

**DEPARTMENT OF FOOD AND AGRICULTURE
PROPOSED CHANGES IN THE REGULATIONS**

TITLE 3. FOOD AND AGRICULTURE
DIVISION 2. ANIMAL INDUSTRY
CHAPTER 2. LIVESTOCK DISEASE CONTROL
Article 11 Emergency Control and Eradication of Animal Diseases

INITIAL STATEMENT OF REASONS

SUBJECT MATTER OF PROPOSED REGULATION

Vesicular Stomatitis Virus - Entry Requirements of Susceptible Animals

SECTIONS AFFECTED

Section 799

PROBLEM STATEMENT

The current regulations do not reflect the proper requirements for the interstate movement of animals susceptible to VSV when being imported from a state where VSV has been diagnosed within the prior 30 days and/or has a quarantined premises with a suspected or confirmed VSV case.

PURPOSE

The Department is proposing to amend section 799, Article 11, Chapter 2, Division 2, of Title 3 of the California Code of Regulations, to define key terms used in this section and update the interstate movement requirements for VSV susceptible animals during an outbreak of VSV.

BENEFITS OF THIS REGULATORY ACTION

The benefit of this amendment is to provide the public with clear and accurate information for the requirements for importation of animals susceptible to VSV, upon the Department's notification by the USDA that a state or country has a confirmed or suspect VSV premises. This amendment also ensures the Department has the ability to properly control, manage, and prevent the spread or introduction of VSV in the State.

An example of a monetary benefit is preventing significant losses to the State's equine industry that produces goods and services valued at approximately \$8.3 billion and includes approximately 550,000 horses.

An example of a nonmonetary benefit would be consumer confidence that safe, wholesome and economical food supply is provided for human consumption.

STATEMENT OF FACTUAL BASIS AND RATIONALE

The Department is responsible for promoting and protecting the agricultural industry of California. Further, the Department seeks to enhance, protect, and perpetuate the ability of the agricultural industry to produce food and fiber in a way that benefits the general welfare and economy of California, and maintains the economic well-being of agriculturally dependent rural communities in California.

It is the intent and responsibility of the Department to prevent and control livestock diseases to ensure a safe, wholesome and economical food supply is available to the citizens of the State. Similarly, California ranchers and farmers work hard to protect their livelihood by keeping their animals healthy and producing meat, milk, and fiber in a manner that meets consumer demands all while keeping consumers confident that their products are healthy and safe. To coordinate the goals and efforts of the Department and California producers, the Department maintains regulations for the prevention, control, and eradication of livestock diseases.

Specifically, the Animal Health Branch (AHB) within the Department is the State's professional veterinary medical unit that protects livestock, consumers, and California's economy from catastrophic animal diseases and other health issues. It addresses diseases and other issues that cannot be successfully controlled on an individual animal or herd basis but require statewide coordinated efforts. The Branch is responsible for deterring any activities that have the potential to compromise California's abundant food supply or the safety of public and animal health.

To ensure the protection of California's livestock industry, the AHB recognizes the need to vigilantly regulate and prevent the introduction and spread of VSV. VSV is a viral animal disease that causes blister-like sores on the mouths or feet of infected animals. The signs of this disease are almost identical to foot and mouth disease (FMD), a devastating livestock disease. Due to the resemblance to FMD, it's critical to identify and then to implement proper disease surveillance and livestock movement requirements when a VSV outbreak occurs within the US or internationally.

VSV is an economically significant livestock disease, in particular it can cause losses to the cattle and horse industries due to animal quarantines and cancellation of events such as cattle auctions and horse shows. In an effort to isolate and control VSV outbreaks, quarantines are utilized to restrict animal movement on premises where there is a confirmed or suspected VSV case. Quarantine periods for premises with suspected or confirmed VSV cases are 14 days from the onset of lesions in the last affected animal on the premises.

VSV susceptible animals are defined as all animals belonging to the equine, bovine, porcine, caprine, ovine, cervidae, and camelidae species. This includes but is not limited to horses, donkeys, mules, cattle, swine, and camelids. Horses are known to be affected the most severely. All susceptible species are causal in the spread of VSV, and act as vectors that transmit the infectious disease to cattle and other susceptible animals by either direct or indirect contact. VSV can be transmitted by direct contact with infected animals and contaminated items such as clothes, shoes, or equipment. Once VSV has entered a herd, the disease spreads between animals through contact with saliva or fluid from ruptured sores from infected animals.

Pursuant to Food and Agricultural Code section 10610 the Department seeks to expand the requirements of entry into the State when there is an active outbreak of VSV. Since the disease is infectious and contagious to cattle, it is necessary for the requirements to apply not only to cattle, but also to the other listed species that are defined as being susceptible to VSV. The expansion of these requirements is critical to meet AHB's responsibility for protecting the state's agricultural economy by preventing the likelihood of serious damage to VSV susceptible animals and consequently damage to the State's economy through its prosperous livestock industry.

The Department has identified a need to update the current interstate movement requirements for animals susceptible to VSV consistent with the proper prevention measures necessary for VSV through animal inspections performed by accredited veterinarians. This amendment reduces the window of time between the inspection of the animals and the issuance of a Certificate of Veterinary Inspection (CVI) prior to entry from 30 days to 7 days. In addition, this amendment requires certification from an accredited veterinarian, in the form of including a general VSV free statement on the issued CVI certifying that all VSV susceptible animals have been inspected within 7 days prior to shipment and do not show any clinical signs of the disease which include: vesicular lesions on the tongue, lips, oral and nasal mucosa, teats, prepuce, or coronary bands. The inclusion of a VSV free statement on a CVI aids California in its efforts to prevent and mitigate the disease entering the State. Because this disease resembles FMD, a devastating livestock disease, it can cause significant economic loss to the State's livestock industry. This extra certification via a VSV free disease statement is essential.

Lastly, with the inclusion of this VSV free statement, the requirement for the inspection to have occurred within 7 days prior to shipment is clear to the regulated public.

SPECIFIC PURPOSE OF EACH ADOPTION, AMENDMENT, OR REPEAL

Outlined below are the specific changes the Department is proposing to Title 3 of the California Code of Regulations.

The Department is proposing to amend section 799, Article 11, Chapter 2, Division 2, of Title 3 of the California Code of Regulations:

Section 799. Amend the heading of section 799 of the California Code of Regulations, to clearly identify the purpose of the section as the requirements for movement of animals susceptible to VSV.

Subsection (a). Amend subsection (a) of section 799 of the California Code of Regulations. The proposed changes include prohibiting entry into the State if animals susceptible to VSV are exposed to VSV within 14 days of entry. This correlates with the known time period for viral shed from lesioned animals that are considered contagious and can spread the disease to other susceptible animals. Additionally, changes are being made to create consistency with the accurate abbreviation for vesicular stomatitis virus, properly correlate this subsection to subsection (d), changes to entry language to provide clarity, and provide a defined scope for clinical signs of VSV and clarify the use of investigation as an investigation initiated by the State of California.

Subsection (b)(1). Amend subsection (b)(1) previously subsection (b) of section 799 of Article 11, Chapter 2, Division 2, of Title 3 of the California Code of Regulations. The proposed change includes adding subsection (1) to break up subsection (b) into two parts to outline the entry requirements and exemptions. A citation of section 830.3 is being included to provide that all other entry requirements provided in existing regulations need to be met in addition to the requirements being added in this section. The Department specifies and expands CVI requirements for animals susceptible to VSV during an emergency/outbreak of VSV to be implemented as a preventative measure in order to prevent and/or mitigate the spread of the contagious disease in the State. The inspection of the animals needs to be within 7 days of shipment because animals should be inspected as close to shipment as possible, ideally within 24-72 hours, but that is a strict requirement that could unnecessarily restrict entry of healthy animals and potentially disrupt economy and food supply. Shortening the time frame for a Certificate of Veterinary Inspection to 7 days also aides effective traceability efforts with the goal of preventing an economic loss. 7 days allows some flexibility to schedule a veterinarian inspection, and covers one potential viral incubation cycle as well, and decreasing

timeframe also reduces need for special permitting as it is closer to real-time traceability.

Subsection (b)(1)(A). Adoption of subsection (b)(1)(A) of section 799 of Article 11, Chapter 2, Division 2, of Title 3 of the California Code of Regulations is needed to provide a definition of VSV susceptible animals.

Subsection (b)(1)(B). Adoption of subsection (b)(1)(B) of section 799 of Article 11, Chapter 2, Division 2, of Title 3 of the California Code of Regulations is needed to clarify the requirement that applies to VSV susceptible animals originating in states where VSV has been diagnosed within the prior 30 days of entry. The original 6-month period is being amended to a 30-day period prior to entry because once all VSV-quarantines in a state are released, the state will be considered returned to VSV-negative status 30 days from the last quarantine release if no new cases are confirmed in the interim. It is recommended during this 30-day countdown that any suspect cases identified be confirmed as either VSV-positive or VSV-negative using appropriate diagnostic testing. Since the State was previously VSV-infected, that State could potentially return to VSV-positive status if the “Subsequent Confirmed Cases in a VSV-Positive State” case definition is met any time during the same outbreak. The inclusion of animals that were unloaded in an infected State is necessary to reduce risk of infection with VSV, though minimal, indirect or direct exposure is possible. If not unloaded, animals in proper transportation vessels essentially remain in isolation.

Subsection (b)(2). Adoption of subsection (b)(1)(B) of section 799 of Article 11, Chapter 2, Division 2, of Title 3 of the California Code of Regulations is needed to provide the exemption for this requirement. Slaughter Animals are exempt from this requirement since these essentially become dead-end hosts and pose no risk to live animals, and food safety protocols and PPE should protect against the low zoonotic risk and indirect fomite transmission. The 3-day time period is consistent with other regulatory requirements in regulation.

Subsection (c). Adoption of subsection (c) of section 799 of Article 11, Chapter 2, Division 2, of Title 3 of the California Code of Regulations is needed to clarify that in addition to the CVI requirements being proposed in this section, all other interstate movement requirements as applicable to each species shall also be met prior to entering the State. This is necessary to provide clarity to the regulated public that all other movement requirements specified in regulation, must be met to be compliant with all State movement requirements.

Subsection (d). Add subsection (d), previously subsection (c) of section 799 of the California Code of Regulations, which authorizes the Department to allow entry if the

State Veterinarian deems the entry poses no threat to livestock in the State. This enables the State Veterinarian to retain the authority of animal movement if certain conditions or requirements that are dictated standard epidemiological practices are met in order to mitigate the spread of VSV. Minor change to this subsection is being made to include the abbreviation of vesicular stomatitis to be consistent with it's use in this section.

Subsection (e). Adoption of subsection (3) of section 799 of Article 11, Chapter 2, Division 2, of Title 3 of the California Code of Regulations is needed to provide clarity for when the additional requirements in this section are no longer required for VSV susceptible animals entering the state of California.

Amend authorities and references cited for this section are necessary to support the interpretation and implementation in the regulations proposed in this section.

TECHNICAL, THEORETICAL, AND EMPIRICAL STUDY, REPORT, OR SIMILAR DOCUMENT

No technical, theoretical or empirical study, report, or similar document was used in the formulation of this proposal

SPECIFIC TECHNOLOGIES OR EQUIPMENT

This regulation does not mandate the use of specific technologies or equipment.

ECONOMIC IMPACT ASSESSMENT

Business Impact

The Department has determined that this regulatory proposal will not have any impact on the creation of jobs or businesses or the elimination of jobs or existing businesses or the expansion of businesses in California.

The Department has made an initial determination that the proposed regulatory action will have no significant, statewide adverse economic impact directly affecting California businesses including the ability of California businesses to compete with businesses in other states.

Persons/Businesses affected by this proposal:

California Equine Industry – there are approximately 550,000 horses in California, which are one of the most highly susceptible species to VSV. On average, approximately 1,200 equine events including high revenue shows and sales are held annually in California,

and over 20,000 horses enter and exit the state annually.

California Beef and Dairy Cattle Industries - The Department estimates this proposal could impact approximately 13,000 individuals/businesses in California having beef or dairy cattle

California Sheep Industry - There are approximately 3,800 premises raising sheep in the State. All sheep and lambs in California between January 1, 2020 and 2021 total inventory of 555,000 head.

Swine Industry – Breeding and Market swine – In California between December 1, 2019 and 2020 includes total inventory of 99,000 head.

Goat Industry – Milk, Meat, and other In California between January 1, 2020 and 2021 total inventory of 123,000 head.

Anticipated compliance requirements for persons or businesses are as follows:

- This proposal requires a CVI be obtained and specifies within what time period ahead of importation into California and requires the CVI to accompany the animal(s) specified at the time of movement.

Benefits of the regulation to the health and welfare of California residents, worker safety, and the State's environment:

Benefits to the health and welfare of California residents, worker safety, and the State's environment include updating requirements for importing animals susceptible to VSV into California that may pose a significant risk to other animals or humans, including an introduction of harmful animal products into the human food chain.

Economic Impact Assessment Conclusion

The Department has made an initial determination that the proposed regulatory action will not have any significant, statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states by making it more costly to produce goods or services, and that it will not create or eliminate jobs or occupations. The proposal does not affect the creation of new businesses or the elimination of existing businesses within the State of California and does not affect the expansion of businesses currently doing business within the State of California. The proposed regulation benefits animal health, public health, the food supply,

and the economy by serving to prevent the spread of VSV in the State of California during a VSV outbreak.

REASONABLE ALTERNATIVES THE DEPARTMENT HAS IDENTIFIED THAT WOULD LESSEN ANY ADVERSE IMPACT ON SMALL BUSINESSES

No alternatives were identified by the Department and no adverse impact to small businesses are expected as a result of this proposed action.

FACTS, EVIDENCE, DOCUMENTS, TESTIMONY OR OTHER EVIDENCE OF NO SIGNIFICANT ADVERSE IMPACT ON BUSINESS

Based upon the reasons stated in the economic impact assessment, the Department has initially determined that these proposed changes to the regulations would not have a significant adverse economic impact to persons that are compliant with section 799, Article 11, Chapter 2, Division 2, of Title 3 of the California Code of Regulations.

This regulatory action is intended to promote and protect the State's thriving livestock industries by including additional measures and verification that incoming livestock is free of a communicable disease.

CONSIDERATION OF REASONABLE ALTERNATIVES

The Department must determine that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed action or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. Interested persons are invited to present statements or arguments with respect to alternatives to the proposed regulations during the written comment period.

DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS

This proposal does not duplicate or conflict with federal regulations.