SENATE JUDICIARY COMMITTEE Senator Thomas Umberg, Chair 2021-2022 Regular Session

SB 703 (Hurtado)

Version: March 11, 2021 Hearing Date: April 6, 2021

Fiscal: Yes Urgency: No

AWM

SUBJECT

Diseased animals: laboratory services

DIGEST

This bill requires the California Department of Food and Agriculture (CDFA) to establish a certification system for laboratories analyzing samples obtained from California livestock and poultry for the purpose of detecting conditions that would trigger a regulatory animal health response.

EXECUTIVE SUMMARY

California's livestock and poultry industry is a backbone of the state economy and feeds the world. Current laws and regulations require certain animal diseases to be reported if detected, and, depending on the nature of the outbreak, further action may be taken to protect the industry. However, current law does not grant CDFA oversight of the laboratories responsible for analyzing samples and detecting conditions that might trigger a regulatory response, or require those laboratories to be certified.

This bill requires CDFA to establish a certification system for laboratories doing the essential work of analyzing samples to detect animal diseases, with an exemption for laboratories that are already certified under related state and federal programs. The bill also sets criteria and procedures for certification applications and renewals, and imposes a civil penalty of up to \$25,000 against any party in violation of the certification requirements. Finally, the bill provides that evidence from a certified laboratory will be prima facie evidence of the discovered condition; the author has agreed to amend the provision to clarify how the evidentiary presumption may be applied.

SB 703 is sponsored by the author and supported by the California Cattlemen's Association, the California Farm Bureau Federation, the California Poultry Federation, the California Veterinary Medical Association, the Dairy Institute of California, and Western United Dairies. There is no known opposition. This bill passed out of the Senate Agriculture Committee with a 5-0 vote.

PROPOSED CHANGES TO THE LAW

Existing law:

- 1) Requires the CDFA to publish and make available a "List of Reportable Conditions for Animals and Animal Products," setting forth conditions that pose or may pose significant threats to public health, animal health, the environment, or the food supply. If a licensed veterinarian, a person operating a diagnostic laboratory, or another person who has reason to recognize the conditions on the list, has reason to know that an animal may have one of the listed conditions, that person must report to the CDFA all necessary information relating to the affected animal(s). (Food & Agr. Code, § 9101.)
- 2) Does not grant the CDFA the authority to set certification standards for private veterinary laboratories performing diagnostic services, such as tests for conditions on the List of Reportable Conditions for Animals and Animal Products.

This bill:

- 1) Provides the following definitions:
 - a) "Emergency or regulatory condition" includes all diseases and conditions on the List of Reportable Conditions for Animals and Animal Products.
 - b) "Laboratory services" means providing a residue or nutrient analysis of animal tissue; providing identification of insects, parasites, bacteria, viruses, prions, or pathogenic organisms in animal tissue; or other services incidental to those analyses or identifications.
- 2) Requires the CDFA to require certification of laboratories providing services in the examination, diagnosis, analysis, testing, quantifying, or identification of any emergency or regulatory condition of poultry or livestock owned or located within the state; to prescribe procedures and requirements for certification; and to develop and implement the necessary regulations to carry out the certifications.
 - Laboratories approved, certified, or accredited by the state or federal government to provide the above services are exempt from the CDFA's certification requirement.
- 3) Provides that it is unlawful for a person to establish, operate, or maintain a laboratory providing the defined laboratory services without being certified by the CDFA, unless the laboratory is exempt due to a different state or federal certification.
- 4) Provides specified procedures and requirements for the CDFA's certification process, including requiring a certified laboratory to use an official nationally approved or validated diagnostic test for diseases of regulatory importance (unless granted an exemption by the department) and requiring a certified laboratory to

report positive and suspect tests only to the party who provided the sample and to the CDFA when required under Food & Agriculture Code section 9101.

- 5) Sets the certification application and renewal fees at \$1,000 before January 1, 2023; after that date, the CDFA may adjust the fee as needed to cover the costs of implementing certification requirements.
- 6) Provides that test results certified by the CDFA are prima facie evidence of the facts stated therein.
- 7) Provides that any person who violates the provisions of the bill or related regulations shall be liable for a civil penalty of no more than \$25,000 per violation. The civil penalty may be imposed administratively by the CDFA or by the superior court upon a petition from the Attorney General made at the request of the State Veterinarian.
 - a) When the CDFA imposes the penalty administratively, the affected person may seek review by the department and, if unsuccessful, appeal to the superior court via the procedures set forth in Chapter 4.5 of Part 1 of Division 3 of Title 2 of the Government Code (Gov. Code, §§ 11400 et seq.).
 - b) The proceeds of any civil penalty collected shall be deposited in the Food and Agriculture Fund.

COMMENTS

1. Author's comment

California's robust livestock and livestock product industry generates \$8.35 billion in annual income for the State plus employment for one million people. [An] occurrence of a foreign animal disease in California that was not immediately detected by a competent laboratory would devastate the state and national livestock industries economically. There is no existing state law that authorizes oversight and certification of laboratories analyzing samples obtained from California livestock and poultry for the purpose of detecting conditions that would trigger a regulatory animal health response. SB 703 ensures that all laboratories providing service specifically for animal diseases of high consequence provide equally reliable results by allowing CDFA to create laboratory certification standards for these laboratories.

2. This bill grants the CDFA oversight into a sensitive component of California's food and livestock industry

California has one of the strongest livestock and poultry sectors in the world. In 2019, the value of California's livestock production was nearly \$12.4 billion.¹ Unfortunately, numerous diseases and pests can severely damage the industry, our food chain, and even human health if they are not efficiently isolated and eliminated.² To help avoid the spread of conditions that could pose significant threats to public health, animal health, the environment, or the food supply, CDFA maintains a List of Reportable Conditions for Animals and Animal Products.³ The current List of Reportable Conditions for Animals and Animal Products includes dire diseases such as bovine spongiform encephalopathy (Mad Cow Disease), Foot-and-mouth disease, Rabies of livestock, and certain Avian influenza strains, and sets forth the time periods in which the condition must be reported to CDFA⁴

The effectiveness of the CDFA's reporting obligation depends heavily on the quality of the diagnostic laboratory performing an analysis to determine whether a reportable condition is present. Under current law, the CDFA has no oversight authority over these laboratories. This bill would require the CDFA to develop certification requirements for diagnostic laboratories and implement the certification process, and make it unlawful for an uncertified diagnostic laboratory to provide services in the examination, diagnosis, analysis, testing, quantifying, or identification of any emergency or regulatory condition of poultry and livestock. To avoid duplicative certification, the bill exempts laboratories that are approved, certified, or accredited by the state or federal government to provide similar services.

In order to enforce the bill, the bill allows the CDFA, or, upon request of the State Veterinarian, the Attorney General, to seek a civil penalty of up to \$25,000 for each violation of the bill or regulations adopted under it. The \$25,000 penalty is consistent with other public-safety-related civil penalties.⁵

¹ CDFA, California Agricultural Statistics Review 2019-2020, https://www.cdfa.ca.gov/Statistics/PDFs/2020_Ag_Stats_Review.pdf [last visited Mar. 18, 2021] at p. 10.

² CDFA Animal Health Branch, *Animal Health Branch Annual Report* 2019/2020, https://www.cdfa.ca.gov/AHFSS/animal_health/pdfs/AHBAnnualReport2020.pdf [last visited Mar. 18, 2021] at pp. 2-4.

³ Food & Agr. Code, § 9101.

⁴ CDFA Animal Health Branch, *List of Reportable Conditions for Animals and Animal Products* (Jan 2021), https://www.cdfa.ca.gov/ahfss/Animal_Health/pdfs/CA_reportable_disease_list_poster.pdf [last visited Mar. 12, 2021].

⁵ *E.g.*, Food & Agr. Code, § 14027 (civil penalty of \$10,000 per day for violation pesticide regulations); Health & Saf. Code, §§ 25189.2 (civil penalty of up to \$70,000 may be imposed for unauthorized disposal or improper storage of hazardous waste), 42401 (civil penalty between \$2,500 and \$25,000 may be imposed for failure to comply with pollution abatement order).

3. This bill provides that a test result from a certified laboratory is prima facie evidence of the facts stated in the results

In addition to providing for certified diagnostic laboratories, this bill would make the test results from such laboratories prima facie evidence of the facts stated in the test. According to the author, this will prevent results from noncertified laboratories being offered to confuse findings and slow down vital public health responses.

It is not unusual within the Food and Agriculture Code to treat results of certain test results as prima facie evidence of the stated condition or fact. Generally, however, these provisions come with qualifiers as to the effect and scope of the preemption, often by clarifying that the presumption affects the burden of proof and is not available in a criminal proceeding. To ensure that the prima facie evidence provision is available to the CDFA for valuable public safety purposes, but does not interfere with due process concerns or otherwise give an undue advantage in suits unrelated to the CDFA's public role, the author has agreed to amend the bill to provide similar limitations.

4. Amendments

The author has agreed to amendments set forth below, to cabin the scope of the prima facie evidence provision, as well as certain amendments clarifying the nature of the certification requirement and when the Attorney General may seek a civil penalty for a violation of the certification requirements.

Amendment 1

On page 3, in line 10, strike out "It is unlawful for a" and insert "A"

Amendment 2

On page 3, in line 10, strike out "to" and insert "shall not"

Amendment 3

On page 4, in line 4, after "or" insert "any"

Amendment 4

On page 4, in line 28, strike out "results." and insert "results for purposes of an action pursuant to subdivision (b) of Section 9157. This section does not apply to a criminal action."

⁶ E.g., Food & Agr. Code, §§ 27611, 40532, 42851, 42852, 52363.

Amendment 5

On page 4, in line 33, strike out "Civil penalties authorized pursuant to this", strike out line 34, and insert "(b)(1) Unless a civil penalty has been imposed pursuant to paragraph (2), the department may administratively impose a civil penalty for a violation described in subdivision (a)."

Amendment 6

On page 4, in line 35, strike out "(b) The" and insert "(2) Unless the department has administratively imposed a civil penalty pursuant to paragraph (1), the"

Amendment 7

On page 4, in line 37, strike out "the" and insert "a"

Amendment 8

On page 4, in line 37, strike out "imposed pursuant to" and insert "for a violation described in"

Amendment 9

On page 4, in line 38, after "to" insert "paragraph (1) of"

Amendment 10

On page 4, in line 39, strike out "(a)" and insert "(b)"

5. Arguments in Support

Bill supporters California Cattlemen's Association (CCA) and Western United Dairies (WUD) state:

Currently, CDFA lacks the authority to set certification standards to ensure the quality, accuracy, and reproducibility of diagnostic services performed by private veterinary laboratories. This is particularly concerning for labs providing diagnostic services for illnesses which are CDFA- and/or U.S. Department of Agriculture-designated emergency conditions (e.g., foot-in-mouth disease in cattle) or regulatory conditions (e.g., bovine brucellosis). The detection of emergency and regulatory conditions may trigger state or federal regulatory responses, recalls, and even trade sanctions from other jurisdictions, meaning the consequences for false-positive, false-negative, or other diagnostic defect can have devastating consequences for California's animal agricultural sectors.

SB 703 has been narrowly tailored to ensure that it does not unnecessarily burden veterinary labs and their clients. For instance, [adopted] amendments to SB 703 would exclude from its provisions laboratories which are already state- or federally-certified to provide diagnostic services relative to emergency or regulatory conditions. This would include many in-house veterinary labs which have been certified by the California Animal Health and Food Safety (CAHFS) Laboratory for the limited purpose of reading trichomonosis samples (trichomonosis being a regulatory condition). CCA and WUD appreciate that SB 703 has been narrowly tailored to avoid unnecessary costs for veterinarians and the ranchers, dairymen, and other agriculturalists they serve.

SUPPORT

California Cattlemen's Association California Farm Bureau Federation California Poultry Federation California Veterinary Medical Association Dairy Institute of California Western United Dairies

OPPOSITION

None known

RELATED LEGISLATION

<u>Pending Legislation</u>: AB 1285 (Flora, 2021) requires the Secretary of the CDFA to appoint a poultry health advisory committee, comprised of a range of industry members, public health experts, and academics, and require the Secretary to consult with the committee before adopting regulations relating to the control or eradication of poultry diseases, the entry and importation of poultry, and poultry disease matters. AB 1285 is pending before the Assembly Agriculture Committee.

<u>Prior Legislation</u>: AB 3252 (Committee on Agriculture, Ch. 289, Stats. 2018) repealed certain cremation requirements for animals that died of contagious diseases.

PRIOR VOTES:

Senate Agriculture Committee (Ayes 5, Nos 0)
