposure to scrapie. Canada employs reporting and surveillance requirements equivalent to those of the United States and has regulations distinctly designed to control the spread of scrapie within the country. Therefore, under the conditions set forth in this final rule, we consider the risk of scrapie from goats in Canada to be negligible.

Under this final rule, goats, regardless of the country of origin, will not need to be certified as coming from a herd in which none of the female goats has been impregnated, during the 5 years immediately preceding shipment of the goats to the United States, with germ plasm from a country other than Australia, Canada, New Zealand, or the United States, or with germ plasm from a herd of unknown scrapie status. In addition, goat germ plasm, regardless of the country of origin, will be required to meet certification requirements, but will not be required to be placed in a herd that participates in the VSFCP. We believe these changes are warranted due to the low risk of transmitting scrapie posed by goats.

Enforcing the Regulations

Several commenters expressed concern about enforcement of our regulations. We are not making any changes based on these comments. We believe these regulations are enforceable

¹ Note: Under this final rule, although it is not required (except in one instance), sheep and goats and sheep germ plasm from Australia, Canada, and New Zealand may be imported into the United States into flocks and herds participating in the VSFCP. Likewise, goat germ plasm, regardless of the country of origin, may be imported into the United States into herds participating in the VSFCP. These importations must, of course, meet the necessary certification, permit, and quarantine requirements.

and that we have adequate manpower to enforce them.

Animals in Quarantine in New Zealand

As pointed out by one commenter, there are sheep currently in quarantine in New Zealand in a Scrapie Free Accreditation Program. These sheep were imported into a New Zealand quarantine facility from a country which the United States does not consider scrapie free. The commenter asks what the "status" of these animals is under our proposed rule.

Under this final rule, imported sheep must be accompanied by a certificate issued under § 92.405. Among other things, § 92.405 requires the certificate to contain a statement that the sheep are not in quarantine in the country of origin. Therefore, as long as the sheep are in quarantine in New Zealand, they cannot be imported into the United States.

As a matter of policy, we do not accept any ruminants from any country which are in quarantine in the source country. To clarify that this requirement applies to all ruminants from all countries, we are amending § 92.405 to include this requirement.

Clarify Regulations

Several commenters asked that different provisions of the proposed regulations be clarified.

The first commenter of this group asked that we clarify whether we are proposing to remove all import requirements for sheep from New Zealand, or whether only some health certificate requirements would be removed. As explained elsewhere in this document, we are removing certain health certificate requirements that apply specifically to sheep imported from New Zealand. In addition, depending upon the circumstances of each individual animal, sheep from New Zealand would not be required to enter a flock participating in the VSFCP. Import permits would still need to be obtained for sheep from New Zealand, and sheep from New Zealand would still need to be accompanied by a certificate, and be quarantined upon arrival in the United States.

The second commenter asked us to clarify the meaning of "suspect." By "suspect," we mean any animal which displays signs that could indicate it is infected with scrapie. There is no live animal test for scrapie, and a positive diagnosis can be made only after the animal dies.

Several commenters asked for clarification of "progeny" when the term is used to refer to animals required to remain in a herd or flock in the

VSFCP. In this connection, we intended the term "progeny" to mean only the first generation of animals resulting from natural breeding, artificial insemination, or embryo transfer. To eliminate any confusion as to the meaning of "progeny," we are amending the proposed regulations to read "first generation progeny" where appropriate. It would be impractical to require progeny beyond the first generation of animals to remain in a VSFCP herd or flock. All VSFCP herds and flocks are maintained under surveillance. In addition, except for animals moving to slaughter, all sheep and goats in participating herds or flocks must be permanently identified, and herd and flock owners must maintain certain records for a minimum of 5 years after an animal dies or has otherwise been removed from the herd or flock. These records, along with the individual animal identification, allows us to trace animals which leave the herd or flock.

One commenter approved of the proposed requirement that progeny resulting from germ plasm imported under the regulations remain in a flock or herd participating in the VSFCP until that flock or herd qualifies as "Certified." The commenter asked if the proposed requirement would apply to each importation of germ plasm. Our response is yes, each importation of germ plasm would be subject to this requirement.

Regulatory Flexibility Act Analysis

One commenter stated that the Regulatory Flexibility Act analysis needed to clarify that it costs "something" to participate in the VSFCP. Flock and herd owners who elect to participate in the VSFCP do incur the costs of making and maintaining records on the animals in their flock or herd. However, the program is completely voluntary, and in most cases any recordkeeping costs would be inconsequential. In addition, the increased value of animals in VSFCP herds and flocks would offset any recordkeeping cost.

Questions

One commenter asked if Boer goats were bred especially to sell in the United States. The term "Boer goat" was used in the 19th century in South Africa to mean farm goat. The term was apparently used to distinguish indigenous goats from imported Angora goats. The present-day Boer goat, bred from native stock, was developed in the early 20th century for meat production.

A couple of other commenters asked for clarification of the length of time under our proposed rule that various

animals would have to remain in a flock or herd that is participating in the VSFCP. All animals must remain in a flock or herd participating in the Program until the flock or herd reaches "Certified" status. This usually takes a minimum of 5 years. If a live animal is imported into the United States, APHIS may give "credit" for years the animal's flock or herd of origin participated in a program which the Administrator of APHIS determines is equivalent to the VSFCP. If germ plasm is imported, the first generation of animals resulting from that germ plasm must remain in a participating flock in the United States until the flock reaches "Certified" status.

Miscellaneous Comments

One commenter suggested that APHIS should certify animals for importation only if they come from a country where scrapie exists. According to the comment, animals from such countries would have some immunity to the disease. Unfortunately, we are not aware of any evidence demonstrating that animals can develop immunity to scrapie. For this reason we are not making any changes based on this comment.

Miscellaneous

Since we published the proposed rule, the regulations in part 98, subpart B, which concern embryos from countries where rinderpest or foot-and-mouth disease (FMD) exists, have been amended (see 61 FR 15180 *et seq.*, Docket No. 94-006-2). Among other things, the regulations were amended so they apply not only to certain cattle embryos, but to all ruminant embryos, including sheep and goat embryos. Therefore, we are amending part 98, subpart B, at this time to add the same health certificate requirements concerning scrapie as are included in this final rule for sheep and goat embryos from countries free of rinderpest and FMD. This amendment will make the requirements consistent in subparts A and B of part 98. We are also amending the language in § 98.14(a), stating who may issue health certificates, to make it consistent with similar language in §§ 92.405, 98.5, and 98.35, as we proposed.

We have also made minor, nonsubstantive changes to correct punctuation and to maintain consistent wording. In addition, in some parts of this final rule, we have set out current regulatory text that did not appear in the proposed rule. This has been done in places where less than an entire sentence appeared in the proposed rule

so that readers will have an easier time understanding the text.

We have also updated our Regulatory Flexibility Act analysis to include the latest available data.

Therefore, based on the rationale set forth in the interim rule of March 11, 1995, and in this document, we are affirming the provisions of the interim rule without change. In addition, based on the rationale set forth in the proposed rule of May 11, 1995, and in this document, we are adopting the provisions of the proposed rule, with the changes discussed in this document.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for purposes of Executive Order 12866, and, therefore, has not been reviewed by the Office of Management and Budget.

This rule requires an import permit for certain sheep and goats imported into the United States from Canada and Mexico through a land border port. In 1994, 28,357 sheep and 527 goats were imported from Canada through a land border port; none were imported from Mexico through a land border port. Over 97 percent of these sheep and goats were wethers or were imported for immediate slaughter. Wethers and sheep and goats imported through land border ports for immediate slaughter continue to be exempt from the requirement for an import permit. Based on these numbers, we expect that only 3 percent of sheep and goats imported from Canada or Mexico through land border ports will be required to be accompanied by an import permit under this rule. APHIS does not charge a user fee specifically for the import permit. However, APHIS does charge a user fee for import or entry services provided at all ports of entry, including land border ports along the United States-Mexico border. These user fees may need to be adjusted to account for the cost of issuing import permits required under this final rule. If this is necessary, a proposed rule will be published for public comment in the Federal Register.

This rule also requires additional certification information for sheep, goats, and germ plasm. However, no direct charges or user fees will be assessed by APHIS as these certificates are issued in foreign countries. The cost impact will be minimal.

In addition, under this rule: (1) Sheep and goat imports from New Zealand will no longer be required to meet special health certification requirements, and (2) regulations governing privately operated quarantine facilities for

imported sheep will apply to privately operated quarantine facilities for imported goats as well. These changes will not have a significant impact on importers or producers. We believe any impact will be positive, in that the changes will facilitate importation of sheep and goats.

Our economic analysis indicates that these amendments will have a positive economic impact on U.S. importers of sheep, goats, and their germ plasm, since importation into the United States will be easier. The current requirements surrounding the importation of sheep, goats, and their germ plasm are confusing and considered by many interested parties to be too restrictive.

In 1995, there were 82,120 agricultural operations with sheep in the United States. Under Small Business Administration criteria, 99 percent of them are believed to be small entities (having less than \$0.5 million in gross annual receipts for domestic producers and fewer than 100 employees for importers). No information is available on the number or U.S. agricultural operations with goats.

We anticipate that participation in the VSFCP will increase, as sheep germ plasm and breeding stock from countries other than Australia, Canada, and New Zealand, will be allowed to be introduced only into VSFCP flocks and herds. Because of the termination by the U.S. government of the subsidy to wool and mohair growers, the expected shift from wool and mohair production to meat production in sheep and goats should create additional demand for breeding stock and germ plasm imports. Wider participation in the Program will better safeguard the U.S. sheep and goat industry against a scrapie outbreak. Participation requires operations to maintain records on their animals, although it is likely that potential importers of breeding animals or germ plasm are already keeping such records. There will be no increase in costs for sheep and goat operations if they participate in the VSFCP.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12778

This rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings

before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB) under OMB control numbers 0579-0040 and 0579-0101.

List of Subjects

9 CFR Part 92

Animal diseases, Imports, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements.

9 CFR Part 98

Animal diseases, Imports.

Accordingly, we are adopting as a final rule, without change, the interim rule that amended 9 CFR 92.400, 92.417, and 92.424, and that was published at 60 FR 13898-13900 on March 15, 1995.

Accordingly, 9 CFR parts 92 and 98 are amended as follows:

PART 92—IMPORTATION OF CERTAIN ANIMALS AND POULTRY AND CERTAIN ANIMAL AND POULTRY PRODUCTS; INSPECTION AND OTHER REQUIREMENTS FOR CERTAIN MEANS OF CONVEYANCE AND SHIPPING CONTAINERS THEREON

1. The authority citation for part 92 continues to read as follows:

Authority: 7 U.S.C. 1622; 19 U.S.C. 1306; 21 U.S.C. 102-105, 111, 114a, 134a, 134b, 134c, 134d, 134f, 135, 136, and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.2(d).

2. Section 92.400 is amended by revising the definition of *Herd* and by adding a definition for *Flock*, in alphabetical order, to read as follows:

§ 92.400 Definitions.

* * * * *

Flock. A herd.

Herd. All animals maintained on any single premises; and all animals under common ownership or supervision on two or more premises which are geographically separated, but among which there is an interchange or movement of animals.

* * * * *

3. Section 92.405 is amended as follows:

a. By revising paragraphs (a) and (b) to read as set forth below.

b. By redesignating paragraph (c) as paragraph (d), and by adding a new paragraph (c) to read as set forth below.

c. In newly designated paragraph (d), by removing the words "paragraphs (a)

and (b)'' and adding in their place the words ''paragraphs (a), (b), and (c)''.

d. By adding a parenthetical at the end of the section to read as set forth below.

§ 92.405 Certificate for ruminants.

(a) All ruminants intended for importation from any part of the world, except as provided in §§ 92.418(a), 92.419(a), 92.423(c), and 92.428(d), shall be accompanied by a certificate issued by a full-time salaried veterinary officer of the national government of the country of origin, or issued by a veterinarian designated or accredited by the national government of the country of origin and endorsed by a full-time salaried veterinary officer of the national government of the country of origin, representing that the veterinarian issuing the certificate was authorized to do so. The certificate shall state:

(1) That the ruminants have been kept in that country during the last 60 days immediately preceding the date of shipment to the United States, and that during this time the country has been entirely free from foot-and-mouth disease, rinderpest, contagious pleuropneumonia, and surra; *provided, however*, that for wild ruminants for exhibition purposes, the certificate need specify only that the district of origin has been free from the listed diseases; *and provided further*, that for sheep and goats, with respect to contagious pleuropneumonia, the certificate may specify only that the district of origin has been free from this disease; and

(2) That the ruminants are not in quarantine in the country of origin.

(b) *Goats.* (1) In addition to the statements required by paragraph (a) of this section, the certificate accompanying goats intended for importation from any part of the world must state:

(i) That none of the goats in the herd from which the goats will be imported is the progeny of a sire or dam that has been affected with scrapie or that has produced offspring that have been affected with scrapie;

(ii) That none of the female goats in the herd from which the goats will be imported has been impregnated, during the 5 years immediately preceding shipment of the goats to the United States, with germ plasm from a herd known to be infected with scrapie;

(iii) That the veterinarian issuing the certificate has inspected the goats in the herd from which the animals will be imported and found the herd to be free of any evidence of infectious or contagious disease; and

(iv) That as far as it is possible for the veterinarian who inspects the animals to

determine, none of the goats in the herd from which the animals will be imported has been exposed to any infectious or contagious disease during the 60 days immediately preceding shipment to the United States.

(2) In addition, the certificate accompanying goats intended for importation from any part of the world except Australia, Canada, and New Zealand must state:

(i) That the goats have not been in any herd nor had contact with sheep or goats that have been in any flock or herd where scrapie has been diagnosed or suspected during the 5 years immediately prior to shipment; and

(ii) That the goats have not had any contact with sheep during the 5 years immediately prior to shipment; *provided that*, this statement is not required if the goats are imported in accordance with § 92.435(a) into a herd in the United States that participates in the Voluntary Scrapie Flock Certification Program.

(c) *Sheep.* (1) In addition to the statements required by paragraph (a) of this section, the certificate accompanying sheep intended for importation from any part of the world must state:

(i) That none of the sheep in the flock from which the sheep will be imported is the progeny of a sire or dam that has been affected with scrapie or that has produced offspring that have been affected with scrapie;

(ii) That none of the female sheep in the flock from which the sheep will be imported has been impregnated, during the 5 years immediately preceding shipment of the sheep to the United States, with germ plasm from a flock known to be infected with scrapie;

(iii) That the veterinarian issuing the certificate has inspected the sheep in the flock from which the animals will be imported and found the flock to be free of any evidence of infectious or contagious disease; and

(iv) That as far as it is possible for the veterinarian who inspects the animals to determine, none of the sheep in the flock from which the animals will be imported has been exposed to any infectious or contagious disease during the 60 days immediately preceding shipment to the United States.

(2) In addition, the certificate accompanying sheep intended for importation from any part of the world except Australia, Canada, and New Zealand must state that the sheep have not been in any flock nor had contact with sheep or goats that have been in any flock or herd where scrapie has been diagnosed or suspected during the 5 years immediately prior to shipment.

(3) In addition, the certificate accompanying sheep intended for importation from Australia, Canada, and New Zealand must state that none of the female sheep in the flock from which the sheep will be imported has been impregnated, during the 5 years immediately preceding shipment of the sheep to the United States, with germ plasm from a country other than Australia, Canada, New Zealand, or the United States, or from a flock of unknown scrapie status; *provided that*, this statement is not required if the sheep are imported in accordance with § 92.435(a) into a flock in the United States that participates in the Voluntary Scrapie Flock Certification Program.

* * * * *

(Approved by the Office of Management and Budget under control number 0579-0040)

4. Section 92.411 is revised to read as follows:

§ 92.411 Quarantine requirements.

(a) Except for cattle from Central America and the West Indies, and except for ruminants from Canada and Mexico, all ruminants imported into the United States shall be quarantined for not less than 30 days counting from the date of arrival at the port of entry.

(b) Wild ruminants shall be subject, during their quarantine, to such inspections, disinfection, blood tests, or other tests as may be required by the Administrator to determine their freedom from disease.

5. In § 92.418, paragraph (a) is revised to read as follows:

§ 92.418 Cattle from Canada.

(a) *Health certificates.* Except for cattle imported for immediate slaughter in accordance with § 92.420, cattle intended for importation from Canada shall be accompanied by a certificate issued in accordance with § 92.405(a). The certificate shall state that the cattle have been inspected and found to be free from any evidence of communicable disease and that, as far as can be determined, they have not been exposed to any such disease during the preceding 60 days. Cattle found unqualified upon inspection at the port of entry will be refused entry into the United States.

* * * * *

6. Section 92.419 is amended as follows:

a. By revising paragraph (a) to read as set forth below.

b. By adding a parenthetical at the end of the section to read as set forth below.

§ 92.419 Sheep and goats from Canada.

(a) Except for sheep and goats imported for immediate slaughter in accordance with § 92.420, sheep and goats intended for importation from Canada shall be accompanied by a certificate issued in accordance with § 92.405.

* * * * *

(Approved by the Office of Management and Budget under control number 0579-0040)

7. Section 92.423 is amended as follows:

a. In paragraph (a), by revising the first sentence to read as set forth below.

b. By revising paragraph (b) to read as set forth below.

c. By adding a parenthetical at the end of the section to read as set forth below.

§ 92.423 Ruminants from Central America and the West Indies.

(a) Ruminants intended for importation from Central America and the West Indies, except as provided in paragraph (c) of this section, must be accompanied by a certificate issued in accordance with § 92.405(a) stating that the animals have been in that country at least 60 days immediately preceding the date of shipment to the United States; that he or she has inspected the ruminants on the premises of origin and found them free from evidence of any communicable disease; and that, as far as it has been possible to determine, the ruminants have not been exposed to any communicable disease during the preceding 60 days. * * *

(b) The certificate accompanying sheep and goats intended for importation from Central America and the West Indies must, in addition to the statements required by paragraph (a) of this section, meet all of the requirements of § 92.405.

* * * * *

(Approved by the Office of Management and Budget under control number 0579-0040)

8. Section 92.427 is amended as follows:

a. In paragraph (b)(1), by revising the first sentence to read as set forth below.

b. By revising paragraphs (b)(2)(i) and (b)(2)(ii) to read as set forth below.

c. In paragraph (c)(1), by revising the last sentence to read as set forth below.

d. By revising paragraph (d)(1) introductory text, to read as set forth below.

§ 92.427 Cattle from Mexico.

* * * * *

(b) *Fever ticks.* (1) Except as provided in paragraph (b)(2) of this section, all cattle intended for importation from Mexico, for purposes other than immediate slaughter, shall be

accompanied by a certificate issued in accordance with § 92.405(a), and showing that the veterinarian issuing the certificate inspected the cattle at the time of movement to the port of entry and found them free from any evidence of communicable disease and that, as far as it has been possible to determine, they have not been exposed to any such disease, including splenetic, southern or tick fever, during the preceding 60 days and, if shipped by rail or truck, the certificate shall further specify that the cattle were loaded into clean and disinfected cars or trucks for transportation direct to the port of entry.

* * *

(2) * * *

(i) The cattle shall be accompanied by a certificate issued in accordance with § 92.405(a), and showing that the veterinarian issuing the certificate has inspected the cattle and found them free from fever ticks and any evidence of communicable disease, and that, as far as it has been possible to determine, they have not been exposed to any such disease, except splenetic, southern, or tick fever, during the 60 days immediately preceding their movement to the port of entry.

(ii) The cattle shall be shown by a certificate issued in accordance with § 92.405(a) to have been dipped in a tickicidal dip within 7 to 12 days before being offered for entry.

* * * * *

(c) * * *

(1) * * * However, cattle, including steers, that originated in herds declared to be tuberculosis-accredited by the Government of Mexico in accordance with that country's standards do not have to comply with the other provisions of this paragraph if they are moved directly to the U.S. port of entry from their herd of origin without having commingled with cattle from any herd not so accredited enroute to the port of entry, and they are accompanied by a health certificate, issued in accordance with § 92.405(a), stating that the cattle originated in such a tuberculosis-accredited herd and identifying the animals by official Mexican Ministry of Agriculture and Water Resources (SARH) blue eartag and tattoo numbers.

* * * * *

(d) * * *

(1) Are accompanied by a certificate issued in accordance with § 92.405(a) stating:

* * * * *

9. Section 92.428 is amended as follows:

a. By revising paragraph (a) to read as set forth below.

b. By adding a parenthetical at the end of the section to read as set forth below.

§ 92.428 Sheep and goats and wild ruminants from Mexico.

(a) Sheep and goats intended for importation from Mexico shall be accompanied by a certificate issued in accordance with § 92.405 and stating, if such sheep and goats are shipped by rail or truck, that such animals were loaded into cleaned and disinfected cars or trucks for transportation direct to the port of entry. Notwithstanding such certificate, such sheep and goats shall be detained as provided in § 92.427(a) and shall be dipped at least once in a permitted scabies dip under supervision of an inspector.

* * * * *

(Approved by the Office of Management and Budget under control number 0579-0040)

10. In § 92.429, the first sentence is revised to read as follows:

§ 92.429 Ruminants for immediate slaughter.

Ruminants, other than sheep and goats, may be imported from Mexico, subject to the applicable provisions of §§ 92.424, 92.425, 92.426, and 92.427(b)(2) for immediate slaughter if accompanied by a certificate issued in accordance with § 92.405(a) and stating that the veterinarian who issued the certificate has inspected the animals in the herd from which the ruminants will be imported and found them free of evidence of communicable disease, and that, so far as it has been possible to determine, they have not been exposed to any such disease common to animals of their kind during the preceding 60 days, and if the ruminants are shipped by rail or truck, the certificate shall further specify that the ruminants were loaded into cleaned and disinfected cars or trucks for transportation directly to the port of entry. * * *

§ 92.433 [Removed and Reserved]

11. Section 92.433, *Sheep from New Zealand*, is removed and reserved.

§ 92.434 [Amended]

12. Section 92.434 is amended as follows:

a. By revising the heading to read as follows:

§ 92.434 Standards for approval of privately operated quarantine facilities for sheep or goats, and handling procedures for the importation of sheep or goats.

* * * * *

b. In paragraph (b) introductory text, by redesignating footnote 19 and the reference to it as footnote 15.

c. In paragraph (d)(1), by redesignating footnote 20 and the reference to it as footnote 16.

d. By adding the words "or goats" after the word "sheep" in the following places:

- i. In paragraph (a).
- ii. In paragraph (b)(2)(i)(B).
- iii. In paragraph (b)(2)(ii)(A).
- iv. In paragraph (b)(2)(ii)(B).
- v. In paragraph (b)(2)(ii)(D) each time it appears.
- vi. In paragraph (b)(2)(ii)(E).
- vii. In paragraph (b)(2)(ii)(F) each time it appears.
- viii. In paragraph (b)(2)(iii)(G), after only the third time "sheep" appears.
- ix. In paragraph (b)(2)(iii)(K).
- x. In paragraph (b)(2)(iii)(L).
- xi. In paragraph (b)(3)(i)(A)(5).
- xii. In paragraph (b)(3)(ii).
- xiii. In paragraph (b)(3)(iv), in the heading and text.
- xiv. In paragraph (b)(3)(iv)(A), in the first sentence.
- xv. In paragraph (b)(3)(iv)(B).
- xvi. In paragraph (b)(3)(v) each time it appears.
- xvii. In paragraph (b)(5) each time it appears.
- xviii. In paragraph (c).
- xix. In paragraph (d)(2) introductory text.
- xx. In paragraph (d)(2)(iv).
- xxi. In paragraph (d)(4).

e. by adding the words "or goat" after the word "sheep" in the following places:

- i. In paragraph (b)(2)(iii)(G), after the first and second time "sheep" appears.
- ii. In paragraph (b)(3)(iv)(A), in the second sentence.
- f. By removing the word "sheep-holding" and adding the words "sheep-or goat-holding" in the following places:
 - i. In paragraph (b)(2)(ii)(K).
 - ii. In paragraph (b)(2)(iii)(J).
 - iii. In paragraph (b)(3)(i)(A) introductory text.
 - iv. In paragraph (b)(3)(i)(A)(1).
 - v. In paragraph (b)(3)(i)(A)(3).
 - vi. In paragraph (b)(3)(ii).

13. A new § 92.435 is added to read as follows:

§ 92.435 Sheep and goats.

(a) Except as provided in paragraph (b) of this section, all sheep and goats imported into the United States must be placed in a flock or herd in the United States that participates in the Voluntary Scrapie Flock Certification Program (see 9 CFR part 54, subpart B) and:

- (1) The flock or herd qualifies as a "Certified" flock or herd; or
- (2) The flock or herd owner has agreed, in writing, to maintain the flock or herd in compliance with all requirements of the Voluntary Scrapie

Flock Certification Program until the flock or herd qualifies as a "Certified" flock or herd.

(b) The following sheep and goats are not subject to paragraph (a) of this section:

- (1) Goats intended for importation from Australia, Canada, or New Zealand;
- (2) Goats intended for importation from any country other than Australia, Canada, or New Zealand, provided that such goats have not had any contact with sheep during the 5 years immediately prior to shipment, in accordance with § 92.405(b)(2)(ii);
- (3) Sheep intended for importation from Australia, Canada, or New Zealand, provided that none of the female sheep in the flock from which the sheep will be imported has been impregnated, during the 5 years immediately preceding shipment of the sheep to the United States, with germ plasm from a country other than Australia, Canada, New Zealand, or the United States, in accordance with § 92.405(c)(3);
- (4) Wethers;
- (5) Sheep or goats imported for immediate slaughter; and
- (6) Wild sheep or goats imported for exhibition purposes to an approved zoological park in accordance with § 92.404(c).

(c) Sheep or goats may be imported under paragraph (a) of this section only if the importer provides the Voluntary Scrapie Flock Certification Program identification number of the receiving flock or herd as part of the application for an import permit.

(d) Sheep and goats may be imported under paragraph (a)(1) of this section only if they come from a flock or herd in the country of origin that participates in a program determined by the Administrator to be equivalent to the Voluntary Scrapie Flock Certification Program, and the flock or herd has been determined by the Administrator to be at a level equivalent to "Certified" in the Voluntary Scrapie Flock Certification Program.

(e) Sheep and goats may be imported under paragraph (a)(2) of this section only if they are placed in a Certifiable Class C flock or herd participating in the Voluntary Scrapie Flock Certification Program; *except*, that if the sheep and goats come from a flock or herd in the country of origin that participates in a program determined by the Administrator to be equivalent to the Voluntary Scrapie Flock Certification Program, then the sheep and goats may be placed in a herd or flock in the United States which would be classified at a level equivalent to or lower (i.e., at

a greater risk) than the certification level, as determined by the Administrator, of the flock or herd from which the sheep or goats are to be imported.

(f) Sheep and goats imported under paragraph (a)(2) of this section must be monitored for scrapie disease until the flock or herd qualifies as a "Certified" flock or herd.

(g) Except for imported sheep and goats placed in Certifiable Class C flocks or herds, the certificate accompanying sheep or goats imported under paragraph (a) of this section must contain the following statement: "The animals identified on this certificate have been monitored by a salaried veterinary officer of [*name of country of origin*], for [*number of months*], in the same source flock or herd which had been determined by the Administrator, APHIS, prior to the exportation of these animals to the United States, to be equivalent to [*certification level*] of the Voluntary Scrapie Flock Certification Program authorized under 9 CFR part 54, subpart B."

(1) The Administrator will determine, based upon information supplied by the importer, whether the flock or herd from which the animals are to be imported participates in a program in the country of origin that is equivalent to the Voluntary Scrapie Flock Certification Program, and if so, at what level the source flock or herd should be classified.

(2) In order for the Administrator to make a determination, the importer must supply the following information with the application for an import permit no less than 1 month prior to the anticipated date of importation:

(i) The name, title, and address of a knowledgeable official in the veterinary services of the country of origin;

(ii) The details of scrapie control programs in the country of origin, including information on disease surveillance and border control activities and the length of time such activities have been in effect;

(iii) Any available information concerning additions, within the 5 years immediately preceding shipment to the United States, to the flock or herd from which the sheep and goats will be imported;

(iv) Any available data concerning disease incidence, within the 5 years immediately preceding shipment to the United States, in the flock or herd from which the sheep or goats are to be imported, including, but not limited to, the results of diagnostic tests, especially histopathology tests, conducted on any animals in the flock or herd;

(v) Information concerning the health, within the 5 years immediately preceding shipment to the United States, of other ruminants, flocks, and herds with which the imported sheep and goats, and with which animals in the sheep or goats' flock or herd might have had physical contact, and a description of the type and frequency of such physical contact; and

(vi) Any other information requested by the Administrator in specific cases as needed to make a determination.

(Approved by the Office of Management and Budget under control numbers 0579-0040 and 0579-0101)

PART 98—IMPORTATION OF CERTAIN ANIMAL EMBRYOS AND ANIMAL SEMEN

14. The authority citation for part 98 continues to read as follows:

Authority: 7 U.S.C. 1622; 19 U.S.C. 1306; 21 U.S.C. 103-105, 111, 134a, 134b, 134c, 134d, 134f, 136, and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.2(d).

15. Section 98.2 is amended by adding definitions for *flock* and *herd*, in alphabetical order, to read as follows:

§ 98.2 Definitions.

* * * * *

Flock. A herd.

Herd. All animals maintained on any single premises; and all animals under common ownership or supervision on two or more premises which are geographically separated, but among which there is an interchange or movement of animals.

* * * * *

16. Section 98.5 is amended as follows:

a. By redesignating the introductory text of the section and paragraphs (a), (b), (c), (d), and (e) as paragraph (a) introductory text and paragraphs (a)(1), (a)(2), (a)(3), (a)(4), and (a)(5), respectively.

b. By revising newly designated paragraph (a) introductory text to read as set forth below.

c. By adding a new paragraph (b) to read as set forth below.

§ 98.5 Health certificate.

(a) Except as provided in subpart B of this part, an animal embryo shall not be imported into the United States unless it is accompanied by a certificate issued by a full-time salaried veterinary officer of the national government of the country of origin, or issued by a veterinarian designated or accredited by the national government of the country of origin and endorsed by a full-time salaried veterinary officer of the national government of the country of

origin, representing that the veterinarian issuing the certificate was authorized to do so. The certificate shall state:

* * * * *

(b) The certificate accompanying sheep or goat embryos intended for importation from any part of the world shall, in addition to the statements required by paragraph (a) of this section, state that:

(1) The embryos' sire and dam have not been in any flock or herd nor had contact with sheep or goats which have been in any flock or herd where scrapie has been diagnosed or suspected during the 5 years prior to the date of collection of the embryos;

(2) The embryos' sire and dam showed no evidence of scrapie at the time the embryos were collected;

(3) Scrapie has not been suspected nor confirmed in any progeny of the embryos' donor dam; and

(4) The parents of the embryos' sire and dam are not, nor were not, affected with scrapie.

17. In part 98, subpart A, a new § 98.10a is added to read as follows:

§ 98.10a Embryos from sheep in countries other than Australia, Canada, and New Zealand.

(a) Except for embryos from sheep in Australia, Canada, or New Zealand, embryos from sheep may only be imported into the United States if they comply with all applicable provisions of this subpart and one of the following conditions:

(1) The embryos are transferred to females in a flock in the United States that participates in the Voluntary Scrapie Flock Certification Program (see 9 CFR part 54, subpart B) and qualifies as a "Certified" flock; or

(2) The embryos are transferred to females in a flock in the United States that participates in the Voluntary Scrapie Flock Certification Program (see 9 CFR part 54, subpart B) and the flock owner has agreed, in writing, to maintain the flock, and all first generation progeny resulting from embryos imported in accordance with this section, in compliance with all requirements of the Voluntary Scrapie Flock Certification Program until the flock, including all first generation progeny resulting from embryos imported in accordance with this section, qualifies as a "Certified" flock.

(b) Sheep embryos may be imported under paragraph (a) of this section only if the importer provides the Voluntary Scrapie Flock Certification Program identification number of the receiving flock as part of the application for an import permit.

(c) Sheep embryos may be imported under paragraph (a)(1) of this section only if they are the progeny of a dam and sire that are part of flocks in the country of origin that participate in a program determined by the Administrator to be equivalent to the Voluntary Scrapie Flock Certification Program, and the flocks have been determined by the Administrator to be at a level equivalent to "Certified" in the Voluntary Scrapie Flock Certification Program.

(d) Sheep embryos may be imported under paragraph (a)(2) of this section only if they are transferred to animals in a Certifiable Class C flock participating in the Voluntary Scrapie Flock Certification Program; *except*, that if the embryos are the progeny of a dam and sire whose flock in the country of origin participates in a program determined by the Administrator to be equivalent to the Voluntary Scrapie Flock Certification Program, then the embryos may be placed in a flock in the United States which would be classified at a level equivalent to or lower (i.e., at a greater risk) than the certification level, as determined by the Administrator, of either the flock of the dam or the flock of the sire, whichever one presents the greater risk.

(e) The flock to which the sheep embryos are transferred pursuant to paragraph (a)(2) of this section must be monitored for scrapie disease until the flock, and all first generation progeny resulting from the embryos imported in accordance with this section, qualifies as a "Certified" flock.

(f) Except for sheep embryos being placed in Certifiable Class C flocks, the certificate accompanying sheep embryos imported under paragraph (a) of this section must contain the following statement: "The embryos identified on this certificate are the progeny of a dam and sire that have been monitored by a salaried veterinary officer of [name of country of origin], for [number of months], in the same source flock which had been determined by the Administrator, APHIS, prior to the exportation of these embryos to the United States, to be equivalent to [certification level (of dam or sire) presenting greater risk] of the Voluntary Scrapie Flock Certification Program authorized under 9 CFR part 54, subpart B."

(1) The Administrator will determine, based upon information supplied by the importer, whether the flock of the embryos' dam and sire participates in a program in the country of origin that is equivalent to the Voluntary Scrapie Flock Certification Program, and if so, at

what level the source flock would be classified.

(2) In order for the Administrator to make a determination, the importer must supply the following information with the application for an import permit, no less than 1 month prior to the anticipated date of importation:

(i) The name, title, and address of a knowledgeable official in the veterinary services of the country of origin;

(ii) The details of scrapie control programs in the country of origin, including information on disease surveillance and border control activities and the length of time such activities have been in effect;

(iii) Any available information concerning additions, within the 5 years immediately preceding collection of the embryos, to the flock of the embryos' sire and dam;

(iv) Any available data concerning disease incidence, within the 5 years immediately preceding collection of the embryos, in the flock of the embryos' sire and dam, including, but not limited to, the results of diagnostic tests, especially histopathology tests, conducted on any animals in the flock;

(v) Information concerning the health, within the 5 years immediately preceding collection of the embryos, of other ruminants, flocks, and herds with which the embryos' sire and dam and the flock of the embryos' sire and dam might have had physical contact, and a description of the type and frequency of the physical contact; and

(vi) Any other information requested by the Administrator in specific cases as needed to make a determination.

(g) All first generation progeny resulting from embryos imported under this section are subject to the requirements of 9 CFR part 54 and all other applicable regulations.

(Approved by the Office of Management and Budget under control numbers 0579-00040 and 0579-0101)

18. In part 98, subpart B, § 98.14 is amended as follows:

a. By revising paragraph (a) to read as set forth below.

b. By redesignating paragraph (d) as paragraph (e).

c. By adding a new paragraph (d) to read as set forth below.

§ 98.14 Health certificate.

(a) Ruminant and swine embryos shall not be imported into the United States unless they are accompanied by a certificate issued by a full-time salaried veterinary officer of the national government of the country of origin, or issued by a veterinarian designated or accredited by the national government

of the country of origin and endorsed by a full-time salaried veterinary officer of the national government of the country of origin, representing that the veterinarian issuing the certificate was authorized to do so.

* * * * *

(d) The health certificate accompanying sheep or goat embryos intended for importation from any part of the world shall, in addition to the statements required by paragraph (b) of this section, state that:

(1) The embryos' sire and dam have not been in any flock or herd nor had contact with sheep or goats which have been in any flock or herd where scrapie has been diagnosed or suspected during the 5 years prior to the date of collection of the embryos;

(2) The embryos' sire and dam showed no evidence of scrapie at the time the embryos were collected;

(3) Scrapie has not been suspected nor confirmed in any progeny of the embryos' donor dam; and

(4) The parents of the embryos' sire and dam are not, nor were not, affected with scrapie.

* * * * *

19. In part 98, subpart B, a new § 98.21 is added to read as follows:

§ 98.21 Embryos from sheep in countries other than Australia, Canada, and New Zealand.

Except for embryos from sheep in Australia, Canada, or New Zealand, embryos from sheep may only be imported into the United States if they comply with all applicable provisions of this subpart and with § 98.10a.

(Approved by the Office of Management and Budget under control numbers 0579-0040 and 0579-0101)

20. In part 98, subpart C, § 98.30 is amended by adding definitions for flock and herd, in alphabetical order, to read as follows:

§ 98.30 Definitions.

* * * * *

Flock. A herd.

Herd. All animals maintained on any single premises; and all animals under common ownership or supervision on two or more premises which are geographically separated, but among which there is an interchange or movement of animals.

* * * * *

21. Section § 98.35 is amended as follows:

a. By revising paragraph (c) to read as set forth below.

b. By adding a new paragraph (e) to read as set forth below.

c. By adding a parenthetical at the end of the section to read as set forth below.

§ 98.35 Declaration, health certificate, and other documents for animal semen.

* * * * *

(c) All animal semen intended for importation into the United States shall be accompanied by a health certificate issued by a full-time salaried veterinary officer of the national government of the country of origin, or issued by a veterinarian designated or accredited by the national government of the country of origin and endorsed by a full-time salaried veterinary officer of the national government of the country of origin, representing that the veterinarian issuing the certificate was authorized to do so.

* * * * *

(e) The certificate accompanying sheep or goat semen intended for importation from any part of the world shall, in addition to the statements required by paragraph (d) of this section, state that:

(1) The semen donor has not been in any flock or herd nor had contact with sheep or goats which have been in any flock or herd where scrapie has been diagnosed or suspected during the 5 years prior to the date of collection of the semen;

(2) The semen donor showed no evidence of scrapie at the time the semen was collected; and

(3) The parents of the semen donor are not, nor were not, affected with scrapie.

(Approved by the Office of Management and Budget under control number 0579-0040)

§ 98.36 [Amended]

22. In § 98.36, paragraph (a), introductory text is amended by adding the words "is not a sheep or goat and" immediately before the colon.

23. A new § 98.37 is added to read as follows:

§ 98.37 Semen from sheep in countries other than Australia, Canada, and New Zealand.

(a) Except for semen from sheep in Australia, Canada, or New Zealand, semen from sheep may only be imported into the United States if it complies with all applicable provisions of this subpart and one of the following conditions:

(1) The semen is transferred to females in a flock in the United States that participates in the Voluntary Scrapie Flock Certification Program (see 9 CFR part 54, subpart B) and qualifies as a "Certified" flock; or

(2) The semen is transferred to females in a flock in the United States that participates in the Voluntary Scrapie Flock Certification Program (see 9 CFR part 54, subpart B), and the flock

owner has agreed, in writing, to maintain the flock, and all first generation progeny resulting from semen imported in accordance with this section, in compliance with all requirements of the Voluntary Scrapie Flock Certification Program until the flock, including all first generation progeny resulting from semen imported in accordance with this section, qualifies as a "Certified" flock.

(b) Sheep semen may be imported under paragraph (a) of this section only if the importer provides the Voluntary Scrapie Flock Certification Program identification number of the receiving flock as part of the application for an import permit.

(c) Sheep semen may be imported under paragraph (a)(1) of this section only if it comes from a donor animal in a flock in the country of origin that participates in a program determined by the Administrator to be equivalent to the Voluntary Scrapie Flock Certification Program, and the flock has been determined by the Administrator to be at a level equivalent to "Certified" in the Voluntary Scrapie Flock Certification Program.

(d) Sheep semen may be imported under paragraph (a)(2) of this section only if it is transferred to animals in a Certifiable Class C flock participating in the Voluntary Scrapie Flock Certification Program; except, that if the semen comes from a donor animal whose flock in the country of origin participates in a program determined by the Administrator to be equivalent to the Voluntary Scrapie Flock Certification Program, then the semen may be used in a flock in the United States which would be classified at a level equivalent to or lower (i.e., at greater risk) than the certification level, as determined by the Administrator, of the flock of the donor animal.

(e) The flock to which the sheep semen is transferred pursuant to paragraph (a)(2) of this section must be monitored for scrapie disease until the flock, and all first generation progeny resulting from the semen imported in accordance with this section, qualifies as a "Certified" flock.

(f) Except for sheep semen being placed in Certifiable Class C flocks, the certificate accompanying the sheep semen imported under paragraph (a) of this section must contain the following statement: "The semen identified on this certificate has been collected from a sire that has been monitored by a salaried veterinary officer of [name of country of origin], for [number of months], in the same source flock which had been determined by the Administrator, APHIS, prior to the

exportation of the semen to the United States, to be equivalent to [certification level] of the Voluntary Scrapie Flock Certification Program authorized under 9 CFR part 54, subpart B."

(1) The Administrator will determine, based upon information supplied by the importer, whether the donor animal's flock participates in a program in the country of origin that is equivalent to the Voluntary Scrapie Flock Certification Program, and if so, at what level the source flock would be classified.

(2) In order for the Administrator to make a determination, the importer must supply the following information with the application for an import permit, no less than 1 month prior to the anticipated date of importation:

(i) The name, title, and address of a knowledgeable official in the veterinary services of the country of origin;

(ii) The details of scrapie control programs in the country of origin, including information on disease surveillance and border control activities and the length of time these activities have been in effect;

(iii) Any available information concerning additions, within the 5 years immediately preceding collection of the semen, to the flock of the semen donor;

(iv) Any available data concerning disease incidence, within the 5 years immediately preceding collection of the semen in the donor animal's flock, including, but not limited to, the results of diagnostic tests, especially histopathology tests, conducted on any animals in the flock;

(v) Information concerning the health, within the 5 years immediately preceding collection of the semen, of other ruminants, flocks, and herds with which the donor animal and the donor animal's flock might have had physical contact, and a description of the type and frequency of the physical contact; and

(vi) Any other information requested by the Administrator in specific cases as needed to make a determination.

(g) All first generation progeny resulting from semen imported under this section are subject to the requirements of 9 CFR part 54 and all other applicable regulations.

(Approved by the Office of Management and Budget under control numbers 0579-0040 and 0579-0101)

Done in Washington, DC, this 9th day of April 1996.

Terry L. Medley,
Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 96-9266 Filed 4-18-96; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 635

[FHWA Docket 95-21]

RIN 2125-AD61

General Material Requirements; Warranty Clauses

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: The FHWA is adopting, as final, a current interim final rule that revises the use of guaranty and warranty clauses on Federal-aid highway construction contracts. This final rule permits greater use of warranties in Federal-aid highway construction contracts within prescribed limits.

EFFECTIVE DATE: August 25, 1995.

FOR FURTHER INFORMATION CONTACT: Mr. James Daves, Office of Engineering, (202) 366-0355 or Mr. Wilbert Baccus, Office of the Chief Counsel, (202) 366-0780, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590.

SUPPLEMENTARY INFORMATION: On August 25, 1995, the FHWA published in the Federal Register (60 FR 44271) an interim final rule along with a request for comments, revising its regulation regarding warranty clauses on Federal-aid highway construction contracts. That action permitted the greater use of warranties in Federal-aid highway construction contracts within prescribed limits.

Discussion of Comments

The public comment period for the interim final rule closed on October 24, 1995. The FHWA received 20 written responses from 19 organizations including 11 associations, six State Departments of Transportation (DOTs), and two private companies. The responses concerning this interim final rule are available for review at the Federal Highway Administration, Public Docket Room 4232, Office of the Chief Counsel, 400 Seventh Street, SW., Washington, DC 20590.

Of the 20 responses received, 13 comments did not support the interim final rule and seven did support the interim final rule. The significant comments are summarized in the following discussion.

Requiring Warranties

An association responding to the interim final rule stated that by revising its regulation the FHWA was requiring