PETITION FOR LISTING

ON

NATIONAL LIST OF APPROVED AND PROHIBITED SUBSTANCES

SEC. 2118. [7 U.S.C. 6517] NATIONAL LIST

Petitioner name: Aquaculture Working Group, % George S. Lockwood, Chair
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Date of petition: June 12, 2012

Check applicable:

○ § 205.609 Synthetic substances allowed for use in organic aquatic *plant* production.

○ § 205.610 Nonsynthetic substances prohibited for use in organic aquatic *plant* production

X § 205.611 Synthetic substances allowed for use in organic aquatic *animal* production.

○ § 205.612 Nonsynthetic substances prohibited for use in organic aquatic *animal* production.

Send to: National List Coordinator, National Organic Program,
USDA/AMS/TM/ NOP, Room 2646–So., Ag Stop 0268,
1400 Independence Ave., SW.,
Washington, DC 20250-0268

Summary of request:

Previous actions by NOSB and NOP allow Biologics – Vaccines for the treatment of organic livestock under:

§ 205.237 Synthetic substances allowed for use in organic livestock production,
(a) As disinfectants, sanitizer, and medical treatments as applicable
(4) Biologics—Vaccines.

This petition is a request for NOSB and NOP to allow Biologics – Vaccines for the medical treatment of aquatic animals under

§ 205.611 Synthetic substances allowed for use in organic aquatic animal production.
(x) As disinfectants, sanitizers, c and medical treatments as applicable.
(*y*) Biologics – Vaccines.

This petition requests the allowance of vaccines, including vaccines made from genetically modified organisms, that are registered with the USDA/APHIS Center for Veterinary Biologics for us in aquatic animals. This includes viruses, serums, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms, and the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment, or prevention of diseases of animals. Products containing biologics are regulated by APHIS.

1. The substance's chemical or material common name.

Biologics – vaccines

2. The manufacturer's or producer's name, address and telephone number and other contact information of the manufacturer/producer of the substance listed in the petition.

Present sources of vaccines are:

True Name of Vaccine	Trade Name	Permittee
Aeromonas salmonicida bacterin	Furogen dip	Novartis
Aeromonas salmonicida-Vibrio anguillarum-Ordalii-salmonicida bacterin	Lipogen forte	Novartis
Arthrobacter vaccine, live culture	Renogen	Novartis
Infectious salmon anemia virus vaccine, Aeromonas salmonicida-Vibrio anguillarum-Ordalii-salmonicida bacterin, killed virus	Forte V1	Novartis
Yersinia ruckeri bacterin	Ermogen	Novartis
Flavobacterium columnare bacterin	FryVacc1	Novartis
Vibrio anguillarum-Ordalii bacterin	Vibrogen 2	Novartis
Flavobacterium columnare vaccine, avirulent live culture	AQUAVAC-COL	Intervet
Edwardsiella ictaluri vaccine, avirulent live culture	AQUAVAC-ESC	Intervet

This is a partial list since additional vaccines will be developed in the future.

Addresses for producers are:

Novartis Animal Health US, Inc.
Larchwood, Iowa, 51241
800-843-3386
U.S. Vet. Permit No. 303A

Intervet Inc.
405 State Street, P.O. Box 318
Millsboro, DE 19966
Tel: 302-934-8051
www.intervetusa.com
U.S. Est. No. 165A

For further information, please see "Approved Vaccines for Use in Aquaculture" Poster produced by U.S. Fish & Wildlife Service, Aquatic Animal Drug Approval Partnership (AADAP) Program at http://www.fws.gov/fisheries/aadap/vaccines_poster_introduction.htm .

Questions concerning the AADAP Program can be directed to:

Dave Erdahl; Program Director
4050 Bridger Canyon Road
Bozeman, MT 59715
Phone: 406-994-9904

3. The intended or current use of the substance such as use as a pesticide, animal feed additive, processing aid, nonagricultural ingredient, sanitizer or disinfectant. If the substance is an agricultural ingredient, the petition must provide a list of the types of product(s) (*e.g.*, cereals, salad dressings) for which the substance will be used and a description of the substance's function in the product(s) (*e.g.*, ingredient, flavoring agent, emulsifier, processing aid).

The intended use of this group of products are for vaccinations. Most vaccines are injected intramuscularly or given orally and once inside the body, cause the immune system to create antibodies (i.e., white blood cells) that upon subsequent exposure, are able to recognize bacteria and viruses and kill them (humoral immunity). Humoral immunity can be strengthened by cell-mediated immunity, which involves other types of cells (e.g., "natural killer cells") that are able to fight off viruses and bacteria that enter inside of the animal's cells.

Vaccines are composed of either weakened live or killed pathogens or antigenic components (molecular subunits) of pathogens . The production process begins when the virus/bacteria are replicated from a "reference" organism and grown in a protein growth medium (viruses are grown on a bovine kidney cell line or in chicken eggs, and bacteria are grown in bioreactors) in the laboratory (DHHS, 2005). After replication, the pathogens are inactivated, killed, and/or modified, depending upon the vaccine being created. Traditionally, live vaccines are weakened by passing them through the laboratory host system. Alternatively, pathogens can be inactivated using one or more chemicals or heat. Other vaccines are created by extracting and purifying a particular part of the pathogenic organism (CAST, 2008). As explained in the Characterization of Petitioned Substance section above, GMO vaccine production differs from traditional vaccine production in that GMO vaccine organisms are altered by deleting, adding, or otherwise genetically modifying the bacteria or virus.

4. A list of the crop, livestock or handling activities for which the substance will be used. If used for crops or livestock, the substance's rate and method of application must be described. If used for handling (including processing), the substance's mode of action must be described.

As described above, vaccines, including GMO vaccines, are presently administered to aquatic animal species to control the infectious diseases listed in #2 above.

5. The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product. Petitioners with concerns for confidential business information may follow the guidelines in the Instructions for Submitting CBI listed in #13.

This section does not apply.

6. A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance. If this information is not available, the petitioner should state so in the petition.

Organic Materials Review Institute

Vaccine – A substance derived from one or more pathogenic organisms that is treated to lose its virulence and administered to animals to stimulate the immune system and protect against infection from these and related pathogenic organisms.

Biologics
Status: Allowed
Class: Livestock Health Care
Origin: Synthetic/Nonsynthetic
Description:
Includes viruses, serums, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms, and the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment, or prevention of diseases of animals. Products containing biologics are regulated by APHIS. See also VACCINES. See Glossary for definition of "biologics."
NOP Rule: 205.2, 205.238(a)(6) & 205.603(a)(4

Generic Materials: Livestock

Biologics Allowed
Class: LH Nonsynthetic
Includes viruses, serums, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms, and the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment, or prevention of diseases of animals. Products containing biologics are regulated by APHIS. See also VACCINES. See Glossary for definition of "biologics."
NOP Rule: *205.2, 205.238(a)(6) & 205.603(a)(4)*

Vaccines Allowed
Class: LH Nonsynthetic

May be used against problems that are endemic. Those derived from excluded methods must be approved in accordance with 205.600(a). See also BIOLOGICS. See Glossary for definition of "vaccine."
NOP Rule: *205.105(e), 205.238(a)(6) & 205.603(a)(4)*

National Standard of Canada
Organic Aquaculture Standards

6. Animal Aquaculture
6.5.7 Vaccinations are permitted. Prophylactic treatment with other synthetic veterinary drugs is prohibited.

Soil Association (UK)

6.11.09
Vaccines that have not been genetically engineered may be used where there is a known disease risk to the operations as part of a disease prevention strategy. Any vaccines should be directed at the specific disease risk in question, not administered as a general preventative.

Naturland (Germany)

"Vaccination either has to be prescribed by a veterinarian (i.e. the vaccination has to be part of the health and hygiene program of the farm), or it has to be a legal requirement (as is the case in some countries)."

KRAV (Sweden)

7.7 Special Standards for Salmonids and Perches

7.7.5.8 Vaccination

Vaccination is permitted if it is established that there is a disease in the area and that it cannot be controlled using prophylactic production methods. KRAV-certification is not affected by vaccination that is recommended by a government agency. Vaccination should be performed so that it causes as little harm to the fish as possible and as few side effects as possible.7. Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers. If this information does not exist, the petitioner should state so in the petition.

European Commission

Vaccination in fish is allowed by oral administration and injection.

In the United States, livestock vaccines are regulated by the USDA's Animal and Plant Health Inspection Service (APHIS) 77 Center for Veterinary Biologics under authority of the Virus-Serum-Toxin Act of 1913. In particular, all vaccines used in agricultural animals must be licensed, and vaccines created using biotechnology (i.e., made with GMOs) must adhere to the same standards for traditional vaccines. Specifically, vaccine makers are required to submit a Summary Information Format (SIF) specific to the type of vaccine (Roth and Henderson, 2001).

A SIF must present information regarding the efficacy, safety, and environmental impact of the vaccine being registered. The purpose of the SIF is to characterize the vaccine's potential for, and likelihood of, risk. Occasionally, peer-review panels are formed to complete risk assessment of vaccines; this was the case for the currently licensed live vector rabies vaccine (to reduce rabies in wildlife).

This petition is for substances that are medicinal products used to prevent illness in food animals. Vaccines do not fall under EPA List 4.

8. The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contains the petitioned substance. If the substance does not have an assigned product number, the petitioner should state so in the petition.

Please see product brochures that are provided in Appendix A, B and C.. Additional product links are contained in 10. below.

9. The substance's physical properties and chemical mode of action including (a) Chemical interactions with other substances, especially substances used in organic production; (b) toxicity and environmental persistence; (c) environmental impacts from its use and/ or manufacture; (d) effects on human health; and, (e) effects on soil organisms, crops, or livestock.

(a) This petition concerns vaccines, which are biological agents with varying physical properties. In general, GMO vaccines are either live or killed pathogens (viral or bacterial) to which specific modifications, additions, or deletions have been introduced into the pathogen's genome.

Vaccines may contain suspending fluids, adjuvants, stabilizers, preservatives, or other substances to improve shelf-life and effectiveness of the vaccine (CDC, 2011). In addition, live vector vaccines (see Additional Question #1 for a definition) contain two different viral strains, providing immunity for two diseases in one vaccine. Other non-vector vaccines may contain more than one disease strain as well.

(b) Please see Product Brochures that are included as appendices and the links provided in 10. below. Petitioner is unaware of any indications of environmental persistence.

(c) Please see Product Brochures that are included as appendices and links provided in 10. that follows below. Petitioner is unaware of any indications of environmental impacts from use or manufacturer of vaccines for aquatic animals.

(d) Biologics-vaccines are administered to healthy aquatic animals in order to assure continued good health when the aquatic animals are challenged by disease organisms. This prevents sick animals from being fed to humans, and prevents animals that have been treated with antibiotics and other medications from being fed to humans. Petitioner is unaware of any adverse effects on human health from vaccines being administered to fish.

(e) Petitioner is unaware of any evidence of impacts on soil organisms, crops, livestock, culture water or other aquatic animals with the administration of vaccines directly to individual fish.

10. Safety information about the substance including a Material Safety Data Sheet (MSDS) and a substance report from the National Institute of Environmental Health Studies. If this information does not exist, the petitioner should state so in the petition.

Trade Name	MSDS No.
Furogen dip	W-018-0

http://www.livestock.novartis.com/MSDS/aqua_msds/furogen-dip_bacterin.pdf

Lipogen forte W-11-2
http://www.livestock.novartis.com/MSDS/aqua_msds/lipogen_forte.pdf

Renogen W-012-1
http://www.livestock.novartis.com/MSDS/aqua_msds/renogen.pdf

Forte V1 W-019-1
http://www.ah.novartis.ca/MSDS/ForteV1Jan1408.pdf

Ermogen W-03-0
http://www.livestock.novartis.com/MSDS/aqua_msds/ermogen_bacterin.pdf

FryVacc 1 W-015-1
http://www.livestock.novartis.com/MSDS/aqua_msds/fryvacc1_bacterin.pdf

Vibrogen 2 W-05-0
http://www.livestock.novartis.com/MSDS/aqua_msds/vibrogen2_bacterin.pdf

AQUAVAC-COL
http://174.132.27.123/~aquavac/media/AquavacCOL_Product_Bulletin.pdf

This is a partial list since additional vaccines will be developed in the future. Material Brochures providing safety information for several materials are in the attached appendices.

11. Research information about the substance which includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List. For petitions to include non-organic agricultural substances onto the National List, this information item should include research concerning why the substance should be permitted in the production or handling of an organic product, including the availability of organic alternatives. Commercial availability does not depend upon geographic location or local market conditions. If research information does not exist for the petitioned substance, the petitioner should state so in the petition.

During the approval process for a new vaccine, extensive scientific documentation must be provided to the Center for Veterinary Biologics (CVB) at the time of application. Such documentation consists of complete scientific reviews of the organism, the disease, and the proposed vaccine. Such reviews must include any negative data or information available. Extensive data sets on Efficacy, Purity, and Safety of the proposed vaccine are also furnished for review.

The vaccine and its proposed method of production and use are also subjected to a Risk Analysis review. The Risk Analysis provides a systematic interdisciplinary approach for conducting risk assessments. Such assessments include, as part of the required National Environmental Policy Act (NEPA) review, hazard analysis identification and characterization that address Animal Safety, Public Health Safety, and Environmental Safety concerns.

The review process insures that all of these assessments are scientifically comprehensive and all information concerning the vaccine and its approval are made available for public inspection (except for proprietary information). The information would therefore be available as supporting information on the petition to be included on the National List**.**

12. A ‘‘Petition Justification Statement’’ which provides justification for any of the following actions requested in the petition:

A. Inclusion of a Synthetic on the National List, §§ 205.609 and 205.611

• Explain why the synthetic substance is necessary for the production or handling of an organic product.

As part of a disease prevention strategy where there is a known disease risk to the operations. Vaccines have been used in humans and animals for several hundreds of years. The first documented use occurred in 1798 when Edward Jenner vaccinated humans with cowpox virus to protect them from smallpox.

Vaccines utilizing recombinant gene technology did not appear on the market until the mid-1980s. Before the introduction of GMO vaccines, substantial portions of food animals were dying due to infectious disease, even with the use of traditional vaccines and other medical treatments. In 1984, 10% of the 45 million cattle and 15% of 94 million swine born that year died of infectious disease (Faras and 113 Muscoplat, 1985). Growth in the veterinary vaccines industry over the past few decades has been primarily the result of new technological advances, drug resistance by pathogens, and new diseases (Frey, 2007).

• Describe any non-synthetic substances, synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned synthetic substance.

Organic producers may choose between traditional and GMO vaccines when treating for most diseases (See the “OFPA, USDA Final Rule” section for further discussion of the regulatory status of traditional and GMO vaccines.) However, there are some diseases or combinations of diseases for which a

GMO vaccine is the only available product (Foley, 2011). For example, with livestock there is no conventional Avian salmonellosis vaccine and there is no conventional combination vaccine for Fowl Pox and *Mycoplasma Gallisepticum* (note that there are conventional vaccines available for the two diseases separately) (USDA, 2011). In addition, the number of available GMO vaccines and conventional vaccines vary with time due to new license issues and previous license terminations on an ongoing basis (as vaccine manufacturers discontinue production of previously approved vaccines and replace them with more efficacious products). It should also be noted that GMO vaccines are sometimes safer, and often more efficacious and cheaper than their traditional counterparts (Shams, 2005).

Vaccines are an integral part of animal agriculture to prevent disease and animal suffering (Morton, 2007). It is unlikely that homeopathic or other methods would render vaccinations unnecessary.

• Describe the beneficial effects to the environment, human health, or farm ecosystem from use of the synthetic substance that support its use instead of the use of a non-synthetic substance or alternative cultural methods.

While viruses or bacteria shed from vaccinated animals may survive in the environment for a short time, the amount of shed pathogen is generally low and may not be excreted from all vaccinated animals. GMO vaccines are not expected to persist in the environment any longer than traditional vaccines. CFIA 217 (2007 and 2008a) stated that any pathogenic bacteria created from gene transfer would be unable to persist in the environment for long periods of time. A safety assessment of a human *V. cholera* live genetically modified vaccine indicated that the shedding of pathogenic vibrios from GMO vaccine-inoculated patients was considerably less than patients administered the non-GMO vaccine strain and that the GMO vaccinated patients shed 106 to 108 times fewer vibrios than those infected with cholera. Furthermore, shedding occurred in only 20-30% of patients inoculated with the GMO vaccine for a maximum of 7 days (Frey, 2007). It is also advantageous that gene-deleted GMO vaccines (e.g., bovine rhinotracheitis, pseudorabies, and classical swine fever vaccines) can be tracked in the environment, as the survival of the organisms in the animal and the environment can be investigated during GMO strain construction. However, vaccines with inactivated (rather than deleted) pathogens cannot be tracked in this way because both vaccinated and infected animals will produce the same antibodies against the disease (Frey, 2007).

All vaccines (conventional and GMO) can be shed in the animal's feces and other secretions, although not all animals will shed vaccine DNA. This shed DNA could potentially infect other animals and spread the virus or bacteria in the environment. However, as discussed above, vaccines cannot survive in the environment for long periods of time. Vaccines contain aluminum salts and other chemical adjuvants or additives; however, it is unclear if these substances are released in high quantities or whether they may impact the environment. Moreover, for both conventional and GMO vaccines, regulatory au-

thorities consider additives when licensing them, establishing residue limits and withdrawal periods (required time between vaccination and slaughtering or milking) when necessary (OIE, 2010).

Because live vaccine pathogens cannot survive long outside of a host, environmental damage is not expected from accidental release or shedding from vaccinated animals. Furthermore, although there is a possibility that non-target species in close proximity to vaccinated animals may become infected with pathogens from vaccine shedding, studies have indicated that this has not been a problem historically. Once again, the ability for the pathogen to spread is limited by its short lifespan in the environment. In addition, some GMO vaccines have been tested in non-target species (e.g., the GMO *Salmonella typhurium* vaccine in rats, mice, calves, and pigs) and have not shown to adversely affect these species (CFIA, 2006).

B. Removal of a Synthetic from the National List, §§ 205.609 and 205.611

Explain why the synthetic substance is no longer necessary or appropriate for the production or handling of an organic product.

Not applicable.

Describe any non-synthetic substances, synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned synthetic substance.

Not applicable.

C. Inclusion of a Prohibition of a Non- Synthetic, §§ 205.610 and 205.612

Explain why the non-synthetic substance should not be permitted in the production of an organic product.

Not applicable.

Describe other non-synthetic substances or synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned substance.

Not applicable.

D. Removal of a Prohibited Non- Synthetic from the National List, §§ 205.610 and 205.611

Explain why the non-synthetic substance should be permitted in the production of an organic product.

Not applicable.

Describe the beneficial effects to the environment, human health, or farm ecosystem from use of the non-synthetic substance that supports its use instead of the use of other non-synthetic or synthetic substances on the National List or alternative cultural methods.

Not applicable

E. Inclusion of a Non-Synthetic, Non-Agricultural Substance onto the National List, § 205.605(a)

Explain why the substance is necessary for use in organic handling.

Not applicable.

Describe non-synthetic or synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned synthetic substance.

Not applicable

Describe any beneficial effects on the environment, or human health from the use of the substance that support its use instead of the use of non-synthetic or synthetic substances on the National List or alternative cultural methods.

F. Removal of a Non-Synthetic, Non-Agricultural Substance from the National List, § 205.605(a)

Explain why the substance is no longer necessary for use in organic handling.

Not applicable.

Describe any non-synthetic or synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned substance.

There are no suitable substances that could replace the use of vaccines.

G. Inclusion of a Non-Organically produced Agricultural Substance onto the National List, § 205.606

Provide a comparative description on why the non-organic form of the substance is necessary for use in organic handling.

Not applicable

Provide current and historical industry information/research/evidence that explains how or why the substance cannot be obtained organically in the *appropriate form, appropriate quality, and appropriate quantity* to fulfill an essential function in a system of organic handling.

Please see prior comments.

Describe industry information on substance non-availability of organic sources including but not limited to the following guidance regarding commercial availability evaluation criteria: (1) Regions of production, including factors such as climate and number of regions; (2) Number of suppliers and amount produced; (3) Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies; (4) Trade related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies, and (5) Other issues which may present a challenge to a consistent supply.

Please see prior comments.

H. Removal of a Non-Organically Produced Agricultural Substance from the National List, § 205.606

• Provide a comparative description as to why the non-organic form of the substance is not necessary for use in organic handling.

Not applicable.

• Provide current and historical industry information/research/evidence that explains how or why the substance can be obtained organically in the *appropriate form, appropriate quality, and appropriate quantity* to fulfill an essential function in a system of organic handling.

Not applicable.

• Provide new industry information on substance availability of organic sources including but not limited to the following guidance commercial availability evaluation criteria: (1) Region of production, including factors such as climate and number of regions; (2) Number of suppliers and amount produced; (3) Current and historical supplies related to weather events such as hurricanes, floods, or droughts that temporarily halt production or destroy crops or supplies; (4) Trade related issues such as evidence of hoarding, war, trade barriers, and civil unrest that may temporarily restrict supplies and; (5) Any other issues which may present a challenge to a consistent supply.

Not applicable.

13. A Confidential Business Information Statement which describes the specific required information contained in the petition that is considered to be Confidential Business Information (CBI) or confidential commercial information and the basis for that determination. Petitioners should limit their submission of confidential information to that needed to address the areas for which this notice requests information. Final determination regarding whether to afford CBI treatment to submitted petitions will be made by USDA pursuant to 7 CFR 1.27(d).

This petition does not contain confidential business information.

14. Other important information.

In general, the use of genetic engineering is prohibited in organic production and handling. Substances, methods, and ingredients that may and may not be used in organic production and handling are defined in 121 7 CFR §205.105. Among the provisions of this section is a requirement that organic products must be produced and handled without the use of "excluded methods," which are defined as follows:

"A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes

> *when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture. "* (7 CFR §205.2)

However, vaccines are specifically excluded (7 CFR §205.105(e)) from the prohibition of excluded methods, provided that the vaccines are approved for use by inclusion on the National List. At present, the National List identifies all vaccines, as a group, as synthetic substances allowed for use in organic livestock production (7 CFR §205.603(a)(4)). Vaccines are not individually listed and no distinction is made between vaccines made with and without the use of genetic engineering.

Conclusions

A basic principle of organic production is to grow healthy animals so as to not require treatment of sick animals. Vaccines are essential for the healthy production of aquatic animals as they are in the production of terrestrial livestock. They are safe, provide no environmental risks, dramatically reduce the need for prophylaxis, and there are no natural alternatives. The administration of vaccines is an accepted practice in organic livestock production.

Previous actions by NOSB and NOP allow vaccines for the treatment of organic livestock under:

§ 205.237 Synthetic substances allowed for use in organic livestock production,
(a) As disinfectants, sanitizers, and medical treatments as applicable
(4) Biologics—Vaccines.

This petition is a request for NOSB and NOP to similarly allow vaccines for the medical treatment of aquatic animals under:

§ 205.611 Synthetic substances allowed for use in organic aquatic animal production.
(*x*) As disinfectants, sanitizers, and medical treatments as applicable.
(*y*) Biologics – Vaccines.

Aquaculture Working Group
George S. Lockwood

Appendix 1
Product Bulletin

QUALITY, The Mark Of A Licensed Vaccine
QUALITY TESTED FOR PURITY, POTENCY AND SAFETY

PRODUCT BULLETIN

AQUAVAC-COL®

FLAVOBACTERIUM COLUMNARE VACCINE / AVIRULENT LIVE CULTURE

An aid in the prevention of columnaris disease in catfish due to *F. columnare* infection

ADVANTAGES

- **High level of protection** — Significantly protects catfish fry vaccinated 7 days post-hatch and older against *F. columnare* challenge[1]
- **Safe** — Use with confidence in early-life stage fry for early protection
- **Easy to use** — Compatible with modern hatchery-management practices; may be added to transport tanks before stocking fry
- **Measurable results** — Trials show fish vaccinated with AQUAVAC-COL have a 72% better survivability rate than non-vaccinates following columnaris challenge
- **Exclusive protection** — First and only modified-live vaccine licensed by USDA against columnaris disease in catfish[2]

AQUAVAC-COL contains an avirulent strain of *Flavobacterium columnare*. The product has been shown to provide significant protection from disease and mortality when vaccinated catfish are challenged with common virulent or wild-type isolates of *F. columnare*.[1] Use as part of a comprehensive fish health management program.

Supplied in 10 X 100,000-dose units.

[1] Data on file, Intervet/Schering-Plough Animal Health.
[2] USDA/ARS Aquatic Animal Health Research Laboratory, Auburn, AL

Intervet
Schering-Plough Animal Health

AQUAVAC-COL®

PRODUCT BULLETIN

READ IN FULL

FLAVOBACTERIUM COLUMNARE VACCINE
Avirulent Live Culture
AQUAVAC-COL®

DESCRIPTION

AQUAVAC-COL contains an avirulent strain of *Flavobacterium columnare*, as a frozen preparation. AQUAVAC-COL is administered to catfish as a timed bath treatment. AQUAVAC-COL has been shown to provide significant protection from disease and mortality when vaccinated catfish are challenged with common virulent wild-type isolates of *F. columnare*.

INDICATIONS FOR USE

The vaccine is indicated as an aid in the prevention of columnaris disease in catfish due to *F. columnare* infection. Catfish should be healthy and free of disease at the time of vaccination. Sick or weak catfish may not develop adequate immunity. Catfish should be at least 7 days of age post hatch or older at the time of vaccination. For maximum benefit, catfish should be vaccinated for a minimum of two minutes at least 14 days prior to anticipated exposure to columnaris disease. Vaccination is not recommended when water temperatures are below 21°C (70°F) or above 29°C (85°F).

VACCINATION PROGRAMS

AQUAVAC-COL is intended for use in a comprehensive program of catfish health management and producers are encouraged to consult with their veterinarian or other fish health professionals before use. AQUAVAC-COL can be applied as a bath at any time during the production cycle. AQUAVAC-COL is easily administered at any time catfish are being handled and can be integrated into routine catfish handling practices such as grading, inventorying, sorting, splitting, hauling, moving or ponding. The most common application is a bath treatment of 7 days post hatch fry in a transport tank before stocking catfish into nursery or fingerling ponds.

DOSAGE

The dosage of AQUAVAC-COL is based on total catfish weight and the volume of water in which they are vaccinated. Each vial of AQUAVAC-COL is sufficient to vaccinate 7.5 pounds of catfish in 5 gallons of water. When applied to fry at 7 days of age post hatch (an average size of 13,000 catfish per pound or 29 catfish/gram or 812 catfish per ounce), each vial of vaccine is sufficient to vaccinate 100,000 fry in 5 gallons of water.

When vaccinating 7 days post hatch fry, the following tables should be used to determine the proper dosage and use of AQUAVAC-COL.

Table A

Number of 7 Day Post Hatch Fry to be Vaccinated as a Single Group					
	200,000	400,000	600,000	800,000	1,000,000
Vials of Vaccine	2	4	6	8	10
Gallons of Water	10	20	30	40	50

When vaccinating catfish older than 7 days post hatch, each ten-pack of AQUAVAC-COL vaccine is sufficient to vaccinate 75 pounds of catfish in 50 gallons of water as described in "Administration". The following table can be used to help determine the proper dosage and use of AQUAVAC-COL.

Table B

Pounds of Catfish to be Vaccinated as a Single Group					
	15	30	45	60	75
Vials of Vaccine	2	4	6	8	10
Gallons of Water	10	20	30	40	50

ADMINISTRATION

Prior to vaccination, ensure that all nets, buckets, tanks and other equipment are thoroughly cleaned and properly disinfected and rinsed prior to use. Ensure that all troughs or hauling tanks have been cleaned and flushed free of any excess feces or feed. To reduce stress, it is recommended that the catfish not be fed for 3 to 4 hours prior to vaccination. Use standard methods to determine the total weight of each group of catfish to be vaccinated.

Caution – because the dosage of AQUAVAC-COL is based on total catfish weight, it is important that the catfish be inventoried as accurately as possible immediately prior to vaccination to ensure full efficacy of the vaccine. Refer to Table A or Table B as guidelines to determine the amount of vaccine and volume of water needed for vaccinating each group of catfish.

AQUAVAC-COL should be kept frozen at or below -60°C (-76°F). If stored frozen at -20°C (-4°F) (non-frost-free freezer), the product must be used within 7 days or discarded. *Caution – do not thaw AQUAVAC-COL until immediately prior to use.*

Tank Vaccination during transport.

1. Calculate the water volume of transport tank and determine the volume of water for vaccination based on guidelines in Table A or Table B. Fill the transport tank with clean water to this level.
2. Turn on oxygen to transport tank. Ensure the air stones are all working and adequate oxygenation is being provided to all areas of the tank.
3. Add catfish to be vaccinated to the transport tank.
4. Thaw the number of vials of vaccine needed by placing vials into a 79°F waterbath.
5. Immediately add thawed vaccine to transport tank, pouring evenly across the surface of the tank. Mix gently but thoroughly.
6. Wait at least two minutes.
7. After two minutes, fill the transport tank with at least an equal amount of water and do not dilute further for at least 15 minutes. Haul to the nursery or fingerling pond for stocking. The usual precautions must be taken to ensure fish in the transport tank are properly tempered to the pond water temperature before discharge.
8. Discharge catfish and vaccine solution into pond and observe for any signs of stress.
9. Begin feeding as usual.

STORAGE CONDITIONS

AQUAVAC-COL should be stored frozen at or below -60°C (-76°F) prior to use. If AQUAVAC-COL is stored frozen at -20°C (-4°F) (non-frost-free freezer), the product must be used within 7 days or discarded. Once AQUAVAC-COL has been thawed, it must be used immediately. At no time should AQUAVAC-COL be exposed to direct sunlight or excessive heat above ambient air or water temperatures.

PRECAUTIONS AND WARNINGS

1. VACCINATE ONLY HEALTHY CATFISH. DO NOT VACCINATE WITHIN 21 DAYS BEFORE HARVEST. Although disease may not be evident, concurrent disease and adverse environmental conditions may cause complications or reduce effectiveness of AQUAVAC-COL vaccine.
2. WITHHOLD ALL CHEMICAL OR ANTIBIOTIC TREATMENTS in the water or feed for 3 days before and 5 days after vaccination.
3. USE AQUAVAC-COL VACCINE IMMEDIATELY FOLLOWING THAWING.
4. DO NOT ATTEMPT TO STORE OR REUSE THE VACCINE ONCE IT HAS BEEN THAWED. Each vial of AQUAVAC-COL vaccine is designed and intended for use in a single application.
5. DILUTE AQUAVAC-COL VACCINE ONLY AS DIRECTED. Any changes in the recommended dilution rate may cause the product to become ineffective.
6. ENSURE ACCURACY OF INVENTORIES PRIOR TO VACCINATION. Because the dosage of AQUAVAC-COL is based on total catfish weight, it is important that the catfish be inventoried as accurately as possible immediately prior to vaccination to ensure full efficacy and safety of the vaccine.
7. DO NOT ATTEMPT TO VACCINATE MORE CATFISH THAN DIRECTED OR OTHERWISE CHANGE THE DOSAGE OF AQUAVAC-COL. To do so can cause the product to become ineffective.
8. USE THE ENTIRE CONTENTS OF EACH VIAL WHEN FIRST THAWED AND OPENED.
9. WHEN VACCINATION HAS BEEN COMPLETED, BURN ALL CONTAINERS AND ANY UNUSED CONTENTS.
10. AVOID CONTACT OF OPEN WOUNDS WITH THE VACCINE. WASH HANDS THOROUGHLY AFTER USING THE VACCINE.
11. ANY ADVERSE OR UNUSUAL EFFECTS ASSOCIATED WITH THE USE OF AQUAVAC-COL SHOULD BE IMMEDIATELY REPORTED TO INTERVET INC. AT THE FOLLOWING TELEPHONE NUMBER: 1-800-441-8272.
12. AQUAVAC-COL IS INTENDED FOR USE IN ANIMALS ONLY.

NOTICE

AQUAVAC-COL has undergone rigid potency, safety and purity tests, and meets Intervet Inc. and USDA requirements. It is designed to stimulate effective immunity when used as directed, but the user must be advised that the response to the product depends upon many factors, including, but not limited to, conditions of storage and handling by the user, administration of the vaccine, health and responsiveness of the individual catfish, environmental conditions following vaccination and the severity and timing of field exposure to *F. columnare* and columnaris disease following vaccination. Therefore, directions should be followed carefully to ensure safe use and optimum performance.

AQUAVAC-COL is not hazardous when used according to directions and poses no known human health risk for healthy individuals. A material safety data sheet (MSDS) is available upon request. This and any other consumer information can be obtained by calling Intervet Customer Service at 1-800-441-8272 or 1-302-934-8061.

RECORDS

The user is advised to keep a written record of vaccination including vaccine, quantity, serial number, expiration date, and place of purchase; the date and time of vaccination; the breed, lot number, pond number, population, age, average size and total weight of catfish vaccinated; names of operators administering the vaccine; water temperature and environmental conditions as well as observations on the general health of the animals at the time of vaccination; and any unusual reactions or conditions observed.

HOW SUPPLIED

10 vials per pack — Ordering Number 03s333

The use of this vaccine is subject to applicable federal, state and local laws and regulations.

USE ONLY AS DIRECTED
STORE VACCINE FROZEN AT OR BELOW -60°C (-76°F)
IF STORED FROZEN AT -20°C (-4°F) (NON-FROST-FREE FREEZER), THE PRODUCT MUST BE USED WITHIN 7 DAYS OR DISCARDED.
DO NOT EXPOSE TO EXCESSIVE HEAT
THIS PRODUCT IS NON-RETURNABLE


UALITY Tested for Purity, Potency, and Safety

INTERVET INC.
Millsboro, Delaware U.S.A.
U.S. Veterinary License No. 286
www.intervetusa.com • 1-800-441-8272

Manufactured and Printed in U.S.A. — Rev. 79s02
U.S. Patent No. 6,881,412

Appendix B

SAFETY INFORMATION

***Aeromonas salmonicida, Vibrio anguillarum-ordalii-salmonicida* Bacterin**

LIPOGEN FORTE **W-11-2**

TRANSPORT REGULATIONS	Avoid exposure of the goods to temperatures in excess of 30°C (86°F). Do Not Freeze.
MANUFACTURER	Aqua Health Ltd, 37 McCarville St.,West Royalty Industrial Park, Prince Edward Island, Canada, C1E 2A7.
RECOMMENDED USE	As an aid in the prevention of furunculosis, vibriosis and cold water vibriosis.
PACKAGING	1000 mL or 750 mL flexible plastic intravenous-type bags with clamp off seal and screw top cap.
METHOD OF USE	Injection - 0.1 mL intraperitoneally
APPROVAL	USDA Vet. Permit No. 335 Product Code: 2138.01 Can Vet Biol Est No. 28 Product Lic. No: 870BA/A16.0/A8
HAZARDOUS INGREDIENTS	Bacterial endotoxin; formalin, emulsifiers Adjuvant: pharmaceutical grade oil;
RISKS	Low risk from ingestion or eye contact; moderate risk from injection
SAFETY PRECAUTIONS	Avoid ingestion or eye contact. If product is accidentally injected, take precautions against localised sepsis and report the incident immediately to the safety officer and **seek medical attention without delay.** Anaphylaxis (shock) may occur in individuals hyper-sensitive to gram-negative bacteria following accidental injection of product. Prior to use of the product, operators should seek medical advice relating to the recognition and immediate treatment in the case of anaphylaxis. Epinephrine or an equivalent drug should be available for immediate use following these instances.

a NOVARTIS company

DISPOSAL	Use the entire contents of bag when opened. Dispose of surplus vaccine by incineration.
STORAGE	Store at 2-7°C (33-36°F); DO NOT FREEZE
ACTION IN CASE OF SPILLAGE	Mop and wash the area of the spill, dispose of product in accordance with local waste disposal regulations.
FLAMMABILITY	Low risk, high ignition temperature.
HARMFUL EFFECTS FIRST AID	EYES: Irritant/irrigate thoroughly with water. INJECTION: Mild to moderate reaction to bacterial endotoxin or the adjuvant, if unusual swelling or redness occurs **SEEK MEDICAL ATTENTION IMMEDIATELY**. INHALATION: None Known. SKIN: None known/wash affected area.
ADDITIONAL INFORMATION	Product is a formalin inactivated, whole-cell bacterin containing no live organisms.
FOR FURTHER INFORMATION CONTACT	Aqua Health Ltd. 37 McCarville St. Charlottetown, P.E.I. Tel: (902)566-4966 Fax: (902)566-3573
DATE	September 22, 2004

Appendix C

SAFETY INFORMATION

RENOGEN **W-012-1**

TRANSPORT REGULATIONS	Avoid exposure of the goods to temperatures in excess of 30°C (86°F).
MANUFACTURER	Aqua Health Ltd, 37 McCarville St.,West Royalty Industrial Park, Prince Edward Island, Canada, C1E 2A7.
RECOMMENDED USE	As an aid in the prevention of Bacterial Kidney Disease caused by *Renibacterium salmoninarum*
PACKAGING	1000 mL flexible plastic intravenous-type bags with clamp off seal and screw top cap
METHOD OF USE	Injection - 0.1 mL intraperitoneally
APPROVAL	USDA Vet. Permit No. 335 Product Code:1K11.00 Can Vet Biol Est No. 28 Product Lic. No: 870VB/R5.0/A8
HAZARDOUS INGREDIENTS	Live Bacterial culture
RISKS	Low risk from ingestion or eye contact; moderate risk from injection
SAFETY PRECAUTIONS	Avoid ingestion or eye contact. If product is accidentally injected, take precautions against localised sepsis and report the incident immediately to the safety officer. If swelling or redness is not localised to the area of injection, seek medical attention without delay. Anaphylaxis (shock) may occur in individuals hyper-sensitive to gram-positive bacteria following accidental injection of product. Prior to use of the product, operators should seek medical advice relating to the recognition and immediate treatment in the case of anaphylaxis. Epinephrine or an equivalent drug should be available for immediate use following these instances.

a NOVARTIS company

DISPOSAL	Use the entire contents of bag when opened; dispose of surplus vaccine by incineration.
STORAGE	Store at 2-7°C (33-36°C); DO NOT FREEZE
ACTION IN CASE OF SPILLAGE	Mop and wash the area of the spill, dispose of product.
FLAMMABILITY	Low risk, high ignition temperature.
HARMFUL EFFECTS FIRST AID	EYES: Irritant/irrigate thoroughly with water. INJECTION: Mild to moderate reaction to bacterial endotoxin if unusual swelling or redness occurs/SEEK MEDICAL ATTENTION IMMEDIATELY. INHALATION: None Known. SKIN: None known/wash affected area.
ADDITIONAL INFORMATION	Product is a live culture formulation of *Arthrobacter (sp.)* and has no known pathogenicity to target species or non-target (including human) species.
FOR FURTHER INFORMATION CONTACT	Aqua Health Ltd. West Royalty Ind. Park Charlottetown, P.E.I. Tel: (902)566-4966 Fax: (902)566-3573

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