Regulatory Analysis Form

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INDEPENDENT REGULATORY REVIEW COMMISSION

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IRRC Number: 2088

(1) Agency

Pennsylvania Department of Agriculture

(2) I.D. Number (Governor's Office Use)

2-128

(3) Short Title

Amendments to Regulations Concerning Diagnostic Testing and Vaccination Techniques and Procedures for Equine Infectious Anemia and Brucellosis

(4) PA Code Cite

7 Pa.Code § 3.103
7 Pa. Code §§ 7.1, 7.47, 7.72, 7.73 and 7.74

(5) Agency Contacts & Telephone Numbers

Primary Contact: Dr. Phillip C. Debok (717) 783-8555

Secondary Contact: Dr. John I. Enck Jr. (717) 772 2852

(6) Type of Rulemaking (check one)

Proposed Rulemaking X
Final Order Adopting Regulation
Final Order, Proposed Rulemaking Omitted

(7) Is a 120-Day Emergency Certification Attached?

No
Yes: By the Attorney General
Yes: By the Governor

(8) Briefly explain the regulation in clear and nontechnical language.

The Department of Agriculture ("Department") proposes that: 1) The use of Strain 19 brucellosis vaccine be discontinued and that only Strain RB 51 brucellosis vaccine be authorized for the routine vaccination of cattle for brucellosis. Additionally, the maximum age for calf-hood vaccination will be raised to 12 months (365 days); and 2) The ELISA test for Equine Infectious Anemia (EIA) be accepted as an official test, in addition to the agar gel immunodiffusion test (Coggins test), for horses imported into the Commonwealth.

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

The Domestic Animal Law (3 Pa.C.S. § 2301 et seq.) The specific statutory provisions effecting this regulation are sections 2, 21, 23 and 25 of the Domestic Animal Law (3 Pa.C.S. §§ 2302, 2321, 2323 and 2325).

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(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

No.

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

This regulation is intended to update the Department's policy regarding the use of vaccines for the prevention of brucellosis in cattle. Recent advances in vaccine technology have rendered the current policy obsolete and relatively inefficient in the management of this disease. A prompt and expedited application of this new technology will provide increased protection to the Commonwealth's extensive cattle population, in addition to being more convenient for the farmer. Until recently, Strain 19 vaccine was the standard vaccine used to vaccinate for brucellosis in the United States. While Strain 19 vaccine has served the cattle industry well, it has suffered the major disadvantage of causing a significant number of animals to react positively to the standard brucellosis tests. This has limited its usefulness and has slowed eradication and control efforts. It also limits the age at which cattle can be vaccinated. A newly developed vaccine is now available and approved for use. This vaccine is reportedly as effective as Strain 19 vaccine, but does not cause a reaction with the standard blood tests for brucellosis and expands the age range for vaccination of cattle.

In addition, this regulation is intended to update the Department's policy on the accepted methods of testing and screening for Equine Infectious Anemia. Pennsylvania is the only state that does not recognize the ELISA test as a suitable test for the importation of horses. The ELISA test is equal in sensitivity to the Coggins test, is similar in cost and requires less time to perform. Since most states recognize the ELISA test there are many instances when horses in interstate traffic arrive in Pennsylvania with only an ELISA test. This is especially a problem at racetracks where many horses are coming in for a race the same day.

(12) State the public health, safety, environmental or general welfare risks associated with non-regulation.

Non-regulation will result in a continued low, but significant number, of false positive animals which will continue to be a regulatory burden and expense to the Department. Strain 19 brucellosis vaccine can also cause infection in humans and is a health risk that veterinary practitioners have faced over the years.

Delay in changing the EIA import requirements will perpetuate the ongoing problem of horses which are entered to race being turned away from the track and will continue to impose an undue hardship on horse owners and the equine industry in this Commonwealth. Many will continue to be required to re-test their horses with a different test in order to qualify for entry into Pennsylvania.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

Pennsylvania farmers will benefit by not having to contend with uninfected animals, which falsely test positive because of prolonged antibody levels caused by vaccination (see para. 17). The Pennsylvania Department of Agriculture will save resources in that it will no longer have to devote scarce resources to investigating and re-testing these false positives. Veterinary practitioners will benefit by using a product, which possesses less of a health risk than the product currently used.

Horse owners and race horse trainers will benefit by not being delayed at the track because of an unnecessary extra test requirement, and will be able to utilize a test which provides more rapid test results. The equine industry in Pennsylvania will benefit by coming into conformity with surrounding states with regard to accepted testing and screening techniques.

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(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

No one is likely to be adversely affected by this regulation. The same company makes both the "new" and "old" vaccines. Strain 19 vaccine is being phased out of use throughout the United States.

There will be no adverse results associated with adoption of the ELISA test. The sensitivity of the test provides for an adequate safety margin as compared to the currently mandated Coggins test.

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

This will potentially affect approximately 1,800 accredited veterinarians who may be required to vaccinate calves for brucellosis.

Pleasure horse and racehorse owners and trainers and equine veterinarians will be required to comply. The exact number of persons effected is difficult to assess, since many will be from out of state. However, the majority of owners, trainers and other persons in the equine industry already use and comply with ELISA testing.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

This regulatory change has been requested by businesses that export cattle and/or embryos to other countries and the pleasure horse/racing industry.

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required.

There will not be an increased cost to the regulated community. Cost of vaccinations will be essentially the same. Approximately 30 cattle test falsely positive each year. Each false positive case costs the farmer approximately $300 in special handling, early culling and reduced value of the animal. These costs will be eliminated with the use of RB 51 vaccine.

Adoption of the ELISA test will not result in any increased cost. The ELISA test is accepted and used by a majority of states and therefore, the majority of owners, trainers and other persons in the equine industry already use and comply with ELISA testing. There is a potential savings in terms of reduced turnaround time for test results. In many cases, horse owners have been required to conduct an additional test at their expense. Also, there have been instances where horses that were entered in a race were denied entrance to the track because of failure to meet PA's unnecessarily rigid EIA requirements. This results in lost opportunity to recoup training expenses.

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(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures which may be required.

There will be little or no effect on local government.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required.

There will be no additional cost to the state. The Department will benefit from not having to conduct additional testing or pay indemnity for condemnation of the approximately 30 animals which test falsely positive each year. Department expenses average approximately $400 per animal.

Savings relative to adoption of the ELISA test are difficult to quantify. It will result in a decreased regulatory workload, since there will be fewer import violations to investigate and manage.

Regulatory Analysis Form

(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	$	$	$	$	$	$
Regulated	6,000	9,000	9,000	8,000	7,000	6,000
Local Government	None	None	None	None	None	None
State Government	9,000	12,000	12,000	11,000	10,000	9,000
Total Savings	15,000	21,000	21,000	19,000	17,000	15,000
COSTS:						
Regulated	None	None	None	None	None	None
Local Government	None	None	None	None	None	None
State Government	None	None	None	None	None	None
Total Costs	None	None	None	None	None	None
REVENUE LOSSES:	N				N	
Regulated	None	None	None	None	None	None
Local Government	None	None	None	None	None	None
State Government	None	None	None	None	None	None
Total Revenue Losses	None	None	None	None	None	None

(20a) Explain how the cost estimates listed above were derived.

Savings: Number of cattle testing falsely positive each year multiplied by the cost to the state ($400) or producer ($300). These falsely positive tests will not occur in cattle vaccinated with RB 51 vaccine.

Savings relative to the ELISA test are not easily quantified and are not listed. However, acceptance of the ELISA test will eliminate the cost of performing a Coggins test on animals which have already been screened for Equine Infectious Anemia through the use of an ELISA test.

Regulatory Analysis Form

(20b) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY -3	FY -2	FY -1	Current FY
Brucellosis	$1,187,802	$1,041,142	$613,781	Similar to previous FY
EIA	$40,000	$40,000	$40,000	$40,000

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

There are no adverse effects or costs which need to be addressed.

(22) Describe the non-regulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

For the past several years use of RB 51 vaccine, rather than Strain 19 vaccine, has been strongly encouraged. In spite of this well-publicized recommendation, some veterinarians continue to use Strain 19 vaccine and have given indication that they will continue to do so as long as its use is authorized. This continued use would perpetuate the potential for false positive blood tests associated with Strain 19 vaccination.

The continued requirement that only a Coggins test may be used to screen horses entering Pennsylvania will preserve the Commonwealth's disadvantage with relation to surrounding states and perpetuate the costly and unnecessary practice of double screening or testing.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

No alternative regulatory schemes were considered.

Regulatory Analysis Form

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

These requirements are consistent with federal guidelines.

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

These regulations are consistent with other states. Until the ELISA test is adopted, Pennsylvania will continue to be at a competitive disadvantage with other states.

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

No.

(27) Will any public hearings or informational meetings be scheduled? Please provide the dates, times, and locations, if available.

No, in both instances the regulated industry is supportive of these changes.

Regulatory Analysis Form

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

No.

(29) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

These regulations are being proposed to ease the burden on cattle and horse owners.

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

The amended regulations will become effective upon publication in the Pennsylvania Bulletin. There are no permits, licenses or other approvals associated with these regulations.

(31) Provide the schedule for continual review of the regulation.

The regulations will be continually reviewed and upgraded to assure the effectiveness of the testing and vaccination techniques approved and in use throughout the country. The testing and vaccination techniques and policies will continue to change as the science in these areas advance.

CDL-1

FACE SHEET FOR FILING DOCUMENTS WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

#2088

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality. Attorney General

By: _____
(Deputy Attorney General)

JAN 13 2000
DATE OF APPROVAL

Check if applicable
Copy not approved. Objections attached.

Copy below is hereby certified to be true and correct copy of a document issued, prescribed or promulgated by:

Department of Agriculture

DOCUMENT/FISCAL NOTE NO. 2-128

DATE OF ADOPTION _____

BY Samuel E. Hayes, Jr.

TITLE Secretary

EXECUTIVE OFFICER CHAIRMAN OR SECRETARY

Copy below is hereby approved as to form and legality Executive or Independent Agencies
Sandra W. Stoner

BY: _____

12/22/99
DATE OF APPROVAL

(Deputy General Counsel)
~~(Chief Counsel - Independent Agency)~~
(Strike inapplicable title)

Check if applicable. No Attorney General Approval or objection within 30 days after submission.

NOTICE OF PROPOSED RULEMAKING

Department of Agriculture
Bureau of Animal Health and Diagnostic Services
7 Pa. Code Chapters 3 & 7
Health Requirements for Importation and Intrastate Transportation of Animals and Brucellosis Regulations

Department of Agriculture – Notice of Proposed Rulemaking

PA Code Cite: 7 Pa. Code Chapters 3 & 7

Regulation Title: Health Requirements for Importation and Intrastate Transportation of Animals and Brucellosis Regulations

I.D. Number: 2-128

SECRETARY'S CERTIFICATION

I, Samuel E. Hayes, Jr. do hereby certify that I have reviewed this regulation and determined that the regulation is consistent with the principles outlined in Executive Order 1996-1.

Samuel E. Hayes, Jr., Secretary (Date) 8/27/99

TITLE 7 - AGRICULTURE
7 Pennsylvania Code
Part 1. Bureau of Animal Health and Diagnostic Services
Chapter 3. Health Requirements for Importation and Intrastate Transportation of Animals
Chapter 7. Brucellosis Regulations.

The Department of Agriculture ("Department"), under the specific authority conferred by Sections 2, 21, 23 and 25 (3 Pa.C.S. §§ 2302, 2321, 2323 and 2325) of the act of July 11, 1996, P.L. 561, No. 100, known as the Domestic Animal Law ("Act") (3 Pa.C.S. § 2301 *et seq.*), hereby proposes to amend the regulations at Chapter 3 and Chapter 7 of Title 7 (7 Pa.Code §§ 3.103, 7.1, 7.47, 7.72, 7.73 and 7.74). These amendments are intended to update the Department's policy on diagnostic testing techniques used to detect the presence of Equine Infectious Anemia ("EIA") and the use of vaccines intended for the prevention of Brucellosis. Section 2 of the act states that "animal health is a major economic interest in the Commonwealth." In addition, section 2 delineates the policy and purpose of the act. The policy of the act is to "assure the health and welfare of animals kept in captivity, to prevent and control diseases ... and to provide desirable management practices for the production, keeping and use of domestic animals. The purpose of the act is to "give the department authority to implement this policy." Section 21(a) (3 Pa.C.S. § 2321(a)) of the act designates Brucellosis and Equine Infection Anemia ("EIA") as dangerous transmissible diseases. Section 21(e) (3 Pa.C.S. § 2321(e)) confers upon the Department the power to "establish regulations addressing the specific ... prevention, ... testing, control and eradication measures which it determines are necessary with respect to any dangerous transmissible disease." Section 25 of the act further defines the Department's authority to prescribe testing techniques and regulate the use of vaccines. Section 23 of the act sets forth the

Department's authority to establish health standards for the importation or intrastate movement of domestic animals in this Commonwealth.

BACKGROUND

Equine Infectious Anemia ("EIA") is an infectious disease of equines caused by a virus. The current regulations, at Chapter 3 of Title 7 (7 Pa.Code § 3.103), require equidae imported into this Commonwealth to be negative to an agar gel immunodiffusion blood test ("Coggins Test"). While the Coggins test is a proven and effective testing device for EIA, a new and reportedly as effective test has been developed. This new test is an enzyme linked immunosorbent assay test (commonly called the ELISA Test). The ELISA test is a screening device that recognizes the presence of the virus responsible for EIA. The ELISA test is widely used to test for the presence of viruses and foreign substances in equidae. It is a scientifically proven and accepted test and is used to screen equidae for EIA in surrounding states. The inability of the Commonwealth to accept the results of ELISA tests has placed it at a great disadvantage with regard to surrounding states. Horse owners who wish to transport their horses into the Commonwealth are required to have a Coggins test administered and to wait for the results of that test even if they have proof of a negative ELISA test for EIA. Such a delay discourages owners from breeding, racing or carrying on other activities economically beneficial to the Commonwealth and the equine industry in Pennsylvania. Given the fact that the ELISA test has been shown to be an effective screening device for EIA, additional testing and the delays caused by it are unnecessary to protect the health of the equine population in the Commonwealth and are economically inefficient. Therefore, the Department proposed to

amend Chapter 3 to allow for the use and acceptance of both the Coggins test and the ELISA test. In addition, language will be added to allow the Department more flexibility to respond to continuing advances in science and medical technology.

Brucellosis is an infectious disease of animals and man that can cause premature birthing or miscarriages in animals and undulating or remittent fevers and joint swelling in humans. A recent advance in vaccine technology has rendered the current vaccine - Strain 19 brucella abortus - prescribed by regulation obsolete and relatively inefficient in the management of this disease. Until recently, Strain 19 brucella abortus ("Strain 19") vaccine was the standard vaccine used to vaccinate for Brucellosis in the United States. While Strain 19 vaccine has served the domestic animal industry well, it has two disadvantages. Its major disadvantage is causing a significant number of animals to react positively to the standard Brucellosis tests. This disadvantage has limited Strain 19 vaccine's usefulness and has slowed eradication and control efforts. The second disadvantage suffered by Strain 19 vaccine is that it limits the age at which domestic animals can be vaccinated. A newly developed vaccine - Strain RB 51 - is now available and approved for use. Strain RB 51 vaccine is reportedly as effective as Strain 19 vaccine and does not cause a reaction, or false positive, with the standard Brucellosis tests. In addition, Strain RB 51 will allow the Department to broaden the age range for vaccination of calves from the current 4 to 8 months of age range to a 4 to 12 months of age range. A prompt and expedited application of this new technology will provide increased protection to the Commonwealth's extensive cattle population and will decrease the costs incurred by the Department to administer additional tests when false positives occur. Therefore, the Department proposes that the use of Strain 19 be

discontinued and that Stain RB 51 be used for the routine vaccination of cattle and any other species of domestic animal for which the vaccine is approved. In addition, language will be added to allow the Department more flexibility to respond to continuing advances in science and medical technology.

In the interest of continuing to carry out the policy of the act, to assure the health and welfare of domestic animals and thereby secure the economic well being of the domestic animal industry, the Department proposes to amend the regulations at Title 7, Chapters 3 and 7 (7 Pa.Code §§ 3.103, 7.1, 7.47, 7.72, 7.73 and 7.74) to effectuate the changes referred to above.

The major features of the proposed amendments are summarized as follows:

SUMMARY OF MAJOR FEATURES

Section 3.1. (relating to definitions) adds the definition of "Pennsylvania State Veterinarian" and "Secretary". These terms are recurring terms in this chapter and needed to be defined in order to add clarity.

Section 3.103. (relating to Agar gel immunodiffusion blood test) changes the heading to read "Test methods". This section sets forth the acceptable testing techniques and the documentation required for importing equine into the Commonwealth. The amendments to this section allow the Department to accept the results of tests other than the agar gel immunodiffusion blood test (commonly referred to as a Coggins test). Specifically, the amendments allow the Department to accept the results of an enzyme linked immunosorbent assay test (commonly called the ELISA test). In addition, the amendments allow the Secretary to designate other tests as acceptable through

publication of an order in the *Pennsylvania Bulletin*. The Department would be required to amend the regulations to bring them into conformity with the order, within one year of the effective date of the order. A subsection was added to address the procedures to be followed in case of inconsistent test results.

Section 7.1. (relating to definitions) adds and defines various recurring terms such as "Accredited veterinarian", "Pennsylvania State Veterinarian" and "Secretary".

Section 7.47. (relating to herd additions) deletes the provision designating brucella abortus vaccine, Strain 19, as the official vaccine to be used for Brucellosis vaccinations. In addition, it adds a sentence referencing Subchapter H, which designates a new vaccine, Strain RB 51, as the official vaccine to be used for Brucellosis vaccinations.

Section 7.72. (relating to procedure) deletes the sentence in 7.72(a) referencing Strain 19 brucella abortus vaccine and designates RB 51 vaccine as the only Brucellosis vaccine authorized for use within the Commonwealth of Pennsylvania. In addition, the amendments allow the Secretary to designate other vaccines as acceptable through publication of an order in the *Pennsylvania Bulletin*. The Department would be required to amend the regulations to bring them into conformity with the order, within one year of the effective date of the order. Subsection (b) is retitled and allows Strain 19 brucella abortus vaccine to be used with express written permission of the Pennsylvania State Veterinarian. Subsection (c) is retitled and expands the time period for an official vaccination. A subsection (d) was added and requires vaccinations to be administered by an accredited veterinarian. Subsection (e) is added and replaces existing subsection (c).

This subsection was amended to allow veterinarians to charge for the cost of the vaccine as well as the cost of their services.

Section 7.73. (relating to identification of calves) amendments to this section change and add to the identification requirements.

Section 7.74. (relating to vaccination report) amendments to this section extend the time period in which reports must be submitted to the Department and reduces the number of copies of vaccination reports that are required to be sent to the Department.

FISCAL IMPACT

Commonwealth

The proposed amendments to the regulations will impose minimal costs and have minimal fiscal impact upon the Commonwealth. The Commonwealth will realize a reduction in costs as a result of the use of RB 51 vaccine. Strain 19 vaccine causes a number of cattle to test falsely positive each year. The cost of each false positive test is approximately ($400) for the Commonwealth and ($300) for the producer. These falsely positive tests will not occur in cattle vaccinated with RB 51 vaccine. Savings relative to the ELISA test are not easily quantified. However, acceptance of the ELISA test will eliminate the cost of performing a Coggins test on animals which, have already been screened for Equine Infectious Anemia through the use of an ELISA test. The Department of Agriculture will benefit from not having to conduct additional testing. In addition, it will result in a decreased regulatory workload, since there will be fewer import violations to investigate and manage.

Political Subdivisions

The proposed amendments to the regulations will impose no costs and have no fiscal impact upon political subdivisions.

Private Sector

The proposed amendments to the regulations will impose minimal costs on private sector organizations and individuals. There will not be an increased cost to the regulated community. Cost of vaccinations will be essentially the same. Approximately 30 cattle test falsely-positive each year. Each false positive case costs the farmer approximately $300 in special handling, early culling and reduced value of the animal. These costs will be eliminated with the use of RB 51 vaccine. The amendments will potentially affect approximately 1800 accredited veterinarians who may be required to vaccinate calves for brucellosis. However, these veterinarians, Pennsylvania and the industry would eventually be forced to use RB 51 vaccine because, the same company makes both the "new" and "old" vaccines and Strain 19 vaccine is being phased out of use throughout the United States. Adoption of the ELISA test will not result in any increased cost. Pleasure horse and racehorse owners and trainers and equine veterinarians will be required to comply. However, the ELISA test is accepted and used by a majority of States and therefore, the majority of owners, trainers and other persons in the equine industry already use and comply with ELISA testing. There is a potential savings in terms of the elimination of additional testing and reduced turnaround time for test results. In many cases, horse owners have been required to conduct the additional Coggins test at their expense. Also, there have been instances where horses that were entered in a race were denied entrance to the track because of failure to meet

Pennsylvania's rigid and unnecessary Equine Infectious Anemia requirements. Such instances result in lost opportunities to race and to recoup training expenses.

General Public

The proposed amendments to the regulations will impose no costs and have no fiscal impact on the general public. The farm community and the general public should benefit through reduced costs to the industry and the Commonwealth. The continued use of Strain 19 vaccine would result in continued low, but significant number, of false positive animals, which will continue to be a regulatory burden and expense to the cattle industry and the Department of Agriculture. Strain 19 brucellosis vaccine can also cause infection in humans and is a health risk that veterinary practitioners have faced over the years. Delay in changing the Equine Infectious Anemia import requirements will perpetuate the ongoing problem of horses which are entered to race being turned away from the track, and will continue to impose an undue hardship on horse owners and the equine industry in this Commonwealth. The equine industry in Pennsylvania will benefit by coming into conformity with surrounding states with regard to accepted testing and screening techniques. Decreased costs and increased opportunities in both industries will benefit the general public.

PAPERWORK REQUIREMENTS

The proposed amendments to the regulations will not result in an appreciable increase of paperwork. The Department has already developed the appropriate forms and procedures to administer the Equine Infectious Anemia testing program and the Brucellosis vaccination program. Only small changes will be required.

REGULATORY REVIEW

Under Section 5(a) of the Regulatory Review Act, the Act of June 30, 1989 (P.L. 73, No. 19), (71 P.S. §§ 745.1 –745.15), as amended by Act 24 of 1997 (P.L. 252, No. 24), the Department submitted a copy of these proposed amendments to the regulations on January 31, 2000 to the Independent Regulatory Review Commission and to the Chairpersons of the House Agriculture and Rural Affairs Committee and the Senate Agriculture and Rural Affairs Committee. In addition to submitting the proposed amendments to the regulations, the Department has provided the Commission and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the agency in compliance with Executive Order 1996-1 "Regulatory Review and Promulgation". A copy of this material is available to the public upon request.

If the Commission has an objection to any portion of the proposed amendments to the regulations, it will notify the Department within 30 days after the close of the public comment period. Such notification shall specify the regulatory review criteria which have not been met by that portion. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the regulations, by the Department, the General Assembly and the Governor of objections raised.

CONTACT PERSON

Further information is available by contacting the Department of Agriculture, Bureau of Animal Health and Diagnostic Services, 2301 North Cameron Street, Harrisburg, Pennsylvania 17110-9408; Attn: Dr. Phillip Debok (717) 783-8555.

EFFECTIVE DATE

These proposed amendments to the regulations would become effective upon publication in the *Pennsylvania Bulletin.*

By the Department of Agriculture

SAMUEL E. HAYES, JR., SECRETARY

Annex "A"

7 Pennsylvania Code
Part 1. Bureau of Animal Health and Diagnostic Services
Chapter 3. Health Requirements for Importation and Intrastate Transportation of Animals
Chapter 7. Brucellosis Regulations.

CHAPTER 3. HEALTH REQUIREMENTS FOR IMPORTATION AND INTRASTATE TRANSPORTATION OF ANIMALS

* * *

Subchapter D. IMPORTATION OF HORSES, MULES, ASSES AND OTHER EQUIDAE

§ 3.1. Definitions.

Pennsylvania State Veterinarian – The Director of the Bureau of Animal Health and Diagnostic Services of the Department.

* * *

Secretary – The Secretary of the Department.

* * *

§ 3.103. [Agar gel immunodiffusion blood test.] Test methods.

(a) *Testing required.* Equidae imported into this Commonwealth for other than immediate slaughter shall be negative to [an] either of the following:

(1) An official agar gel immunodiffusion blood test (commonly called The Coggins Test), conducted by a Federally approved laboratory within 12 months prior to date of entry; or

(2) An enzyme linked immuno sorbent assay test (commonly called The ELISA Test), conducted by a federally approved laboratory within 12 months prior to date of entry.

(b) *Documentation required.* A copy of the official test shall accompany the animal to its final destination.

[(b)] (c) *Inconsistent results.* If an equid receives more than one of the tests described in subsection (a), and one test shows a negative result and another a positive result, the equid shall not be imported into the Commonwealth unless permission is granted by the Pennsylvania State Veterinarian.

(d) *Designation of other tests as acceptable.* In the event the Secretary determines that a test other than the tests described in subsection (a) is adequate to detect equine infectious anemia and is appropriate for use in equidae imported into the Commonwealth, the Secretary may so designate that test by publishing an order to that effect in the *Pennsylvania Bulletin.* The order shall take effect upon publication and the Department shall, within one year of the effective date of that order, amend this section to bring it into conformity with the published order.

(e) *Exception.* Foals under 6 months of age, accompanied by dam with negative agar gel immunodiffusion test, a negative enzyme linked immunosorbent assay test or some other test approved by the Secretary and published in the Pennsylvania Bulletin, do not require a negative test.

* * *

CHAPTER 7. BRUCELLOSIS REGULATIONS.

Subchapter A. GENERAL PROVISIONS

§ 7.1. Definitions.

The following words and terms, when used in this chapter, have the following meanings [, unless the context clearly indicates otherwise]:

Accredited veterinarian – A licensed veterinarian jointly accredited by APHIS-USDA and the Department in the state the veterinarian is licensed to perform official duties on behalf of APHIS-USDA or the Department in the state the veterinarian is licensed to practice veterinary medicine. See accreditation standards established by 9 CFR Parts 160 and 161 (relating to definition of terms; and requirements and standards for accredited veterinarians and suspension or revocation of such accreditation).

* * *

Pennsylvania State Veterinarian – The Director of the Bureau of Animal Health and Diagnostic Services of the Department.

* * *

Secretary – The Secretary of the Department.

* * *

Subchapter E. INDIVIDUAL CERTIFIED BRUCELLOSIS HERD PLAN

* * *

§ 7.47. Herd additions.

* * *

(c) Animals officially vaccinated [with brucella abortus vaccine, Strain 19] in accordance with Subchapter H (relating to vaccination), and under 18 months of age, may enter a herd without a blood test but shall be accompanied by a health certificate.

* * *

Subchapter H. [CALFHOOD] VACCINATION

* * *

§ 7.72. Procedure.

(a) [Only accredited veterinarians selected by the owner may vaccinate female calves with Strain 19 brucella abortus vaccine.] *Designation of vaccine.* Strain RB 51 vaccine is hereby designated the only brucellosis vaccine authorized for use within the Commonwealth of Pennsylvania. In the event the Secretary determines that some other brucellosis vaccine is appropriate for use in cattle in the Commonwealth, the Secretary may so designate that vaccine by publishing an order to that effect in the *Pennsylvania Bulletin*. The order shall take effect upon publication and the Department shall, within one year of the effective date of that order, amend this section to bring it into conformity with the published order.

(b) *State veterinarian approval required.* Strain 19 vaccine may only be used with the express written permission of the Pennsylvania State Veterinarian.

(c) *Official vaccination.* An official vaccination shall consist of [an approved] Strain RB 51 vaccine administered to female calves from 4 through [8] 12 months of age ([120 – 269] 120-365 days). A vaccination of cattle over the age of 12 months (365 days) shall not be considered an official vaccination unless done with the guidance and express written permission of the Pennsylvania State Veterinarian.

(d) *Veterinarian to administer vaccine.* An official vaccination may only be administered by an accredited veterinarian.

[(c)] (e) Veterinarian *fees*. Accredited veterinarians shall be permitted to charge the herd owner for [the cost of the services] their services and the vaccine.

§ 7.73. Identification of calves.

(a) *Tattoo required.* Veterinarians vaccinating calves shall tattoo [with] in the right ear the letter "R", followed by a United States Registered "V" Shield [, including "V," in the right ear, preceded by the numeral of the quarter of the year and], followed by the last number of the year.

(b) *Official state vaccination tag or official breed registry tattoo required.* An orange official State vaccination tag shall be placed in the right ear. If the calf has an official breed registry tattoo, an official state vaccination tag shall not be required.

(c) *Identification on vaccination report.* Calves shall be identified on the vaccination report by [the] date of birth, official [Pennsylvania ear tag in the right ear,] state vaccination tag number and[,]/or when applicable, their breed registration number or registration number of the dam.

§ 7.74. Vaccination report.

Vaccinations shall be reported to the Department within [7] 30 days following vaccination of the calves. The reports shall be made on forms provided by the Department. The original and [two copies] one copy shall be forwarded to the Department, one copy given to the herd owner for his or her records and one copy retained by the veterinarian.

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
LEGAL OFFICE

January 31, 2000

The Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17120

RE: NOTICE OF PROPOSED RULEMAKING
Department of Agriculture
Bureau of Animal Health & Diagnostic Services
7 Pa. Code Chapters 3 & 7: Health Requirements for Importation and Intrastate Transportation of Animals & Brucellosis
I.D. No. 2-128

Dear Sir or Madam:

Please find enclosed copies of the Face Sheet, Preamble, Annex "A" and Regulatory Analysis Form with respect to the above proposed regulation.

Copies of these documents have been submitted to the majority and minority chairpersons of the House and Senate Agriculture and Rural Affairs Committees and to the Legislative Reference Bureau on this date.

The proposed regulation will be published in the February 12, 2000 edition of the *Pennsylvania Bulletin*. If I may be of further information, please advise.

Sincerely,

David C. Kennedy

David C. Kennedy
Assistant Counsel

Enclosures

DCK:amg

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TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

RECEIVED

2000 JAN 31 PM 3:39

INDEPENDENT REGULATORY REVIEW COMMISSION

I.D. NUMBER:	2-128
SUBJECT:	Health Requirements for Importation & Intrastate Transportation of Animals & Brucellosis
AGENCY:	DEPARTMENT OF AGRICULTURE

TYPE OF REGULATION

X Proposed Regulation

Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation
a. With Revisions b. Without Revisions

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
1-31		HOUSE COMMITTEE ON AGRICULTURE & RURAL AFFAIRS
1-31		
1/31	Madeline Bailey	SENATE COMMITTEE ON AGRICULTURE & RURAL AFFAIRS
1/31		
1/31/00		INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
01/31/00		LEGISLATIVE REFERENCE BUREAU

January 20, 2000