COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
LEGAL OFFICE

September 27, 2000

Mr. Robert E. Nyce
Executive Director
Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17101

Dear Mr. Nyce:

The Independent Regulatory Review Commission ("Commission") has suggested revisions to sections of the final-form regulation # 2-128 (IRRC #2088) (relating to Importation and Intrastate Transportation of Animals; Brucellosis), which was submitted to the Commission and the House and Senate Standing Committees for Agriculture and Rural Affairs ("Committees") on September 14, 2000. The Commission suggested revisions to section 7.1 (relating to Definitions) and section 7.72 (a) and (c) (relating to Procedure).

Please accept this letter as written notice of the Pennsylvania Department of Agriculture's ("PDA's") request that the above-referenced final-form regulation be "tolled" in accordance with § 5.1(g) of the Regulatory Review Act (71 P.S. § 745.5a(g)). This tolling request is delivered within the time parameters prescribed by § 5.1(g)(1) of the Regulatory Review Act (71 P.S. § 745.5a(g)(1)) and the regulation at 1 Pa. Code § 307.4(d) (relating to tolling the review period). The Committees have received this notice on this date.

In accordance with the requirements of the regulation at 1 Pa. Code § 307.5 (relating to procedure for filing), I offer the following:

1. Citation to sections being considered for revision.

PDA is considering revising section 7.1 (relating to Definitions) and section 7.72 (a) and (c) (relating to Procedure) of the final-form regulation it delivered to the Commission and the Committees on September 14, 2000.

2301 NORTH CAMERON STREET
HARRISBURG, PA 17110-9408
717-787-6744
FAX 717-787-1270

2. Description of revisions being considered.

(1) PDA is considering a recommendation by the Chief Counsel for the Commission that section 7.1 of the final-form regulation be revised as follows:

OFFICIAL ADULT VACCINATION - STRAIN RB 51 VACCINE ADMINISTERED TO FEMALE CATTLE OR BISON OVER THE AGE OF 12 MONTHS (365 DAYS). ~~SUCH VACCINATION MAY ONLY BE ADMINISTERED WITH THE EXPRESS GUIDANCE AND WRITTEN PERMISSION OF THE PENNSYLVANIA STATE VETERINARIAN.~~

(2) PDA is considering a recommendation by the Chief Counsel for the Commission and the Senior Regulatory Analyst assigned to this regulation that section 7.72(a) of the final-form regulation be revised to reference subsection 7.72(b) of the final-form regulation as follows:

§ 7.72. Procedure.

(a) [Only accredited veterinarians selected by the owner may vaccinate female calves with Strain 19 brucella abortus vaccine.] *Designation of vaccine.* EXCEPT AS AUTHORIZED UNDER SUBSECTION (B) (RELATING TO STATE VETERINARIAN APPROVAL REQUIRED), 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.~~

(3) PDA is considering a recommendation by the Regulatory Analyst assigned to this regulation that section 7.72(c) of the final-form regulation be revised as follows:

[(b)] (c) *Official vaccination.* An official vaccination shall consist of [an approved] Strain RB 51 vaccine administered to female [calves] CATTLE OR BISON from 4 through [8] 12 months of age ([120 – 269] 120-365 days). A vaccination of FEMALE cattle OR BISON 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. ALL

REQUESTS TO ~~VACCINATE CATTLE OVER THE AGE OF 12 MONTHS~~ ADMINISTER AN OFFICIAL ADULT VACCINATION SHALL BE MADE IN WRITING ON A FORM PROVIDED BY THE DEPARTMENT. THE REQUEST SHALL SET FORTH THE REASONS FOR THE REQUEST, THE VACCINE TO BE ADMINISTERED AND THE AGE OF THE ANIMAL AT THE TIME OF THE REQUEST. THE PENNSYLVANIA STATE VETERINARIAN MAY REQUEST ADDITIONAL INFORMATION AS MAY BE NECESSARY TO ASSURE THE HEALTH OF THE ANIMAL AND TO PREVENT AND CONTROL DISEASES AND DANGEROUS SUBSTANCES THAT MAY THREATEN THE HEALTH AND SAFETY OF ANIMALS AND HUMANS. THE PENNSYLVANIA STATE VETERINARIAN SHALL PROVIDE A WRITTEN APPROVAL OR DENIAL OF SUCH A REQUEST WITHIN 3 WORKING DAYS OF RECEIVING THE WRITTEN REQUEST AND ALL NECESSARY INFORMATION PERTAINING THERETO.

3. Explanation of how revision would satisfy the concerns of the Commission or the Committees.

(1) The revision to section 7.1 of the final-form regulation was suggested because the second sentence of the definition is substantive in nature and therefore does not belong in a definition. In addition, this language appears in the text of the regulation and therefore does not need to be included in the definition. The revision would satisfy the concerns of the Chief Counsel.

(2) The revisions to section 7.72(a) of the final-form regulation were suggested because, section 7.72(b) provides an exception to the statement made in 7.72(a) that Strain RB 51 is the "...only brucellosis vaccine authorized for use within the Commonwealth of Pennsylvania." Adding the language "[E]xcept as authorized under subsection (b) (relating to State veterinarian approval required)," denotes the exception and clarifies the regulation.

(3) There are two revisions to section 7.72(c) of the final-form regulation. These revisions were suggested in order to add clarity and consistency to the final-form regulation. The Commission noted that the first sentence of the section referred to female "**calves** or bison" and that all other references in the final-form regulation were to "**cattle** or bison". In response, the first revision would replace the word "calves" in the first sentence with the word "cattle". In addition, the Commission noted that the third sentence in section 7.72(c) referred **only to cattle** and did not include bison. The Commission suggested that PDA delete the language "vaccinate cattle over the age of 12 months" from the third sentence and replace it with a reference to an "official adult vaccination." The revisions set

forth above would change section 7.72(c) of the final-form regulation to allow it to cover vaccinations of both cattle and bison instead of just cattle. These revisions add clarity and consistency to the final-form regulation.

PDA will deliver its revised regulation, or a written notice that the final-form regulation will not be revised, to the Commission and the Committees within the 30-day maximum span of this tolling period.

Although the Commission *has* the statutory authority to object to this tolling request and cause the review of the final-form regulation to continue, it is respectfully submitted that the revision being considered is not broader than or inconsistent with those recommended by the Commission, and that the standard for Commission objection set forth in the regulation at 1 Pa. Code § 307.4(f) (relating to tolling the review period) has not been met in this instance.

If I may be of further information, please advise.

Sincerely,

David C. Kennedy
Assistant Counsel

cc: Honorable Raymond Bunt, Jr.
Honorable Italo S. Cappabianca
Honorable Noah W. Wenger
Honorable Patrick J. Stapleton
Sandra W. Stoner, Deputy General Counsel

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
LEGAL OFFICE

DATE: September 18, 2000

Original: 2088

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

TO: Sarah Miller, Regulatory Analyst
The Independent Regulatory Review Commission

FROM: David C. Kennedy DCK
Assistant Counsel

Please find attached hereto a **Revised Copy** of the above-referenced final-form regulation (**Annex "A"**). This revised copy of Annex "A" should replace the current Annex "A". The revised copy has the proper text format indicating the changes made from the proposed regulation. The formatting is consistent with the Independent Regulatory Review Commission's regulations at section 307.2(c)(6) of Title 1 of the Pennsylvania Code (1 Pa.Code § 307.2(c)(6)).

Attachment

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

* * *

Original: 2088

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] the Coggins Test), conducted by a Federally approved laboratory within 12 months prior to date of entry~~; or~~.

(2) An enzyme-linked immunosorbent assay test (commonly called [The] 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. A PERSON SEEKING SUCH PERMISSION SHALL DO SO IN WRITING ON A FORM PROVIDED BY THE DEPARTMENT SETTING FORTH THE TEST DATES, RESULTS OF THE TESTS AND ANY OTHER PERTINENT INFORMATION. THE PENNSYLVANIA STATE VETERINARIAN MAY REQUEST ADDITIONAL INFORMATION AS MAY BE NECESSARY TO ASSURE THE HEALTH OF THE ANIMAL AND TO PREVENT AND CONTROL DISEASES AND DANGEROUS SUBSTANCES THAT MAY THREATEN THE HEALTH AND SAFETY OF ANIMALS AND HUMANS. THE PENNSYLVANIA STATE VETERINARIAN SHALL PROVIDE A WRITTEN APPROVAL OR DENIAL OF SUCH A REQUEST WITHIN 3 WORKING DAYS OF RECEIVING THE WRITTEN REQUEST AND ALL NECESSARY INFORMATION PERTAINING THERETO.

~~(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.~~

~~(c)~~ (D) *Exception.* Foals under 6 months of age, accompanied by dam with negative agar gel immunodiffusion test~~,~~ OR 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).

* * *

OFFICIAL VACCINATION - AN OFFICIAL CALFHOOD OR ADULT VACCINATION.

* * *

OFFICIAL ADULT VACCINATION - STRAIN RB 51 VACCINE ADMINISTERED TO FEMALE CATTLE OR BISON OVER THE AGE OF 12 MONTHS (365 DAYS). SUCH VACCINATION MAY ONLY BE ADMINISTERED WITH THE EXPRESS GUIDANCE AND WRITTEN PERMISSION OF THE PENNSYLVANIA STATE VETERINARIAN.

* * *

OFFICIAL CALFHOOD VACCINATION - STRAIN RB 51 VACCINE ADMINISTERED TO FEMALE CATTLE OR BISON FROM 4 TO 12 MONTHS OF AGE.

* * *

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)(7 PA.CODE §§ 7.71 – 7.74), 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. ALL REQUESTS FOR PERMISSION TO ADMINISTER STRAIN 19 VACCINE MUST BE MADE IN WRITING ON A FORM PROVIDED BY THE DEPARTMENT. THE PENNSYLVANIA STATE VETERINARIAN MAY REQUEST ADDITIONAL INFORMATION AS MAY BE NECESSARY TO ASSURE THE HEALTH OF THE ANIMAL AND TO PREVENT AND CONTROL DISEASES AND DANGEROUS SUBSTANCES THAT MAY THREATEN THE HEALTH AND SAFETY OF ANIMALS AND HUMANS. THE PENNSYLVANIA STATE VETERINARIAN SHALL PROVIDE A WRITTEN APPROVAL OR DENIAL OF SUCH A REQUEST WITHIN 3 WORKING DAYS OF RECEIVING THE WRITTEN REQUEST AND ALL NECESSARY INFORMATION PERTAINING THERETO.

[(b)] (c) *Official vaccination.* An official vaccination shall consist of [an approved] Strain RB 51 vaccine administered to female calves OR BISON from 4 through [8] 12 months of age ([120 – 269] 120-365 days). A vaccination of FEMALE cattle OR BISON 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. ALL REQUESTS TO VACCINATE CATTLE OVER THE AGE OF 12 MONTHS SHALL BE MADE IN WRITING ON A FORM PROVIDED BY THE DEPARTMENT. THE REQUEST SHALL SET FORTH THE REASONS FOR THE REQUEST, THE VACCINE TO BE ADMINISTERED AND THE AGE OF THE ANIMAL AT THE TIME OF THE REQUEST. THE PENNSYLVANIA STATE VETERINARIAN MAY REQUEST ADDITIONAL INFORMATION AS MAY BE NECESSARY TO ASSURE THE HEALTH OF THE ANIMAL AND TO PREVENT AND CONTROL DISEASES AND DANGEROUS SUBSTANCES THAT MAY THREATEN THE HEALTH AND SAFETY OF ANIMALS AND HUMANS. THE PENNSYLVANIA STATE VETERINARIAN SHALL PROVIDE A WRITTEN APPROVAL OR DENIAL OF SUCH A REQUEST WITHIN 3 WORKING DAYS OF RECEIVING THE WRITTEN REQUEST AND ALL NECESSARY INFORMATION PERTAINING THERETO.

(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] OFFICIALLY VACCINATED ANIMALS.

(a) *Tattoo required.* Veterinarians [vaccinating calves] ADMINISTERING OFFICIAL CALFHOOD OR OFFICIAL ADULT VACCINATIONS shall tattoo [with] in the right ear OF THE ANIMAL 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~~ VACCINATED ANIMAL has an official breed registry tattoo, an official state vaccination tag ~~is~~ SHALL not BE required.

(c) *Identification on vaccination report.* [Calves] OFFICIALLY VACCINATED ANIMALS shall be identified on the vaccination report by [the] date of birth, AND AN official [Pennsylvania ear tag in the right ear,] State vaccination tag ~~number~~ [and,] ~~or~~ [when applicable], their breed registration number AND/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] ANIMAL. 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~~ THE OWNER'S records and one copy retained by the veterinarian.

Original: 2088

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
LEGAL OFFICE

September 27, 2000

Mr. Robert E. Nyce
Executive Director
Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17101

Dear Mr. Nyce:

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1. Citation to sections being considered for revision.

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HARRISBURG, PA 17110-9408
717-787-8744
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(2) The revisions to section 7.72(a) of the final-form regulation were suggested because, section 7.72(b) provides an exception to the statement made in 7.72(a) that Strain RB 51 is the "...only brucellosis vaccine authorized for use within the Commonwealth of Pennsylvania." Adding the language "[E]xcept as authorized under subsection (b) (relating to State veterinarian approval required)," denotes the exception and clarifies the regulation.

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forth above would change section 7.72(c) of the final-form regulation to allow it to cover vaccinations of both cattle and bison instead of just cattle. These revisions add clarity and consistency to the final-form regulation.

PDA will deliver its revised regulation, or a written notice that the final-form regulation will not be revised, to the Commission and the Committees within the 30-day maximum span of this tolling period.

Although the Commission *has* the statutory authority to object to this tolling request and cause the review of the final-form regulation to continue, it is respectfully submitted that the revision being considered is not broader than or inconsistent with those recommended by the Commission, and that the standard for Commission objection set forth in the regulation at 1 Pa. Code § 307.4(f) (relating to tolling the review period) has not been met in this instance.

If I may be of further information, please advise.

Sincerely,

David C. Kennedy

David C. Kennedy
Assistant Counsel

cc: Honorable Raymond Bunt, Jr.
Honorable Italo S. Cappabianca
Honorable Noah W. Wenger
Honorable Patrick J. Stapleton
Sandra W. Stoner, Deputy General Counsel

PHONE: (717) 783-5417
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http://www.irrc.state.pa.us

INDEPENDENT REGULATORY REVIEW COMMISSION

333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

September 27, 2000

Honorable Samuel E. Hayes, Jr.
Secretary of Agriculture
211 Agriculture Building
2301 North Cameron Street
Harrisburg, PA 17110-9408

RE: Regulation # 2-128 (IRRC # 2088)
Importation and Intrastate Transportation of Animals; Brucellosis

Dear Secretary Hayes:

On September 26, 2000, we discussed several issues presented by this final-form regulation with the Department's Counsel, David Kennedy. Questions on these issues can be resolved through the tolling procedure. Therefore, we recommend that you toll the review period to consider revising the provisions of the regulation discussed below.

1. Section 7.1. Definitions.
The second sentence in the definition of "official adult vaccination" should be deleted. This is a substantive requirement and should not be placed in a definition.

2. Section 7.72. Procedure.
For clarification, subsection (a) should be revised as follows: Strain RB 51 is hereby designated the only brucellosis vaccine authorized for use within the Commonwealth of Pennsylvania, EXCEPT AS PROVIDED IN SUBSECTION (B).

3. Section 7.72. Procedure.
To clarify that the official adult vaccination requirements apply to bison as well as to cattle, the third sentence in subsection (c) should be revised as follows: ALL REQUESTS TO ADMINISTER THE OFFICIAL ADULT VACCINE SHALL BE MADE IN WRITING ON A FORM PROVIDED BY THE DEPARTMENT. In the alternative, the words "or bison" may be added after "cattle."

4. Section 7.72. Procedure.
   To correct an error, the word "cattle" should be substituted for "calves" in the first sentence of paragraph (c).

   As required by Section 307.5 of our regulations, written notice must include:

   1. A citation to the section(s) the Department is considering revising.

   2. A description of the revisions being considered.

   3. An explanation of how the revisions will satisfy our concerns.

If the Commission objects to tolling the review period, we will notify you and the committees within two business days after receipt of your tolling notice. In that event, the review period will not be tolled, the Commission will consider your regulation at our public meeting on October 5, 2000. If the Commission does not object, the review period will tolled for up to 30 days beginning with receipt of your letter and ending on the day you resubmit the regulation.

Please contact me at 783-5506 if you have any questions.

Sincerely,

Robert E. Nyce
Executive Director

PHONE: (717) 783-5417
FAX: (717) 783-2664
irrc@irrc.state.pa.us
http://www.irrc.state.pa.us

INDEPENDENT REGULATORY REVIEW COMMISSION

333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

September 27, 2000

Honorable Samuel E. Hayes, Jr.
Secretary of Agriculture
211 Agriculture Building
2301 North Cameron Street
Harrisburg, PA 17110-9408

Re: Regulation #2-128 (IRRC #2088)
Department of Agriculture
Importation and Intrastate Transportation or Animals; Brucellosis

Dear Secretary Hayes:

Today, we received your letter notifying us that you are tolling the review period. We do not object.

By October 27, 2000, the Department must deliver to the Commission and the Committees either the revised regulation or written notice that the regulation will not be revised. The revised regulation or notice must be accompanied by a transmittal sheet (copy enclosed) confirming delivery to the Committees and the Commission on the same date. The regulation will be deemed withdrawn, if the Department does not return the regulation or provide the required notification by that date.

If you have any questions, please contact me at 783-5506 or bobn@irrc.state.pa.us.

Sincerely,

Robert E. Nyce
Executive Director
wbg
Enclosure
cc: Honorable Raymond Bunt, Jr., Majority Chairman, House Agriculture & Rural Affairs Committee
Honorable Italo S. Cappabianca, Democratic Chairman, House Agriculture & Rural Affairs Committee
Honorable Noah W. Wenger, Vice Chairman, Senate Agriculture & Rural Affairs Committee
Honorable Patrick J. Stapleton, Minority Chairman, Senate Agriculture & Rural Affairs Committee
David J. DeVries, Esq., Office of Attorney General
Dr. Phillip C. DeBok
Dr. John I. Enck, Jr.
Sandra Stoner, Esq., Office of General Counsel
David Kennedy, Esq., Department of Agriculture

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE
REGULATORY REVIEW ACT

I.D. NUMBER:

SUBJECT:

AGENCY:

TYPE OF REGULATION

_____ 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
_____	_____	HOUSE COMMITTEE ON
_____	_____	
_____	_____	SENATE COMMITTEE ON
_____	_____	
_____	_____	INDEPENDENT REGULATORY REVIEW COMMISSION
_____	_____	ATTORNEY GENERAL
_____	_____	LEGISLATIVE REFERENCE BUREAU

Regulatory Analysis Form

This space for use by IRRC

RECEIVED

2000 SEP 14 PM 3:29

REGULATORY REVIEW COMMISSION

(1) Agency

Pennsylvania Department of Agriculture

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

2-128

IRRC Number: 2088

(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
Final Order Adopting Regulation X
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).

Regulatory Analysis Form

(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific 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 one of the few states 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.

Regulatory Analysis Form

(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 cattle and bison 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.

Regulatory Analysis Form

(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 additional approvals associated with these regulations. Approval by the State Veterinarian for importation and vaccination of domestic animals was already required. The amended regulations merely clarify the process.

(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)

_____ _____
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
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 _____

9/12/00
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

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NOTICE OF FINAL 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

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 authority conferred by 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 amends 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).

Authority

The Department has the power and authority to amend and adopt these regulations. This authority includes:

(1) The general duty to implement the policy of the Act set forth at Section 2 (3 Pa.C.S. § 2302), which is to "... assure the health and welfare of animals kept in captivity, to prevent and control diseases and dangerous substances that may threaten the safety of animals and humans, and to provide for desirable management practices for the production, keeping and use of domestic animals."

(2) The general authority to regulate the keeping and handling of domestic animals to exclude or contain dangerous transmissible diseases and hazardous substances and to test and treat domestic animals exposed to or contracting a dangerous transmissible disease or hazardous substance as delineated at Sections 5 and 29 (3 Pa.C.S. §§ 2305 and 2329) of the Act, and

4/12/00

(3) The specific authority and duties conferred upon the Department by Sections 21, 23 and 25 of the Act (3 Pa.C.S. §§ 2321, 2323 and 2325)(relating to detection, containment or eradication of certain diseases). Section 21(a) of the Act (3 Pa.C.S. § 2321(a)) designates Brucellosis and Equine Infection Anemia ("EIA") as dangerous transmissible diseases. Section 21(e) of the Act (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 (3 Pa.C.S. § 2325) further defines the Department's authority to prescribe testing techniques and regulate the use of vaccines. Section 23 of the Act (3 Pa.C.S. § 2323) sets forth the Department's authority to establish health standards for the importation or intrastate movement of domestic animals in this Commonwealth

Need for the Regulations

These amendments are necessary 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 (3 Pa.C.S. § 2302) states that "animal health is of major economic interest in this Commonwealth." In addition, Section 2 of the Act (3 Pa.C.S. § 2302) 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 for

desirable management practices for the production, keeping and use of domestic animals" (3 Pa.C.S. § 2302).

Equine Infectious Anemia

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, for other than immediate slaughter, 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, requiring a Coggins Test in addition to or instead of an ELISA test 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.

Brucellosis

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 (false positives). 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 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.

In summary, the Department is satisfied there is a need for the regulations, and that they are otherwise consistent with Executive Order 1996-1, "Regulatory Review and Promulgation."

Comments

Notice of Proposed Rulemaking was published at 30 *Pennsylvania Bulletin* 768 (February 12, 2000). The Notice of Proposed Rulemaking did not contain a statement regarding the length of the public comment period. A Notice, clarifying the length of the public comment period, providing that the public comment period was the statutorily required 30 days, was published at 30 *Pennsylvania Bulletin* 1255 (March 4, 2000).

Comments were received from the Independent Regulatory Review Commission (IRRC).

Comment: IRRC objected to two provisions of the proposed regulations, stating that the provisions were not consistent with the Department 's statutory authority and the

intent of the General Assembly. The sections objected to were Section 3.103(d) of the proposed amendments to Chapter 3 of Title 7 (7 Pa.Code § 3.103)(regarding designation of other tests as acceptable), and Section 7.72(a) of the proposed amendments to Chapter 7 of Title 7 (7 Pa.Code § 7.72(a))(regarding designation of vaccine). Both sections provide in whole or in part, that the Secretary may designate a new testing procedure or vaccine by publishing an order in the *Pennsylvania Bulletin*, provided a proposed regulation is published within one year of such order.

Response: Upon further review, the Department agrees with this objection and will delete any language regarding the Secretary's ability to designate a new test or vaccine through issuance and publication of an order in the *Pennsylvania Bulletin*. Although the Department believes it is inconsistent with the purpose of the Act to require the Department to wait until regulations are published in order to approve and use a new and effective vaccine or testing technique which could eradicate, prevent or control diseases and thereby assure the health and welfare of domestic animals and humans, the regulatory provisions the Department seeks to amend implement Section 25 of the Domestic Animal Act (3 Pa.C.S. § 2325), which requires the Department to promulgate regulations governing diagnostic agents and vaccines.

Comment: IRRC commented that Section 3.103(c) (regarding inconsistent results) and Section 7.72(c) (regarding official vaccination) need to be clarified. IRRC's concern is that neither section sets forth the procedure the regulated community must follow in order to comply with those sections of the regulations. IRRC suggested the

regulations should outline the procedure to be followed or provide a cross reference to an existing regulation if there is one.

Response: The Department agrees with this comment. The Department has revised Section 3.103(c) and 7.72(c) to address IRRC's concerns. A person seeking permission to import an equid with inconsistent tests results into the Commonwealth or seeking permission for the vaccination of cattle over the age of 12 months must do so in writing on a form provided by the Department, and must state the reasons for and facts relating to the request. The State Veterinarian shall then provide a written approval or denial of such request. In addition, we added the same language to Section 7.72(b), which also required approval of the State Veterinarian.

Comment: IRRC had an additional comment, again concerning clarity, with regard to Section 7.72(c) (relating to official vaccination). The language of the section states that a vaccination given to cattle over 12 months of age is not considered an official vaccination. IRRC suggested that the Department either cross reference the federal code of regulations, at 9 CFR 78.1 or define "official vaccination".

Response: The Department agrees that the term "official vaccination" and what constitutes an "official vaccination" needs to be clarified. In order to clarify this term the Department has added three definitions to the regulations. The Department defines "official vaccination", "official calfhood vaccination" and "adult vaccination". An "adult vaccination" may only be given and will only constitute an "official vaccination" with the

express written permission of the State Veterinarian. The Department has also outlined the procedure for obtaining the express written permission of the State Veterinarian.

Comment: IRRC pointed out a typographical error in Section 7.73(c). IRRC suggested the Department should delete "or" from the last sentence, leaving "and" in its place.

Response: This is not a typographical error. The identification on the vaccination report may be the official State vaccination tag, the breed registration number, the registration number of the dam or any combination thereof. The Department has changed the wording of the sentence to better reflect this intent.

FISCAL IMPACT

Commonwealth

The final-form 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 final-form regulations will impose no costs and have no fiscal impact upon political subdivisions.

Private Sector

The final-form 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 final-form 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 numbers, 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 final-form 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.

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.

REGULATORY REVIEW

Under Section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), the Department submitted a copy of the Notice of Proposed Rulemaking published at 30 *Pennsylvania Bulletin* 768 (February 12, 2000), 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 for review and comment. In compliance with § 5(b.1) (71 P.S. § 745.5(b.1)), the Department also provided the Commission and the Committees with copies of all comments received, as well as other documentation.

In preparing these final-form regulations, the Department has considered all comments received from the Commission, the Committees and the public.

These final-form regulations were (deemed) approved by the House Agricultural and Rural Affairs Committee on _____, were (deemed) approved by the Senate Agriculture and Rural Affairs Committee on _____, and were (deemed) approved by the Commission on _____.

FINDINGS

The Department of Agriculture finds the following:

(1) Public notice of its intention to adopt the regulations encompassed by this Order has been given under Sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240)(45 P.S. §§ 1201 and 1202) and their attendant regulations at 1 Pa.Code, Sections 7.1 and 7.2.

(2) A public comment period was provided as required by law and all comments received were considered.

(3) The modifications that were made to these regulations in response to comments received do not enlarge the purpose of the proposed regulations published at 30 *Pennsylvania Bulletin* 768 (February 12, 2000).

(4) The adoption of the regulations in the manner provided in this Order is necessary and appropriate for the administration of the authorizing statute.

ORDER

The Department of Agriculture, acting under authority of the authorizing statute, orders the following:

(1) The new regulations of the Department of Agriculture at 7 Pa. Code Chapter 3 (regarding Health Requirements for Importation and Intrastate Transportation of Animals) and Chapter 7 (regarding Brucellosis Regulations) are adopted as set forth in Annex "A" attached hereto.

(2) The Secretary of Agriculture shall submit this Order and Annex "A" to the Office of General Counsel and to the Office of Attorney General for review and approval as to legality and form, as required by law.

(3) The Secretary of Agriculture shall certify this Order and Annex "A" and deposit them with the Legislative Reference Bureau, as required by law.

(4) This Order shall take effect 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 immunosorbent assay test (commonly called The ELISA Test), conducted by a federally approved laboratory within 12 months prior to date of entry

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(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. A person seeking such permission shall do so in writing on a form provided by the Department setting forth the test dates, results of the tests and any other pertinent information. The Pennsylvania State Veterinarian may request additional information as may be necessary to assure the health of the animal and to prevent and control diseases and dangerous substances that may threaten the health and safety of animals and humans. The Pennsylvania State Veterinarian shall provide a written approval or denial of such a request within 3 working days of receiving the written request and all necessary information pertaining thereto.

(d) *Exception.* Foals under 6 months of age, accompanied by dam with negative agar gel immunodiffusion test or a negative enzyme linked immunosorbent assay test 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 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)

* * *

Official vaccination An official calfhood or adult vaccination

* * *

Official adult vaccination Strain RB 51 vaccine administered to female cattle or bison over the age of 12 months (365 days). Such vaccination may only be administered with the express guidance and written permission of the Pennsylvania State Veterinarian

* * *

Official calfhood vaccination - Strain RB 51 vaccine administered to female cattle or bison from 4 to 12 months of age

* * *

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)(7 Pa.Code §§ 7.71 - 7.74), 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

(b) *State veterinarian approval required.* Strain 19 vaccine may only be used with the express written permission of the Pennsylvania State Veterinarian. All requests for permission to administer Strain 19 vaccine must be made in writing on a form provided by the Department. The Pennsylvania State Veterinarian may request additional

information as may be necessary to assure the health of the animal and to prevent and control diseases and dangerous substances that may threaten the health and safety of animals and humans. The Pennsylvania State Veterinarian shall provide a written approval or denial of such a request within 3 working days of receiving the written request and all necessary information pertaining thereto.

(c) *Official vaccination.* An official vaccination shall consist of [an approved] Strain RB 51 vaccine administered to female calves or bison from 4 through [8] 12 months of age ([120 – 269] 120-365 days). A vaccination of female cattle or bison 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. All requests to vaccinate cattle over the age of 12 months shall be made in writing on a form provided by the Department. The request shall set forth the reasons for the request, the vaccine to be administered and the age of the animal at the time of the request. The Pennsylvania State Veterinarian may request additional information as may be necessary to assure the health of the animal and to prevent and control diseases and dangerous substances that may threaten the health and safety of animals and humans. The Pennsylvania State Veterinarian shall provide a written approval or denial of such a request within 3 working days of receiving the written request and all necessary information pertaining thereto.

(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] officially vaccinated animals.

(a) *Tattoo required.* Veterinarians [vaccinating calves] administering official calfhood or official adult vaccinations shall tattoo [with] in the right ear of the animal 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 vaccinated animal has an official breed registry tattoo, an official state vaccination tag shall not be required.

(c) *Identification on vaccination report.* [Calves] Officially vaccinated animals shall be identified on the vaccination report by [the] date of birth and an official [Pennsylvania ear tag in the right ear,] state vaccination tag number [and, when applicable], their breed registration number and/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] animal. 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
September 14, 2000

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

RE: FINAL-FORM REGULATION
Department of Agriculture
Bureau of Animal Health & Diagnostic Services
7 Pa. Code Chapters 3 & 7: Health Requirements for Importation & Intrastate Transportation of Animals & Brucellosis
I.D. No. 2-128
Proposed Rulemaking: 30 *Pennsylvania Bulletin* 768 (February 12, 2000)
Final-Form Regulation Approved by the Office of General Counsel: September 12, 2000

Dear Sir or Madam:

Please find enclosed a copy of the above-referenced final-form regulation (Preamble and Annex "A"). Copies of the Notice of Proposed Rulemaking and Regulatory Analysis Form are also enclosed.

I respectfully request the Independent Regulatory Review Commission review and approve the above-referenced final-form regulation in accordance with the requirements and procedures of the Regulatory Review Act.

This Department's responses to the comments received from the public, the Legislature and the Independent Regulatory Review Commission with respect to the proposed regulation are set forth in the Preamble to the final-form regulation. Copies of this final-form regulation have been delivered to applicable Legislative Committees (the House and Senate Committees for Agriculture and Rural Affairs), and have been mailed or delivered to each commentator on this date.

The Department will provide you with any assistance you may require to facilitate a thorough review of this final-form regulation. Thank you for your attention to this matter.

Sincerely,

David C. Kennedy
Assistant Counsel

Enclosures

2301 NORTH CAMERON STREET
HARRISBURG, PA 17110-9408
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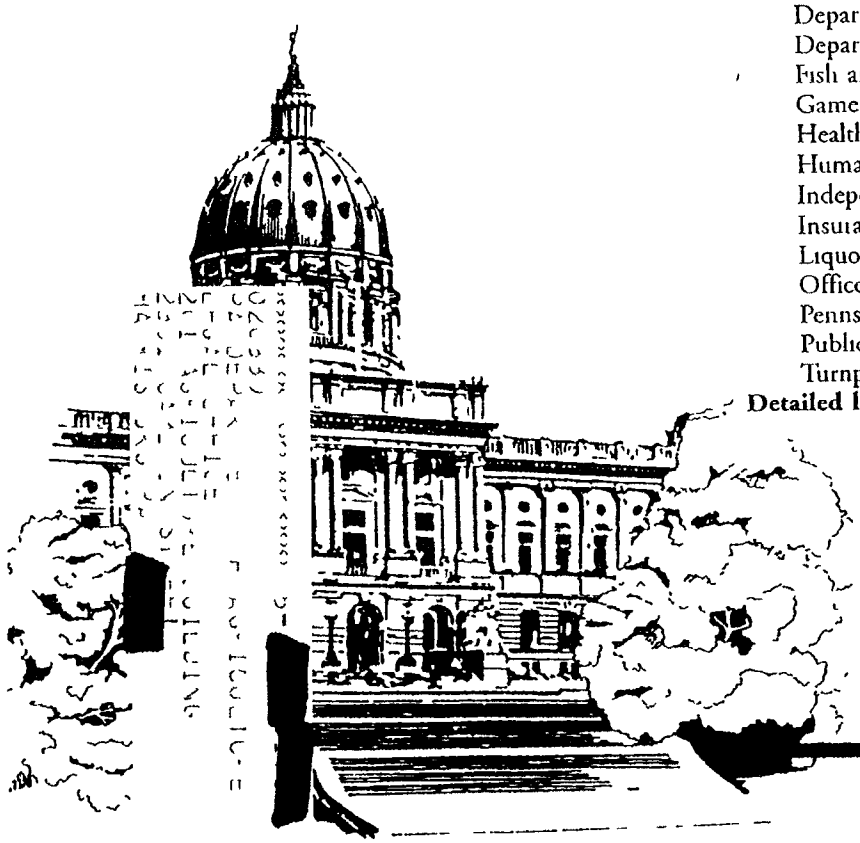
FAX 717-787-1270

PENNSYLVANIA BULLETIN

Volume 30 Number 7
Saturday, February 12, 2000 • Harrisburg, Pa.
Pages 755—856

Agencies in this issue:

Detailed list of contents appears inside.



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PROPOSED RULEMAKING

DEPARTMENT OF AGRICULTURE

[7 PA. CODE CHS. 3 AND 7]

Importation and Intrastate Transportation of Animals; Brucellosis

The Department of Agriculture (Department), under the specific authority conferred by the Domestic Animal Law (act), 3 Pa.C.S. §§ 2302, 2321, 2323 and 2325 proposes to amend §§ 3 103, 7.1, 7.47 and 7.72—7.74. These proposed 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 2302 of the act (relating to finding, policy and purpose) states that "animal health is a major economic interest in the Commonwealth." In addition, section 2302 of the act 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 2321(a) of the act (relating to dangerous transmissible diseases) designates Brucellosis and EIA as dangerous transmissible diseases. Section 2321(e) of the act 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 2325 of the act (relating to use of biologicals, antibiotics, genetic material, chemicals, diagnostic agents and other substances) further defines the Department's authority to prescribe testing techniques and regulate the use of vaccines. Section 2323 of the act (relating to health requirements) sets forth the Department's authority to establish health standards for the importation or intra-State movement of domestic animals in this Commonwealth.

Background

EIA is an infectious disease of equines caused by a virus. The current regulation, in § 3.103 (relating to agar gel immunodiffusion blood test), 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 this 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. This delay discourages owners from breeding, racing or carrying on other activities economically beneficial to the Commonwealth and the equine industry in this Commonwealth. 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 this Commonwealth and are economically inefficient. Therefore, the Department proposes to amend Chapter 3 (relating to health requirements for importation and intrastate transportation of animals) 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 (Strain 19)—prescribed by regulation obsolete and relatively inefficient in the management of this disease. 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 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 this 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 Strain 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 §§ 3.103, 7.1, 7.47 and 7.72—7.74 to effectuate the changes previously discussed.

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

Summary of Major Features

Proposed § 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.

The proposal to § 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 this Commonwealth. The amendments to this section allow the Department to accept the results of tests other than the Coggins Test. Specifically, the proposed amendments allow the Department to accept the results of 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 1 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.

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

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

Proposed § 7.72. (relating to procedure) deletes the sentence in subsection (a) referencing Strain 19 and designates Strain RB 51 vaccine as the only Brucellosis vaccine authorized for use within this Commonwealth. In addition, the proposed 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 1 year of the effective date of the order. Subsection (b) is retitled and allows Strain 19 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.

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

Proposed § 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 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 Strain 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 Strain 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 EIA through the use of an ELISA Test. The Department 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 will impose no costs and have no fiscal impact upon political subdivisions.

Private Sector

The proposed amendments 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 Strain RB 51 vaccine. The proposed amendments will potentially affect approximately 1,800 accredited veterinarians who may be required to vaccinate calves for Brucellosis. However, these veterinarians, the Commonwealth and the industry would eventually be forced to use Strain 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 when horses that were entered in a race were denied entrance to the track because of failure to meet the Commonwealth's rigid and unnecessary EIA requirements. These instances result in lost opportunities to race and to recoup training expenses.

General Public

The proposed amendments 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. Strain 19 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. The equine industry in this Commonwealth 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 will not result in an appreciable increase of paperwork. The Department has already developed the appropriate forms and procedures to administer the EIA testing program and the Brucellosis vaccination program. Only small changes will be required.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on January 31, 2000, the Department submitted a copy of these proposed amendments to the Independent Regulatory Review Commission (IRRC) 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, the Department has provided IRRC 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.

Under section 5(g) of the Regulatory Review Act, if IRRC has an objection to any portion of the proposed amendments, it will notify the Department within 10 days after the close of the Committees' review period. The 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, PA 17110-9408; Attn: Dr. Phillip Debok (717) 783-8555.

Effective Date

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

SAMUEL E. HAYES, Jr.,
Secretary

Fiscal Note: 2-128. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 7. AGRICULTURE

PART I. BUREAU OF ANIMAL HEALTH AND DIAGNOSTIC SERVICES

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

Subchapter A. GENERAL PROVISIONS

§ 3.1. Definitions.

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

* * * * *

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

* * * * *

***Secretary*—The Secretary of the Department.**

* * * * *

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

EQUINE INFECTIOUS ANEMIA

§ 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] the** Coggins Test), conducted by a Federally approved laboratory within 12 months prior to date of entry.

(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 may not be imported into this Commonwealth unless permission is granted by the Pennsylvania State Veterinarian.**

(d) ***Designation of other tests as acceptable.*** **If 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 this 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 will, within 1 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 this Commonwealth. If the Secretary determines that some other brucellosis vaccine is appropriate for use in cattle in this 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 will, within 1 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.

[(b)] (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) will 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 is not 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] the owner's records and one copy retained by the veterinarian.

[Pa B Doc No 00 240 Filed for public inspection February 11, 2000, 9 00 a m]

[7 PA. CODE CH. 138i]

Farm Safety and Occupational Health Tuition Assistance Program

The Department of Agriculture (Department), under the specific authority conferred by sections 5 and 6 of the Farm Safety and Occupational Health Act (act) (3 P. S. §§ 1905 and 1906), proposes to adopt Chapter 138i (relating to Farm Safety and Occupational Health Tuition Assistance Program (Program) Section 5 of the act delineates the duties of the Secretary of Agriculture (Secretary) and directs the Secretary to ". . adopt and promulgate any regulations which may be necessary to implement and administer the act" Section 6(a) of the act allows the Secretary to establish a grant program to provide tuition assistance to rural emergency service providers, farmers, members of farm families, farm laborers and others involved in agricultural production to attend farm safety and occupational health training and emergency response programs. Section 6(d) of the act requires the Secretary to adopt and promulgate regulations to govern the awarding of grants under section 6 of the act.

The proposed regulations establish the procedures governing the submission, processing and review of grant applications. In addition, they set forth the documentation required to accompany applications, eligibility criteria, criteria for determining grant amounts and verification, cancellation, notification and reporting requirements.

Background

This Commonwealth's approximately 51,000 farms are the foundation of a $35 billion industry, employing over 650,000 workers in farming and related services, food processing and food wholesale and retail sales. The National Safety Council reports agriculture as this Nation's most hazardous industry with a work death rate 22% higher than the second most hazardous industry, mining and quarrying. Farming accounts for over 80% of agriculture's injury toll From 1990 through 1995 at least 249 Commonwealth citizens have lost their life to hazards associated with farming. The victims included 17 infants, toddlers and preschoolers—all under 5 years of age. Another 29 victims were at least 75 years of age. The oldest was 89 years old. In 1994, a Statewide survey

showed one in every ten farm operations in the State had at least one recordable work-related injury. Even more startling was that approximately 5% of those injuries resulted in some type of permanent disability to the victim. The numbers evidence the need for farm safety and occupational health programs. In 1994 alone, there was a total of 5,100 injuries and 250 permanent disability injuries related to farming

The purpose of the Program is to provide tuition assistance to rural emergency service providers and members of the farm community to assist them and encourage their attendance at farm safety and occupational health programs and seminars intended to facilitate avoidance and elimination of farming hazards. The Program will compliment the Farm Safety and Occupational Health Grant Program, which exists as a statement of policy in Chapter 138g, but will be supplanted by regulations that are currently in the proposal stage and the proposed Farm Safety and Occupational Health Developmental and Instructional Program intended to be established as Chapter 138j.

(*Editor's Note*. For the text of the proposed rulemaking concerning Chapter 138k (relating to Farm Safety Occupational Health Grant Program) see 30 Pa.B 781 (February 12, 2000) For the text of the proposed rulemaking concerning Chapter 138j (relating to Farm Safety and Occupational Health Developmental and Instructional Program) see 30 Pa B. 776 (February 12, 2000))

In the interest of continuing to carry out its statutory duties and promoting the development and implementation of technical and educational farm safety programs that benefit the farming community, the Department has promulgated this proposed rulemaking. This proposed rulemaking is intended to establish reasonable guidelines, standards, criteria and procedures for the administration and implementation of grants under the Program

Summary of Major Features

Proposed § 138i.1. (relating to authority) delineates the Secretary's authority to establish the Program and sets forth the Secretary's power and duty to adopt and promulgate regulations to govern the awarding of grants under section 6 of the act

Proposed § 138i.2. (relating to program objectives) sets forth that the objective of the Program is to provide tuition assistance to rural emergency service providers, farmers, members of farm families, farm laborers and others involved in agricultural production, to allow them to attend farm safety and occupational health programs and emergency response programs. It stipulates that grants will be awarded on a funds available basis and through a competitive application process.

Proposed § 138i.3. (relating to definitions) defines various recurring terms such as "Board," "farm," "farm laborers," "members of farm families," "project," "rural emergency service provider" and "Secretary."

Proposed § 138i.4. (relating to limitations on grants) defines who is an eligible applicant, describes the proper use of grant funds and sets forth the procedure for substitution of person or project. This section specifically delineates the total dollar amount an eligible applicant may be awarded in tuition assistance. Each applicant may receive up to $100 in tuition assistance per calendar year. This section also sets forth restrictions on the use of grant funds.

Proposed § 138i.5. (relating to general conditions) provides that a grant recipient will be required to sign the approved grant application form, which shall then constitute the grant agreement. Additionally, this section sets forth default, verification and failure to verify provisions.

Proposed § 138i.6. (relating to applications generally) provides that an eligible applicant shall submit an application prepared by the Department and provides information regarding how to obtain an application and who to contact for assistance. This section notifies the applicant that additional information may be requested by the Secretary and that the application shall be received prior to the date of the project the applicant wishes to attend.

Proposed § 138i.7. (relating to processing of applications) describes the procedure for processing applications and delineates review and approval powers of the Secretary and the Board. This section sets forth processing requirements for applications which are incomplete or contain inaccurate information

Proposed § 138i.8. (relating to review of application) delineates the specific information that shall be included in a grant application, defines applicant eligibility criteria and sets forth the factors to be considered by the Secretary in selecting grant recipients.

Proposed § 138i 9. (relating to conflicts of interest) sets forth the legal provisions a Board member shall follow to avoid a conflict of interest, when the Board member or his agent or employe is a grant applicant.

Proposed § 138i.10. (relating to notice of disposition of applications) sets forth the type of notice required and the time periods for notification.

Proposed § 138i 11. (relating to recordkeeping) describes the type of records which shall be kept by the grant recipient and the time period for which those records shall be kept. This section also provides for inspection and audit of those records by the Department.

Proposed § 138i.12. (relating to grant cancellation) provides for the cancellation of a grant when funds have not been spent in accordance with the grant agreement or this chapter or upon failure of the recipient to satisfy the verification requirements of this chapter.

Proposed § 138i.13. (relating to right of recovery) sets forth the Department's right to make a claim for grant money not expended in accordance with the act, the grant agreement or the regulations.

These proposed regulations set forth the basic process by which the Department will exercise its administrative discretion with respect to the expenditure of the funds appropriated to it by the General Assembly for Farm Safety and Occupational Health Programs.

Fiscal Impact

Commonwealth

The proposed regulations will impose minimal costs and have minimal fiscal impact upon the Commonwealth including projected increases in program costs. The Department has an appropriation for use in developing the various Farm Safety and Occupational Health Grant Programs allowed under section 6 of the act. The Secretary, with the advice of the Board, will determine the amount of funds to allocate to each grant program promulgated under section 6 of the act.

Political Subdivisions

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

Private Sector

The proposed regulations will impose minimal costs on those organizations or individuals who are interested in applying for Program grants. The costs that may be associated with the regulations would involve the time spent to obtain and fill out a grant application. Organizations and individuals receiving grants would benefit by receiving funds to cover tuition costs associated with attending some farm safety and occupational health programs. The private sector may also benefit through the realization of reduced health care and occupational costs resulting from increased attendance at the educational and preventative programs espoused by the act and these proposed regulations.

General Public

The proposed regulations will impose no costs and have no fiscal impact on the general public. The farm community and the general public should benefit through the reduction of health care and occupational costs which are likely to result from increased attendance at educational and preventative programs such as those espoused by the act and these regulations.

Paperwork Requirements

The proposed regulations will not result in an appreciable increase of paperwork. The Department will have to develop a grant application form to administer the Program. However, the administrative provisions of the Program are very similar to the administrative provisions of the Farm Safety and Occupational Program and the Department has already developed a grant application form and grant agreement for use in administering the Farm Safety and Occupational Program and has administered that Program, under Chapter 138g, since 1996.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)) on January 31, 2000, the Department submitted a copy of these proposed regulations to the Independent Regulatory Review Commission (IRRC) 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 regulations, the Department has provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the agency in compliance with Executive Order 1996-1. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, if IRRC has an objection to any portion of the proposed regulations, it will notify the Department within 10 days after the close of the Committees' comment period. The 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 proposed 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, Farm Safety and Occupation Health Grant Program, 2301 North Cameron Street, Harrisburg, PA 17110-9408; Attn: John Tacelosky (717) 772-5217.

Effective Date

These proposed regulations will become effective upon publication as final-form in the *Pennsylvania Bulletin*.

SAMUEL E. HAYES, Jr.,
Secretary.

Fiscal Note: 2-123. (1) General Fund; (2) Implementing Year 1999-00 is $20,000; (3) 1st Succeeding Year 2000-01 is $20,000, 2nd Succeeding Year 2001-02 is $20,000; 3rd Succeeding Year 2002-03 is $20,000; 4th Succeeding Year 2003-04 is $20,000; 5th Succeeding Year 2004-05 is $20,000; (4) Fiscal Year 1998-99 $N/A; Fiscal Year 1997-98 $N/A; Fiscal Year 1996-97 $N/A; (7) Farm Safety; (8) recommends adoption.

Annex A

TITLE 7. AGRICULTURE

PART V-C. FARMLAND AND FOREST LAND

CHAPTER 138i. FARM SAFETY AND OCCUPATIONAL HEALTH TUITION ASSISTANCE PROGRAM

Sec
138i.1 Authority
138i.2 Program objectives
138i.3 Definitions
138i.4 Limitation on grants
138i.5 General conditions
138i.6 Applications
138i.7 Processing of applications
138i.8 Review of applications
138i.9 Conflict of interest
138i.10 Notice of disposition of application
138i.11. Recordkeeping
138i.12 Grant cancellation
138i.13 Right of recovery

§ 138i.1. Authority.

The act bestows upon the Secretary the power and duty to "... administer the provisions of this act and .. adopt and promulgate any regulations which may be necessary to implement and administer this act" (3 P. S. § 1905). In addition, section 6(a) of the act (3 P. S. § 1906(a)) allows the Secretary to establish a grant program to provide tuition assistance to certain individuals and groups to attend farm safety and occupational health training and emergency response programs. Section 6(d) of the act directs the Secretary to adopt and promulgate regulations to govern the awarding of grants under section 6 of the act.

§ 138i.2. Program objectives.

(a) *Purpose.* The purpose of the Program is to provide tuition assistance to rural emergency service providers, farmers, members of farm families, farm laborers and others involved in agricultural production, to allow them to attend farm safety and occupational health projects and emergency response programs.

(b) *Competitive program.* The Program is competitive. Grant applications and related documents will be collected by the Department and reviewed by the Secretary or a designee. Grants will be awarded annually.

(c) *Funds available basis.* Grants will not be awarded unless funds are available.

§ 138i.3. Definitions.

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

Act—The Farm Safety and Occupational Health Act (3 P. S. §§ 1901—1915).

Agricultural production—The production for commercial purposes of crops, livestock and livestock products. The term includes the processing or retail marketing of these crops, livestock or livestock products if more than 50% of the processed or merchandised products are produced by the farmer.

Board—The Farm Safety and Occupational Health Advisory Board.

Department—The Department of Agriculture of the Commonwealth.

Farm—Land in this Commonwealth which is being used for agricultural production, including all farm structures, buildings, facilities and farm family residences situated on the land.

Farmer—A person who is engaged in agricultural production for commercial purposes.

Farm laborer—An individual employed by a farmer in raising, cultivating, fertilizing, seeding, planting, pruning, harvesting, gathering, washing, sorting, weighing or handling, drying, packing, packaging, grading, storing or delivering to market in its unmanufactured state, an agricultural commodity as defined in 3 Pa.C.S. Chapter 45 (relating to Agricultural Commodities Marketing) or a farm product as defined in 1 Pa.C.S. § 1991 (relating to definitions).

Members of farm families—Any son, daughter or spouse of a farmer or any lineal relation of the farmer who works on the farm or any collateral relation of the first degree who works on the farm.

Person—An individual, partnership, corporation, association or other form of business enterprise.

Program—The Farm Safety and Occupational Health Tuition Assistance Program.

Project—Any course, training, program, activity or event pertaining to farm safety and occupational health or emergency response programs.

Rural emergency services providers—An employe, agent, member or officer of a paid or volunteer fire company, ambulance service or rescue squad located in or servicing a rural area of this Commonwealth which is regularly engaged in providing emergency medical care and transportation, fire protection services or rescue services.

Secretary—The Secretary of Agriculture of the Commonwealth.

Volunteer ambulance services—A nonprofit chartered corporation, association or organization located in this Commonwealth and which is regularly engaged in the services of providing emergency medical care and transportation of patients.

Volunteer fire company—A nonprofit chartered corporation, association or organization located in this Commonwealth which provides fire protection services and other voluntary emergency services within this Commonwealth.

Volunteer rescue squad—A nonprofit chartered corporation, association or organization located in this Commonwealth which provides rescue services within this Commonwealth.

§ 138i.4. Limitation on grants.

(a) *Tuition assistance.* The Program will award grants to provide tuition assistance to approved applicants under this chapter. The Program will provide grants of up to $100 per calendar year to an approved applicant.

(b) *Eligible applicants.* An eligible applicant may apply for more than one Program grant per year. However, an eligible applicant may not be awarded more than $100 in tuition assistance grants in any calendar year.

(c) *Recipient's use of Program grant funds.* A recipient of a Program grant may only use the funds to cover or supplement the cost of tuition for the specific project delineated in the recipient's grant application.

(d) *Substitution of person.* Once an applicant has been approved to receive tuition reimbursement for a specific project, no other person or project may be substituted. Any change in person or project shall require submission and review of a new application.

(e) *Eligible courses, programs, training, activities or events.* Program grants may be awarded to cover or supplement tuition for the types of projects delineated in section 4(b) of the act (3 P. S. § 1904(b)).

(f) *Additional limitations.*

(1) Program grant funds may only be used to provide tuition assistance for farm safety and occupational health projects or emergency response programs administered within the geographic boundaries of this Commonwealth.

(2) Program grant funds may not be used to cover the cost of travel, lodging or any other expenses incurred by the grant recipient other than the cost of tuition.

(3) Program grant funds may not be used for or applied to any training, programs, activities, certification or licensing requirement or events pertaining to the Pennsylvania Pesticide Control Act of 1973 (3 P.S. §§ 111.21—111.60) or Chapters 128 and 128a (relating to pesticides, and chemsweep pesticide disposal program—statement of policy).

(4) Program grant funds shall be awarded to reimburse the tuition expenses of an approved applicant who submits the documentation required by this chapter.

§ 138i.5. General conditions.

(a) *Grant agreement.* The approved, signed application for a Program grant shall constitute the grant agreement. The recipient of a Program grant shall sign the application which shall set forth the amount of the grant and other terms and conditions as the Department may reasonably require. Upon completion of all the terms of the agreement, a reimbursement check will be issued in the name of the recipient and mailed to the address indicated on the recipient's approved and signed application.

(b) *Default.* Any recipient of a Program grant who fails to abide by the terms of the grant agreement or the provisions of the act or this chapter shall be in default. The Secretary may waive a default after consultation with the Board in the event of a physical disability suffered by the recipient or as a result of other extenuating circumstances.

(c) *Verification.* To receive a Program reimbursement payment, a recipient shall, within 2 weeks of the completion of the specific project delineated in the recipient's grant application, submit to the Department a final report which includes a written receipt evidencing the cost of tuition and records of any other pertinent documentation evidencing the grant recipient's attendance and the program agenda. At the same time, the applicant shall also submit a narrative report of at least one page but not more than two pages, describing the effectiveness of the project and the experience gained and personal knowledge acquired.

(d) *Failure to verify.* If the required receipts, records and documentation are not submitted within the 2 week period, the Program grant recipient shall be deemed to have defaulted. The Secretary may direct that no Program grant funds be paid to the defaulting recipient. The Secretary may extend the verification deadline if the Secretary determines the grant recipient has made a reasonable effort to verify, but the verification was incomplete, or for extenuating circumstances.

§ 138i.6. Applications.

(a) *Application required.* An interested rural emergency service provider, farmer, member of a farm family, farm laborer or anyone else involved in agricultural production within this Commonwealth, may submit a grant application to the Department.

(b) *Obtaining an application and assistance.* An application for a grant under this chapter shall be made on a form prepared by the Department For applications and for assistance, contact the Farm Safety and Occupational Health Grant Program, Department of Agriculture, 2301 North Cameron Street, Harrisburg, Pennsylvania 17110

(c) *Additional information.* The Secretary or a designee may require an applicant to submit additional documentation to complete, verify or clarify the application

(d) *Application deadline.* Applications for grants under this chapter shall be received by the Department prior to the date of the project the applicant wishes to attend

§ 138i.7. Processing of applications.

(a) *Review by the Secretary.* Upon receipt of an application for a Program grant and the required supporting documentation, the Secretary or a designee will review this information for completeness and accuracy. The Secretary or a designee has the power to approve, approve with special conditions or reject applications and issue grants in accordance with the general considerations and criteria of the act and this chapter. If the Secretary or a designee determines the application is incomplete or inaccurate, final processing of the application may be discontinued or additional data may be requested If additional data is requested, processing of the application will cease until the applicant supplies the requested data. The Secretary or a designee will terminate the processing of an incomplete application when the additional data requested is not supplied within 10 days of the request for such data. The Secretary or a designee may exercise judgement in approving applications and in determining the distribution of grants so that the widest possible audience becomes acquainted with farm safety and occupational health practices and techniques espoused by the act and this chapter. The Secretary or a designee may impose restrictions or special conditions upon the issuance of a grant.

(b) *Board.* The Board shall recommend program priorities to the Secretary. Additionally, the Board shall recommend the amount of funds to be allocated for Program grants.

§ 138i.8. Review of applications.

(a) *Evaluation.* The Secretary or a designee will evaluate an application based on the applicant eligibility and grant application requirements, as well as the factors in the act and this chapter.

(b) *Applicant eligibility.* To be eligible for a Program grant, the applicant shall be a rural emergency service provider, farmer, member of a farm family or farm laborer or be otherwise involved in agricultural production. An emergency service provider shall submit an application for each individual member for which it wishes to receive a Program grant. Each member for which it receives a Program grant shall comply with the criteria established by the act and this chapter, including the verification criteria.

(c) *Grant application requirements.* An application for a Program grant will not be considered by the Secretary or a designee unless the following items are attached:

(1) A detailed description of the farm safety project to be attended by the applicant, including documentation delineating the focus of the project.

(2) A reasonable and accurate statement of the estimated or actual cost of tuition

(3) Information regarding the skills, knowledge or experience to be gained from the project.

(4) Documentation regarding the name and location of the person administering the project.

(d) *Factors.* Factors to be considered by the Secretary or a designee in selecting grant recipients include the following:

(1) The relevance of the project to farm safety or rural health issues.

(2) The innovativeness of the project.

(3) The effect the project will have on hazard elimination.

(4) The scope of the project and how it relates to program components delineated in section 4(b) of the act (3 P. S. § 1904(b)).

(5) The number and type of people or groups who will be affected by the project as described in the application.

(6) The impact upon and the value and benefits to the agricultural community of the project described in the application.

(7) The continual and progressive nature of the project and the benefits and knowledge gained therefrom.

(8) The value to those who work directly with farm accident victims.

(9) Whether the applicant has been the recipient of a Program grant within the same year.

(10) The availability of funding to the applicant from a source other than the Program.

(11) The priorities as the Secretary, in consultation with the Board, set in accordance with section 4(c) of the act

§ 138i.9. Conflict of interest.

A member of the Board may apply for a grant if all decisions regarding the grant application are subject to 65 Pa.C.S. § 1103(j)) (relating to restricted activities) and the action does not violate the State Adverse Interest Act (71 P. S. §§ 776.1—776.9) or 4 Pa. Code Chapter 7, Subchapter K (relating to code of conduct for appointed officials and State employees).

§ 138i.10. Notice of disposition of application.

(a) *Applications deemed complete.* The Secretary will notify grant applicants within 30 days of receipt of their completed grant application of a decision to approve, approve with special conditions or reject the grant. This notice will be sent by regular mail to the address indicated by the applicant on the grant application.

(b) *Applications deemed incomplete.* Within 30 days of receipt of a grant application, the Secretary or a designee will notify the applicant of a decision to reject the grant application or notify the applicant of a deficiency in the grant application and request additional data. If additional data is requested, notification shall be in writing and detail the additional data needed. The Secretary will follow the action prescribed in § 138i.7(a) (relating to processing of applications).

§ 138i.11. Recordkeeping.

A Program grant recipient shall maintain all receipts, supporting documents, final reports and other documents pertaining to the project and the Program grant. These records shall be retained for 1 year beginning at the conclusion of the project. The records shall be made available to the Department upon request

§ 138i.12. Grant cancellation.

A Program grant may be canceled by the Secretary upon a determination that the funds were not properly used, or upon failure of the recipient to satisfy the verification requirements of this chapter

§ 138i.13. Right of recovery.

The Department has the right to make a claim for and receive from the grant recipient moneys not expended in accordance with the act, the grant agreement of this chapter

[Pa.B. Doc. No. 00-241. Filed for public inspection February 11, 2000, 9:00 a.m.]

[7 PA. CODE CH. 138j]

Farm Safety and Occupational Health Developmental and Instructional Program

The Department of Agriculture (Department), under the specific authority conferred by sections 5 and 6 of the Farm Safety and Occupational Health Act (act) (3 P. S. §§ 1905 and 1906) proposes to adopt Chapter 138j (relating to Farm Safety and Occupational Health Developmental and Instructional Program) (Program). Section 5 of the act delineates the duties of the Secretary of Agriculture (Secretary) and directs the Secretary to "... adopt and promulgate any regulations which may be necessary to implement and administer the act." Section 6(c)(1) of the act allows the Secretary to establish a grant program for the purpose of awarding grants to the Pennsylvania Fire Academy, public and private colleges and universities, community colleges and vocational and technical schools which provide technical courses of instruction in farm safety and occupational health to emergency service providers and the farm community or which develop farm safety and occupational health training programs for implementation by the Department. Section 6(d) of the act requires the Secretary to adopt and promulgate regulations to govern the awarding of grants under section 6 of the act.

The proposed regulations establish the procedures governing the submission, processing and review of grant applications. In addition, this proposed chapter sets forth the documentation required to accompany the applications, eligibility criteria, criteria for determining grant amounts and verification, cancellation, notification and reporting requirements.

Background

This Commonwealth's approximately 51,000 farms are the foundation of a $35 billion industry, employing over 650,000 workers in farming and related services, food processing and food wholesale and retail sales. The National Safety Council reports agriculture as this Nation's most hazardous industry with a work death rate 22% higher than the second most hazardous industry, mining and quarrying. Farming accounts for over 80% of agriculture's injury toll. From 1990 through 1995, at least 249 Commonwealth citizens have lost their lives to hazards associated with farming. The victims included 17 infants, toddlers and preschoolers—all under 5 years of age. Another 29 victims were at least 75 years of age. The oldest was 89 years of age. In 1994, a Statewide survey showed one in every ten farm operations in the State had at least one recordable work-related injury. Even more startling was that approximately 5% of those injuries resulted in some type of permanent disability to the victim. The numbers evidence the need for farm safety and occupational health programs. In 1994 alone, there was a total of 5,100 injuries and 250 permanent disability injuries related to farming.

The act bestows upon the Secretary the authority to establish a grant program to provide grants of up to $30,000 to organizations, colleges, universities and vocational and technical schools which provide technical courses in farm safety and occupational health. The purpose of this Program is to provide funding for technical and educational programs, directed toward the farm community, which will increase awareness of potential farm hazards and provide information and technical support intended to facilitate avoidance and elimination of these hazards. This Program will compliment the Farm Safety and Occupational Health Grant Program, which exists as a statement of policy in Chapter 138g, but will be supplanted by regulations that are currently in the proposal stage. (*Editor's Note*: For text of the proposed rulemaking concerning Chapter 138k (relating to Farm Safety and Occupational Health Grant Program, see 30 Pa.B. 781 (February 12, 2000).)

Therefore, in the interest of continuing to carry out its statutory duties and promoting the development and implementation of technical and educational farm safety programs that benefit the farming community, the Department has promulgated this proposed rulemaking. This proposed rulemaking is intended to establish reasonable guidelines, standards, criteria and procedures for the administration and implementation of grants under the Program.

Summary of Major Features

Proposed § 138j.1 (relating to authority) delineates the Secretary's authority to establish this Program and sets forth the Secretary's power and duty to adopt and promulgate regulations to govern the awarding of grants under section 6 of the act.

Proposed § 138j.2 (relating to program objectives) sets forth that the objective of this grant Program is to fund the development and implementation of programs which will increase the awareness of farm safety and occupational health issues among the farm community. The awarding of the grant moneys are on a funds available basis and through a competitive application process.

Proposed § 138j.3 (relating to definitions) defines various recurring terms such as "farm," "farm laborer," "members of farm families," "emergency service provider" and "project."

Proposed § 138j.4 (relating to limitations on grants) describes the type of organization and project which is eligible for a grant award. This section specifically delineates that eligible applicants may be awarded financial assistance in amounts of up to $30,000. This section also sets forth restrictions on the use of grant funds.

Proposed § 138j.5 (relating to general conditions) provides that a grant recipient is required to sign a grant agreement and sets forth default, verification and failure to verify provisions.

Proposed § 138j.6 (relating to applications generally) provides that an eligible applicant shall submit an application prepared by the Department and provides information regarding how to obtain an application and who to contact for assistance. This section notifies the applicant that additional information may be requested by the Secretary and that the application deadline will be October 31, of the year preceding the fiscal year in which the grant funds are sought.

Proposed § 138j.7 (relating to processing of applications) describes the procedure for processing applications and delineates review and approval powers of the Secretary and the Board. This section sets forth processing requirements for applications which are incomplete or contain inaccurate information.

Proposed § 138j.8 (relating to review of application) delineates the specific information that must be included in a grant application, defines applicant eligibility requirements and sets forth the factors to be considered by the Secretary in selecting grant recipients.

Proposed § 138j.9 (relating to conflicts of interest) sets forth the legal provisions a Board member shall follow to avoid a conflict of interest, when the Board member or his agent or employe is a grant applicant.

Proposed § 138j.10 (relating to notice of disposition of applications) sets forth type of notice required and the time periods for notification.

Proposed § 138j.11 (relating to recordkeeping) describes the type of records which shall be kept by the grant recipient and the time period for which those records shall be kept. This section also provides for inspection and audit of those records by the Department.

Proposed § 138j.12 (relating to grant cancellation) provides for the cancellation of a grant when funds are not being or have not been spent in accordance with the grant agreement or these regulations.

Proposed § 138j.13 (relating to right of recovery) sets forth the Department's right to make a claim for grant money not expended in accordance with the act, the grant agreement or the regulations.

Proposed § 138j.14 (relating to deficits) provides that the Department's financial obligation is limited to the amount of the grant.

These proposed regulations set forth the basic process by which the Department may exercise its administrative discretion with respect to the expenditure of the funds appropriated to it by the General Assembly for Farm Safety and Occupational Health Programs.

Fiscal Impact

Commonwealth

The proposed regulations will impose minimal costs and have minimal fiscal impact upon the Commonwealth, including projected increases in program costs. The Department has an appropriation for use in developing the various farm safety and occupational health grant programs allowed under section 6 of the act. The Secretary with the advice of the Board will determine the amount of funds to allocate to each grant program promulgated under section 6 of the act.

Political Subdivisions

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

Private Sector

The proposed regulations will impose minimal costs on those organizations who are interested in applying for grant moneys. The costs which may be associated with the regulations would involve the time spent to obtain and fill out a grant application. Organizations receiving grants would benefit by receiving funds to cover all or part of the costs associated with developing or developing and implementing the projects set forth in their grant application. The private sector will also benefit through the realization of reduced health care and occupational costs associated with educational and preventative programs such as those espoused by the act and these proposed regulations.

General Public

The proposed regulations will impose no costs and have no fiscal impact on the general public. The farm community and the general public should benefit through the reduction of health care and occupational costs which are likely to be associated with educational and preventative programs such as those espoused by the act and these proposed regulations.

Paperwork Requirements

The proposed regulations will not result in an appreciable increase of paperwork. The Department will have to develop a grant application form and a grant agreement to administer the Program. However, the administrative provisions of the Program are very similar to the administrative provisions of the Farm Safety and Occupational Health Grant Program and the Department has already developed a grant application form and grant agreement for use in administering the Farm Safety and Occupational Health Grant Program and has administered that program, under Chapter 138g, since 1996.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on January 31, 2000, the Department submitted a copy of these proposed regulations to the Independent Regulatory Review Commission (IRRC) 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 regulations, the Department has provided IRRC 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.

Under section 5(g) of the Regulatory Review Act, if IRRC has an objection to any portion of the proposed regulations, it will notify the Department within 10 days after the close of the Committees' review period. The 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.

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER: 2-128

SUBJECT: Health Requirements for Importation and Intrastate Transportation of Animals and Brucellosis

AGENCY: DEPARTMENT OF AGRICULTURE

TYPE OF REGULATION

Proposed Regulation

X 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

RECEIVED
2000 SEP 14 PM 3:29
REVIEW COMMISSION

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
9/14/00		HOUSE COMMITTEE ON AGRICULTURE & RURAL AFFAIRS
9/14	L. Kaufman	SENATE COMMITTEE ON AGRICULTURE & RURAL AFFAIRS
9/14/00		INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
		LEGISLATIVE REFERENCE BUREAU

September 12, 2000

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
LEGAL OFFICE

Original: 2088

2301 N. CAMERON STREET, ROOM 201
HARRISBURG, PA 17110
TEL: (717) 787-6744
FAX: (717) 787-1270

Facsimile:

To: Mary Lou Harris and Sarah Miller **From: David C. Kennedy**

Fax: (717) 783-2664 **Pages: 9**

Phone: **Date: September 27, 2000**

Re: Draft of suggested changes to final-form regulation # 2-128 (IRRC#2088)

Urgent **X For Review**

Please Comment ☐ **Please Reply** ☐ **Please Recycle**

• Comments:

Attached please find a draft of final-form regulation #2-128 regarding EIA and Brucellosis. The draft contains the Department's proposed language based on the changes recommended by the Commission. In addition, I have attached a copy of the letter requesting the Commission toll the regulation. I thought attaching the letter might assist you in your review, because the letter contains citations to the sections to be changed and delineates the revisions made. I appreciate your assistance in this matter.

Thank you,

Dave K.

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).

* * *

OFFICIAL VACCINATION - AN OFFICIAL CALFHOOD OR ADULT VACCINATION.

* * *

OFFICIAL ADULT VACCINATION - STRAIN RB 51 VACCINE ADMINISTERED TO FEMALE CATTLE OR BISON OVER THE AGE OF 12 MONTHS (365 DAYS). ~~SUCH VACCINATION MAY ONLY BE ADMINISTERED WITH THE EXPRESS GUIDANCE AND WRITTEN PERMISSION OF THE PENNSYLVANIA STATE VETERINARIAN.~~

* * *

OFFICIAL CALFHOOD VACCINATION - STRAIN RB 51 VACCINE ADMINISTERED TO FEMALE CATTLE OR BISON FROM 4 TO 12 MONTHS OF AGE.

* * *

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)(7 PA.CODE §§ 7.71 – 7.74), 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.* EXCEPT AS

AUTHORIZED UNDER SUBSECTION (B) (RELATING TO STATE VETERINARIAN APPROVAL REQUIRED), 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. ALL REQUESTS FOR PERMISSION TO ADMINISTER STRAIN 19 VACCINE MUST BE MADE IN WRITING ON A FORM PROVIDED BY THE DEPARTMENT. THE PENNSYLVANIA STATE VETERINARIAN MAY REQUEST ADDITIONAL INFORMATION AS MAY BE NECESSARY TO ASSURE THE HEALTH OF THE ANIMAL AND TO PREVENT AND CONTROL DISEASES AND DANGEROUS SUBSTANCES THAT MAY THREATEN THE HEALTH AND SAFETY OF ANIMALS AND HUMANS. THE PENNSYLVANIA STATE VETERINARIAN SHALL PROVIDE A WRITTEN APPROVAL OR DENIAL OF SUCH A REQUEST WITHIN 3 WORKING DAYS OF RECEIVING THE WRITTEN REQUEST AND ALL NECESSARY INFORMATION PERTAINING THERETO.

[(b)] (c) *Official vaccination.* An official vaccination shall consist of [an approved] Strain RB 51 vaccine administered to female [calves] CATTLE OR BISON from 4 through [8] 12 months of age ([120 – 269] 120-365 days). A vaccination of

FEMALE cattle OR BISON 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. ALL REQUESTS TO ~~VACCINATE CATTLE OVER THE AGE OF 12 MONTHS~~ ADMINISTER AN OFFICIAL ADULT VACCINATION SHALL BE MADE IN WRITING ON A FORM PROVIDED BY THE DEPARTMENT. THE REQUEST SHALL SET FORTH THE REASONS FOR THE REQUEST, THE VACCINE TO BE ADMINISTERED AND THE AGE OF THE ANIMAL AT THE TIME OF THE REQUEST. THE PENNSYLVANIA STATE VETERINARIAN MAY REQUEST ADDITIONAL INFORMATION AS MAY BE NECESSARY TO ASSURE THE HEALTH OF THE ANIMAL AND TO PREVENT AND CONTROL DISEASES AND DANGEROUS SUBSTANCES THAT MAY THREATEN THE HEALTH AND SAFETY OF ANIMALS AND HUMANS. THE PENNSYLVANIA STATE VETERINARIAN SHALL PROVIDE A WRITTEN APPROVAL OR DENIAL OF SUCH A REQUEST WITHIN 3 WORKING DAYS OF RECEIVING THE WRITTEN REQUEST AND ALL NECESSARY INFORMATION PERTAINING THERETO.

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

[(c)] (c) 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] OFFICIALLY VACCINATED ANIMALS.

(a) *Tattoo required.* Veterinarians [vaccinating calves] ADMINISTERING OFFICIAL CALFHOOD OR OFFICIAL ADULT VACCINATIONS shall tattoo [with]

in the right ear OF THE ANIMAL 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~~ VACCINATED ANIMAL has an official breed registry tattoo, an official state vaccination tag ~~is~~ SHALL not BE required.

(c) *Identification on vaccination report.* [Calves] OFFICIALLY VACCINATED ANIMALS shall be identified on the vaccination report by [the] date of birth, AND AN official [Pennsylvania ear tag in the right ear,] State vaccination tag ~~number~~ [and,] or [when applicable], their breed registration number AND/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] ANIMAL. 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~~ THE OWNER'S records and one copy retained by the veterinarian.