

July 12, 2021

Dr. Elizabeth Cox
Program Manager
Animal Care Program
California Department of Food & Agriculture
1220 N Street
Sacramento California 95814

**Re – Chapter 10 of Division 2 of Title 3 of the California Code of Regulations:
Article 2 Veal Calves; Article 3 Breeding Pigs; Article 4: Exceptions; Article 5
Certification and Accredited Certifiers.**

Dear Dr. Cox:

The North American Meat Institute (NAMI or the Meat Institute) submits comments regarding the Proposed Regulatory Text (rules) in the above-referenced articles as provided on the California Department of Food & Agriculture (CDFA or the agency) Proposition 12 (Prop 12 or the law) website. The Meat Institute is the nation's oldest and largest trade association representing packers and processors of beef, pork, lamb, veal, turkey, and processed meat and poultry products. NAMI member companies account for more than 95 percent of the United States' output of these products. Many NAMI members sell pork and veal to customers in California and several NAMI members own and raise hogs and veal calves in various states across the country. For those reasons the Meat Institute has a substantial interest in how CDFA implements Proposition 12.

Prop 12 prohibits the sale in California of certain pork and veal products derived from animals not raised under specific space and other requirements. Many aspects of the rules mirror the draft proposed rules CDFA posted last July. However, the Notice of Proposed Action (notice) and Initial Statement of Reasons (statement) accompanying the rules include several comments and observations that support what the Meat Institute has contended since Prop 12 was enacted – the law provides no food safety or animal welfare benefit and imposes substantial burdens on interstate commerce.

The rules, if finalized, would create a burdensome, bureaucratic labyrinth of regulatory provisions:

- requiring an unworkable annual certification of veal and breeding pig (sow) facilities;
- creating an overly complex accreditation process for entities allowed to certify those facilities;
- imposing detailed recordkeeping requirements on producers and throughout the supply chain;

- imposing problematic labeling provisions;¹ and
- granting legally questionable enforcement authority.

For the reasons discussed below in greater detail, multiple sections of the rules should be withdrawn or substantially revised.

Articles 2 and 3 Comments

Many sections of Articles 2 and 3, veal calves and breeding pigs, are identical or similar. For these comments, NAMI's suggestions and observations apply to both Articles, with distinctions made between veal and pork identified when necessary.

Definitions

The definition of "audit trail" as proposed will impose onerous requirements, especially on distributors. Requiring a distributor to have documents regarding "the identification, source, supplier, transfer of ownership, transportation, storage, segregation, handling, packaging, distribution" is overly broad. Distributors can be several steps removed from where calves are raised or breeding pigs (sows) are housed. Section 25993.1 of the law provides:

It shall be a defense to any action to enforce subdivision (b) of Section 25990 that a business owner or operator relied in good faith upon a written certification by the supplier that the whole veal meat, whole pork meat, shell egg, or liquid eggs at issue was not derived from a covered animal who was confined in a cruel manner, or from the immediate offspring of a breeding pig who was confined in a cruel manner.

This same approach should be applied throughout the supply chain. For example, a distributor should be required to have information from its supplier that the product offered is Prop 12 compliant. That distributor should not be required to have on file the names, addresses, *etc.* of the hog or veal calf producers who supplied hogs or calves to a packer. Nor should a distributor have to keep records showing how the packer who harvests the hogs segregates the carcasses (if necessary), transports the pork, *etc.* It should be sufficient for a supplier to certify the animal or product it is providing is Prop 12 compliant.

The definition of "commercial sale" is overly broad. Section 25991(o) of the law provides that a sale is a "commercial sale" but excludes any "sale undertaken at an establishment at which mandatory inspection is provided under the Federal Meat Inspection Act (21 U.S.C. Sec. 601 et seq.)" The law also provides "[F]or purposes of this section, a sale shall be deemed to occur at the location where the buyer takes physical possession of an item covered by Section 25990." (Emphasis added)

¹ The rules would go so far as to impose labeling requirements on products not subject to Prop 12. See discussion *infra*, p. 6.

The proposed definition of “commercial sale,” goes well beyond what the law provides. CDFA cannot by regulation expand Prop 12’s reach by having it apply to circumstances in which, for example, a company simply offers for sale, exposes for sale, or possesses for sale a product. By the plain meaning of the words offering for sale is not a sale. Nor is simply possessing product one intends to sell. The commercial sale definition, taken to its illogical extreme for example, could subject to penalties a company that possesses in a warehouse non-Prop 12 compliant pork or veal it intends to offer for sale on its website.

The proposed “commercial sale” definition also would capture products further processed or simply repacked before being sold to an out of state or out of country customer. This approach should be abandoned. It is not only inconsistent with the law, it is bad policy. CDFA concedes Prop 12 will raise the cost of products subject to the law, which Californians agreed to endure when enacting the law. For CDFA to impose those additional cost burdens on citizens in other states, however, is unacceptable and impermissible. Whatever the merits of the purported justifications for Prop 12, the food safety and animal welfare issues do not apply to products received into California, further processed or just repackaged, and then sent to another state, *e.g.* Nevada. Prop 12 should not attach to those products.

The proposed “commercial sale” definition also should highlight that pork shipped to a federally inspected establishment and subsequently shipped out of state or out of the country is not subject to Prop 12. The agency also should reconsider referencing the “M” in 1321/2(e)(2) because often an establishment’s mark of inspection does not show an “M.” The proposed rule also should be broadened to capture facilities with voluntary inspection provided by the Food Safety and Inspection Service (FSIS).

The commercial sale exemptions also should be expanded to cover sales to a governmental entity, *e.g.*, federal prisons and military bases, and any school or university. The state has acknowledged Prop 12 will cause prices of covered products to rise. It is bad enough that individual consumers will bear those costs, but schools, governments, *etc.* should not be so encumbered. Moreover, California voters who pay taxes and voted against Prop 12 should not bear that burden nor should voters in other states who pay federal taxes have to pay for Prop 12.²

NAMI supports CDFA’s decision to exempt “Donations to religious, charitable, scientific, educational, or other nonprofit organizations that have a tax exemption under section 501(c)(3) of the Internal Revenue Code.” Although the definition of “commercial sale” appropriately exempts donations, but should extend to the donated product itself. Some donated products may be processed into products sold with profits going to charitable causes. These sales should also be exempt.

CDFA should add in the “Document of title” definition the words “but are not limited to” after the word “include” in the examples sentence to help ensure certifying agents know the list provided is not all inclusive.

² Nor should voters in other states who pay federal taxes bear that burden.

The definition of “uncooked,” coupled with definitions for ready-to eat (RTE) and “requiring cooking” provide an appropriate way to delineate products subject to Prop 12 and those not.

Section 1321(s), “kept for the purpose of producing,” coupled with section 1321(aa)(1), highlights what the Meat Institute asserts in its lawsuit challenging Prop 12: the law discriminates against out of state veal producers by exempting calves initially kept for dairy, are undoubtedly not provided 43 square feet of usable space and yet, when culled, are sold as veal. In the Statement of Reasons (Statement) CDFA says “because female dairy calves on farms are often kept to replace older or unproductive adult dairy cattle, the definition would not apply.”³ The Statement, however, fails to explain why the agency elected not to apply the 43 square feet standard when a dairy calf is culled and the meat from that animal sold as veal.

Confinement

NAMI appreciates CDFA’s recognition that certification is impossible to achieve by January 1, 2022, and allows distributors and producers to self-certify. The Meat Institute respectfully suggests, however, that, given the complexities of the accreditation process and the fact that process cannot begin until rules are final, coupled with there being many entities that will need to be certified, the January 1, 2023, date for certification is not realistic.

The Statement says CDFA

estimates third-party certifiers pursuant to this proposal will potentially need to annually certify as compliant with the Act:

- Approximately 6,000 distributors selling covered product in California;
- 1,100 in-state egg and pork producer operations; and
- 12,750 out-of-state, including out-of-country, egg, pork, and veal producer operations raising animals for covered product destined to be sold in California.⁴

Simple math compels the conclusion: this many entities cannot be certified by January 1, 2023.

The comment period closes July 12, 2021. CDFA must then review the comments filed and prepare final rules and a preamble responding to the issues raised in a comprehensive manner. To believe that work can be completed with a final rule published by the end of September likely is fantasy. Even assuming it can be accomplished that fast, that scenario still leaves only 15 months before 19,850 distributors and producer operations need to be certified. And they cannot become certified on, for example October 1, 2021, because the only entity accredited to certify on that date will be CDFA.

³ Statement of Reasons, p. 45.

⁴ Statement, p. 9.

In the Statement CDFA concedes it cannot “manage the oversight of this volume of entities participating in the raising and sale of covered animals and covered product in the State” and so the agency chose to allow third-party certifiers.⁵ But the accreditation process CDFA would establish in Article 5 is complex and entities that wish to be accredited cannot begin that process until final rules are published, much less go through the accreditation process.

Setting aside the challenges with entities becoming accredited, assuming there is a “sufficient” number of accredited entities on, for example, December 31, 2021, based on the agency’s own numbers and working every single day would require 54 distributors and producer operations to be certified each day to get all 19,850 entities certified. This result is almost certainly not achievable. Given that a significant percentage of the producer operators are hog operations, this calculation does not consider that, for biosecurity reasons, it will not be possible for a person who certifies breeding pig operations to go on farm more than once every five days.

The proposed January 1, 2023, certification date must be reconsidered. Adherence to that date will only exacerbate the pork and veal shortages already predicted.

Distributor Registration.

CDFA should reconsider the distributor registration section given the burdens it would place on distributors. Requiring annual certification will overload the certification system. Annual certification is unnecessary given CDFA would require distributors to provide the agency with “any change in ownership, business name, business location, business closure, or change in contact information of a registered facility must be reported to the Department within 30 business days of such change”⁶ The proposed self-certification is necessary but requiring certification of every distributor by an accredited entity by January 1, 2023, is unrealistic and will only exacerbate the economic hardships California consumers will face.

Shipping Document Requirements

The labeling elements in the shipping document section is overreach. Assuming subsection (a)(1) does not impose labeling requirements preempted by the Federal Meat Inspection Act, the requirements in (a)(2) are unnecessary. If documents accompanying products represent the products to be Prop 12 compliant with the CA43+ or CA24+ mark, then product moving through the state should not need to bear the “Not for California Consumption” or “Not for California Sale” declaration. Surely, enforcement officials and others can infer from the absence of the CA 43+/24+ mark that the product is destined for sale outside California. Also, companies whose sales are not covered by Prop 12 will likely not be closely following the regulatory process and thus not be aware of these requirements. The requirement to put a disclaimer, whether it is “CA43+,” “CA24+,” “Not for California Sale,” or any other, on every shipping document is overly burdensome and unnecessary. If a disclaimer is necessary, it should only be required to be included in the shipping documents and not specifically on each document.

⁵ *Id.*

⁶ Statement at 48.

Subsection (a)(3) requires modification because it fails to recognize that product originally going to one federally inspected establishment occasionally may be diverted to another federally inspected establishment. In either location Prop 12 is not applicable and the wording should be changed to read “Only for use at a federally inspected establishment” or something similar. And requiring inclusion of the “M” as part of the establishment number could cause confusion because most establishments’ marks of inspection do not include “M.” Indeed, the marks in 9 CFR 312.2 do not include “M.”⁷

CDFA also needs to consider how it will ensure that, for several months into 2022, meat (pork and veal) not subject to Prop 12’s requirements will move into the state. For example, pork from pigs born on December 15, 2021, from a sow not afforded 24 square feet of usable space complies with Prop 12.⁸ CDFA must ensure enforcement officials and certifying agents understand those products are eligible to bear the CA24+ mark.

Distributor Recordkeeping

The distributor recordkeeping requirements could prove exceptionally problematic. It is one thing for a distributor to keep records showing its supplier, *i.e.*, a packer or another distributor provided evidence the product was Prop 12 compliant. It is another matter altogether, and would be exceptionally burdensome, if subsections (b) and (c) require the distributor to have records proving all the way back to the veal calf or hog producer the product is Prop 12 compliant. These products may exchange hands several times before landing with a distributor. Requiring the distributor to have all the records, which would have to travel with the product, would be problematic.

CDFA should also reconsider the two-year recordkeeping requirement. Notwithstanding what was said during the days leading up the vote in 2018, Prop 12 is unrelated to food safety. As CDFA knows, all veal and pork consumed in California is subject to federal inspection. No one has suggested that, should product be found noncompliant, it should be subject to recall or market withdrawal. A one-year recordkeeping requirement is more than sufficient to determine compliance. For example, the Agricultural Marketing Service requires records be kept for one year for mandatory country-of-origin labeling.⁹

Inspection of Conveyances.

The several elements of the inspection conveyance section border on an outrageous regulatory overreach not authorized by the law. Section 25991(o) provides “[F]or purposes of this section, a sale shall be deemed to occur at the location where the buyer takes physical possession of an item covered by Section 25990.”¹⁰ It is inappropriate for the state to assert it has the authority to stop a truck, inspect paperwork and maybe even the cargo on the side of the road, and then deny entry or divert a truck absent a sale in California.

⁷ 9 CFR 312.2

⁸ https://www.cdfa.ca.gov/AHFSS/pdfs/Prop_12_FAQ_March_2021.pdf. See question 7.

⁹ 7 CFR 65.500(c)(4).

¹⁰ Section 25990(o) (Emphasis added).

If no sale has occurred, there can be no violation of the law, and absent a violation, the state cannot justify stopping the truck, denying entry, forcing diversion, *etc.* The proposed provisions are inappropriate because there is no threat to the public health or welfare from the covered products. Enforcement should occur where the buyer takes possession, not at the state line. And the Statement offers no statutory support for the state's assertion that inspection of cargo and ultimately even diversion of the truck. The law offers remedies to the state if there is evidence of a violation.

Ironically, although a purported justification for enacting Prop 12 was food safety, the proposed articles, if adopted, could jeopardize food safety. Cargo inspections conducted to verify compliance with a paperwork requirement jeopardize several federal requirements (*e.g.*, the FSIS HACCP/Pathogen Reduction Rule, FSMA Sanitary Transport Rule, and FSMA Intentional Adulteration Rule). Products subject to Prop 12 are refrigerated during transport. Opening refrigerated containers on the side of the road in a California summer, or winter, is an unacceptable food safety practice that could cause product spoilage or bacterial growth. More practically, containers may be sealed as part of the chain of custody, and these seals are often required by FSIS (and FDA). California enforcement officers would need to be trained in how to maintain the chain of custody and carry seals to reseal containers to prevent loads from being rejected by receivers.

The proposal also ignores the challenges associated with truck drivers likely not being well versed regarding Prop 12 requirements. Given the pressures associated with on-time delivery and complying with federal Department of Transportation rules for drive time, CDFA should reconsider these sections.

Tagging and Seizure of Meat

These sections would allow enforcement officers to apply a warning tag or notice to documents or containers of pork and veal “produced, packaged, stored, labeled, marked, identified, transported, delivered, or sold in violation” of Prop 12. Similarly, CDFA would allow enforcement officers to “seize and hold any containers, sub-containers, lots or loads” they “have reasonable suspicion to believe is in violation of the provisions of sections 25990-25992 of the Health and Safety Code, or the provisions of this Article.”¹¹ Prop 12, however, does not authorize CDFA to take these proposed actions. The words “seizure,” “tag,” and “detain” are nowhere to be found in Prop 12’s text. The remedies available for violating the law are the criminal penalties the state may pursue and the civil relief available to entities put at a competitive disadvantage. In short, the law does not authorize CDFA to take the actions in 1321/2.7 or 1321/2.6.

Written Certification.

These sections would be overly burdensome on retailers and other suppliers.¹²

¹¹ Section 1321.7 and Section 1322.7

¹² See discussion about audit trail, p. 2-3.

Denial, Suspension, or Revocation of Distributor Registration.

This section also over-reach because it would allow denial, suspension, or revocation of a distributor registration for violating a regulation that could have resulted in the sale of non-compliant product. Such a draconian action should, at minimum, be reserved for when a violation occurs.

Article 4. Exceptions.

The proposed definition of “Individual treatment” should be maintained. Unfortunately, Prop 12 is likely to result in higher sow mortality. However, deciding how pigs and veal calves should be treated medically should be left to those most qualified to make those decisions: veterinarians.¹³ The proposed definition affords the flexibility to provide the best veterinary care and limiting the ability of those trained professionals is not in the animals’ best interests.

CDFA should broaden the “Medical Research” exception. Limiting the exception to the Institutional Animal Care and Use Committee related research arguably eliminates research funded otherwise, privately or through other mechanisms, that benefit animal health.

Article 5. Certification and Accredited Certifiers.

Article 5 would create a bureaucratic morass that likely will result in even less pork and veal being shipped to California; only increasing prices Californians will pay for those goods. The burdens attendant to the recordkeeping requirements and onsite inspection, coupled with the annual renewal component, will drive producers away from supplying Prop 12 compliant livestock. And the labyrinthian process one would have to go through to become accredited to certify producer operations and distributors will be a significant disincentive and to the extent it is not, it will result in those entities who get accredited charging exorbitant fees when providing certification services.

General Requirements for Certification

Sections 1326.1(b)-(d) should be modified to ensure the certifying agent is limited to areas and records that involve products, and the animals that yield them, intended for sale in California. For example, section 1326.1(d) should be limited to “examine all covered products – for sale or distribution to California.” Without this limitation, the regulation could be interpreted to include inspection of veal, and pork products not sold into California. Products not destined for sale in California should not have to be available for inspection by a certifying agent.

¹³ “Estimated ongoing cost is greater than the initial cost of conversion at \$100,000 per year for a typical breeding pig farm due to smaller inventory of breeding pigs, lower piglet output per animal and **increased breeding pig mortality**.” (Emphasis added) Statement p. 143.

Recordkeeping by Certified Operations.

A theme running through these comments is whether a distributor must have documents from its supplier identifying that supplier and asserting the products provided are Prop 12 compliant records or whether a distributor must have records from every participant through the supply chain showing the product is compliant, including the name of the veal calf or hog producer. The former approach is not overly burdensome, allows the certifying or enforcement entity to contact the distributor's supplier to confirm compliance, and is consistent with the law. The latter approach, requiring onsite documents regarding "the identification, source, supplier, transfer of ownership, transportation, storage, segregation, handling, packaging, distribution, and sale of covered products" places an enormous recordkeeping burden on a distributor. That the section would require these documents be kept for two years only worsens the burden.

Subsection 1326.2(b)(5) would require a distributor to have records for the "preceding two-year period pertaining to the production, processing, handling, packaging, storage, transportation, or sale of covered animals or covered products sold, intended for sale in California or identified or represented as compliant with the confinement requirements of the Act and this Chapter." Unclear is how CDFA expects a distributor to have information about many of these activities, e.g. pork production, processing, or packaging. For example, how would a warehouse or distribution center have access to documents about production and processing that occurred at a federally inspected harvest establishment or further processing facility? Also unclear, and the Statement does not explain, what CDFA means by production or processing (for example) and why CDFA or a certifying entity needs to see documents about production or processing.

On-site Inspections.

Earlier discussion highlighted the problem of requiring certification by January 1, 2023. With almost 20,000 distributors and producers to be certified section 1326.5's requirement that "[A]n on-site inspection must be conducted at least once every 12 months thereafter for each certified operation that produces or distributes covered animals or covered products for the purpose of determining whether to approve the request for certification or whether certification of the operation should continue" will create a never-ending cycle where producers and distributors cannot be certified in a timely manner. For this reason alone certification renewal should be required not more than every three years.

On-site inspections of each production unit would be difficult, if not impossible, for many swine operations. Setting aside cost considerations (certifying entities will charge, and charge dearly, for services), CDFA undoubtedly knows the biosecurity concerns and challenges facing the hog industry. Not only are domestic diseases such as Porcine Reproductive and Respiratory Syndrome a significant threat to pork production units, foreign animal diseases such as African Swine Fever are also serious threats. The proposal's allowance for inspections, "announced and unannounced" would create significant biosecurity problems for producers who wish to be certified. For biosecurity reasons, an individual person working for a certifying agent and conducting an on-site inspection generally cannot visit an operation more than once every five days. Simple math shows the administrative burden and logistics associated with proposed annual inspection

is not only impractical, it is not feasible. Unannounced visits also create the possibility that the necessary personnel are not on site to ensure an inspection can be properly conducted.

The irony is, annual recertification is unnecessary because compliance is largely a function of facility design. As the industry has made abundantly clear, redesigning facilities is costly and time consuming. It is unnecessary for a certifying entity to make an annual trek to each production location. Given the absence of a legitimate food safety or public health concern, CDFA should consider requiring on site visits far less frequently, *e.g.*, every five years.¹⁴

Rather than require annual on-site inspections it would be more efficient for the agency to require certified entities to advise the certifying agent of any noteworthy changes. Such an approach facilitates the process, saving certified entities and CDFA resources.

Areas and Duration of Accreditation as a Certifying Agent

The Meat Institute supports the provision that allows certifying agents to be accredited for five years.

General Requirements for Accredited Certifying Agents.

That private entities, indeed all entities, that wish to be accredited need to be qualified for that role is understood. However, the number of accredited entities and what they must do to become accredited could become a chokepoint for products entering the state. If the number of accredited entities is limited, the cost of their services will rise – costs ultimately borne by California consumers. The fewer the number of accredited entities, the longer the wait for hog and veal calf operations to become certified and the more problematic recertification becomes should CDFA insist on annual certification.

Section 1326.10(a)(1) requires a private certifying entity to have “sufficient expertise” but there is no discussion in the Statement as to what term means. That requirement is repeated in 1326.13

Applicant Information for Accreditation as a Certifying Agent

A significant problem with the proposed rules is the extensive information a certifying agent would have to provide. It is understandable that CDFA needs information such as the certifying agent’s business name, primary office location, mailing address, etc. Unclear is why CDFA needs to know a lot of the other information required, *e.g.*, the names of people responsible for a certifying agent's day-to-day operations, an applicant's fee schedule for services provided, as well as “documentation showing the entity's status and organizational purpose, such as Articles of incorporation and by-laws or ownership or membership provisions, and its date of establishment.”

¹⁴ Indeed, FDA inspects production facilities subject to its jurisdiction for food safety purposes on average every 7-10 years. Requiring annual recertification is simply setting up everyone, including CDFA, for failure.

The more onerous the agency makes the application process, the fewer the number of entities willing to become a certifying agent and the fewer the number of those agents the more difficult it will be to get distributors and producer operations certified. CDFA needs to make the accreditation process simpler to encourage more companies to apply.

Evidence of Expertise and Ability

Section 1326.13 highlights why some entities may choose not to be accredited. The provision in section 1326.13(a) that would require a certifying entity to provide the names of all auditors and similar employees, *etc.* is unduly burdensome and does not recognize the ebb and flow of the workforce. Employees come and go and the provision will impose administrative costs on the certifying entity, then the operations, and ultimately the consumer. Likewise, section 1326.13(d) would require a certifying agent candidate to provide evidence of other certifying activities. Given the “uniqueness” of Prop 12’s requirements, other certifying activities a candidate conducts are likely irrelevant to its ability to operate under Prop 12.

On-site Evaluations

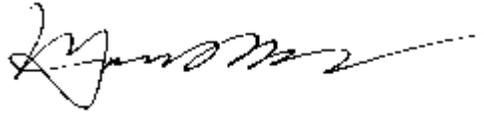
Section 1326.16’s requirement that CDFA representatives conduct site evaluations of accredited certifying agents is inexplicable and will become another chokepoint that keeps covered products out of the state. It is difficult to imagine CDFA has the staff to review all the paperwork required of a candidate for accreditation, or one already accredited, much less staff who can travel throughout the country, or to other countries for veal calf and hogs, to perform an onsite evaluation of proposed certifying agents. The on-site evaluation requirement also presents a problem for CDFA officials may not travel to certain locations given the state’s travel restrictions to certain states. For example, can CDFA officials travel to Texas to conduct a site evaluation for a certification candidate or one already accredited? If not, how can a potential certifying organization in those states become accredited?

* * * * *

The Meat Institute appreciates the opportunity to submit these comments. NAMI wishes to repeat its request that CDFA postpone implementing Prop 12 for at least two years and longer as necessary to ensure conversations and a common understanding among the agency, the industry, and consumers about the law’s economic impact and the alleged rationales underlying Prop 12.

Please contact me if you have questions about this request or anything else regarding this matter. Thank you for your consideration.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Mark Dopp', with a long horizontal flourish extending to the right.

Mark Dopp
Senior Vice President
Regulatory & Scientific Affairs
and General Counsel

Cc: Dr. Annette Jones
Dr. Stephen Beam
Julie Anna Potts
Pete Thomson
Sarah Little
Casey Gallimore