

No. 21-468

In the Supreme Court of the United States

NATIONAL PORK PRODUCERS COUNCIL & AMERICAN
FARM BUREAU FEDERATION,

Petitioners,

v.

KAREN ROSS, ET AL.,

Respondents.

**On Petition for a Writ of Certiorari to
the United States Court of Appeals for the
Ninth Circuit**

REPLY BRIEF FOR PETITIONERS

DAN HIMMELFARB
COLLEEN M. CAMPBELL
Mayer Brown LLP
1999 K Street, NW
Washington, DC 20006
(202) 263-3000

TIMOTHY S. BISHOP
Counsel of Record
BRETT E. LEGNER
Mayer Brown LLP
71 South Wacker Drive
Chicago, Illinois 60606
(312) 701-7829
tbishop@mayerbrown.com

Counsel for Petitioners
Additional Counsel Listed on Signature Page

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This case—which challenges Proposition 12 as a violation of protections for horizontal federalism embodied in the Commerce Clause—comes to this Court from the grant of a motion to dismiss. Respondents pay lip service to the requirement that petitioners’ plausible allegations be accepted as true and the facts construed in the light most favorable to petitioners’ claims, but their briefs are full of untested factual assertions that contradict the allegations in the complaint. It is precisely because this case arises from dismissal of a detailed complaint, however, that it provides such a good vehicle to resolve important issues of constitutional law that California concedes (at 16) spawn large amounts of litigation. No factual dispute or need for speculation stands in the way of resolving the legal issue of whether petitioners’ complaint states an extraterritoriality or *Pike* claim.¹

California consumes 13% of U.S. pork, but produces only 0.1% of what it consumes. Pet. App. (“App.”) 80a, 150a-151a. Proposition 12’s sow-housing requirements thus fall almost exclusively on farmers outside of its borders. The Ninth Circuit accurately described petitioners’ allegations about how those requirements operate extraterritorially to disrupt the \$26-billion-a-year market in pork, force California’s preferred production methods on farmers everywhere, and impose the high costs of those methods on out-of-state farmers and consumers:

¹ Denial of certiorari in *NAMI* is of no moment. There, packers—not the farmers who will bear the burden of Proposition 12—sought review of denial of a preliminary injunction, a posture in which certiorari is extraordinarily rare. And *NAMI* did not allege a central element of petitioners’ claim: that processing a pig into many cuts sold into different markets means that Proposition 12’s costs are exported nationwide.

A single hog is butchered into many different cuts which would normally be sold throughout the country. In order to ensure they are not barred from selling their pork products into California, all the producers and the end-of-chain supplier will require assurances that the cuts and pork products come from [sows] confined in a manner compliant with Proposition 12. * * * As a practical matter, given the interconnected nature of the nationwide pork industry, all or most [sow] farmers will be forced to comply with California requirements. The cost of compliance with Proposition 12's requirements is high, and would mostly fall on non-California transactions, because 87% of the pork produced in the country is consumed outside California.

App. 9a. The Ninth Circuit also accurately described petitioners' allegations about the extraterritorial consequences of Proposition 12, observing that petitioners have "plausibly alleged" that it "will have dramatic upstream effects," "require pervasive changes to the pork production industry nationwide," cause "cost increases to market participants and customers" everywhere, and impose "complex compliance requirements on out-of-state farmers," including "allow[ing] access to [California's] agent[s]." App. 11a-12a, 18a, 20a.

State regulation "is invalid under the Commerce Clause" if its "practical effect" is "to control conduct beyond the boundaries of the State." *Healy*, 491 U.S. at 332, 336. And the "fact that the effects of [a state's law] are triggered only by sales * * * within the State" does not "validate the law if it regulates the out-of-

state transactions of [those] who sell in-state.” *Brown-Foreman*, 476 U.S. at 580. If those principles have continuing vitality, the complaint here states a claim. See U.S. CA9 Am. Br. at 1 (ECF 23) (“[t]he district court erred by dismissing the complaint” under those standards). If they do not—if they are “overbroad” “dicta” “moving in [the] direction” of being “a dead letter” (App. 7a, 19a)—this Court should so inform the regulated parties and States (like the 20 *amicus* States here) that continue to litigate in the belief that this Court’s extraterritoriality precedents provide important protection from overreaching state legislatures and interest-group-driven initiatives like Proposition 12. And if they do not, there is nothing to stop any state from boycotting goods that are not union-made, or come from companies that do not pay the state’s minimum wage, or have any other perceived moral failing. See *Baldwin*, 294 U.S. at 524 (mocking the idea that the Commerce Clause allows a state to “condition importation [of goods] upon proof of a satisfactory wage scale”).

There is nothing “stale” about petitioners’ allegations. HSUS Opp. 18. Respondents’ observation that some packers say they will comply with Proposition 12 merely confirms our allegations that large packing companies that purchase, slaughter, and distribute the meat of the vast majority of market hogs are already requiring their suppliers to comply with Proposition 12. Pet. 10-13.² This means that,

² California’s specific assertions (at 18-19) are misleading. Hormel Foods owns few sows and sells a significant amount of processed, ready-to-eat products that are not covered by Proposition 12. App. 196a-199a, ¶¶253-256. Hormel emphasizes “the manufacturing and distribution of branded value-added consumer items rather than commodity fresh meat products.”

first, the costs of compliance will be built into every market hog regardless of where it is sold; second, independent sow farms that cannot afford the huge costs of conversion will eventually go out of business, increasing industry consolidation; third, California will have succeeded in dictating costly and, we allege, affirmatively harmful sow-housing practices in Iowa, Minnesota, and all other pig-producing states, including in Ohio where state law expressly allows the gestation stalls that Proposition 12 prohibits (Pet. 4, 18). Far from suggesting that our claims are “stale”—an odd assertion when Proposition 12 has not yet gone into effect—the substantial market changes being wrought are the direct effect of California’s extraterritorial law and clear evidence that this Court’s intervention is urgently needed.³

Hormel Foods Corp., Annual Report (Form 10-K) (Dec. 4, 2020), <http://d18rn0p25nwr6d.cloudfront.net/CIK-0000048465/049e9679-5c2b-48fc-a67f-945fdc05db1f.pdf>, Part 1, item 1. Niman Ranch is a small specialty producer that charges a significant premium for its products everywhere, proving our point: Proposition 12 will drive up consumer prices nationwide.

³ California’s suggestion (at 3, 8) that “stand-up, turn-around” has been in effect since 2018 without the sky falling is a red herring. Though hardly any sow farm satisfies “stand-up, turn-around,” California has never enforced it and has no certification and labeling scheme in place to enable it to do so. No mention of that requirement appeared in the proposed rules until December 3, 2021, days before California filed its brief. Supplemental Appendix, *infra*, 13a, 82a.

A. The Petition Squarely Raises The Important Constitutional Question Of The Continuing Vitality Of The Extraterritoriality Doctrine, An Essential Part Of The Dormant Commerce Clause’s Protection Of Our Federalism

1. Respondents do not dispute that the dormant Commerce Clause’s protections are essential to our federalism. The dormant Commerce Clause vindicates the Constitution’s “special concern” to maintain unimpeded nationwide markets and state autonomy. *Healy*, 491 U.S. at 335-36. It requires meaningful and vigorous judicial enforcement because, when the burden of a state regulation falls predominantly on those outside the state, that burden “is unlikely to be alleviated by the operation of those political restraints normally exerted when interests within the state are affected.” *S. Pac. Co.*, 325 U.S. at 767 n.2. Without the safeguards of the dormant Commerce Clause, the nationwide economy could swiftly be plunged into the chaos created by incompatible state economic regulation of out-of-state conduct.

Proposition 12 is a perfect example: Californians passed a referendum that imposes what the Ninth Circuit acknowledged are “dramatic” effects and “pervasive” changes on sow-farming operations, knowing that such operations are virtually non-existent in the State. Thus, Californians adopted what they believe to be beneficial farming practices—requirements that petitioners plausibly allege are prohibitively expensive for farmers to implement and harmful to the animals—but the price of complying with them falls almost entirely on out-of-state businesses and consumers. The question presented here is whether a state is permitted to upend an entire

nationwide industry in this way. Both states and regulated communities need an answer to that question.

2. This Court long ago recognized the threat to our federalism, including harmful Balkanization of the American economy, if states regulate wholly out-of-state conduct either directly or indirectly. Writing for the unanimous Court in *Baldwin*, Justice Cardozo was unequivocal that one state cannot “regulate[] by indirection” commerce in other states. 294 U.S. at 524. By eliminating the prohibition against indirect regulation of out-of-state activity when the regulation does not involve price control, that is exactly what the Ninth Circuit has permitted California to do.

This Court has never held that the extra-territoriality doctrine means anything other than exactly what it says: the dormant Commerce Clause is violated when “the practical effect of the statute is to control conduct beyond the boundaries of the state.” *Healy*, 491 U.S. at 336⁴ But the Ninth Circuit held that the *Baldwin-Healy* line cannot mean what the cases say and that the dormant Commerce Clause is becoming “a dead letter.” App. 7a, 19a. This Court’s intervention is required to explain whether the Ninth Circuit’s consignment of the extraterritoriality doctrine to the dead-letter office is correct.

⁴ Some circuits, including panels of the Ninth Circuit, have held that *Walsh* limited the reach of the extraterritoriality doctrine. App. 8a. But as the Fourth Circuit has explained, *Walsh* “does not suggest that ‘the rule that was applied in *Baldwin* and *Healy*’ applies *exclusively* to ‘price control or price affirmation statutes.’” *Ass’n for Accessible Medicines*, 887 F.3d at 671. This circuit split over the meaning of *Walsh* alone justifies granting the petition.

California says there is no conflict with the *Baldwin-Healy* line because the Ninth Circuit “acknowledged this Court’s recognition that a law *could* violate the dormant Commerce Clause if it had the ‘practical effect’ of regulating commerce occurring wholly out-of-state.” Opp. 12-13 (citing App. 7a). But that superficial argument ignores what the court of appeals actually did: it paid lip service to the practical-effects rule, then misread *Walsh* to limit the extraterritoriality doctrine “only to state laws that are ‘price control or price affirmation statutes.’” App. 8a. And the court then held that even a broader interpretation of the doctrine does not prohibit Proposition 12 because it does not “directly regulat[e] transactions conducted entirely out of state,” only in-state sales. App. 13a-14a.

For those reasons, respondents’ arguments that the Ninth Circuit did not reject petitioners’ extraterritoriality theory as a legal matter and petitioners merely lost below under their own theory of the case are wrong. Cal. Opp. 12-13; HSUS Opp. 9-11. The court of appeals first held that the extraterritoriality doctrine applies only to price-control statutes and petitioners’ claims failed under that “narrow interpretation.” App. 7a-8a. That is unquestionably a rejection of petitioners’ legal theory and in square conflict with *Baldwin*, *Healy*, and *Walsh*, none of which imposed such a limitation.

The court then acknowledged that some Ninth Circuit decisions apply a broader interpretation of the doctrine, not limited to price controls. But it categorically held that state laws that directly regulate only in-state conduct like sales “do not have impermissible extraterritorial effects.” App. 10a. In its ensuing discussion of Ninth Circuit decisions

invalidating state laws as impermissibly extra-territorial, the court explained that those laws “*directly* regulated transactions conducted entirely out of state.” App. 13a (emphasis added). Those holdings cannot be reconciled with *Baldwin*’s clear statement that the dormant Commerce Clause addresses both direct and indirect regulation of out-of-state conduct.

Thus, the Ninth Circuit’s decision is in square conflict with the *Baldwin-Healy* line in three ways: (1) it states that this Court’s extraterritoriality cases are not to be taken literally; (2) it applies a misunderstanding of *Walsh* to support a narrow interpretation limiting the extraterritoriality doctrine to price-control cases; and (3) even under a “broader” interpretation of the doctrine, the court removes indirect regulation of out-of-state conduct from the extraterritoriality equation.

3. There is also a circuit split on the meaning of *Walsh*. As we explained, at least the Fourth, Sixth, and Seventh Circuits have disagreed with the Ninth and Tenth Circuits on whether *Walsh* limited the extraterritoriality doctrine to the price-control context. Pet. 26-28.

California contends that the circuits are nonetheless in agreement that in-state sales restrictions cannot have an impermissible extraterritorial effect even if they impose indirect upstream costs on out-of-state businesses. Cal. Opp. 13-14. First, this Court has never so restricted the *Baldwin-Healy* line. To the contrary, this Court has long “eschewed formalism” in dormant Commerce Clause cases, making clear that “[o]ur Commerce Clause jurisprudence is not so rigid as to be controlled by the form by which a State erects barriers to commerce.” *West*

Lynn Creamery, Inc. v. Healy, 512 U.S. 186, 201 (1994).

Second, courts have *not* uniformly held that in-state sales restrictions cannot violate the dormant Commerce Clause. For instance, the Seventh Circuit struck down an Indiana law in *Legato Vapors* that imposed invasive requirements on out-of-state manufacturers who wished to sell electronic-cigarette products in Indiana. 847 F.3d at 833. There was no direct regulation of businesses—the businesses only had to conform their practices to Indiana’s requirements if they wanted to sell their products in that State, just as with farmers under Proposition 12. The Seventh Circuit concluded that the upstream effects of Indiana’s law, which would have required businesses to change their physical operations to meet Indiana’s standards and submit to detailed inspections of their out-of-state plants by Indiana agents, violated the dormant Commerce Clause. Proposition 12 has the same type of upstream effects on the much larger, nationwide pork industry. Given that circuit split, and the split on whether the extra-territoriality doctrine stops at price regulation, some states can constitutionally impose their legal regimes outside their borders, while others cannot.

Third, California ignores the factual allegations in the complaint. Petitioners allege that this is not a situation where producers may freely choose to alter their operations to comply with state regulation, which often, as with the case of state labelling requirements, does not impact products sold in other states. Instead, petitioners allege that the segmented nature of hog production and dispersed sale of cuts from each hog mean that farmers outside California will be forced to either comply with Proposition 12 or

withdraw from the business: that is the “undeniable effect” of Proposition 12. *Healy*, 491 U.S. at 337. The result is that California’s regulations will govern countless transactions in pork meat, from farmers to packers to distributors to consumers, occurring entirely outside of California. No case California cites rests on remotely similar facts.

B. The Ninth Circuit Guttled the *Pike* Test

Proposition 12, petitioners allege, burdens interstate commerce in a way that is “clearly excessive in relation to the putative local benefits” and so flunks *Pike* balancing. 397 U.S. at 142. The Ninth Circuit recognized Proposition 12’s market distortions. App. 17a-18a, 20a. But it refused to treat them as a significant burden on commerce triggering *Pike*, reductively describing them as merely increasing sellers’ “compliance costs.” App. 17a. Almost all laws can ultimately be reduced to cost effects. But Proposition 12 goes much further in its impacts on farmers and the pork industry: it requires substantial changes in the means of production and the operation of the complex, segmented nationwide market, and it affects animal health. Pet. 29. This is not a case where, as the Ninth Circuit insinuated, the impact of the law will simply be to “cause[] some business to shift from one interstate supplier to another.” App. 18a.

California’s and HSUS’s response is to offer alternative “facts.” *E.g.*, Cal. Opp. 21, HSUS Opp. 32. But at the motion-to-dismiss stage the relevant question is whether petitioners’ well-pleaded facts state a claim. Respondents’ untested, contrary assertions anyway do not withstand a closer look.

For example, California argues (at 21) that the industry is already moving in the “general direction” of group housing. But petitioners allege that “almost the entire industry” is currently out of compliance with Proposition 12 (App. 204a, ¶289) and would need to undergo dramatic changes to comply. App. 207a-213a, ¶¶ 305-340. Very few farmers provide 24 square feet per sow (App. 204a, ¶285), and almost no pork producers use group housing for the 30 to 40 days from when a sow finishes weaning until a new pregnancy is confirmed. App. 204a, ¶287.⁵ California’s reference (at 18-19) to specialist producers that do—and that charge premium prices nationwide—proves our point that Proposition 12 will distort the national pork market.

To justify Proposition 12’s disruption of interstate commerce, respondents point to its animal-cruelty rationale. This is not a “local benefit” under *Pike* (397 U.S. at 142) because the pig farms Proposition 12 regulates are nearly all outside of California. As the United States told the Ninth Circuit, it is “an improper purpose” for California to regulate to prevent “what California considers animal cruelty” “occurring entirely outside the State’s borders.” U.S. CA9 Am. Br. at 2; Cato Am. Br. at 7-9. Providing some Californians with peace of mind about pork raised out-of-state (HSUS Opp. 33-34) cannot outweigh Proposition 12’s serious harm to interstate commerce. And respondents ignore petitioners’ allegations that

⁵ California pretends (at 22 n.18) that petitioners do not explain the burden of converting from 16 or 18 square feet per sow to 24 square feet. Petitioners do so (App. 208a, ¶¶ 308-316), and also allege multiple harms from Proposition 12’s restrictions on breeding stalls.

Proposition 12 affirmatively harms pigs. App. 220a, ¶¶379, 221a-224a, ¶¶390-410.

California belatedly and half-heartedly attempts to revive Proposition 12's purported human-health justification as a "precautionary" measure to address "potential" foodborne-illness threats. Opp. 23. But we allege there is no connection whatever between the space sows are afforded and the wholesomeness of meat from market pigs; the rapid separation of sows from piglets (not to mention the federal inspection apparatus) eliminates any risk. Pet. 30. CDFA initially admitted that its regulations "do[] not directly impact human health." App. 55a. CDFA's new, litigation-driven "clarification" still admits that "there is not currently a consensus in peer-reviewed published scientific literature" that Proposition 12 "reduce[s] the risk of human food-borne illness" (Supplemental Appendix, *infra*, 74a), and petitioners allege that there is none. Respondents' unsupported assertions cannot justify a law with the sweeping impact of Proposition 12.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

DAN HIMMELFARB
COLLEEN CAMPBELL
Mayer Brown LLP
1999 K Street, NW
Washington, DC 20006

TIMOTHY S. BISHOP
Counsel of Record
BRETT E. LEGNER
Mayer Brown LLP
71 South Wacker Drive
Chicago, Illinois 60606
(312) 701-7829
tbishop@mayerbrown.com

ELLEN STEEN
TRAVIS CUSHMAN
American Farm Bureau
Federation
Suite 1000W
600 Maryland Avenue
SW
Washington, DC 20024

MICHAEL C. FORMICA
National Pork
Producers Council
122 C Street NW
Suite 875
Washington, DC 20001

Counsel for Petitioners

DECEMBER 2021

SUPPLEMENTAL APPENDIX

**TITLE 3. FOOD AND AGRICULTURE 15-DAY
NOTICE OF MODIFIED TEXT AND DOCU-
MENTS ADDED TO THE RULEMAKING FILE
RELATING TO ANIMAL CONFINEMENT**

NOTICE IS HEREBY GIVEN that the Department of Food and Agriculture (Department), Animal Care Program, is proposing to modify the proposed regulation text for sections 1320, 1320.1, 1320.2, 1320.3, 1320.4, 1320.5, 1320.6, 1320.7, 1320.8, 1320.9, and 1320.10 of Article 1; 1321, 1321.1, 1321.2, 1321.3, 1321.4, 1321.5, 1321.6, 1321.7, 1321.8, 1321.9, and 1321.10 of Article 2; 1322, 1322.1, 1322.2, 1322.3, 1322.4, 1322.5, 1322.6, 1322.7, 1322.8, 1322.9, and 1322.10 of Article 3; 1324 and 1324.1 of Article 4; 1326, 1326.1, 1326.3, 1326.4, 1326.5, 1326.6, 1326.7, 1326.8, 1326.10, 1326.12, 1326.13, 1326.14, 1326.15, 1326.16, 1326.17, 1326.18, 1326.20, 1326.21, and 1326.22 of Article 5; and 1327.2 and 1327.3 of Article 6, Chapter 10, Division 2, of Title 3 of the California Code of Regulations. The proposal pertains to the action described in the Informative Digest published in the *California Regulatory Notice Register* on May 28, 2021 [Notice File No. Z2021-0518-22, Register 2021, No. 22-Z], relating to the Department's proposal to implement, interpret, or make specific the requirements relating to the confinement of egg-laying hens, veal calves, and breeding pigs, and/or selling specified whole veal meat, whole pork meat, shell eggs, and liquid eggs in California in accordance with sections 25990, 25991, 25992, 25993.1, and 25994 of the Health and Safety Code (HSC). The Department is now providing notice of modifications to the regulation text to make clarifying changes and to address concerns raised during the Department's 45-day public comment period and/or during the public hearing. A copy of the proposed modified text is enclosed.

NOTICE IS HEREBY GIVEN of the following document added to the rulemaking file to provide rationale for the proposed modified text and to clarify statements made in the Initial Statement of Reasons (ISOR) pursuant to Government Code sections 11346.8(d) and 11347.1:

- Addendum to the ISOR

In addition, the following documents are added to the rulemaking file as Materials Relied Upon pursuant to Government Code sections 11346.8(d) and 11347.1:

- *American Association for Accreditation of Laboratory Animal Care International, Bylaws, May 2, 2019* to provide support for the proposed modified text (Materials Relied Upon Document Added – 1).
- *Organic 101: Ensuring Organic Integrity Through Inspections* to provide additional support for the Department’s proposal pertaining to on-site inspections (Materials Relied Upon Document Added – 2).
- *Title 7, Code of Federal Regulations, Part 205, section 205.406* to provide additional support for the Department’s proposal pertaining to on-site inspections (Materials Relied Upon Document Added – 3).
- *American Humane Certified™, Becoming American Humane Certified™* to provide additional support for the Department’s proposal pertaining to inspections (Materials Relied Upon Document Added – 4).
- *Humane Farm Animal Care, Policy Program Manual* to provide additional support for the Department’s proposal pertaining to on-site

inspections (Materials Relied Upon Document Added – 5).

- *A Greener World, A Greener World Compliance Policy Manual – North America* to provide additional support for the Department’s proposal pertaining to on-site inspections (Materials Relied Upon Document Added – 6).
- *Global Animal Partnership, Pig Standards* to provide additional support for the Department’s proposal pertaining to on-site inspections (Materials Relied Upon Document Added – 7).

The documents pertain to the regulatory action as described above *in the California Regulatory Notice Register* on May 28, 2021 [Notice File No. Z2021-0518-22, Register 2021, No. 22-Z].

Written comments regarding the original proposal: The written comments received by the Department for this proposal during the initial 45-day public notification period which began on May 28, 2021 and ended on July 12, 2021 remain in the Department’s rulemaking file.

Verbal comments received during the public hearing regarding the original proposal: The verbal comments received by the Department for this proposal during the public hearing held August 27, 2021 remain in the Department’s rulemaking file.

Written comments received the day of the public hearing regarding the original proposal: The written comments received by the Department for this proposal the day of the public hearing held August 27, 2021 remain in the Department’s rulemaking file.

Written comments regarding the proposed modified text and the documents added to the rulemaking file:

If any person wishes to comment on the proposed modifications to the regulatory text or to the documents added to the rulemaking file, the written comment must be submitted to the contact person named in this notice **beginning December 3, 2021 and ending December 17, 2021**. The written comments are to be restricted to the recent modifications as shown in the attached proposed modified regulatory text and/or to the documents added to the rulemaking file. The Department is not required to respond to comments received in response to this notice on other aspects of the proposal. All written comments received no later than **December 17, 2021**, which pertain to the indicated changes and/or documents added to the rulemaking file will be reviewed and responded to by Departmental staff as part of the compilation of the rulemaking file.

Dated: November 30, 2021

**DEPARTMENT OF FOOD AND AGRICULTURE
ANIMAL HEALTH AND FOOD SAFETY
SERVICES PROPOSED REGULATIONS
ANIMAL CONFINEMENT
PROPOSED MODIFIED TEXT**

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Proposed deleted text is displayed in ~~striketrough~~.
Proposed added text is displayed in double underline.

Chapter 10. Animal Confinement.

* * *

Article 3. Breeding Pigs.

Section 1322. Definitions.

Unless the context otherwise requires, the following definitions apply to this Article and words in the singular form shall be deemed to impart the plural and vice versa, as the case may demand:

(a) "Act" means the Farm Animal Cruelty statute, as amended (Chapter 13.8 (commencing with section 25990) of Division 20 of the Health and Safety Code).

(b) "Audit trail" means records that are in sufficient detail to document the identification, source, supplier, transfer of ownership, transportation, storage, segregation, handling, packaging, distribution, and sale of whole pork meat that was derived from a breeding pig, or immediate offspring of a breeding pig, confined in compliance with sections 25991 and 25992 of the Health and Safety Code and this Article, and

from pork producers that hold a valid certification as a certified operation issued pursuant to Article 5 of this Chapter.

(c) “Breeding pig” means, pursuant to section 25991(a) of the Health and Safety Code, any female pig of the porcine species kept for the purpose of commercial breeding who is six (6) months of age or older, or pregnant.

(d) “Certified operation” means as defined in section 1326(e) of this Chapter.

(e) “Certifying agent” means as defined in section 1326(f) of this Chapter.

(f) “Commercial sale” for purposes of section 25991(o) of the Health and Safety Code and this Article means to sell, offer for sale, expose for sale, possess for sale, exchange, barter, trade, transfer title or possession, or otherwise distribute, conditional or otherwise, in California commerce including, but not limited to, transactions by a retailer with a consumer and electronic transactions made using the internet. It shall not include any of the following transactions or transfers of possession, which apply only to a specific transaction listed below, not to the covered product itself, and therefore does not apply to all subsequent commercial sales of whole pork meat:

(1) Whole pork meat produced outside of the state that enters and exits California, without additional processing or repackaging, exclusively for purposes of transshipment or export for human consumption outside of the state;

(2) Any sale of whole pork meat undertaken on the premises of an establishment at which mandatory

inspection is provided under the Federal Meat Inspection Act (21 U.S.C. Sec. 601 et seq.) and that holds an official establishment number (prefix "M") granted by the Food Safety Inspection Service of the United States Department of Agriculture; or that is made directly to federal agencies or that takes place on federal lands located within the state; or

(3) Any sale of whole pork meat which takes place on tribal lands located within the state; or

~~(3)(4) 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 (26 U.S.C.).~~

~~(4) The exception to definition of commercial sale applies only to a specific transaction listed above, not to the covered product itself, and therefore does not apply to all subsequent sales of whole pork meat.~~

(g) "Consumer" means any person who purchases whole ~~uncooked~~ pork meat, as defined in section 25991(u) of the Health and Safety Code and this Article, for the sole purpose of their own ~~family~~ personal use or consumption, or that purchases or consumes cooked pork meat at a restaurant, food facility, or other business that serves cooked or ready-to-eat pork meat to customers or patrons.

(h) "Container" means any box, case, basket, tote, can, carton, sack, pouch, bag, package, wrapper, receptacle, or any other device which is used to facilitate the handling, distribution, transportation, or commercial sale of whole pork meat.

(i) "Cottage food operation" means an establishment as defined in section 113758 of the Health and Safety Code.

(j) “Curing agents” for purposes of section 25991(u) of the Health and Safety Code and this Article means any substance listed and described in section 424.21(c) of Title 9 of the Code of Federal Regulations.

(k) “Cut” for purposes of section 25991(u) of the Health and Safety Code and this Article means any uncooked primal, wholesale, sub-primal or retail cut including, but not limited to, those identified and described in the United States Department of Agriculture’s Institutional Meat Purchase Specifications: Fresh Pork Series 400 (November 2014 Edition) and the 2014 Uniform Retail Meat Identity Standards developed by the Industry-Wide Cooperative Meat Identification Standards Committee, but shall exclude any ground or otherwise comminuted meat products.

(l) “Department” means the California Department of Food and Agriculture.

(m) “Document of title” means a document which in the regular course of business or financing is treated as adequately evidencing that the person in possession of it is entitled to receive, hold, and dispose of the document and the whole pork meat it covers. Examples of such documents include, but are not limited to, bill of lading, dock warrant, dock receipt, warehouse receipt, or an order for the delivery of whole pork meat.

(n) “Enclosure” means a structure used to confine a covered animal or animals. For purposes of this subsection and this Article, a structure means any cage, crate, pen, or other construction used to confine a breeding pig.

(o) “End-user” means any of the following:

(1) A consumer;

(2) A retailer that is not a pork producer and only conducts commercial sales directly to a consumer, without any further distribution, of whole pork meat that was purchased or received from a pork distributor;

(3) A food processing facility or cottage food operation that receives whole pork meat solely for use as an ingredient to manufacture a combination food product that does not meet the definition of whole pork meat as defined in this Article; or

(4) A restaurant, food facility or other business that only cooks and serves pork meat, and/or serves only ready-to-eat pork meat, to customers, patrons or guests for purposes of consumption.

~~(p)~~ “Enforcement officer” means any of the following:

(1) Persons employed by and under the supervision and control of the Department; or

(2) Persons employed by and under the supervision and control of the Department of Public Health.

~~(p)~~(p) “Flavoring” for purposes of section 25991(u) of the Health and Safety Code and this Article means any substance, whether artificial or natural, the function of which is to impart flavor rather than nutrition, and includes the substances listed and described in sections 172.510, 172.515(b), 182.10, 182.20, 182.40, and 182.50, and substances with a use described as a flavoring, flavoring agent, or flavoring enhancer in part 184 of Title 21 of the Code of Federal Regulations.

~~(p)~~(q) “Food facility” means a facility as defined in section 113789 of the Health and Safety Code.

~~(s)~~(r) “Food processing facility” means a facility as defined in section 109947 of the Health and Safety Code.

~~(t)~~(s) “Person” means any individual, firm, partnership, joint venture, association, limited liability company, corporation, estate, trust, receiver, or syndicate

~~(u)~~(t) “Pork distributor” means a person or facility engaged in the business of commercial sales or distribution of whole pork meat (as a pork producer or otherwise) to an end-user in California. This definition shall not apply to a person or facility that only receives whole pork meat as an end-user.

~~(v)~~(u) “Pork producer” means a person engaged in the business of keeping, maintaining, confining and/or housing a female pig of the porcine species that is six (6) months of age or older, or is pregnant, for the purpose of commercial breeding to produce pork meat from the breeding pig or her immediate offspring for human food consumption. This definition shall not apply to an establishment at which mandatory inspection is provided under the Federal Meat Inspection Act (21 U.S.C. Sec. 601 et seq.) and that holds an establishment number (prefix “M”) granted by the Food Safety Inspection Service of the United States Department of Agriculture.

(v) “Production cycle” means the lifecycle of a commercial breeding pig for the generation of immediate offspring. A production cycle for gilts begins when they are six months or older and moved into an enclosure for breeding and ends when a litter of piglets is weaned. A new production cycle for sows begins when each litter of piglets is weaned.

(w) “Ready-to-eat (RTE)” means in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, gastronomic, or culinary purposes. RTE product is not required to bear a safe-handling instruction (as required for non-RTE products by sections 317.2(l) and 381.125(b)) of Title 9 of the Code of Federal Regulations) or other labeling that directs that the product must be cooked or otherwise treated for safety and can include frozen meat products.

(x) “Records” means any information in written, visual, or electronic form that documents the activities undertaken by a producer, distributor, or certifying agent to comply with the Act and this Chapter.

~~(x)~~(y) “Requiring cooking” for the purposes of section 25991(r) of the Health and Safety Code and this Article means not ready-to-eat in the condition sold, offered for sale or otherwise distributed.

~~(y)~~(z) “Retailer” means a facility location that conducts commercial sales of whole pork meat to a consumer.

~~(z)~~(aa) “Seasoning” for purposes of section 25991(u) of the Health and Safety Code and this Article is synonymous with the term “spice” and means any aromatic vegetable substance in the whole, broken, or ground form, whose primary function in food is seasoning rather than nutritional and from which no portion of any volatile oil or other flavoring principle has been removed. Spices include onions, garlic, peppers, and the spices listed in section 182.10, and Part 184 of Title 21 of the Code of Federal Regulations.

(bb) “Takes physical possession” for the purposes of section 25991(o) of the Health and Safety Code and this Article means when the whole pork meat is delivered to the buyer in California, regardless of whether the title transfer takes place outside of the state, whether the seller and buyer have provided otherwise by a contract, or whether an agent of the buyer accepts the whole pork meat outside of the state for transportation into California.

(aa)(cc) “Uncooked” means requiring cooking prior to human consumption.

(dd) “Usable floorspace” shall be calculated by dividing the total square footage of floorspace provided to breeding pigs in an enclosure by the number of breeding pigs in the enclosure. This floorspace shall also include ground-space for enclosures that are outdoor pens or pastures accessible at all times by all breeding pigs confined in the enclosure.

(bb)(ee) “Whole pork meat” means, pursuant to section 25991(u) of the Health and Safety Code, any uncooked cut of pork, including bacon, ham, chop, ribs, riblet, loin, shank, leg, roast, brisket, steak, sirloin, or cutlet, that is comprised entirely of pork meat, except for seasoning, curing agents, coloring, flavoring, preservatives, and similar meat additives. Whole pork meat does not include combination food products, including soups, sandwiches, pizzas, hotdogs, or similar processed or prepared food products, that are comprised of more than pork meat, seasoning, curing agents, coloring, flavoring, preservatives, and similar meat additives.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990, 25991, 109947, 113758, and 113789, Health and Safety Code; Title 9, Part 317, section 317.2(l), Part 381, section

381.125(b), and Part 424, section 424.21(c), Title 21, Part 172, sections 172.510 and 172.515(b), Part 182, sections 182.10, 182.20, 182.40, 182.50; and Part 184, Code of Federal Regulations; Federal Meat Inspection Act, 21 U.S.C. section 601 et seq.; and Internal Revenue Code, 26 U.S.C. section 501(c)(3).

Section 1322.1. Breeding Pig Confinement.

(a) No ~~pork producer or pork distributor~~ person shall knowingly sell or contract to sell ~~engage in a commercial sale within the state of whole pork meat for human consumption food in the state if it the whole pork meat is the product of a breeding pig, or the product of the immediate offspring of a breeding pig, that was confined at any time during the production cycle for said product in an enclosure that fails to comply with the following standards:~~

(1) An enclosure shall allow the breeding pig to lie down, stand up, fully extend limbs, and turn around freely.

(1)(2) Commencing January 1, 2022 After December 31, 2021, an enclosure shall provide a minimum of 24 square feet of usable floorspace per breeding pig.

(2) The amount of usable floorspace required by (a)(1) of this section shall be calculated by dividing the total square footage of floorspace provided to breeding pigs in an enclosure by the number of breeding pigs in the enclosure. For purposes of this section, floorspace shall also include ground space for enclosures that are outdoor pens or pastures accessible at all times by all pigs in the enclosure.

(3) Exceptions to the requirements of this section are specified in section 25992 of the Health and Safety

Code and Article 4 of this Chapter ~~apply to the requirements of this section.~~

(b) Commencing January 1, 2023~~4~~, any person engaged in business in ~~this the~~ state as a pork producer, or any out-of-state pork producer that is keeping, maintaining, confining, and/or housing a breeding pig for purposes of producing whole pork meat, from the breeding pig or its immediate offspring, for human food ~~use for commercial sale in California,~~ shall hold a valid certification issued pursuant to Article 5 of this Chapter as a certified operation.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990, 25991, and 25992, Health and Safety Code.

Section 1322.2. Pork Distributor Registration.

(a) Commencing January 1, 2023, ~~Any~~ in-state or out-of-state person engaged in ~~business a commercial sale into or within this the~~ state as a pork distributor, or any out of state pork distributor selling whole pork meat into California for purposes of human food ~~use in the state,~~ shall ~~register~~ hold a valid registration with the Department pursuant to this Article.

(b) Any person ~~required to~~ registering pursuant to (a) of this section shall submit an application for registration provided by the Department including the following information: Business name, physical address of distribution operation, mailing address, phone number, email address, website address, federal tax identification number, and name, phone number and email of person authorized to act on the applicant's behalf.

(c) The registration shall not be transferable to any person and shall be applicable only to the location for which originally issued.

(d) A registration is required for each facility location from which whole pork meat is sold, distributed, or otherwise supplied to the location of an end-user.

(e) A pork distributor shall not engage in the commercial sale of whole pork meat within, or into, California unless such person has obtained and holds a valid registration from the Department pursuant to this section for each facility location.

(f) Any change in ownership, change of business name, change in business location, closure of business, or change of name, address, phone number or email of person authorized to act on behalf of the registered distributor must be reported to the Department within 30 business calendar days of such change.

(g) All information set forth on applications for registrations and renewals for registrations, including but not limited to any documentation of certification required by (j) of this section, shall be truthful and not misleading.

(h) Every registration expires 12 months from the date of issue.

(i) A registration may be renewed each 12-month period by the Department in response to an application for renewal by a pork distributor if the business of the facility applying for renewal was conducted in accordance with the requirements of this Article and sections 25990 and 25991 of the Health and Safety Code during the preceding 12 months for which the renewal is requested.

(j) An application to the Department by a pork distributor for initial registration, or for purposes of

renewal, shall be accompanied by documentation of valid certification pursuant to Article 5 of this Chapter for each location where registration is being sought. A registration shall not be issued for any facility location for which the valid certification required by this section has not been submitted to the Department.

~~(k) Notwithstanding the requirements of (j) of this section, a registration may be granted prior to January 1, 2023⁴ to a pork distributor that submits a self-certification to the Department that the For purposes of the valid certification required in (j) of this section, a self-certification by a pork distributor that they complies with all applicable requirements of sections 1322.4 and 1322.5 of this Article, and distributes whole pork meat within or into California only from pork producers that comply with section 1322.1 of this Article, will be accepted by the Department prior to January 1, 2024.~~

~~(l) This section shall not apply to a~~An establish-
ment at which mandatory inspection is provided under the Federal Meat Inspection Act (21 U.S.C. Sec. 601 et seq.) and that holds an establishment number (prefix “M”) granted by the Food Safety Inspection Service of the United States Department of Agriculture with prefix of “M” is excluded from mandatory registration pursuant to this section.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990 and 25991, Health and Safety Code and Federal Meat Inspection Act (21 U.S.C. section 601 et seq.).

Section 1322.3. Inspection and Audit of Registered Pork Distributor Facilities.

(a) Every person ~~required to be~~ registered pursuant to section 1322.2 of this Article shall comply with this section.

(b) Every pork distributor by submitting an application for registration of a facility agrees as a condition of registration to provide the Department, and/or certifying agent, entrance and access to the premises and business records of the facility for purposes of inspection and audit as described in Article 5 of this Chapter.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990 and 25991, Health and Safety Code.

Section 1322.4. Whole Pork Meat Shipping Document Requirements.

(a) Shipping Documents.

(1) ~~Commencing January 1, 2022, a~~All documents of title, shipping invoices, bills of lading, and shipping manifests for ~~all~~ shipments of whole pork meat entering the state or transported within the state for commercial sale in California shall include the statement “California 24+ Compliant” and may be ~~abbreviated to read “CA 24+”~~ “Pork CA Prop 12 Compliant”. The statement shall be clearly legible and plainly printed or stamped.

(2) For shipments of whole pork meat that was not produced in compliance with section 25991 of the Health and Safety Code and this Article, and enter California exclusively for purposes of transshipment, ~~or export, donation, or sale to federal agencies or on tribal lands for human consumption outside of the state~~ and are not destined for commercial sale in California, all documents of title, shipping invoices, bills of lading, and shipping manifests shall, upon entrance

into the state and during transportation and storage within the state, be marked with the statement “~~Not for California Consumption~~” or “~~Not for California Sale~~” “For Export”, “For Transshipment”, or “Not Prop 12 Compliant”; The statement shall be legible and plainly printed or stamped.

(3) For shipments of whole pork meat not produced in compliance with section 25991 of the Health and Safety Code and this Article that originate from a facility, whether located inside or outside of the state, under mandatory inspection and that holdings an establishment number with prefix “M” granted by the Food Safety Inspection Service of the United States Department of Agriculture under the Federal Meat Inspection Act (21 U.S.C. Sec. 601 et seq.) and being transported to another facility in California under mandatory inspection and that holdings an establishment number with prefix “M” granted by the Food Safety Inspection Service of the United States Department of Agriculture under the Federal Meat Inspection Act (21 U.S.C. Sec. 601 et seq.), solely for purposes of using the whole pork meat for making food products not covered by the Act or this Article, all documents of title, shipping invoices, bills of lading, and shipping manifests shall, upon entrance into the state and during transportation within the state, be clearly marked with the statement “Only for use at” immediately followed by the complete establishment number, including the prefix “M”, granted by the Food Safety Inspection Service of the United States Department of Agriculture for the specific facility where the shipment is destined for delivery.

(b) No person shall label, identify, mark, advertise, or otherwise represent, pigs or whole pork meat for commercial sale in California using the statements

in (a) of this section, or as meeting the requirements of the Act or otherwise meeting California enclosure space requirements, unless they were produced in compliance with section 25991 of the Health and Safety Code and this Article.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990 and 25991, Health and Safety Code and Federal Meat Inspection Act, 21 U.S.C. section 601 et seq.

Section 1322.5. Pork Distributor Recordkeeping.

(a) A pork distributor, as a condition of registration pursuant to section 1322.2 of this Article, shall maintain records that comply with all the requirements of this section.

(b) Records shall be sufficient for purposes of an audit trail as defined in section 1322(b) of this Article and the applicable recordkeeping requirements described in section 1326.2 of this Chapter.

(c) Records shall document in a traceable manner that whole pork meat being distributed for commercial sale into or within California originates from pork producers that are in compliance with all requirements of section 1322.1 of this Article.

(d) Records shall document the address of the location where the distributor, as the buyer, takes physical possession of whole pork meat for each sales transaction.

(e) Records shall be maintained for two (2) years from the date of creation and be made accessible for inspection and audit by the Department and/or a certifying agent as required by section 1322.3 of this Article.

~~(f) This section shall not apply to an establishment at which mandatory inspection is provided under the Federal Meat Inspection Act (21 U.S.C. Sec. 601 et seq.) and granted an establishment number (prefix "M") by the Food Safety Inspection Service of the United States Department of Agriculture with prefix of "M".~~

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990 and 25991, Health and Safety Code and Federal Meat Inspection Act, 21 U.S.C. section 601 et seq.

Section 1322.6. Inspection of Conveyances.

(a) Every pork distributor by submitting an application for registration agrees as a condition of registration to provide the Department or ~~other enforcement officer, and/or~~ a certifying agent, access to inspect in California any vehicle or other conveyance under the registrant's operation or control that is transporting whole pork meat into or within the state.

(b) Every person shall stop at the request of ~~an enforcement officer~~ the Department at any California Border Protection Station for purposes of inspection of cargo and any accompanying shipping documents, manifests, and bills of lading, any vehicle or other conveyance transporting into or within the state whole pork meat.

(c) The Department, ~~or other enforcement officer in California,~~ may deny entry to or order diversion from the state any vehicle or other conveyance transporting whole pork meat intended for commercial sale that was produced, packaged, identified, or shipped in violation of the requirements of sections 25990-25992 of the Health and Safety Code, or the provisions of this

Article, including but not limited to shipping document requirements specified in section 1322.4 of this Article.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990, 25991, and 25992, Health and Safety Code.

Section 1322.7. Tagging and Seizure of Whole Pork Meat.

(a) ~~The Department or other enforcement officer~~ may affix a warning tag or notice to shipping documents, manifests, containers, sub-containers, lots, or loads of whole pork meat which have been produced, packaged, stored, labeled, marked, identified, transported, delivered, or sold in violation of the requirements of sections 25990-25992 of the Health and Safety Code, or the provisions of this Article, and may give notice of such violation to the pork producer, pork distributor, owner, or other person in possession of the whole pork meat.

(b) No person shall remove a warning tag or notice from the place it is affixed except upon written permission or specific direction of the Department ~~or other enforcement officer.~~

(c) ~~An enforcement officer~~ The Department may seize and hold any containers, sub-containers, lots or loads of whole pork meat in California which 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. If the Department ~~or other enforcement officer~~ seizes any container, sub-container, lot, or load of whole pork meat, a hold notice shall be issued to the person that has control of the whole pork meat, and a tag or notice

may be affixed to the container, sub-container, lot, or load which states it is so held.

(d) Any whole pork meat for which a hold notice is issued shall be held by the person having control of the whole pork meat and shall not be disturbed, moved, diverted, or offered for sale except under the specific directions of the Department or other enforcement officer.

(e) A person may request an informal hearing to contest tagging, hold notice, or seizure of whole pork meat pursuant to section 1327.1 of this Chapter.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990, 25991, and 25992, Health and Safety Code.

Section 1322.8. Written Certification.

(a) For purposes of section 25993.1 of the Health and Safety Code, any written certification from a supplier to a buyer engaged in commercial sales of whole pork meat that was not derived from a breeding pig, or offspring of a breeding pig, confined in a cruel manner shall be based upon an audit trail as defined in section 1322(b), of this Article, and shall be traceable to pork producers compliant with all requirements of section 1322.1 of this Article.

(b) A retailer or food processing facility that is an end-user and takes physical possession, whether by use of a common carrier, private carrier or other means of conveyance, of whole pork meat at, or directly from, an establishment at which mandatory inspection is provided under the Federal Meat Inspection Act (21 U.S.C. Sec. 601 et seq.), ~~granted that~~ holds an establishment number (prefix "M") granted by the Food Safety Inspection Service of the United States Department of Agriculture with a prefix of "M",

and that does not hold a valid pork distributor registration, shall:

(1) Maintain records documenting written certifications that meet the requirements of this section for whole pork meat received during the preceding 12-month period.

(2) Maintain records documenting the address of the location where the retailer or food processor, as the buyer, takes physical possession of whole pork meat for each sales transaction.

(3) Make the records required by this subsection available on-site for inspection by the Department state or local health agencies upon request. Electronic records are considered on-site if they are accessible from an on-site location.

(c) Subsection (b) of this section shall not apply to a whole pork meat end-user that is an ~~official~~ establishment under mandatory inspection under the Federal Meat Inspection Act (21 U.S.C. Sec. 601 et seq.) and ~~granted~~ that holds an establishment number (prefix "M") granted by the Food Safety Inspection Service of the United States Department of Agriculture.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25900 and 25991, Health and Safety Code and Federal Meat Inspection Act, 21 U.S.C. section 601 et seq.

Section 1322.9. Denial, Suspension, or Revocation of Pork Distributor Registration.

(a) The Department may deny, suspend, or revoke a registration issued pursuant to this Article for any of the following:

(1) Violations that resulted, or reasonably could have resulted, in the commercial sale of whole pork meat from breeding pigs, or offspring of breeding pigs, that was not confined in compliance with this Article;

(2) Repetitive failure to comply with the requirements of this Article and/or statutes pertaining to whole pork meat or breeding pigs in sections 25990-25992 of the Health and Safety Code;

(3) Refusal to grant access for, or interference with, inspections or audits described in sections 1322.3 or 1322.6 of this Article;

(4) Misrepresenting whole pork meat as being produced in compliance with this Article; or

(5) Providing false information on an application for registration.

(b) Proposed suspension or revocation. The Department shall send a written notice of proposed suspension or revocation of registration to the pork distributor. The notice of proposed suspension or revocation shall state:

(1) The date the proposed suspension or revocation is issued;

(2) The reasons for the proposed suspension or revocation;

(3) The effective date of the proposed suspension or revocation;

(A) The effective date of suspension or revocation is 30 calendar days after the date that the proposed suspension or revocation is issued;

(4) The impact of a suspension or revocation on future eligibility for registration including conditions for reinstatement; and

(5) The right to request a formal hearing pursuant section 1327.2 of this Chapter within 30 calendar days of the date the proposed suspension or revocation was issued. Registration shall remain in effect pending the outcome of a formal hearing.

(b)(c) A person may appeal the Department's decision to refuse to issue, or to deny, suspend, or revoke an application or renewal of a registration certificate by requesting a formal hearing pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code section 1327.2 of this Chapter within 30 calendar days of the date of the notice of denial.

(e) The Department's decision to deny, suspend, or revoke a registration shall remain in effect pending the outcome of an appeal process.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990, 25991, and 25992, Health and Safety Code.

Section 1322.10. Registration with the California Department of Public Health.

(a) Notwithstanding section 1322.2 of this Article, any person operating a food processing establishment in California shall also register with the California Department of Public Health pursuant to section 110460 of the Health and Safety Code. The registration requirement applies to all forms of processed pork.

(b) Evidence of this registration shall be provided to the Department or its designee upon request.

Note: Authority cited: Sections 25993 and 110065, Health and Safety Code. Reference: Sections 25990, 25991, 109875, 109935, 110045, and 110460, Health and Safety Code.

Article 4. Exceptions.

Section 1324. Definitions.

Unless the context otherwise requires, the following definitions apply to this Article and words in the singular form shall be deemed to impart the plural and vice versa, as the case may demand:

(a) "Breeding pig" means any female pig of the porcine species kept for the purpose of commercial breeding who is six (6) months of age or older, or pregnant.

(ab) "Individual treatment" for purposes of section 25992 of the Health and Safety Code, and this Chapter, means any protocol, practice, procedure, or application of care concerned with the diagnosis, treatment, mitigation, or prevention of animal disease, injury or harm that is administered by, or conducted under the order or recommendation of, a licensed veterinarian as part of a veterinarian-client-patient relationship as defined in section 530.3(i) of Title 21 of the Code of Federal Regulations.

(bc) "Medical research" for purposes of section 25992 of the Health and Safety Code, and this Chapter, means any basic and applied research that relates or contributes to the scientific understanding, promotion, or protection of human or animal health, fitness, function, performance, welfare or care, and that is conducted under the review of an Institutional Animal Care and Use Committee operating in accordance with section 2.31 of Title 9 of the Code of Federal Regulations or is conducted at a facility that holds a valid accreditation by the American Association for Accreditation of Laboratory Animal Care.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990, 25991, and

25992, Health and Safety Code and Title 9, Part 2, section 2.31 and Title 21, Part 530, section 530.3(i), Code of Federal Regulations.

Section 1324.1. Confinement Standards Exceptions.

(a) The Act and this Chapter shall not apply:

(1) During medical research;

(2) During examination, testing, individual treatment, or operation for veterinary purposes;

(3) During transportation;

(4) During rodeo exhibitions, state or county fair exhibitions, 4-H programs, and similar exhibitions;

(5) During slaughter when performed in accordance with the provisions of Chapter 6 (commencing with Section 19501) of Part 3 of Division 9 of the Food and Agricultural Code, relating to humane methods of slaughter, and other applicable laws and regulations;

(6) To a breeding pig during the five-day period prior to the breeding pig's expected date of giving birth, and any day that the breeding pig is nursing piglets; or

(7) During temporary periods for animal husbandry purposes for no more than six hours in any 24-hour period, and no more than 24 hours total in any 30-day period.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Section 25992, Health and Safety Code.

Article 5. Certification and Accredited Certifiers.

Section 1326. Definitions.

Unless the context otherwise requires, the following definitions apply to this Article and words in the

singular form shall be deemed to impart the plural and vice versa, as the case may demand:

(a) “Accreditation or accredit” means a determination made by the Department that authorizes a private entity to conduct certification activities as a certifying agent under this Chapter.

(b) “Act” means the Farm Animal Cruelty statute, as amended (Chapter 13.8 (commencing with section 25990) of Division 20 of the Health and Safety Code).

(c) “Area of operation” means the ~~types of facilities and records for covered animal production or covered product distribution operations,~~ including veal calves and whole veal meat, breeding pigs and whole pork meat, egg-laying hens and shell eggs or liquid eggs, or any combination thereof that a certifying agent may be accredited to certify under this Chapter.

(d) “Certification or certify” means a determination made by a certifying agent that a production or distribution operation is in compliance with the Act and this Chapter, which is documented by a certificate of California farm animal confinement compliance.

(e) “Certified operation” means a production or distribution operation, or portion of such operation, that is certified by a certifying agent as utilizing a system of animal confinement or distribution as described by the Act and this Chapter.

(f) “Certifying agent” means any private entity accredited by the Department as a third-party certifying agent for the purpose of certifying a production or distribution operation as a certified operation, the Department, or any government entity that the Department recognizes as providing functionally equivalent

certification services to the requirements of this Chapter.

(g) “Certifying agent’s operation” means all sites, facilities, personnel, and records used by an accredited private certifying agent to conduct certification activities under the regulations in this Chapter.

(h) “Covered animal” means any calf raised for veal, breeding pig, or egg laying hen who is all of the following animals when kept on a farm pursuant to sections 25991(f) and (i) of the Health and Safety Code for purposes of producing covered products:

(1) Breeding pig as defined in section 25991(a) of the Health and Safety Code and section 1322(c) of this Chapter;

(2) Calf as defined in section 25991(d) of the Health and Safety Code and section 1321(c) of this Chapter; and

(3) Egg-laying hen as defined in section 25991(g) of the Health and Safety Code and section 1320(l) of this Chapter.

(i) “Covered product” means all of the following:

(1) Shell eggs as defined in section 25991(p) of the Health and Safety Code and section 1320(aa)(z), of this Chapter; ~~or~~

(2) Liquid eggs as defined in section 25991(l) of the Health and Safety Code and, section 1320(u) of this Chapter;

(3) Whole veal meat as defined in section 25991(v) of the Health and Safety Code and section 1321(bb)(ee) of this Chapter; ~~or and~~

(4) Whole pork meat as defined in section 25991(u) of the Health and Safety Code and section 1322(~~bb~~)(ee) of this Chapter.

(j) “Department” means the California Department of Food and Agriculture.

(k) “Distributor” means an egg distributor as defined in section 1320(k), a veal distributor as defined in section 1321(~~z~~)(cc), and a pork distributor as defined in section 1322(~~u~~)(t), of this Chapter.

(l) “Distributor operation” means any operation or portion of an operation that conducts activities as a distributor.

(m) “Employee” means any person providing paid or volunteer services for a certifying agent.

(n) “Governmental entity” means any local, state, or federal domestic government, tribal government, or foreign governmental subdivision providing certification services.

(o) “Immediate family” means the spouse, minor children, or blood relatives who reside in the immediate household of a certifying agent or in the immediate household of employee, inspector, contractor, or other personnel of the certifying agent. For the purpose of this Chapter, the interest of a spouse, minor child, or blood relative who is a resident of the immediate household of a certifying agent or an employee, inspector, contractor, or other personnel of the certifying agent shall be considered to be an interest of the certifying agent or an employee, inspector, contractor, or other personnel of the certifying agent.

(p) “Inspection” means the act of examining and evaluating the production or distribution area of oper-

ation of an applicant for certification or a certified operation to determine compliance with the Act and this Chapter.

(q) “Inspector” means any person retained or used by a certifying agent to conduct inspections of certification applicants or certified production or distribution operations, or an authorized representative of the Department.

(r) “Label” means a display of written, printed, or graphic material on the immediate container of a covered product or any such material affixed to any covered product or affixed to a bulk container containing a covered product, except for package liners or a display of written, printed, or graphic material which contains only information about the weight of the product.

(s) “Labeling” means all written, printed, or graphic material accompanying a covered product at any time or written, printed, or graphic material about the covered product displayed at retail stores about the product.

(t) “Person” means any individual, firm, partnership, joint venture, association, limited liability corporation, corporation, estate, trust, receiver, or syndicate.

(u) “Private entity” means any domestic or foreign nongovernmental, for-profit, or not-for-profit organization providing certification services.

(v) “Producer” means an egg producer as defined in section 1320(m), a veal producer as defined in section 1321~~(aa)~~(dd), and a pork producer as defined in section 1322~~(v)~~(u).

(w) “Records” means any information in written, visual, or electronic form that documents the activities undertaken by a producer, distributor, or certifying agent to comply with the Act and this Chapter.

(x) “Responsibly connected” means any person who is a partner, officer, director, holder, manager, or owner of 10 percent or more of the voting stock of an applicant, or a recipient of certification or accreditation.

(y) “Split operation” means an operation that produces or distributes covered animals and/or covered products from operations, or portions of an operation, that are both in conformance and out-of-conformance with the confinement standards of the Act and this Chapter.

(z) “State” means any of the several States of the United States of America, its territories, the District of Columbia, and the Commonwealth of Puerto Rico. Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990 and 25991, Health and Safety Code.

Section 1326.1. General Requirements for Certification.

A person seeking to receive or maintain certification under this Chapter must:

(a) Comply with the Act and applicable regulations of this Chapter;

(b) Allow on-site inspections by the certifying agent, and/or authorized representatives of the Department, with access to the production and/or distribution operation, and offices as provided for in sections 1326.2 and 1326.5 of this Article;

(c) If a producer, allow access by the certifying agent, and/or authorized representatives of the Department, to pastures, fields, structures, and houses where covered animals and covered animal products may be kept, produced, processed, handled, stored or transported, including the inspection of all enclosures for covered animals;

(d) If a distributor, allow access by the certifying agent, and/or authorized representatives of the Department, to examine all covered products that are sold or intended, held, segregated, stored, packaged, labeled, or represented for sale or distribution in California;

(e) Allow access by the certifying agent, and/or authorized representatives of the Department, to containers, labels, labeling, invoices, documents of title, and bills of lading used in the handling, storage, packaging, sale, transportation, or distribution of covered products in California;

(f) Allow access by the certifying agent, and/or authorized representatives of the Department, during normal business hours for review and copying of records required by section 1326.2 of this Article; and

(g) Immediately notify the certifying agent concerning any change in a certified operation or any portion of a certified operation that may affect its compliance with the Act and this Chapter.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990 and 25991, Health and Safety Code.

Section 1326.2. Recordkeeping by Certified Operations.

(a) In order to receive and maintain certification, a certified operation must maintain records concerning the production and distribution of covered animals and/or covered products.

(b) Such records must:

(1) Be maintained by a producer in sufficient detail to document that covered animals were confined in compliance with sections 25991 and 25992 of the Health and Safety Code and the requirements of this Chapter;

(2) Be maintained by a distributor in sufficient detail to document the identification, source, supplier, transfer of ownership, transportation, storage, segregation, handling, packaging, distribution, and sale of covered products that were derived from animals confined in compliance with sections 25991 and 25992 of the Health and Safety Code and this Chapter;

(3) Be maintained for not less than two (2) years beyond their creation;

(4) Include records of all covered animal and/or covered product transactions for the preceding two-year period. The records must indicate the date, quantity, identity of the buyer and seller, and the address where physical possession of covered product took place for each transaction;

(5) Include documentation and 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;

(6) Include documentation of the size of the certified operation, the quantity of covered animals and/or covered products produced or processed from each facility or farm unit in the certified operation, the number of covered animal enclosures for each facility or farm unit, the size of each enclosure, the number of covered animals housed in each enclosure, and the dates of stocking, harvest and production;

(7) If the facility is a split operation, include documentation sufficient to demonstrate the identification, segregation, distribution, and handling of covered animals and/or covered products to prevent commingling with any animals or products that do not comply with requirements of the Act; and

(8) Include documentation of registration issued by the Department pursuant to sections 1320.2, 1321.2, and 1322.2 of this Chapter, as applicable to the certified operation.

(c) The inspection and audit of any records and documents required by this section, may be conducted by the Department, or other certifying agent, by on-site inspection at the certified operation location, or by utilizing email, phone, teleconference, or any combination thereof, at the discretion of the certifying agent or the Department.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990, 25991, and 25992, Health and Safety Code.

Section 1326.3. Application for Certification.

(a) A person seeking certification of a production or distribution operation by a certifying agent under

this Article must submit an application for certification that includes all the following information:

(1) The name of the person completing the application; the applicant's business name, physical address, mailing address, and telephone number; and, when the applicant is a corporation, the name, address, email, and telephone number of the person authorized to act on the applicant's behalf;

(2) The name(s) of any certifying agent(s) to which application has previously been made; the year(s) of application; the outcome of the application(s) submission, including, when available, a copy of any notification of noncompliance, denial or revocation of certification issued to the applicant for certification; and a description of the actions taken by the applicant to correct the noncompliance noted in the notification of noncompliance, including evidence of such correction;

(3) A description of the type and quantity of covered animals and/or covered products to be produced and/or distributed at the facility for which certification is being requested;

(4) A description of the covered animal confinement system to be used at the facility, including but not limited to the number of enclosures, size of enclosures and maximum number of covered animals to be housed in each, and additional information as deemed necessary by the certifying agent to determine compliance with the Act and this Chapter; and

(5) A description of the management practices, physical barriers, and standard operating procedures established to prevent commingling of covered animals or covered products if the facility is a split operation; and

(b) If the certifying agent is a government entity other than the Department, it may use its own authorized procedures for application for certification in lieu of this section's requirements.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990 and 25991, Health and Safety Code.

Section 1326.4. Review of Application for Certification.

(a) Upon acceptance of an application for certification, a certifying agent must:

(1) Review the application to ensure completeness pursuant to section 1326.3 of this Article;

(2) Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of the Act and this Chapter;

(3) Verify that an applicant who previously applied to another certifying agent and received a notification of noncompliance, or denial or revocation of certification, pursuant to section 1326.7 of this Article, has submitted documentation to support the correction of any issues of noncompliance identified in the notification of noncompliance or denial of certification, as required in section 1326.7(e) of this Article; and

(4) Schedule an on-site inspection, pursuant to section 1326.5 of this Article, of the production or distribution operation to determine whether the applicant qualifies for certification if the review of application materials reveals that the production or distribution operation may be in compliance with the applicable requirements of the Act and this Chapter.

(b) A certifying agent shall:

(1) Review the application materials received and communicate its findings to the applicant; and

(2) Provide the applicant with a copy of the on-site inspection report, as approved by the certifying agent, for any on-site inspection performed.

(c) The applicant may withdraw its application at any time. An applicant that voluntarily ~~withdrew~~ withdraws its application prior to the issuance of a notice of noncompliance will not be issued a notice of noncompliance. Similarly, an applicant that voluntarily ~~withdrew~~ withdraws its application prior to the issuance of a notice of certification denial will not be issued a notice of certification denial.

(d) If the certifying agent is a government entity other than the Department, it may use its own authorized procedures for application review in lieu of this section's requirements as long as such review includes an on-site ~~verification~~ inspection of an applicant's compliance with the Act and applicable provisions of this Chapter by a process equivalent to that described in section 1326.5 of this Article.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990 and 25991, Health and Safety Code.

Section 1326.5. Certification On-site Inspections.

(a) On-site inspections.

(1) In order to grant certification, a certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or distributes covered animals or covered products that is included in an operation for which certification is requested. An 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.

(2) The Department may require that additional inspections be performed by an accredited certifying agent or the Department for the purpose of determining compliance with the Act and this Chapter. Additional inspections may be announced or unannounced as required by the Department.

(b) Scheduling.

(1) The initial on-site inspection must be conducted within 3 months following a determination that the applicant appears to comply or may be able to comply with the requirements of the Act and this Chapter.

(2) All on-site inspections must be conducted when an authorized representative of the operation who is knowledgeable about the operation is present, can access operation records, and at a time when facilities and activities that demonstrate the operation's compliance with or capability to comply with the applicable provisions of the Act and this Chapter can be observed, ~~except that this requirement does not apply to unannounced on-site inspections.~~

(c) Verification of information. The on-site inspection of an operation must verify:

(1) The operation's compliance or capability to comply with the Act and this Chapter; and

(2) That the information provided in accordance with sections 1326.3 and 1326.8 of this Article accurately reflects the practices used or to be used by the applicant for certification or by the certified operation.

(d) Exit interview. The ~~inspector~~ certifying agent must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The ~~inspector~~ certifying agent must also address the need for any additional information as well as any issues of concern.

(e) A copy of the on-site inspection report shall be sent to the inspected operation by the certifying agent. Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990 and 25991, Health and Safety Code.

Section 1326.6. Granting Certification.

(a) After completion of the initial on-site inspection, a certifying agent must review the on-site inspection report, and any additional information requested from or supplied by the applicant. If the certifying agent determines that the confinement or distribution system and all procedures and activities of the applicant's operation are in compliance with the Act and this Chapter, the certifying agent shall grant certification.

(b) When a certifying agent issues a certificate of compliance it shall specify all the following:

- (1) Name and address of the certified operation;
- (2) Effective date of certification;
- (3) Date of most recent on-site inspection;

(4) Categories of operation, including whether the operation is a producer, distributor or both, a split operation, and the species of covered animals and/or types of covered products produced or distributed by the certified operation; and

(5) Name, address, and telephone number of the certifying agent.

(c) Notwithstanding (a) of this section, the Department will accept certifications granted by another government entity using procedures established under the authority of that government entity, provided such certification is based on on-site ~~verification~~ inspection of a certified operation's compliance with the Act and applicable provisions of this Chapter by a process equivalent to that described in section 1326.5 of this Article, and that the certificate specifies at a minimum the information described in paragraph (b) of this section.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990 and 25991, Health and Safety Code.

Section 1326.7. Denial of Certification.

(a) When the certifying agent, based on a review of the information specified in sections 1326.2, 1326.3, 1326.4 or 1326.5 of this Article, determines that an applicant for certification is not in compliance with the Act and this Chapter, the certifying agent shall provide a written notification of noncompliance to the applicant. When correction of a noncompliance is not possible, a notification of noncompliance and a ~~notification~~ notice of denial of certification may be combined in one ~~notification~~ notice. ~~The~~ A notification of noncompliance shall provide:

(1) A description of each noncompliance;

(2) The facts upon which the notification of non-compliance is based; and

(3) The date by which the applicant must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.

(b) Upon receipt of such notification of noncompliance, the applicant may:

(1) Correct noncompliances and submit a description of the corrective actions taken with supporting documentation to the certifying agent;

(2) Correct noncompliances and submit a new application to another certifying agent: Provided, that the applicant must include a complete application, the notification of noncompliance received from the first certifying agent, and a description of the corrective actions taken with supporting documentation; or

(3) Submit written information to the issuing certifying agent to rebut the noncompliance described in the notification of noncompliance.

(c) After issuance of a notification of noncompliance, the certifying agent must:

(1) Evaluate the applicant's corrective actions taken and supporting documentation submitted or the written rebuttal and conduct an on-site inspection if necessary;

(2) When the corrective action or rebuttal is sufficient for the applicant to qualify for certification, issue the applicant an approval of certification pursuant to section 1326.6 of this Article; or

(3) When the corrective action or rebuttal is not sufficient for the applicant to qualify for certification,

issue the applicant a written notice of denial of certification.

(d) A certifying agent must issue a written notice of denial of certification to an applicant who fails to respond to the notification of noncompliance within 30 calendar days of the date issued.

(e) A notice of denial of certification must state the reason(s) for denial and the applicant's right to:

(1) Reapply for certification pursuant to sections 1326.3 and 1326.8 of this Article;

(2) Request mediation pursuant to section 1327.23 of this Chapter within 30 calendar days of date of notice of denial; or

(3) ~~File an appeal for~~ Request a formal hearing of the denial of certification pursuant to ~~Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code~~ section 1327.2 of this Chapter within 30 calendar days of date of notice of denial.

(f) An applicant for certification who has received a written notification of noncompliance or a written notice of denial of certification may apply for certification again at any time with any certifying agent, in accordance with sections 1326.3 and 1326.8 of this Article. When such applicant submits a new application to a certifying agent other than the certifying agent who issued the notification of noncompliance or notice of denial of certification, the applicant for certification must include a copy of the notification of noncompliance or notice of denial of certification and a description of the actions taken, with supporting documentation, to correct the noncompliances noted in the notification of noncompliance.

(g) A certifying agent who receives a new application for certification, which includes a notification of noncompliance or a notice of denial or revocation of certification, must treat the application as a new application and begin a new application process pursuant to sections 1326.3 and 1326.4 of this Article.

(h) Notwithstanding (a) of this section, if a certifying agent has ~~reason to believe evidence~~ that an applicant for certification has ~~willfully~~ made a false statement or otherwise ~~purposefully~~ misrepresented the applicant's operation or its compliance with the certification requirements pursuant to this Article, the certifying agent may deny certification pursuant to (e) of this section without first issuing a notification of noncompliance.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990 and 25991, Health and Safety Code.

Section 1326.8. Continuation of Certification.

(a) To continue certification, a certified operation must annually submit the following renewal information, as applicable, to the certifying agent:

(1) A summary statement, supported by documentation, detailing any deviations from, or changes to, information submitted on the previous year's application, including but not limited to any additions to or deletions from the information required pursuant to section 1326.3 of this Article;

(2) An update on the correction of ~~minor~~ any non-compliances previously identified by the certifying agent as requiring correction for continued certification; and

(3) Other information as deemed necessary by the certifying agent to determine compliance with the Act and this Chapter.

(b) Following the receipt of the information specified in subsection (a) of this section, the certifying agent shall arrange and conduct an on-site inspection of the certified operation pursuant to section 1326.5 of this Article to determine compliance with the Act and this Chapter.

(c) If the certifying agent determines, based on the on-site inspection and a review of the information specified in (a) of this section, that a certified operation is not complying with the requirements of the Act and this Chapter, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with section 1326.20 of this Article.

(d) If the certifying agent determines, based on the on-site inspection and a review of the information specified in subsection (a) of this section, that the certified operation is complying with the Act and this Chapter, the certifying agent shall issue an updated certificate of compliance pursuant to section 1326.6(b) of this Article.

(e) Any change in ownership, change of business name, or change in business location, closure of business, or change of name, address, phone number or email of person authorized to act on behalf of the certified operation must be reported to the certifying agent within 30 calendar days of such change.

(f) If the certifying agent is a government entity other than the Department, it may use its own authorized procedures for continuation of certification in lieu of this section's requirements as long as such renewal process includes an on-site ~~verification~~ inspection of

the certified operation's to determine compliance with the Act and applicable provisions of this Chapter by a process equivalent to that described in section 1326.5. Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990 and 25991, Health and Safety Code.

Section 1326.9. Areas and Duration of Accreditation as a Certifying Agent.

(a) The Department may accredit a qualified domestic or foreign applicant to certify a domestic or foreign production or distribution operation as a certified operation.

(b) Accreditation shall be for a period of five (5) years from the date of approval of accreditation pursuant to section 1326.14 of this Article.

(c) In lieu of accreditation under (a) of this section, the Department will accept a foreign certifying agent's accreditation to certify production or distribution operations if the Department determines, upon the request of a foreign government, that the standards under which the foreign government authority accredited the foreign certifying agent are functionally equivalent to the requirements of this Chapter.

(d) Notwithstanding any provision of this Chapter, the Department may, at its discretion, certify a production or distribution operation as a certified operation after determining an operation is in compliance with the provisions of the Act and this Chapter. Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990 and 25991, Health and Safety Code.

Section 1326.10. General Requirements for Accredited Certifying Agents.

(a) In order to receive and maintain accreditation, a private entity accredited as a certifying agent under this Chapter must:

(1) Have sufficient expertise in covered animal production and covered product distribution techniques to fully comply with and implement the terms and conditions of the certification program established under this Chapter;

(2) Carry out the provisions of the Act and this Chapter, including the provisions of certifying operations as described in sections 1326.3 through 1326.8 of this Article;

(3) Use a sufficient number of adequately trained personnel, including inspectors, and certification review personnel, to comply with and implement the certification program established under this Chapter;

(4) Ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in covered animal production and covered product distribution to successfully perform the duties assigned;

(5) Provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and this Chapter;

(6) Maintain all records pursuant to section 1326.17(b) of this Article and make all such records available for inspection and copying during normal business hours by authorized representatives of the Department;

(7) Not disclose any information collected pursuant to this Article that was obtained while certifying producers or distributors for compliance with this Chapter to any third-party without approval by the Department. Any request to an accredited certifying agent for records or documents must be submitted to the Department for review and approval pursuant to the California Public Records Act (Government Code section 6250 et seq.);

(8) Prevent conflicts of interest by:

(A) Not certifying a production or distribution operation if the certifying agent or a responsibly connected party of such certifying agent has or has held a commercial interest in the production or distribution operation, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification;

(B) Excluding any person, including contractors, with conflicts of interest from work, discussions, and decisions in all stages of the certification process and the monitoring of certified production or distribution operations for all entities in which such person has or has held a commercial interest, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification;

(C) Not permitting any employee, inspector, contractor, or other personnel to accept payment, gifts, or favors of any kind, other than prescribed fees, from any business inspected.

(9) Refrain from making false or misleading claims about its accreditation status, the accreditation program for certifying agents, or the nature or qualities of covered products; and

(10) Submit to the Department a copy of:

(A) Within 14 calendar days of creation, any notice of proposed suspension or revocation and ~~notification~~ notice of suspension or revocation sent pursuant to section 1326.20 of this Article; and

(B) Annual report as described in section 1326.17(a) of this Article including the name, address, and telephone number of each operation granted initial certification pursuant to section 1326.6 of this Article or an updated certification pursuant to section 1326.8 of this Article, during the preceding year.

(b) A private entity accredited as a certifying agent must:

(1) Hold the Department harmless for any failure on the part of the certifying agent to carry out the provisions of the Act and this Chapter; and

(2) Transfer to the Department all records or copies of records concerning the person's certification activities related to this Article in the event that the certifying agent dissolves or loses its accreditation; provided, that, such transfer shall not apply to a merger, sale, or other transfer of ownership of a certifying agent.

(c) No certifying agent under this Article shall exclude from participation in or deny the benefits of certification to any person due to discrimination because of race, color, sex, national origin, gender, religion, age, disability, political beliefs, sexual orientation, national origin, source of income, or marital or family status.

(d) A private entity seeking accreditation under this Article must sign and return a statement of agreement prepared by the Department which affirms

that, if granted accreditation as a certifying agent under this Chapter, the applicant will carry out the provisions of the Act and this Chapter, including but not limited to all applicable requirements of this section.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990 and 25991, Health and Safety Code.

Section 1326.11. Applying for Accreditation as a Certifying Agent.

(a) A private entity seeking accreditation as a certifying agent under this section must submit an application for accreditation provided by the Department which contains the applicable information and documents set forth in sections 1326.12 and 1326.13 of this Article.

(b) Following the receipt of the information and documents, the Department will determine, pursuant to sections 1326.12 and 1326.13 of this Article, whether the applicant for accreditation should be accredited as a certifying agent.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990 and 25991, Health and Safety Code.

Section 1326.12. Applicant Information for Accreditation as a Certifying Agent.

A private entity seeking accreditation as a certifying agent must submit the following information:

(a) The business name, primary office location, mailing address, name of the person(s) responsible for the certifying agent's day-to-day operations, contact numbers (telephone, facsimile, email and Internet address) of the applicant, and the entity's federal taxpayer identification number;

(b) The name, office location, mailing address, and contact numbers (telephone, facsimile, email and Internet address) for each of its organizational units, such as Chapters or subsidiary offices, and the name of a contact person for each unit;

(c) Each area of operation (veal calves, breeding pigs, egg-laying hens, or distribution) for which accreditation is requested and the estimated number of each type of operation anticipated to be certified annually by the applicant along with a copy of the applicant's schedule of fees for all services to be provided under these regulations by the applicant;

(d) The type of entity the applicant is (e.g., for-profit business, not-for-profit membership association) and 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; and

(e) A list of each State or foreign country in which the applicant has previously conducted certification services and a list of each State or foreign country in which the applicant intends to certify production or distribution operations pursuant to this Chapter. Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990 and 25991, Health and Safety Code.

Section 1326.13. Evidence of Expertise and Ability.

A private entity seeking accreditation as a certifying agent must submit to the Department all of the following documents and information:

(a) Personnel.

(1) The name and position description of personnel in the certifier's operation performing inspections.

members of any certification review and evaluation committees, and inspection contractors.

(2) A description of the qualifications, including experience, training, and education in auditing, inspection, covered animal production and/or covered product distribution, or other relevant areas of work for:

(A) Each inspector to be used by the applicant; and

(B) Each person to be designated by the applicant to review or evaluate applications for certification.

(3) A description of procedures, practices, and training, including biosecurity training, to ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, auditing and decision-making responsibilities have sufficient expertise to successfully perform the duties assigned and to comply with and implement the requirements of the Act and this Chapter.

(b) Administrative policies and procedures.

(1) A copy of the procedures to be used to evaluate certification applicants, make certification decisions, and issue ~~certification~~ certificates;

(2) A copy of the procedures to be used for reviewing and investigating certified operations compliance with the Act and this Chapter and the reporting of violations of the Act and this Chapter to the Department; and

(3) A copy of the procedures to be used for complying with the recordkeeping requirements set forth in section 1326.10(a)(6) of this Article.

(c) Conflicts of interest. A copy of procedures to be implemented to prevent the occurrence of conflicts of interest, as described in section 1326.10(a)(8) of this Article.

(d) Other information. Any other information the applicant believes may assist in the Department's evaluation of the applicant's expertise and ability.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990 and 25991, Health and Safety Code.

Section 1326.14. Granting Accreditation.

(a) Accreditation will be granted when:

(1) The accreditation applicant has submitted the information required by sections 1326.12 and 1326.13 of this Article; and

(2) The Department determines that the applicant for accreditation meets the requirements for accreditation as stated in section 1326.10 of this Article, as determined by a review of the information submitted in accordance with sections 1326.12 and 1326.13 of this Article and, if necessary, a review of the information obtained from an on-site ~~evaluation~~ inspection as provided for in section 1326.16 of this Article.

(b) On making a determination to approve an application for accreditation, the Department will notify the applicant of the granting of accreditation in writing, stating:

(1) The area(s) for which accreditation is given;

(2) The effective date of the accreditation; and

(3) The date of expiration of the accreditation.

(c) The accreditation of a certifying agent shall continue in effect until such time as the certifying

agent fails to renew accreditation as provided in section 1326.17(c) of this Article, the certifying agent voluntarily ceases its certification activities, or accreditation is suspended or revoked pursuant to section 1326.21 of this Article.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990 and 25991, Health and Safety Code.

Section 1326.15. Denial of Accreditation.

(a) If the Department has ~~reason to believe~~ evidence, based on a review of the information specified in sections 1326.12 and 1326.13 of this Article or after an on-site ~~evaluation~~ inspection as specified in section 1326.16, that an applicant for accreditation is not able to comply or is not in compliance with the requirements of the Act and this Chapter, the Department shall provide a written notification of noncompliance to the applicant. Such notification shall provide:

(1) A description of each noncompliance;

(2) The facts upon which the notification of non-compliance is based; and

(3) The date by which the applicant must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.

(b) When each noncompliance has been resolved, the Department will send the applicant a written notification of noncompliance resolution and proceed with further processing of the application.

(c) If an applicant fails to correct the noncompliances, fails to report the corrections by the date specified in the notification of noncompliance, fails to file a rebuttal of the notification of noncompliance by the

date specified, or is unsuccessful in its rebuttal, the Department will provide the applicant with written notification notice of accreditation denial. An applicant who has received written notification notice of accreditation denial may apply for accreditation again at any time in accordance with sections 1326.12 and 1326.13 of this Article or ~~appeal the denial of accreditation in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code~~ request a formal hearing pursuant to section 1327.2 of this Chapter within 30 calendar days of the notice of denial.

(d) If the certifying agent was accredited prior to an on-site evaluation inspection and the on-site evaluation inspection reveals issues of noncompliance, the Department will begin the noncompliance procedures for accredited certifying agents according to section 1326.21 of this Article.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990 and 25991, Health and Safety Code.

Section 1326.16. Certifying Agent On-site Evaluations Inspections.

(a) In order to receive and maintain accreditation, an accredited certifying agent must allow on-site evaluations inspections for the purpose of examining the certifying agent's operations and records to evaluate its compliance with the Act and this Chapter. On-site evaluations inspections shall include a review of the certifying agent's certification procedures, facilities, administrative and management systems for production or distribution operations certified by the certifying agent. On-site evaluations inspections shall be conducted by a representative(s) of the Department.

(b) An initial on-site ~~evaluation~~ inspection of an accreditation applicant may, at the discretion of the Department, be conducted before or after issuance of the applicant's "~~notification~~ notice of accreditation." An on-site ~~evaluation~~ inspection shall be conducted after application for renewal of accreditation, but prior to the issuance of a notice of renewal of accreditation. One or more on-site ~~evaluations~~ inspections will be conducted during the period of accreditation to determine whether an accredited certifying agent is complying with the requirements set forth in section 1326.10 of this Article.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990 and 25991, Health and Safety Code.

Section 1326.17. Annual Report, Recordkeeping, and Renewal of Accreditation.

(a) Annual report. An accredited certifying agent must submit annually to the Department, on or before January 30, the following reports:

(1) A complete and accurate update of information submitted pursuant to sections 1326.10(a)(10)(B), 1326.12 and 1326.13 of this Article;

(2) Information supporting any changes being requested in the areas of accreditation described in section 1326.9 of this Article; and

(3) A description of the measures implemented in the previous year and any measures to be implemented in the coming year to satisfy any terms and conditions determined by the Department to be necessary, as specified in the most recent on-site inspection report.

(b) Recordkeeping. Accredited private certifying agents must maintain records according to the following schedule:

(1) Records obtained from applicants for certification and certified operations must be maintained for not less than three (3) years beyond their receipt;

(2) Records created by the certifying agent regarding applicants for certification and certified operations must be maintained for not less than three (3) years beyond their creation; and

(3) Records created or received by the certifying agent pursuant to the accreditation requirements of this Article, ~~excluding any records covered by section 1326.17(b)(2) of this Article,~~ must be maintained for not less than three (3) years beyond their creation or receipt.

(c) Renewal of accreditation.

(1) An accredited certifying agent's application for accreditation renewal must be received at least 6 months prior to the fifth anniversary of issuance of the ~~notification notice~~ of accreditation and each subsequent renewal of accreditation. Certifying agents with an expired accreditation shall not perform certification activities under the Act and this Chapter.

(2) Following receipt of the information submitted by the certifying agent in accordance with (a) of this section and the results of an on-site ~~evaluation~~ inspection, the Department will determine whether the certifying agent remains in compliance with the Act and this Chapter and should have its accreditation renewed.

(d) Notice of renewal of accreditation. Upon a determination that the certifying agent is in compliance

with the Act and this Chapter, the Department will issue a notice of renewal of accreditation according to 1326.14(b) of this Article.

(e) Notice of denial of renewal of accreditation. If the certifying agent is found not to be in compliance with the Act and this Chapter, and the accreditation has expired, the Department will issue a notice of denial of renewal and include reason(s) why renewal was denied and corrective actions to be taken by the certifying agent before applying again according to sections 1326.12 and 1326.13 of this Article. A notice of denial of renewal of accreditation can be appealed by requesting a formal hearing pursuant to ~~Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code~~ section 1327.2 of this Chapter within 30 calendar days of the notice of denial.

(f) Noncompliance. Upon a determination that the certifying agent is not in compliance with the Act and this Chapter, and the accreditation has not expired, the Department will initiate proceedings to suspend or revoke the certifying agent's accreditation as described in section 1326.21 of this Article.

(g) Amending accreditation. Amendment to scope of an accreditation may be requested at any time. The application for amendment shall be provided by the Department and shall contain information applicable to the requested change in accreditation, and a complete and accurate update of the information submitted pursuant to sections 1326.12 and 1326.13 of this Article.

(h) Any change in ownership, change of business name, change in business location, closure of business, or change of name, address, phone number or

email of person authorized to act on behalf of the accredited certifier must be reported to the Department within 30 calendar days of such change.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990 and 25991, Health and Safety Code.

Section 1326.18. General Compliance.

(a) As a condition of certification and accreditation as a private certifying agent, the Department may inspect and review certified production and distribution operations and accredited certifying agents that are private entities for compliance with the Act or this Chapter.

(b) The Department may initiate suspension or revocation proceedings against a certified operation as described in section 1326.20 of this Article:

(1) When the Department has determined a certified operation has violated or is not in compliance with the Act or this Chapter; or

(2) When a certifying agent, other than the Department, has failed to take appropriate action to enforce the Act or this Chapter.

(c) The Department may initiate suspension or revocation of a private certifying agent's accreditation, as described in section 1326.21 of this Article, if the certifying agent that is a private entity fails to meet, conduct, or maintain accreditation requirements pursuant to the Act or this Chapter.

(d) Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued pursuant to sections 1326.20, 1326.21, and 1327.32 and each response to such notification must

be sent in writing to the recipient's place of business via a delivery service which provides dated return receipts.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990 and 25991, Health and Safety Code.

Section 1326.19. Investigation of Certified Operations.

A certifying agent shall report to the Department complaints of noncompliance with the Act or this Chapter concerning production and distribution operations certified as compliant with the Act and this Chapter by the certifying agent. The Department may at its discretion investigate complaints of noncompliance with the Act and require additional inspections by a certifying agent.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990 and 25991, Health and Safety Code.

Section 1326.20. Noncompliance Procedure for Certified Operations.

(a) Notification. When an inspection, review, or investigation of a certified operation by a certifying agent reveals any noncompliance with the Act or regulations in this Chapter, a written notification of noncompliance shall be sent by the certifying agent to the certified operation. Such notification shall provide:

(1) The date issued;

(1)(2) A description of each noncompliance;

(2)(3) The facts upon which the notification of noncompliance is based; and

(3)(4) The date by which the certified operation must rebut or correct each noncompliance and submit

supporting documentation of each such correction when correction is possible.

(b) Resolution. When a certified operation demonstrates that each noncompliance has been resolved within the prescribed time period, the certifying agent shall send the certified operation a written notification of noncompliance resolution.

(c) Proposed suspension or revocation. When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent shall send the certified operation a written ~~notification~~ notice of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance. When correction of a noncompliance is not possible, the notification of noncompliance and the notice of proposed suspension or revocation of certification may be combined in one notification. The ~~notification~~ notice of proposed suspension or revocation of certification shall state:

(1) The date the proposed suspension or revocation was issued;

~~(1)~~(2) The reasons for the proposed suspension or revocation;

~~(2)~~(3) The ~~proposed~~ effective date of ~~proposed~~ suspension or revocation;

(A) The ~~maximum~~ number of days from date of ~~notification~~ the notice of proposed suspension or revocation and effective date of suspension or revocation is 30 calendar days;

~~(3)~~(4) The impact of a suspension or revocation on future eligibility for certification including conditions for reinstatement; and

~~(4)(5)~~ The right to request mediation pursuant to section 1327.23 of this Chapter or to request a formal hearing pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code section 1327.2 of this Chapter within 30 calendar days of the date the proposed suspension or revocation was issued. The notice of proposed suspension or revocation shall remain in effect pending the outcome of an appeals process.

(6) The certifying agent and the Department shall not issue a notice of suspension or revocation while the outcome from mediation or a formal hearing is pending.

(d) Willful violations. Notwithstanding (a) of this section, if a certifying agent has evidence that a certified operation has willfully violated the Act or this Chapter, the certifying agent shall send the certified operation a ~~notification~~ notice of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the non-compliance.

(e) Suspension or revocation.

(1) If the certified operation fails to correct the noncompliance according to the prescribed time period, to resolve the issue through rebuttal or mediation, or to ~~file an appeal~~ request a formal hearing of the proposed suspension or revocation of certification before the suspension or revocation goes into effect ~~according to the notice of proposed suspension or revocation~~, the certifying agent shall send the certified operation a written ~~notification~~ notice of suspension or revocation.

(2) A certifying agent must not send a notification notice of suspension or revocation to a certified operation that has requested mediation pursuant to section 1327.23 of this Chapter or filed an appeal pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code a formal hearing pursuant to section 1327.2 of this Chapter, while final resolution of either is pending.

(f) Eligibility.

(1) A certified operation whose certification has been suspended under section 1326.20 of this Article may at any time, unless otherwise stated in the notification notice of suspension, submit a request to the Department for reinstatement of its certification. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and this Chapter.

(2) A certified operation or a person responsibly connected with an operation whose certification has been revoked under section 1326.20 of this Article will be ineligible to receive certification for a period of two (2) years following the date of such revocation.

(3) A certified operation whose certification is suspended or revoked by a certifying agent has the right to appeal this decision pursuant to section 1327.2 of this Chapter or through a formal hearing pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code. The notice of suspension or revocation shall remain in effect pending the outcome of an appeals process.

(g) Notwithstanding (a) through (e) of this section, if the certifying agent is a government entity

other than the Department, the noncompliance procedures for certified operations established under the authority of that government entity may be followed in lieu of sections 1326.20(a) through (e) of this Article.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990 and 25991, Health and Safety Code.

Section 1326.21. Noncompliance Procedure for Accredited Certifying Agents.

(a) Notification. When an inspection, review, or investigation of an accredited certifying agent by the Department reveals any noncompliance with the Act or this Chapter, a written notification of noncompliance shall be sent by the Department to the certifying agent. Such notification shall provide:

(1) A description of each noncompliance;

(2) The facts upon which the notification of noncompliance is based; and

(3) The date by which the certifying agent must rebut or correct each noncompliance and submit supporting documentation of each correction when correction is possible.

(b) Resolution. When the certifying agent demonstrates that each noncompliance has been resolved within the prescribed time period, the Department shall send the certifying agent a written notification of noncompliance resolution.

(c) Proposed suspension or revocation. When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the Department shall send a written notification

notice of proposed suspension or revocation of accreditation to the certifying agent. The notification of proposed suspension or revocation shall state whether the certifying agent's accreditation or specified areas of accreditation are to be suspended or revoked. When correction of a noncompliance is not possible, the notification of noncompliance and the notice of proposed suspension or revocation may be combined in one notification. The notification notice of proposed suspension or revocation of accreditation shall state:

(1) The date that the proposed suspension or revocation was issued;

(1)(2) The reasons for the proposed suspension or revocation;

(2)(3) The proposed effective date of the proposed suspension or revocation;

(A) The maximum number of days from date of notification the notice of proposed suspension or revocation and effective date of suspension or revocation is 30 calendar days;

(3)(4) The impact of a suspension or revocation on future eligibility for accreditation including conditions for reinstatement; and

(4)(5) The right to file request a formal hearing appeal pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code section 1327.2 of this Chapter within 30 calendar days from the date that the proposed suspension or revocation was issued. The Department's notice of proposed suspension or revocation shall remain in effect pending the outcome of an appeals process.

(6) The Department shall not issue a notice of suspension or revocation while the outcome of a formal hearing is pending.

(d) Willful violations. Notwithstanding paragraph (a) of this section, if the Department has reason to believe evidence that a certifying agent has willfully violated the Act or this Chapter, the Department shall send a written ~~notification~~ notice of proposed suspension or revocation of accreditation to the certifying agent.

(e) Suspension or revocation. When the accredited certifying agent fails to correct the issues of non-compliance as described in the proposed suspension or revocation, or fails to file request a formal hearing ~~appeal~~ of the proposed suspension or revocation of accreditation within ~~the prescribed time~~ 30 calendar days from the date the proposed suspension or revocation was issued, the Department shall send a written notice of suspension or revocation of accreditation to the certifying agent.

(f) Cessation of certification activities. A certifying agent whose accreditation is suspended or revoked must:

(1) Cease all certification activities under this Chapter in each area of accreditation and in each State for which its accreditation is suspended or revoked; and

(2) Transfer to the Department all records concerning its certification activities that were suspended or revoked.

(g) Eligibility.

(1) A certifying agent whose accreditation is suspended by the Department under this section may at

any time, unless otherwise stated in the notification notice of suspension, submit a request to the Department for reinstatement of its accreditation. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and this Chapter.

(2) A certifying agent whose accreditation is revoked by the Department shall be ineligible to be accredited as a certifying agent under the Act and this Chapter for a period of not less than 2 years following the date of such revocation.

~~(3) A certifying agent whose accreditation is suspended or revoked by the Department has the right to appeal this decision pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code. The Department's decision to suspend or revoke an accreditation shall remain in effect pending the outcome of an appeal process.~~

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990 and 25991, Health and Safety Code.

Section 1326.22. Government Entity Providing Certification.

(a) A government entity acting as a certifying agent and performing certification of producer or distribution operations for compliance with the Act and this Chapter may:

(1) Register annually with the Department;

(2) Submit to the Department a copy of any notice of proposed suspension or revocation of certification and ~~notification~~ notice of suspension and revocation of

certification sent pursuant to section 1326.20 of this Article; and

(3) Submit to the Department a list, on January 30 of each year, the name, address, and telephone number of each operation granted initial certification pursuant to section 1326.6 of this Article ~~or and an~~ updated certification pursuant to section 1326.8 of this Article, during the preceding year.

(b) For issues of ~~certifier~~ certifying agent noncompliance, the Department will use substantially equivalent procedures to section 1327.23 of this Chapter to resolve any noncompliance in a government entity's certification activities under this Chapter, and if the government entity fails to correct such noncompliance, to notify the government entity that the Department will no longer accept its certifications for compliance with the Act and this Chapter.

Article 6. ~~Informal~~ Hearings and Mediation.

Section 1327.1. Seizure or Holding of Covered Product Informal Hearing Procedures.

(a) A respondent may request an informal hearing to contest a notice of adverse determination that seizes or places a hold on covered product pursuant to sections 1320.7, 1321.7, and 1322.7 of this Chapter.

(b) The request for an informal hearing shall be submitted to the Department by electronic mail, facsimile, or by telephone within three (3) business days from the date of receipt of the notice of adverse determination.

(c) The notice of adverse determination shall remain in effect pending the outcome of the informal hearing.

(d) Hearings conducted under this section shall be held within three (3) business days after the Department receives the request for an informal hearing.

(e) The informal hearing shall be presided over and conducted by a Hearing Officer designated by the Secretary.

(f) The standard of proof to be applied by the Hearing Officer shall be preponderance of the evidence unless statutes or regulations applicable to the determination provide a higher standard.

(g) A teleconference line shall be made available at every hearing.

(h) Hearings shall be recorded by the Department. A transcript of the recording or an electronic copy of the recording shall be provided to any interested party upon written request.

(i) The decision of the Hearing Officer shall be in writing, issued within three (3) business days after the conclusion of the hearing, and shall be effective immediately upon issuance.

(j) The decision shall be served on the respondent by U.S. Mail or, if available, by electronic mail.

(k) The respondent may appeal the Hearing Officer's decision and order by filing a petition for a writ of administrative mandamus in accordance with section 1094.5 of the Code of Civil Procedure.

Note: Authority cited: Section 25993, Health and Safety Code and section 11400.20, Government Code. Reference: Sections 11445.30, 11445.40, 11445.50, and 11445.60, Government Code and sections 25990, 25991, and 25992, Health and Safety Code.

Section 1327.2. Formal Hearing Procedures.

(a) A respondent may request a formal hearing to contest a notice of adverse determination pursuant to sections 1320.9, 1321.9, 1322.9, 1326.7, 1326.15, 1326.17, 1326.20, and 1326.21 of this Chapter.

(b) The request for a formal hearing shall be made by written correspondence to the California Department of Food and Agriculture, Legal Office of Hearings and Appeals, 1220 N Street, Suite 315, Sacramento, California 95814.

(c) Formal hearings shall be conducted in accordance with the provisions of Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(d) The notice of adverse determination shall remain in effect pending the outcome of a formal hearing.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990 and 25991, Health and Safety Code.

Section 1327.23. Mediation.

(a) Mediation may be requested for any adverse actions that include denial of certification under section 1326.7 or any proposed suspension or revocation or noticed suspension or revocation of certification under section 1326.20.

(b) Any request for mediation shall be requested in writing to the applicable certifying agent within 30 calendar days of the date a denial of certification, proposed suspension or revocation, or noticed suspension or revocation of certification was issued.

(c) The certifying agent may accept or reject the request for mediation of an adverse action.

(1) If the certifying agent rejects the request for mediation, the certifying agent shall provide written notification to the applicant for certification or certified operation of the rejection. The written notification shall advise the applicant for certification or certified operation of the right to request an appeal of the proposed adverse action, pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, section 1326.2 of this Chapter within 30 calendar days of the date of the written notification of rejection of the request for mediation.

(2) If the certifying agent accepts the request for mediation, certifying agent shall provide written notification to the applicant or certified operation of the acceptance.

(d) The mediation shall be conducted by a qualified mediator mutually agreed upon by the parties to the mediation.

(e) The parties to the mediation shall have no more than 30 calendar days to reach an agreement following a mediation session. If mediation is unsuccessful, the applicant for certification or certified operation shall have 30 calendar days from termination of mediation to appeal the certifying agent's decision to deny, suspend, or revoke certification pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code section 1327.2 of this Chapter.

(f) Any agreement reached during or as a result of the mediation process shall be in compliance with the Act and this Chapter.

(g) If the certifying agent is an out-of-state government entity, the mediation procedures established

under the authority of that government entity may be followed in lieu of this section.

Note: Authority cited: Section 25993, Health and Safety Code. Reference: Sections 25990 and 25991, Health and Safety Code.

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**TITLE 3. FOOD AND AGRICULTURE
ADDENDUM TO THE INITIAL STATEMENT
OF REASONS RELATING TO ANIMAL CON-
FINEMENT**

Subject Matter of Proposed Regulation

Animal Confinement

Sections Affected for Proposed Modified Text

Sections 1320, 1320.1, 1320.2, 1320.3, 1320.4, 1320.5, 1320.6, 1320.7, 1320.8, 1320.9, 1320.10, 1321, 1321.1, 1321.2, 1321.3, 1321.4, 1321.5, 1321.6, 1321.7, 1321.8, 1321.9, 1321.10, 1322, 1322.1, 1322.2, 1322.3, 1322.4, 1322.5, 1322.6, 1322.7, 1322.8, 1322.9, 1322.10, 1324, 1324.1, 1326, 1326.1, 1326.3, 1326.4, 1326.5, 1326.6, 1326.7, 1326.8, 1326.10, 1326.12, 1326.13, 1326.14, 1326.15, 1326.16, 1326.17, 1326.18, 1326.20, 1326.21, 1326.22, 1327.2, and 1327.3.

Summary of Revisions to the Proposed Regulations

The Department of Food and Agriculture (Department) is now publishing proposed modified text and adding to the rulemaking file this addendum to the Initial Statement of Reasons (ISOR) to provide rationale for the proposed modified text, to clarify statements made in the ISOR, and to include additional Materials Relied Upon to further support the Department's proposal pertaining to annual on-site inspections.

After consideration of comments received during the 45-day comment period which closed on July 12, 2021, the public hearing held on August 27, 2021, and written comments received on August 27, 2021, revisions to the proposed regulation text are shown in the accompanying document using double underline for additions and single strikeout for deletions. These revisions are consistent with the original purpose of proposed regulations to implement the Act by establishing a program of registration, certification, conveyance inspection, and labeling and marking requirements for the sale of shell eggs, liquid eggs, whole veal meat, and whole pork meat in the state. Revisions to the text were made to increase clarity of the regulations for stakeholder compliance, increase consistency with the language used in statute and regulations, and after careful consideration, as a response to stakeholder concerns.

Responses to all comments received during rulemaking will be included in the Final Statement of Reasons, which will be published upon approval by the Office of Administrative Law.

Updates to the Initial Statement of Reasons

Benefits of the Regulatory Action and Economic Impact Assessment

The Department's statements in the "Benefits of this Regulatory Action" section of the Initial Statement of Reasons (ISOR) conclude: "This proposal does not directly impact human health and welfare of California residents, worker safety, or the State's environment, however the Department can infer that benefits accrue to Californians knowing that breeding pigs, veal calves, and egg-laying hens are raised with a minimum space requirement, which may be more space

than covered animals previously were allotted. There are no quantitative studies that document or measure the effect of confinement of covered animals according to the standards outlined in the Act for people in California.” Additionally, the Economic Impact Assessment section (f) in the ISOR, the Notice of Proposed Action, and the Standardized Regulatory Impact Assessment (SRIA) make similar statements. In response to comments received, the Department adds the following clarification regarding the proposal’s impact on human health and safety:

The Department recognizes that text of the Proposition 12 ballot initiative, as approved by voters, General Election (November 6, 2018), stated that the initiative’s purpose was “to prevent animal cruelty by phasing out extreme methods of farm animal confinement, which also threaten the health and safety of California consumers, and increase the risk of food-borne illness and associated negative fiscal impacts on the State of California.” The Department’s prior statements reflect only that there is not currently a consensus in peer-reviewed published scientific literature that would allow the Department to independently confirm, according to its usual scientific practices, that the specific minimum confinement standards outlined in Health and Safety Code (HSC) 25991 reduce the risk of human food-borne illness, promote worker safety, or other human or safety concerns. The Department does not suggest, however, that it was unreasonable for California’s voters to pass the Proposition 12 initiative as a precautionary measure to address any potential threats to the health and safety of California consumers while such

health and safety impacts remain a subject of scientific scrutiny. For example, the scientific literature supporting the potential public health benefits related to egg-laying hens that are provided additional space and the opportunity to express natural behavior continues to increase well after an earlier standard on confining hens (Proposition 2, 2008) went into effect.

Estimated Costs for Businesses to Comply

The Department's statement in the Estimated Costs for Businesses to Comply section of the ISOR describes initial and ongoing costs for a typical business in California to comply with the Act and proposed regulations and is also indicated in section B of form STD 399. There are two estimates listed for both initial and ongoing costs for the two typical California businesses that will be impacted: pork producers and egg producers. For pork producers making whole pork meat the ISOR states, "Estimated ongoing cost is greater than the initial cost of conversion at \$100,000 per year for a typical breeding pig farm due to lower piglet output per sow and increased sow mortality." This statement results from determinations made in the "Farm Cost Increase" section in the SRIA which states, "Hog farms must allow breeding pigs at least 24 square feet per pig of usable floor space and therefore hog farms may adopt a group housing system to meet housing regulations." ... "The increase in feed cost per pig would mainly come from higher sow mortality and less efficient breeding in new housing systems." The Department adds the following clarification regarding the proposal's statements related to sow mortality:

Proposition 12 prohibits confinement of breeding pigs in a manner that prevents them from

lying down, standing up, fully extending their limbs, or turning around freely and after December 31, 2021, that fails to provide a minimum usable floorspace of twenty-four square feet per breeding pig. How a pork producer decides to implement these confinement standards on their operation will be specific to their farm and may include housing breeding pigs separately or in groups. There is no requirement in Proposition 12 for breeding pigs to be housed in a group setting, although the Department recognizes pork producers may choose this option for confining breeding pigs under Proposition 12. Empirical evidence is not conclusive that confining breeding pigs in a group setting with a minimum of twenty-four square feet per pig will increase sow mortality. The SRIA states, "Based on discussion with farmers and industry members, we assess that currently, most farms use gestation crates or allow about 20 square feet of usable floor space for group-housed breeding sows, and it would be costly to meet the Prop 12 requirements." Proposition 12 minimum confinement standards of twenty-four square feet of usable floorspace per breeding pig is greater than the current industry standard of only providing twenty square feet per breeding pig in group housing. The Department does not know if confining breeding pigs in groups with twenty-four square feet per breeding pig will increase sow mortality. The statement related to sow mortality in the SRIA was written in the context of estimating "potential" economic impacts, not as a definitive statement on breeding

pig health impacts of Proposition 12 implementation.

Modifications Provided for in the 15-Day Comment Period

Specific details of proposed modifications to the text may be found below by article and section.

* * * *

Article 3. Breeding Pigs.

Section 1322. Definitions.

1322(a) made a punctuation edit.

1322(b) added language to clarify that the records consisting of an audit trail are applicable to the breeding pig, as well as the immediate offspring of a breeding pig, which is necessary for consistency with the HSC.

1322(c) struck reference to the HSC because it is unnecessary.

1322(f) struck “offer for sale”, “expose for sale”, “possess for sale”, added “title or”, struck “otherwise”, and added “conditional or otherwise” to clarify the intent of and accurately describe the meaning of a commercial sale in the context of the proposed regulations and the statute. The Department additionally revised the definition to include the exclusion as stated in subsection (4) for organizational purposes and added “commercial” for consistency in the regulatory text when referring to the sale of whole pork meat.

1322(f)(1) struck “for human consumption” to clarify the intent of the subsection which is to specify that any whole pork meat produced outside of the state, not only whole pork meat intended for human consumption as currently stated, entering, and exiting California, without additional processing or repacking and

exported outside of the state is not included in the definition of whole pork meat and therefore is not included in commercial sale pursuant to the regulations.

1322(f)(2) struck “official” for consistency when referencing federal processing plants under the authority of the USDA, FSIS. The subsection also added clarification to those transactions or transfers of possession of covered product to federal agencies or taking place on federal lands are excluded from the definition of commercial sale.

1322(f)(3) added a new subsection to clarify transactions or transfers of possession of covered product taking place on tribal lands in California are not considered a commercial sale, and therefore excluded from the Act and regulations. This change is in response to stakeholder and commenter questions about sales on tribal lands.

1322(f)(3) revised the subsection numbering to read 1322(f)(4).

1322(f)(4) struck “religious, charitable, scientific, educational, or other”. This change is in response to stakeholder and commenter requests for the Department to clarify the exclusion from definition of a commercial sale for non-profits donating covered products.

1322(f)(4) struck the entire subsection and revised the text for inclusion in subsection (f) for organizational purposes.

1322(g) struck “uncooked” for consistency of terms used throughout the Chapter. The subsection also struck “family” and added “personal” to clarify how use or consumption of whole pork meat occurs by a consumer pursuant to the proposal.

1322(m) made a grammatical edit and added “but are not limited to” with punctuation edits, to clarify that the provided list of examples of the documents constituting a document of title is not exhaustive.

1322(o)(2) struck text to define an end-user accurately and clearly in the context of a retailer. An end-user is a retailer whether the whole pork meat they sell to a consumer is purchased or received from a pork distributor.

1322(p) struck the definition of “enforcement officer” because only the Department will implement the requirements of this proposal and therefore a general term which includes the Department and the DPH is unnecessary.

1322(q) revised the subsection number to read 1322(p).

1322(q) added text to clarify and narrow the scope of the reference to Part 184 of Title 21 of the Code of Federal Regulations to substances with a use described as a flavoring, flavoring agent, or flavoring enhancer, which came at the request of stakeholders and commenters.

1322(r) revised the subsection number to read 1322(q).

1322(s) revised the subsection number to read 1322(r).

1322(t) revised the subsection number to read 1322(s).

1322(u) revised the subsection number to read 1322(t).

1322(v) revised the subsection number to read 1322(u).

1322(u) added text to the definition of “pork producer” to clarify the source of the whole pork meat as “from a

breeding pig or her immediate offspring”, which is consistent with the HSC. The Department also revised the text to clarify the purpose of the pork meat is for “human” consumption.

1322(v) added “production cycle” to clarify the meaning of the term as used throughout the article. This change is in response to stakeholder and commenter concerns that the regulations lacked clarity regarding life stages of a breeding pig in relation to the regulations and the Act.

1322(x) added a new term which is necessary to make the proposed recordkeeping requirements specific by defining what forms or type of information the Department considers “records”. This change is in response to stakeholder and commenter concerns that the Department’s record requirements should be more specific and allow for electronic records.

1322(x) revised the subsection number to read 1322(y).

1322(y) revised the subsection number to read 1322(z).

1322(z) revised the subsection number to read 1322(aa).

1322(bb) added a definition for “takes physical possession” in response to stakeholder and commenter concerns. The Department is clarifying what “takes physical possession” means for the regulated industry to understand that when a covered product is delivered to a buyer in California, this considered a sale under the Act and the proposal, regardless of any title changes or sales contract specifics negotiated for possession to take place prior to delivery of a covered product to a buyer within the state.

1322(aa) revised the subsection number to read 1322(cc).

1322(dd) relocated to this section, a term used and defined in section 1322.1(a)(2). This change is in response to stakeholder and commenter concerns that the Department did not include a definition for the term.

1322(bb) revised the subsection number to read 1322(ee).

1322(ee) struck text as the reference to the HSC is unnecessary.

Section 1322.1. Breeding Pig Confinement.

1322.1(a) struck “pork producer or pork distributor” and added “person” which is necessary to correctly state that the subsection applies to any person, not only pork producers or pork distributors. The subsection also deletes “sell or contract to sell” and adds “engage in a commercial sale within the state of” to clarify the subsection only applies to those persons who are contracting to sell within the state whole pork meat for human food and therefore must be in compliance with the confinement standards of the Act. These changes were made in response to stakeholder and commenter concerns regarding their confusion with a commercial sale and selling compliant product in the state. The subsection struck “consumption”, added “food”, and added “the whole pork meat” to clarify the use of whole pork meat is for human food. The subsection also added text to clarify compliance with the confinement standards for a breeding pig, or the product of the immediate offspring of a breeding pig, is required “at any time during the production cycle” for said product, which is consistent with the definition of

“production cycle.” Lastly, the subsection made grammatical edits as necessary.

1322.1(a)(1) added a new subsection to include the mandate of the Act requiring that “An enclosure shall allow the breeding pig to lie down, stand up, fully extend limbs, and turn around freely”. This change is in response to stakeholder and commenter concerns that the Department did not address the “turn around/turning around freely” requirements of the Act. The Department’s addition of the requirement in the regulatory text also makes it convenient for stakeholders, so they do not have to reference to the HSC when determining compliance standards.

1322.1(a)(1) struck the subsection numbering to read 1322.1(a)(2).

1322.1(a)(2) struck “Commencing January 1, 2022” and added “After December 31, 2021” for consistency with the requirements as stated in the Act.

1322.1(a)(2) relocated the definition of “useable floor-space” to subsection 1322(dd) for organizational purposes.

1322.1(a)(3) revised the text for clarity.

1322.1(b) revised the text to state the requirements for pork producer third-party certification begins January 1, 2024 which is in response to stakeholder and commenter requests for the Department to delay the requirement for third-party certification of pork producers. The subsection also made a grammatical change and added “for commercial sale” to further clarify the intent of the subsection is to apply to commercial sales in California.

Section 1322.2. Pork Distributor Registration.

1322.2(a) added text to include an implementation date of January 1, 2023 for pork distributor registration in response to stakeholder and commenter requests for the Department to delay the requirement for pork distributor registration. The subsection also revised the text to clarify the intent of the subsection which is to require that any “in-state or out-of-state” person engaged in “a commercial sale into or within” the state as a pork distributor shall hold a valid registration with the Department and made other grammatical edits as necessary.

1322.2(b) revised the text for clarity.

1322.2(f) revised the text to state “calendar” days rather than business days for the timeframe within which a distributor must notify the Department of a change to their registration. This change makes the 30-day timeframe to report changes to the Department easier to determine.

1322.2(k) revised the text to clearly state when a pork distributor submits an application for pork distributor initial or renewal registration, a self-certification in lieu of the valid third-party certification required of subsection (j) will be accepted by the Department prior to January 1, 2024. These changes are in response to stakeholder and commenter requests for the Department to delay the requirement for pork distributor third-party certification and for organizational purposes.

1322.2(l) revised the text to restate and clarify the exclusion from required distributor registration for official plants under mandatory federal inspection. These

changes are in response to stakeholder and commenter requests for clarity regarding sales at USDA, FSIS establishments and for organizational purposes.

Section 1322.3. Inspection and Audit of Registered Pork Distributor Facilities.

1322.3(a) struck obsolete text for organizational purposes.

Section 1322.4. Whole Pork Meat Shipping Document Requirements.

1322.4(a)(1) struck “Commencing January 1, 2022,” because regulations will not be implemented by this date. The subsection struck “shipping invoices” and “bills of lading” because the definition of documents of title includes these documents, therefore repeating them was redundant. The subsection additionally struck text requiring specified verbiage on whole pork meat shipping documents and added new shipping document verbiage. These changes come in response to stakeholder and commenter concerns that the originally proposed shipping document statements may imply that the whole pork meat was produced in California. Therefore, the Department is proposing a change to the shipping document wording to clarify the whole pork meat represented was produced in compliance with California Proposition 12.

1322.4(a)(2) revised the regulatory text to clarify the requirement for noncompliant whole pork meat entering California for sale to federal agencies or on tribal lands and not destined for commercial sale in California, to maintain specified marking requirements on shipping documents. This change is in response to stakeholder and commenter requests for the Department to clarify whether the sale of whole pork meat to

federal facilities or on tribal lands falls under the definition of commercial sale. The subsection also revised the marking statements required on shipping documents to identify the product as intended for export, transport, donation, or that it is not compliant, as specified. These changes are in response to stakeholder and commenter concerns that the originally proposed wording on shipping documents may be disparaging or otherwise prejudice export products and may cause refusal for acceptance by other countries. Lastly, the subsection added a statement to require the markings on shipping documents shall be legible and plainly printed or stamped, for consistency of marking requirements in the regulations.

1322.4(a)(3) revised language for consistency when referencing federal processing plants under the authority of the USDA, FSIS.

Section 1322.5. Pork Distributor Recordkeeping.

1322.5(f) struck the entire subsection for organizational purposes because it is unnecessary since section 1322.2(l) excludes official plants under mandatory inspection under the Federal Meat Inspection Act from the requirement for registration as a pork distributor.

Section 1322.6. Inspection of Conveyances.

1322.6(a) struck text referring to an “enforcement officer” because it is unnecessary and redundant.

1322.6(b) struck text referring to an “enforcement officer” and added “the Department” to clarify every person shall stop at the request of the Department, as specified.

1322.6(c) struck text referring to an “enforcement officer” because it is unnecessary and redundant.

Section 1322.7. Tagging and Seizure of Whole Pork Meat.

1322.7(a) struck text referring to an “enforcement officer” because it is unnecessary and redundant. The subsection also added “whole” to read “whole pork meat” two times for consistency with terms used throughout the Chapter.

1322.7(b) struck text referring to an “enforcement officer” because it is unnecessary and redundant.

1322.7(c) struck text referring to an “enforcement officer” and added “The Department” to clarify the Department may seize and hold containers, sub-containers, lots, or loads of whole pork meat, as specified. The subsection also struck a second “enforcement officer” reference and added “whole” to read “whole pork meat” three times for consistency with terms used throughout the Chapter.

1322.7(d) struck text referring to an “enforcement officer” because it is unnecessary and redundant.

Section 1322.8. Written Certification.

The Department is adding to the statement of purpose and necessity for stakeholder clarity that this proposed section would establish specific requirements to strengthen the basis of written attestations to ensure they are accurate, truthful, and auditable. A business owner or operator may rely on written certification because HSC section 25993.1 provides that 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 pork meat was not derived from a breeding pig who was confined in a cruel manner.

1322.8(b) added “physical” to clarify where possession of product takes place for consistency with new subsection 1322(bb) which defines “takes physical possession”. The subsection made changes for consistency of terms used throughout the Chapter and added “which does not hold a valid pork distributor registration” to clarify who needs to follow the requirements of the subsection. An official plant at which mandatory inspection is maintained under the Federal Meat Inspection Act may register with the Department as a pork distributor, but it is not a requirement. If a retailer or food processor end-user takes physical possession of whole pork meat from a registered pork distributor, then this section does not apply. Changes to this subsection are for organizational purposes to clarify the intent as proposed.

1322.8(b)(3) struck “state or local health agencies” because implementation of the requirements will take place under the authority and direction of the Department.

1322.8(c) revised the text for consistency when referencing federal processing plants under the authority of the USDA, FSIS.

Section 1322.9. Denial, Suspension, or Revocation of Pork distributor Registration.

1322.9(b) added a new subsection to describe the procedures taken by the Department for a proposed suspension or revocation of a pork distributor registration, which is to provide notice of the proposed action and to inform the distributor of the: (1) date the proposed suspension or revocation is issued; (2) reason for the proposed suspension or revocation; (3) effective date of the proposed suspension or revocation, including a statement that the effective date is 30 calendar

days after the date issued; (4) future eligibility for registration including conditions for reinstatement; and (5) right to request a formal hearing which must be requested within 30 calendar days of the date the proposed suspension or revocation was issued. The subsection also informs the distributor that their registration shall remain in effect pending the outcome of a formal hearing which is necessary, so the distributor understands the status of their registration during this time.

1322.9(b) revised the subsection numbering to read 1322.9(c).

1322.9(c) deleted obsolete text and clarified that a person may appeal the Department's decision to deny a registration or a renewal of a registration and struck "certificate" because it was redundant. The Department replaced the reference to the formal hearing proceedings specified in Government Code with the formal hearing proceedings specified in section 1327.2 of these regulations and added "within 30 calendar days of date of the notice of denial" to inform the distributor of the timeframe for appealing a notice of denial.

1322.9(c) struck the entire subsection because the proposed requirements are revised and included in modified subsection (b)(5).

Section 1322.10. Registration with the California Department of Public Health.

1322.10 struck the entire section to avoid confusion because stakeholders will need to comply with all other applicable laws and regulations outside of this proposal, not only those laws and regulations with Department of Public Health.

Article 4. Exceptions.

Section 1324. Definitions.

The subsection added an introductory statement for consistency with the definition sections in all articles of this proposal.

1324(a) added a definition for “breeding pig” to define the term as used in the article, which is consistent with the term defined in Article 3. Breeding Pigs.

1324(a) revised the subsection number to read 1324(b).

1324(b) revised the subsection number to read 1324(c).

1324(c) revised the definition of “medical research” to additionally include medical research conducted at a facility accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC). The AAALAC is an international organization whose primary purpose is to improve the welfare of animals produced for or used in research, teaching and testing, and to enhance the quality of these activities through accreditation of the animal care and use program. This change is in response to stakeholder and commenter comments that the definition as originally proposed may limit funding sources for legitimate medical research and recommendation the definition should be expanded to provide for medical research funded privately or through other mechanisms. In support of this addition to the definition, the Department added the AAALAC International, Bylaws (May 2, 2019) to the rulemaking file for inclusion in the list of Materials Relied Upon (Document Added – 1).

Section 1324.1. Confinement Standards Exceptions.

The Department added new section heading and section 1324.1(a)(1) through (7) to inform the regulated industry of exceptions to the confinement standards as stated in the Act. This change is in response to stakeholder and commenter concerns that the Department should include all relevant exceptions to the confinement standards as stated in the Act for egg-laying hens, calves, and breeding pigs, rather than referencing the HSC in the confinement section of each article. The Department recognizes repeating exact wording of statute into regulatory text is uncommon, however the Department's addition of the exceptions as stated in the Act into the proposed modified regulatory text as subsections 1324.1(a)(1) through (7) in this case, makes it less confusing and convenient for stakeholders, so they do not have to reference to the HSC when determining applicable exceptions to the Act's compliance standards. The Department also added the required authority and reference citations.

Article 5. Certification and Accredited Certifiers.

Section 1326. Definitions.

1326.(b) made a punctuation edit.

1326(c) revised the text to clarify the specific areas and items that a certifying agent may certify pursuant to the Chapter and made other changes for consistency of terms used throughout the Chapter.

1326(h) added text to ensure the details provided by definitions in the HSC for a breeding pig, calf, and an egg-laying hen are also considered in the definition of "covered animal."

1326(i)(1) revised the reference to the definition of shell eggs and made a grammatical edit.

1326(i)(2) made an edit for grammatical purposes.

1326(i)(3) revised the reference to the definition of whole veal meat and made grammatical edits.

1326(i)(4) revised the reference to the definition of whole pork meat.

1326(k) revised the references to the definitions of veal distributor and pork distributor.

1326(p) added “area of” for clarity.

1326(v) revised the references to the definitions of veal producer and pork producer.

Section 1326.1. General Requirements for Certification.

1326.1(d) added “in California” to clarify the intent of the subsection.

1326.1(e) added “in California” to clarify the intent of the subsection.

Section 1326.3. Application for Certification.

1326.3(a)(4) added “and” for grammatical purposes.

1326.3(a)(5) made a punctuation edit and struck “and” for grammatical purposes.

Section 1326.4. Review of Application for Certification.

1326.4(a)(3) made a punctuation edit, added “or” and struck “or revocation” to clarify revocation of certification is not applicable to this subsection.

1326.4(c) made a grammatical change to read “with-draws” two times.

1326.4(d) replaced “verification” with “inspection” as inspection is the appropriate term.

Section 1326.5. On-site Inspections.

The section heading added “Certification” to differentiate between the certifying agent on-site inspections as proposed in section 1326.16.

In the Department’s justification for subsections (a) and (a)(1), the Department made the following statements, “This subsection goes on to require that a certifying agent conduct an annual inspection once every 12 months for a certified operation to maintain certification. An annual inspection is an agricultural industry standard for frequency of visits to ensure participants continue to maintain standards as required for specific programs, therefore the Department proposes a similarly structured schedule for on-site inspections.” In support of annual inspections once every 12 months, the Department added references to several farm animal welfare certification sources successfully implementing annual inspections used to verify an operation’s conformity with the standards required by the entity from which they are seeking certification. As several public comments received by the Department raised concern that annual inspections as proposed were too frequent, the Department added the below Materials Relied Upon in further support of proposed annual on-site inspections. For simplicity of renewal certifications and logistics for the operations in scheduling on-site inspections, the Department proposes to keep on-site inspections at 12-month intervals.

The Department added the following documents to the list of Materials Relied Upon in support of annual on-site inspections as proposed:

- *Organic 101: Ensuring Organic Integrity Through Inspections* (Document Added – 2)

- *Title 7, Code of Federal Regulations, Part 205, section 205.406* (Document Added – 3)
- *American Humane Certified™, Becoming American Humane Certified™* (Document Added–4)
- *Humane Farm Animal Care, Policy Program Manual* (Document Added – 5)
- *A Greener World, A Greener World Compliance Policy Manual – North America* (Document Added – 6)
- *Global Animal Partnership, Pig Standards* (Document Added – 7)

1326.5(b)(2) added text to clarify when a certifying agent schedules an on-site inspection, the authorized representative of the operation who is knowledgeable about the operation must have access to operation records. The Department added this condition in response to stakeholder and commenter concerns that it was important to have a representative of the farm present during an on-site inspection. Having a farm employee present during the on-site visit is necessary to ensure biosecurity protocol of the farm is followed and to provide access to locations and paperwork related to covered animals and covered product only. The Department, however, retains the right to unannounced visits at the location of covered animals and covered product to verify compliance because verification of compliance cannot be performed at a central corporate office or via paperwork alone, therefore, this on-site inspection is needed for program integrity.

1326.5(d) revised the text for consistent use of the word “certifying agent” two times in the subsection.

Section 1326.6. Granting Certification.

1326.6(a) added “certifying” to read “certifying agent” for clarity.

1326.6(c) replaced “verification” with “inspection” as inspection is the appropriate term.

Section 1326.7. Denial of Certification.

1326.7(a) replaced “notification” with “notice” twice for consistency of terms used throughout the Chapter and made a grammatical edit.

1326.7(d) added “within 30 calendar days of the date issued” to clarify the timeframe for responding to the notice of noncompliance.

1326.7(e)(2) revised the reference to read “section 1327.3” for clarity and added “within 30 calendar days of date of notice or denial” to clarify the timeframe for requesting mediation.

1326.7(e)(3) revised the text to correctly state an applicant’s right to “request” a formal hearing. The subsection also struck reference to the formal hearing proceedings as specified in Government Code and instead references to section 1327.2 of this proposal which describes the proposed formal hearing procedures.

1326.7(f) added “certifying” to clarify certifying agent.

1326.7(g) made a punctuation edit, added “or” and struck “or revocation” to clarify revocation of certification is not applicable to this subsection.

1326.7(h) replaced “reason to believe” with “evidence” and struck “willfully” and “purposefully” for consistency of terms used throughout the Chapter.

Section 1326.8. Continuation of Certification.

1326.8(a)(2) struck “minor” and added “any” to require a certified operation to update the correction of “any” noncompliances previously identified by a certifying agent when submitting renewal information as a part of continued certification. This change comes in response to stakeholder and commenter concerns to prevent application of inconsistent standards when determining a continued certification.

1326.8(e) added “calendar” for clarity.

1326.8(f) replaced “verification” with “inspection” as inspection is the more appropriate term, made a punctuation edit, and added “to determine” for clarity.

Section 1326.10. General Requirements for Accredited Certifying Agents.

1326.10(a)(7) added “that was” for grammatical purposes.

1326.10(a)(10)(A) added “calendar” to clarify the timeframe as stated and replaced “notification” with “notice” for consistency of terms used throughout the Chapter.

1326.10(c) added text to fully describe possible reasons for discrimination consistent with California’s Fair Employment Practices Act.

Section 1326.12. Applicant Information for Accreditation as a Certifying Agent.

1326.12(a) made a punctuation edit.

1326.12(c) struck “veal” for consistency when referring to calves and made an organizational edit.

Section 1326.13. Evidence of Expertise and Ability.

1326.13(a)(1) deleted “and evaluation” for clarity.

1326.13(a)(3) added “including biosecurity training” to the required documents and information a prospective certifying agent must submit to the Department to demonstrate personnel conducting inspections have sufficient expertise to successfully perform the duties of a certifying agent pursuant to the proposal. This added text is in response to stakeholder and commenter concerns that certifying agents coming on to a farm for inspections must follow the farm’s biosecurity protocols and must be sufficiently trained and familiar with animal production.

1326.13(b)(1) replaced “certification” with “certificates” for clarity.

Section 1326.14. Granting Accreditation.

1326.14(a)(2) replaced “evaluation” with “inspection” for consistency of terms used throughout the Chapter.

Section 1326.15. Denial of Accreditation.

1326.15(a) replaced “reason to believe” with “evidence” and “evaluation” with “inspection” for consistency of terms used throughout the Chapter.

1326.15(c) replaced “notification” with “notice” twice and struck the Government Code reference to formal hearing proceedings. The subsection added a reference to section 1327.2 describing the formal hearing proceedings pursuant to these regulations and added “within 30 calendar days of the notice of denial” to inform the applicant of the timeframe for requesting a formal hearing.

1326.15(d) replaced “evaluation” with “inspection” twice for consistency of terms used throughout the Chapter.

Section 1326.16. On-site Evaluations.

Added “Certifying Agent” to the section heading to differentiate between the certification on-site inspections proposed in section 1326.5 and replaced “Evaluations” with “Inspections” for consistency of terms used throughout the Chapter.

1326.16(a) replaced “evaluation” with “inspection” three times for consistency of terms used throughout the Chapter and added “records to” and made a grammatical edit to allow for the review of records held by a certifying agent during an on-site visit which is needed to receive and maintain accreditation.

1326.16(b) replaced “evaluation” with “inspection” three times and replaced “notification” with “notice” for consistency of terms used throughout the Chapter.

Section 1326.17. Annual Report, Recordkeeping, and Renewal of Accreditation.

1326.17(b)(3) struck text excluding specified recordkeeping because it no longer applies to the proposed text.

1326.17(c)(1) replaced “notification” with “notice” for consistency of terms used throughout the Chapter.

1326.17(c)(2) replaced “evaluation” with “inspection” for consistency of terms used throughout the Chapter.

1326.17(e) replaced the Government Code reference to formal hearing proceedings with a reference to section 1327.2 describing the formal hearing proceedings pursuant to these regulations and added “within 30 calendar days of the notice of denial” to inform the applicant of the timeframe for requesting a formal hearing.

326.17(h) added “calendar” to clarify the timeframe as stated.

Section 1326.18. General Compliance.

1326.18(b)(2) added specified text to clarify the Department may initiate suspension or revocation proceedings when the certifying agent is not the Department.

1326.18(d) revised the text to clarify notification by the Department to a certifying agent as specified, must be sent “in writing” and struck requirements stating the location and method of such notification which provide for more flexibility when making the notification to a recipient.

Section 1326.20. Noncompliance Procedure for Certified Operations.

1326.20(a)(1) added a new subsection stating “The date issued” to require the notification of noncompliance to include this information for clarity.

1326.2(a)(1) revised the subsection number to read 1326.20(a)(2).

1326.2(a)(2) revised the subsection number to read 1326.20(a)(3).

1326.2(a)(3) revised the subsection number to read 1326.20(a)(4).

1326.20(c) replaced “notification” with “notice” two times for consistency of terms used throughout the Chapter, added “notice of” for clarity, and struck “in one notification” because the text is obsolete.

1326.20(c)(1) added a new subsection to state “The date the proposed suspension or revocation was issued” requiring the notice of proposed suspension or revocation of certification to include this information for clarity.

1326.20(c)(1) revised the subsection number to read 1326.20(c)(2).

1326.20(c)(2) revised the subsection number to read 1326.20(c)(3).

1326.20(c)(3) relocated “proposed” for clarity.

1326.20(c)(3)(A) struck “maximum” because it is obsolete to the intent of the subsection and replaced “notification” with “the notice” for consistency of terms used throughout the Chapter. 1326.20(c)(3) revised the subsection number to read 1326.20(c)(4). 1326.20(c)(4) revised the subsection number to read 1326.20(c)(5)

1326.20(c)(5) revised the reference to read section 1327.3 which describes the mediation proceedings pursuant to these regulations, replaced the reference to the formal hearing proceedings specified in Government Code with the formal hearing procedures specified in section 1327.2 of these regulations, and added “within 30 calendar days of the date the proposed suspension or revocation was issued” for clarity. These changes describe content of the notice of proposed suspension or revocation of certification which is necessary to inform a certified operation of the options they have when a certifying agent is proposing a suspension or revocation of their certification and the timeframe for requesting mediation or a formal hearing. The subsection additionally deleted language describing the pending outcome of an appeal. This deleted text is revised and restated in new subsection (6) below.

1326.20(c)(6) added a new subsection restating from subsection (5) above that the certifying agent and the Department will not issue a notice of suspension or

revocation while the outcome from mediation or a formal hearing is pending which was necessary to clearly describe the intent of the subsection.

1326.20(d) replaced “notification” with “notice” for consistency of terms used throughout the Chapter.

1326.20(e)(1) replaced “file an appeal” with “request a formal hearing”, added “the”, struck obsolete text “according to the notice of proposed suspension or revocation”, and replaced “notification” with “notice” for consistency of terms used throughout the Chapter.

1326.20(e)(2) replaced “notification” with “notice” for consistency of terms used throughout the Chapter, revised the reference to read section 1327.3 which describes the mediation proceedings pursuant to these regulations, and replaced the reference to the formal hearing proceedings specified in Government Code with the formal hearing proceedings specified in section 1327.2 of these regulations for clarity.

1326.20(f)(1) replaced “notification” with “notice” for consistency of terms used throughout the Chapter.

1326.20(f)(3) struck the entire subsection because the proposed requirements are revised and included in modified subsections (e)(1) and (e)(2).

Section 1326.21. Noncompliance Procedure for Accredited Certifying Agents.

1326.21(c) replaced “notification” with “notice” two times and added “notice of” for consistency of terms used throughout the Chapter to correctly refer to the notice of proposed suspension or revocation of accreditation. The subsection additionally struck obsolete text stating the notification would state whether the certifying agent’s accreditation or specified areas of accreditation are “to be” suspended or revoked which

does not apply because the suspension or revocation is only being “proposed”.

1326.21(c)(1) added a new subsection stating “the date the proposed suspension or revocation was issued” to require the notice of proposed suspension or revocation of accreditation to include this information for clarity.

1326.21(c)(1) revised the subsection to read 1326.21(c)(2).

1326.21(c)(2) revised the subsection to read 1326.21(c)(3).

1326.21(c)(3) relocated “proposed” for clarity.

1326.21(c)(3)(A) struck “maximum” because it is not applicable to the intent of the subsection and replaced “notification” with “the notice” for consistency of terms used throughout the Chapter.

1326.21(c)(3) revised the subsection to read 1326.21(c)(4).

1326.21(c)(4) revised the subsection to read 1326.21(c)(5).

1326.21(c)(5) replaced “file” with “request” with respect to the formal hearing, replaced the reference to the formal hearing proceedings specified in Government Code with the formal hearing proceedings specified in section 1327.2 of these regulations, and added “within 30 calendar days of the date the proposed suspension or revocation was issued” for clarity. These changes describe content of the notice of proposed suspension or revocation of accreditation which is necessary to inform an accredited certifying agent of the options they have when the Department is proposing a suspension or revocation of their accreditation and the

timeframe for requesting mediation or a formal hearing. The subsection additionally deleted language describing the pending outcome of an appeal. This deleted text is revised and restated in new subsection (6) below.

1326.21(c)(6) added a new subsection restating from subsection (5) above that the Department will not issue a notice of suspension or revocation while the outcome from a formal hearing is pending which was necessary to clearly describe the intent of the subsection.

1326.21(d) replaced “reason to believe” with “evidence” and replaced “notification” with “notice” for consistency of terms used throughout the Chapter.

1326.21(e) replaced “file” with “request” and deleted “appeal” for consistency of terms used throughout the Chapter. The subsection additionally added “30 calendar days from the date the proposed suspension or revocation was issued” to inform the accredited certifying agent of the timeframe to request the formal hearing.

1326.21(g)(1) replaced “notification” with “notice” for consistency of terms used throughout the Chapter.

1326.21(g)(3) struck the entire subsection because the proposed requirements are revised and included in modified subsection (c)(5).

Section 1326.22. Government Entity Providing Certification.

1326.22(a)(2) replaced “notification” with “notice” for consistency of terms used throughout the Chapter.

1326.22(a)(3) replaced “or” with “and” for consistency of terms used throughout the Chapter.

1326.22(b) replaced “certifier” with “certifying agent” for consistency of terms used throughout the Chapter.

Article 6. Informal Hearing and Mediation.

The Department struck “Informal” from the section heading for clarity and made a grammatical edit.

Section 1327.2. Formal Hearing Procedures.

The Department added a new subsection to inform the regulated industry of the procedures required when requesting a formal hearing to contest a notice of adverse determination issued by the Department.

1327.2(a) informs a respondent that they may contest a notice of adverse determination pursuant to the sections as specified. This subsection is necessary to identify the sections in the Chapter where a formal hearing may be used to contest the notice of adverse determination.

1327.2(b) informs the respondent that the request for a formal hearing must be in writing and sent to the Department as specified.

1327.2(c) informs the respondent the conduct of the formal hearing which is pursuant to the Government Code authorizing use of formal hearings.

1327.2(d) informs a respondent that the adverse determination shall remain in effect pending the outcome of a formal hearing which is necessary, so the respondent understands the status of the adverse determination during this time.

The subsection added the applicable authority and reference citations pertaining to the regulation section.

Section 1327.2. Mediation.

The Department revised the section numbering to read Section 1327.3. Mediation.

1327.2(a) revised the text to clearly state mediation may be requested for “adverse actions that include” for clarity.

1327.2(c) added “of an adverse action” to clarify the intent of the subsection.

1327.2(c)(1) added “of the proposed adverse action” to clarify the intent of the subsection, replaced the reference to the formal hearing proceedings specified in Government Code with the formal hearing proceedings specified in section 1327.2, and added “calendar” to clarify the timeframe as stated.

1327.2(e) added “calendar” two times to clarify the timeframe as stated, added “to deny, suspend, or revoke certification” to accurately state the intent of the subsection, and replaced the reference to the formal hearing proceedings specified in Government Code with the formal hearing proceedings specified in section 1327.2 of these regulations.