For further information contact: please call (202) 799-7039 before coming.

sure someone is there to help you, through Friday, except holidays. To be

hours are 8 a.m. to 4:30 p.m., Monday

Washington, DC. Normal reading room

Supplemental Information:

For information regarding the

environmental assessment or the risk

analysis, or to request a copy of the

environmental assessment (as well as

the risk analysis with confidential

business information redacted), contact

Dr. Patricia L. Foley, Risk Manager,

Center for Veterinary Biologics, Policy,

Evaluation, and Licensing, VS, APHIS,

4700 River Road, Unit 148,

Riverdale, MD 20737–1231; phone (301)

851–3426, fax (301) 734–4314.

For information regarding the

environmental assessment or the risk

analysis, or to request a copy of the

environmental assessment (as well as

the risk analysis with confidential

business information redacted), contact

Dr. Patricia L. Foley, Risk Manager,

Center for Veterinary Biologics, Policy,

Evaluation, and Licensing, VS, APHIS,

1920 Dayton Avenue, P.O. Box 844,

Ames, IA 50010; phone (515) 337–6100,

fax (515) 337–6120.

Supplementary Information:

Under the

Virus-Toxin Act (21 U.S.C. 151 et seq.), the Animal and Plant Health

Inspection Service (APHIS) is

authorized to promulgate regulations
designed to ensure that veterinary

biological products are pure, safe,
potent, and efficacious before a

veterinary biological product license

may be issued. Veterinary biological

products include viruses, serums,
toxins, and analogous products of

natural or synthetic origin, such as

vaccines, antitoxins, or the

immunizing components of microorganisms

intended for the diagnosis, treatment, or

prevention of diseases in domestic

animals.

APHIS issues licenses to qualified

establishments that produce veterinary

biological products and issues permits
to importers of such products. APHIS

also enforces requirements concerning

production, packaging, labeling, and

shipment of these products and sets

standards for the testing of these

products. Regulations concerning

veterinary biological products are

contained in 9 CFR parts 101 to 124.

A field test is generally necessary to

satisfy prelicensing requirements for

veterinary biological products. Prior to

conducting a field test on an unlicensed

product, an applicant must obtain

approval from APHIS, as well as obtain

APHIS’ authorization to ship the

product for field testing.

To determine whether to authorize

shipment and grant approval for the

field testing of the unlicensed product

referred to in this notice, APHIS

considers the potential effects of this

product on the safety of animals, public

health, and the environment. Based

upon a risk analysis and other relevant

data, APHIS has prepared an

environmental assessment (EA)

concerning the field testing of the

following unlicensed veterinary

biological product:

Requester: Biomune Company.

Product: Bursal Disease–Marek’s

Disease–Newcastle Disease Vaccine,

Serotype 3, Live Marek’s Disease Vector.

Possible Field Test Locations:

Alabama, Delaware, Georgia, Maryland,

North Carolina, Pennsylvania, and

Virginia.

The above-mentioned product is a

live Marek’s Disease serotype 3 vaccine

virus containing a gene from the

Newcastle disease virus and a gene from

the infectious bursal disease virus. This

vaccine would be the recombinant

fraction used in combination with a

conventional live Marek’s disease

vaccine virus, either a serotype 1 or

serotype 2 strain, during the field safety

tests. The attenuated vaccine is

intended for use in healthy 18-day-old

or older embryonated eggs or day-old

chickens, as an aid in the prevention of

infectious bursal disease, Marek’s
disease, and Newcastle disease.

The EA has been prepared in

accordance with: (1) The National

Environmental Policy Act of 1969

(NEPA), as amended (42 U.S.C. 4321 et

seq.); (2) regulations of the Council on

Environmental Quality for

implementing the procedural provisions

of NEPA (40 CFR parts 1500–1508), (3)

USDA regulations implementing NEPA

(7 CFR part 1b), and (4) APHIS’ NEPA

Implementing Procedures (7 CFR part

372).

We are publishing this notice to

inform the public that we will accept

written comments regarding the EA

from interested or affected persons for a

period of 30 days from the date of this

notice. Unless substantial issues with

adverse environmental impacts are

raised in response to this notice, APHIS

intends to issue a finding of no

significant impact (FONSI) based on the

EA and authorize shipment of the above

product and the two products with a

conventional live Marek’s disease

vaccine virus, either a serotype 1 or

serotype 2 strain, that incorporate it as

a recombinant fraction, for the initiation

of field tests following the close of the

comment period for this notice.

Because the issues raised by field

testing and by issuance of a license are

identical, APHIS has concluded that the

EA that is generated for field testing

would also be applicable to the

proposed licensing action. Provided that

the field test data support the

conclusions of the original EA and the

issuance of a FONSI, APHIS does not

intend to issue a separate EA and FONSI

to support the issuance of the associated

product licenses, and would determine

that an environmental impact statement

need not be prepared. APHIS intends to

issue a veterinary biological product

license for this vaccine and the two

associated products containing it

following satisfactory completion of the

field test, provided no adverse impacts

on the human environment are

identified and provided the product

meets all other requirements for

licensing.


Done in Washington, DC, this 11th day of


Kevin Shea,

Administrator, Animal and Plant Health

Inspection Service.

[FR Doc. 2017–01010 Filed 1–17–17; 8:45 am]

Billing code 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2016–0079]

Updates to the Biotechnology

Regulatory Services BQMS Program

AGENCY: Animal and Plant Health

Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public

that Biotechnology Regulatory Services of the

Animal and Plant Health Inspection Service (APHIS) is updating

its Biotechnology Quality Management System Program and renaming it the

Biotechnology Quality Management Support Program to offer a more

flexible, more customizable, and less costly program that is easily accessible

to a wider universe of researchers and developers conducting biotechnology

activities under APHIS’ regulations.

These updates represent the next step in
SUPPLEMENTARY INFORMATION: The U.S. Department of Agriculture’s Animal and Plant Health Inspection Service (APHIS), regulates the importation, interstate movement, and environmental release of genetically engineered (GE) organisms that are, or may be, plant pests. In September 2007, APHIS’ Biotechnology Regulatory Services (BRS) announced a voluntary, audit-based compliance assistance program known as the Biotechnology Quality Management System (BQMS) Program to assist the regulated community in achieving and maintaining compliance with requirements for field trials and movements of GE organisms under its regulations in 7 CFR part 340.

Under the BQMS Program, APHIS–BRS has provided support for the voluntary adoption by participants of a quality management system to improve their management of domestic research and development of regulated GE organisms in order to fully comply with regulations. The BQMS Program included a mandatory audit standard that provided extensive criteria for the development, implementation, and an objective evaluation of the participant’s quality management system.

We are notifying the public that BRS is updating its BQMS Program and renaming it the Biotechnology Quality Management Support Program, which will use the same BQMS acronym, in order to reach a broader audience. After engaging with current and prospective BQMS participants, APHIS–BRS determined a modularized, more flexible, Web-based approach reaches a wider universe of researchers and developers conducting biotechnology activities. Small organizations, academics, and first-time users now have access to a program that previously was only within the means of a select few with considerable resources. The new BQMS Program is no longer audit-based, and no longer requires an “all or nothing” quality management system that relies on a BRS-developed audit standard, a required 3-day BRS-led training session for all participants, and a third-party audit cycle to maintain Program recognition. The new BQMS Program remains a voluntary compliance assistance program but with fewer impediments to users—no required multi-day training, no cost-prohibitive third-party audits and associated travel expenses, and no exhaustive resource commitments.

The new BQMS Program is a flexible, Web-based, modular approach designed to enhance compliance by enabling organizations large and small to develop sound quality management practices. Users can select any or all critical control points applicable to their organizations’ compliance assistance needs such as: Site selection planning, procedures for storage, transportation (interstate movement and importation), environmental release planning and monitoring, post-harvest handling and transfer, devitalization and final disposition, potential regulatory compliance incidents, and a reporting form for regulatory compliance incidents. User costs should decrease with the ability to easily choose only the modules they need to meet their unique compliance assistance needs.

The new BQMS Program offers a comprehensive repository of user-friendly, Web-based templates, guidelines, and checklists to assist users in the implementation of processes, procedures, and the foundation for a quality management system. No matter how big or small their organization, BQMS users will continue to have the option of requesting one-on-one tailored assistance from BRS staff, as in the past.

Organizations participating in the voluntary program will be encouraged to use BQMS resources as a foundation to ensure all personnel are properly trained regarding the requirements for working with GE organisms; identify and develop control measures to minimize the risk or occurrence of unauthorized releases; and monitor quality management practices and procedures.

These updates are the next step in the continual improvement of the voluntary BQMS Program.

Done in Washington, DC, this 11th day of January 2017.

Kevin Shea,
Administrator, Animal and Plant Health Inspection Service.

DEPARTMENT OF AGRICULTURE
Animal and Plant Health Inspection Service

Notice of Request for Extension of Approval of an Information Collection; Interstate Movement of Fruit From Hawaii

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service’s intention to request an extension of approval of an information collection associated with the regulations for the interstate movement of fruit from Hawaii.

DATES: We will consider all comments that we receive on or before March 20, 2017.

ADDRESSES: You may submit comments by either of the following methods:
• Federal eRulemaking Portal: Go to http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0113.
• Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS–2016–0113, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0113 or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the regulations for the interstate movement of fruit from Hawaii, contact Dr. Robert Baca, Assistant Director, Permitting and Compliance Coordination, Compliance and Environmental Coordination Branch, PPQ, APHIS, 4700 River Road, Unit 150, Riverdale, MD 20737; (301) 851–2292. For copies of more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS’ Information Collection Coordinator, at (301) 851–2483.