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A Uniform Approach to Farm Animal Welfare Laws: Thought for Our Food Instead of Food for Our Thought

Channing Burd

I. Introduction

We have all seen the commercials and know "Happy Cows Come from California,"[1] but there is a larger issue hidden inside the phrase. Why should not all farm animals be happy, regardless of which state they were raised in? Why are only the cows in California happy, but not the chickens and the hogs as well? Farm animal welfare in the United States needs regulatory overhaul, and we needed it decades ago. This is not to say there are no regulations surrounding the welfare of farm animals, because they do exist. Upon examining them in the latter parts of this article, we will understand how ineffective those regulations are. This article will illustrate why regulatory overhaul is needed. First, we will examine how a new system of laws, which are part of a uniform code enacted by every state, is the best solution to the problem surrounding farm animal welfare.[2] Second, we will examine the increased consumer interest in farm animal welfare.[3] Third, we will examine how consumers in some states have gone so far as to create laws through the voting process to address the needs they see.[4] Fourth, we will examine how those laws do not help with the issue but instead make matters worse.[5] Fifth, we will see how states have a variety of approaches to handling animal welfare, which creates a very fractionated approach across the country.[6] Lastly, we will examine the federal legislation which has been ineffective and is outdated, lacking any true ability to address the issue.[7]

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[1] For a brief synopsis of commercials using this slogan *see*, People for the Ethical Treatment of Animals, Inc. v. Cal. Milk Producers Advisory Bd., 125 Cal. App. 4th 871 (Cal. Ct. App. 2005).
[2] *See infra* Part II.
[3] *See infra* Part III.
[4] *See infra* Part III(a).
[5] *See infra* Part III(a)(i).
[6] *See infra* Part IV.
[7] *See infra* Part V.

When looking at the entirety of this article, we need to keep in mind that animals are not homogenous, but our current legislation is a one-size-fits-all approach. Trying to apply the same laws to cows as we do poultry, or vice versa, is simply ineffective and illogical. One of the biggest differences between the cattle industry, beef or dairy, compared to poultry and pork is: the supply chain. Both the pork and poultry industries are vertically integrated, meaning they have a streamlined approach in which the person, or entity, at the end of the supply chain is the same at the beginning of the supply chain. On the other hand, beef is not a vertically integrated system. Cows typically begin on a family owned cow-calf operation, where they are weaned from the mother, and then sold once they reach a certain weight.[8] Next, they will either be moved to a backgrounding operation where they will be fed until they reach the ideal weight; or they will remain on the original operation until the ideal weight is achieved. Upon reaching the ideal weight, the cattle are then sold, or transported, to a feedlot. At the feedlot, or Confined Animal Feeding Operation (often referred to as a "CAFO") they will go through the finishing process. The finishing process involves cattle being fed a specific diet, until they reach slaughter weight.

With varying approaches, or systems, for different farm animals in this country we cannot treat them all the same. It is like trying to fit a round peg into a square hole. If a uniform welfare code were to be created, and enacted, there could be different sections of the code applicable to different animals. The ability to treat each species as their own instead of having an umbrella approach as we currently do, would be advantageous to all species of farm animals and their welfare.

Like commercial transactions in the early 1900's, every state currently has varying laws creating a system in which a farmer in Missouri does not have to follow the same regulations, at the state level, as a farmer in Arkansas even if they are selling their animals to the same corporation. The comparison to commercial transactions is intentional, because to address the issue a century ago, the Uniform Commercial Code was drafted and enacted.

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[8] *The Beef Lifecycle*, PA BEEF COUNCIL, https://www.pabeef.org/raising-beef/beef-lifecycle.

Once again, this article is not meant to critique current practices by producers who are raising farm animals in the United States, but rather to improve the ability to enforce laws governing farm animal welfare.

II. Analysis: Why Uniformity Is Necessary

So, why should we create a uniform act to have each state adopt regarding farm animal welfare? We need to clean up the regulatory body of work in this area of law. When there is no consistency in the definition of animal cruelty amongst the states, companies cannot give their employees comprehensive training before they begin employment. Currently, companies would have to teach workers in each state, individually, about the state specific laws. If we enacted a uniform set of laws, the companies would be able to provide comprehensive training to every employee allowing them all to be trained in the same manner. Not only would a uniform act allow for comprehensive training, but it could be drafted in a way which holds managers and C-suite executives accountable for the actions of their companies, unlike the current system.[9]

Along the same lines, producers in each state are currently held to different standards of welfare practices. This allows producers in some states to produce at a higher rate than others, which is no fault of the farmer. They are still practicing humane methods and complying with their state laws. When a producer in Missouri can raise egg-laying hens in smaller cages than their competition in California, we are giving one group of producers an advantage in the marketplace. None of this is to say that farmers are using inhumane practices. But when a farmer is running a business, they are going to want to make the most money they possibly can (any good businessperson would do the same thing).

With a lack of common definitions for animal cruelty, a lack of civil penalties, a lack of prosecutions regarding

[9] See Fair Oaks Farm case where only the employees who were mistreating the animals were charged for an example. *See eg.,* Dave Bangert, *Felony Charge Dropped for only ex-Fair Oaks Farms Worker Arrested in Animal Abuse Case*, LAFAYETTE JOURNAL & COURIER, (Dec. 18, 2019), https://www.jconline.com/story/news/2019/12/18/fair-oaks-farms-animal-abuse-felony-charge-dropped-former-employee/2695688001/.

violations of law, and a lack of uniformity regarding the way certain animals should be raised, we have created a very fractionated approach. When a businessperson in the early 1900's contracted with a businessperson from a different state, no one really knew which state laws would apply[10], very similar to the state of agricultural laws in the United States now. The Uniform Commercial Code is now taught to every first-year law student in the country, so why can the same not be done with agriculture?

Another thing to consider is not every state has the same sectors of agriculture, and every state has different animals being raised inside the state. We cannot treat cows the same as chickens, nor pigs the same as we treat cows. Animals are not homogenous and cannot all be placed under the umbrella of a few pieces of legislation. A uniform set of laws could be drafted in a manner which allows for different chapters of the law to address the different animals we produce across the country. A uniform act could also allow for state agencies to be the enforcement arm of the law, alleviating the pressure on federal agencies to enforce numerous laws across the entire country. This would limit the number of producers each agency oversees and allow for agencies to have the ability to ensure producers are being held accountable more consistently than they currently are under federal enforcement.

Lastly, a uniform act would allow for a baseline approach to be implemented across the country. A baseline which would allow for expansion, the initial piece could address farm animal welfare laws. But the next step could be addressing the greenwashing or label fatigue we will examine later in this article.[11] While labeling is handled at the federal level, a uniform act would allow for expansion to address the loopholes in labeling requirements and third-party certifications we see companies taking advantage of to increase their profitability. The expansion could then trend in the direction the American public sees fit. One example of this would be creating educational materials or opportunities for consumers to understand what happens on a farm and hopefully

[10] Application of the UCC, U.C.C. https://uniformcommercialcode.uslegal.com/application-of-the-ucc/ (last visited Oct. 29, 2022).

[11] *See infra* Part III.

bridge the gap between consumer and producer. Or even go one step further to allow for meat produced at state-inspected slaughterhouse to be sold interstate.

While a piece-by-piece approach could cause issues such as certain amendments being challenged, the ability to create a set of laws which allows for the uniform act to stay modern and change if there are hiccups in the process. The possibility of issues occurring down the road cannot be enough to deter us from creating a system of laws which can enact sweeping change in an area which desperately needs it. This process cannot be done with the states handpicking certain sections of the uniform code to enact. It must be done in entirety, so we do not end up back in the same situation of state laws having no uniformity.

Now that we have discussed the benefits of a uniform code in farm animal welfare, the rest of this article will provide background information on the current state of regulation and consumer interests in the United States.

III. Consumer Interest in Animal Welfare

The American consumer is becoming more aware of the way animals are being treated and how the food they are consuming was treated during its lifetime. Not only is the average consumer becoming more aware, but they are also making decisions in the grocery store aisle based on how the animal(s) were treated.[12] Whether the decision is a decision to buy meat because they believe they were treated humanely,[13] or not purchasing from certain companies due to learning about a poor reputation the company has regarding their treatment of animals.[14] Regardless of the decision, consumers are placing significantly more weight on the welfare of the animals they are purchasing. Further, consumers have shown a strong

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[12] *Consumer Perceptions of Farm Animal Welfare,* ANIMAL WELFARE INST., https://awionline.org/sites/default/files/uploads/documents/ConsumerPerceptionsFarmWelfare.pdf (last visited Oct. 31, 2022).

[13] *Id.* at 1 (citing to T Johnson, *Alternative Proteins, Animal Welfare Concerns Shift Beef, Pork Preferences,* MEATINGPLACE, Feb. 12, 2019).

[14] *Id*. (citing to Jamie Ballard, *Women More Likely Than Men to Care About Ethical Meat*, YOUGOV. (Nov. 26, 2018), https://today.yougov.com/topics/consumer/articles-reports/2018/11/26/ethical-meat-price-quality-animal-rights.

support for regulations which address farm animal welfare.[15] To support this survey finding, we must look no further than the likelihood of a product being purchased based on the labeling claiming the animals were raised in a welfare-friendly manner.[16]

A majority of consumers pay significant attention to the labels, resulting in sales increasing for items making claims the animal was raised in a humane manner.[17] These labels can become misleading, whether intentionally or unintentionally, to consumers.[18] With labels occasionally being misleading, the ability to have uniform regulations in place requiring all animals to be raised in such a manner would eliminate some of the confusion we see in the grocery aisle. One study even suggests there is "label fatigue," causing consumers to be overwhelmed with the claims on the packaging of food they are seeing in the store.[19] A uniform code, in the beginning may not be comprehensive enough to change labeling certifications but having more regulations surrounding the welfare of these animals would make the label claims superfluous. When animals are being raised in a manner consistent with a uniform code promoting animal welfare, we no longer need all the label claims to illustrate which animals have been raised in accordance with the certification(s) guidelines.

With so many corporations knowing they have the ability to market their products in a certain way, making their products more likely to be purchased, we are experiencing a phenomenon of "greenwashing."[20] Greenwashing happens when a company appears to be acting in a manner that is

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[15] *Id.* at 4 (citing *More Consumers Concerned About Animal Welfare,* FEEDSTUFFS, (Jun. 2, 2017), http://www.feedstuffs.com/news/survey-more-consumers-concerned-about-animal-welfare).

[16] *Id.* at 9 (citing D.S. Conner et al., *Consumer Preferences for Pasture-Raised Animal Products: Results from Michigan*, 39 J. OF FOOD DISTRIB. RSCH, Vol. 12 (2008)).

[17] Alicia Kelso, *Consumers are willing to pay a premium for animal welfare certifications*, GROCERYDIVE, (Jul. 17, 2018) https://www.grocerydive.com/news/grocery--consumers-are-willing-to-pay-a-premium-for-animal-welfare-certifications/533852/.

[18] ANIMAL WELFARE INST., *supra* note 12, at 11 (citing *Millennials Drive Rise in Fresh-Meat Buying: Study*, MEATINGPLACE, (May 21, 2018), http://www.micausa.org/millennials-drive-rise-fresh-meat-buying-study/).

[19] *Id*.

[20] Carlyann Edwards, *What is Greenwashing?*, BUS. NEWS DAILY (Aug. 05, 2022), https://www.businessnewsdaily.com/10946-greenwashing.html.

environmentally conscious but is not actually acting in accordance with their portrayal.[21] Greenwashing is more of a reference to companies portraying themselves as being environmentally friendly, the comparison to label fatigue might be a bit of a stretch. The two things run hand in hand though, because label claims and greenwashing are both examples of how companies use marketing to boost their products (and their bottom line) while not actually acting in accordance with the claims they are making.

A. Ballot Initiatives

The next example of consumers showing their concerns about the treatment of farm animals comes in the form of a ballot initiative. A ballot initiative is sometimes referred to as a ballot measure, but regardless of the name they are "proposals to enact new laws or constitutional amendments."[22] The proposal is added to the ballot using a petition.[23] Only 26 of the 50 states have a ballot initiative process.[24]

Voters in certain states have proposed, and passed, ballot initiatives to create laws addressing the raising of farm animals.[25] California's Proposition 2, which was passed in 2008, prohibited confinement of certain animals in a manner which did not allow them to turn around freely, lie down, stand up, and fully extend their legs.[26] Proposition 2 dealt with the confinement of pregnant pigs, calves being raised for veal, and egg-laying hens.[27] This law gave producers until January 1, 2015, to come into compliance with the regulations but only

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[21] *Id*.
[22] *What are ballot propositions, initiatives, and referendums*? UNIV. S. CAL., http://www.iandrinstitute.org/quick-facts.cfm (last visited Nov. 1, 2022).
[23] *Id.* (Proposals are added to ballots only after collecting signatures of a certain number of citizens.)
[24] *States with initiative or referendum*, BALLOTPEDIA, https://ballotpedia.org/States_with_initiative_or_referendum (last visited Nov. 1, 2022).
[25] *See, e.g.,* Prevention of Farm Animal Cruelty Act, CAL. HEALTH & SAFETY CODE § 25990 (Deering 2022) (amended 2018); FLA. CONST. art. X, § 21 (amended 2002).
[26] CAL. HEALTH & SAFETY CODE § 25990 (2008).
[27] *Id*.

applied to those producers which were in California, but not producers in other states who sold their eggs in California.[28]

The next ballot initiative in California was Proposition 12, which was enacted in 2018. This proposition set certain measurement minimums for cages.[29] This time the law even went a step further to ban the sale of any animal raised in confinement which was not in compliance with the law, regardless of which state the animal was raised in.[30] In 2002, Florida voters passed an amendment that addressed the confinement of pregnant pigs, defining the way pregnant pigs could be confined.[31] The law was like the first California initiative, because it did not set minimum measurements.[32] The three voter enacted laws we just briefly examined are a great illustration of consumers taking matters into their own hands and addressing welfare issues.

i. Problems with Ballot Initiatives

Ballot initiatives are without a doubt better than sitting back and doing nothing to address, or improve, the welfare of farm animals. Unfortunately, they still bring about challenges for both consumer and producer. One of the challenges is how they have the potential to harm in-state producers while allowing out-of-state producers to not change their behaviors. Secondly these initiatives seem to pit the consumer against the producer, instead of allowing them to work together to achieve the same goal. They have the potential to harm in-state producers while allowing out-of-state producers to not change their behaviors. Third, ballot initiatives are not available in all states. But, even those states which do allow them have

[28] *Proposition 2*, UNIV. CAL., BERKELEY, https://igslibrary.berkeley.edu/library/elections/proposition-2 (last visited Nov. 1, 2022).

[29] *California Proposition 12, Farm Animal Confinement Initiative (2018)*, BALLOTPEDIA, https://ballotpedia.org/California_Proposition_12,_Farm_Animal_Confinement_Initiative_(2018) (last visited Nov. 1, 2022).

[30] *Id*.

[31] *Animal Cruelty Amendment: Limited Cruel and Inhumane Confinement of Pigs During Pregnancy*, MICH. STATE UNIV. ANIMAL LEGAL & HIST. CTR., https://www.animallaw.info/statute/fl-initiatives-florida-amendment-article-x-section-19-pregnant-pigs (last visited Nov. 1, 2022).

[32] *Id*. (Not allowing confinement of a pregnant pig in a "cage, crate or other enclosure," in such a way which prevented the animal from freely turning around).

possible constitutional challenges which can stand in the way of achieving their desired end goal.

The best example of in-state producers being harmed comes from California's Proposition 2. This law did not eradicate the sale of all eggs from hens raised in confinement not in compliance with the law, but only the eggs of hens raised in the state which were out of compliance.[33] At the time of the law being passed, the egg industry in California was a large player in the state's agriculture.[34] Also, during that time, California relied on imported eggs whether they be in liquid form or shell.[35]

For a California producer to be compliant with the law, they would be required to switch to non-cage production systems.[36] In order to switch to a non-cage production system, farmers would have increased production costs resulting in 20% higher than those out-of-state producers who could keep using the cage system egg-laying hens are typically raised in.[37] One study suggested this laws "impact would be the almost complete elimination of egg production in California."[38] The reasoning was relatively simple, the production cost of non-cage systems is too high when compared to the cage systems out-of-state producers would be able to use, giving California producers very little ability to compete in the market.[39] This is not to say all in-state production would be eliminated. There would likely be smaller farms who kept producing, but the large-scale operations would have to decide if the non-cage production system was one in which they could remain competitive. The price of eggs was not expected to increase significantly, because out-of-state producers had "already demonstrated their ability to compete successfully in the California market."[40] The new law would not have any effect

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[33] *California Proposition 2, Farm Animal Confinement Initiative,* BALLOTPEDIA, https://ballotpedia.org/California_Proposition_2,_Farm_Animal_Confinement_Initiative_(2008) (last visited Nov. 1, 2022).
[34] DANIEL A. SUMNER ET AL., ECONOMIC EFFECTS OF PROPOSED RESTRICTIONS ON EGG-LAYING HEN HOUSING IN CALIFORNIA i (Univ. of Cal, Agric. Issues Ctr. 2008).
[35] *Id*.
[36] *Id*. at ii.
[37] *Id*.
[38] *Id*. at iv.
[39] SUMNER, *supra* note 34.
[40] *Id*. at v.

on how the eggs sold in California were produced, it would just change where those eggs were produced.[41] The economic ramifications of Proposition 2 were likely not intentional but are a great example of how these ballot initiatives present challenges the voter probably did not expect.

This leads us to our next consequence of ballot initiatives: animosity between consumer and producer. Where does the gap between producers, consumers, and their food come from? Almost all of the people in America agree that there is a connection between food production and the success of the country.[42] While most consumers say they spend time thinking about food production, a large majority of them admit to not knowing how the food gets to their dinner table from a farm.[43] More than 70% of consumers in America have very limited, or no knowledge, about what farmers and ranchers do, or even what those careers involve.[44]

If ballot initiatives are used to create the regulations of farm animal welfare, it is more than likely the consumer deciding what is or is not humane, not the farmer. When you consider this along with more than three quarters of all farmers saying the consumers have limited, or zero knowledge, about what is proper care for animals,[45] you can see why there would be a divide between these two groups. Farming is viewed as a highly profitable industry because the large companies are profitable, but very few understand the producers on the ground level are not experiencing the same profits as the corporations who sell the final product.

Farmers and ranchers both think very similarly to the consumer when it comes to issues surrounding the environment and how animals are treated.[46] Almost every farmer and rancher agreed the environment and humane animal welfare are important to their business.[47] So while consumers are passing ballot initiatives, farmers are having to jump through hoops to

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[41] *Id*.
[42] *See Nationwide Surveys Reveal Disconnect Between Americans and Their Food*, PR NEWSWIRE, (Sep. 22, 2011, 4:00 AM), https://www.prnewswire.com/news-releases/nationwide-surveys-reveal-disconnect-between-americans-and-their-food-130336143.html.
[43] *Id*.
[44] *Id*.
[45] *Id.*
[46] *Id*.
[47] PR NEWSWIRE, *supra* note 42.

comply with the laws. But, each side is after the same thing ultimately: humane welfare for animals. We are experiencing animosity between two groups, who are simply disconnected from each other. One of the biggest reasons for this disconnect is the lack of access for consumers to see what happens on a farm.[48] This divide could be addressed by a uniform code, through access to farms or educational information being dedicated to creating a more palpable relationship between the two sides. A uniform code drafted with both sides of the divide would allow for a set of regulations each side is likely to be happy with more so than if they had no voice in the process.

One final thing to consider when examining ballot initiatives is the possible constitutional challenges they could face once they have been passed and enacted. Since not every state allows for ballot initiatives it would lead to even more of a fractionated approach to animal welfare laws. The constitutional challenge which has been the basis for lawsuits against California's Proposition 12 was based on the Commerce Clause.[49] The Commerce Clause combined with the Necessary and Proper Clause,[50] is where the ability of Congress to regulate interstate commerce is grounded today. There are three channels in which Congress holds the power to regulate: (1) "the use of the channels of interstate commerce;"[51] (2) "the instrumentalities of interstate commerce, or persons or things in interstate commerce, even though the threat may come only from intrastate activities;"[52] and (3) "those activities having a substantial relation to interstate commerce, i.e., those activities that substantially affect interstate commerce."[53]

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[48] Victoria G. Myers, *Bridging the Gap Between Consumers and Producers*, PROGRESSIVE FARMER (Jan. 17, 2020, 5:58 AM), https://www.dtnpf.com/agriculture/web/ag/news/business-inputs/article/2020/01/17/bridging-gap-consumers-food.

[49] U.S. CONST. art. I, § 8, cl. 3 (giving the power to Congress to "regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes").

[50] *Id*. cl. 18 (giving Congress the power to "make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers, and all other Powers vested by this Constitution in the Government of the United States, or in any Department or Officer thereof").

[51] United States v. Lopez, 514 U.S. 549, 558 (1995).

[52] *Id*. (citing Southern R. Co v. United States, 222 U.S. 20 (1911)).

[53] *Id.* at 558–59 (citing NLRB v. Jones & Laughlin Steel Corp., 301 U.S. 1, 37 (1937)).

While the Commerce Clause is a great avenue for a constitutional challenge, one must not forget about the dormant Commerce Clause which does not allow a state to create any tax or regulation "that discriminates against or unduly burdens interstate commerce."[54] California's Proposition 12 was challenged by the National Pork Producers Council for allegedly violating the dormant Commerce Clause because the law banned "the sale of whole pork meat (no matter where produced) from animals confined in a manner inconsistent with California standards.[55] The main argument was the law "has an indirect 'practical effect' on how pork is produced and sold outside California."[56] The ninth circuit court "rejected the argument that such upstream effects violate the dormant Commerce Clause."[57] The reasoning of the court was that while the requirements of the law applied to both in-state and out-of-state producers, "and merely impose a higher cost on production, rather than affect interstate commerce."[58] The plaintiffs argued the law was a violation of "the dormant Commerce Clause because it poses a risk of inconsistent regulations that undermines a 'compelling need for national uniformity in regulation.'"[59] The court did not agree with this argument though because "[u]nless a state law at issue interferes with a system of national concern, it does not violate the dormant Commerce Clause."[60] Further, the court reasoned "laws that increase compliance costs, without more, do not constitute a significant burden on interstate commerce."[61]

The Supreme Court of the United States will be hearing oral arguments on California's Proposition 12.[62] Most recently, the Solicitor General of the United States, Elizabeth Prelogar, has even spoke out against California's law, saying she believes the law is a violation of the Dormant Commerce

[54] Gen. Motors Corp. v. Tracy, 519 U.S. 278, 287 (1997).
[55] Nat'l Pork Producers Council v. Ross, 6 F.4th 1021, 1025 (9th Cir. 2021).
[56] *Id.* at 1028-29.
[57] *Id.*
[58] *Id.*
[59] *Id.* at 1031.
[60] Nat'l Pork Producers Council, 6 F.4th at 1025.
[61] *Id.* at 1032.
[62] Monthly Argument Calendar For the Session Beginning October 3, 2022, U.S. (Sept. 28, 2022) https://www.supremecourt.gov/oral_arguments/argument_calendars/MonthlyArgumentCalOctober2022.pdf.

Clause.[63] Prelogar, in her thirty-four page amicus curiae brief, concluded by saying "[t]he judgment of the court of appeals should be reversed . . ."[64] Prelogar's reasoning was based in part on the decision in *Baldwin*, where the Court held "that when a State undertakes regulation of out-of-state commercial activity, it must at least advance a legitimate local interest. . ."[65] Further, in her brief, she said California was regulating an "out-of-state activity in service of an interest that is *not* a legitimate basis for regulation under our federal system of sovereign States."[66] This ballot initiative being taken up by the Supreme Court is a great example of how state ballot initiatives can make the welfare regulations even more convoluted.

The same law was challenged by the North American Meat Institute ("NAMI"), alleging the law "operates as an impermissible protectionist trade barrier, blocking the flow of goods in interstate commerce unless out-of-state producers comply with California's regulations."[67] The district court denied the request for a preliminary injunction and the ninth circuit upheld the dismissal because they agreed there was a "lack of evidence that the state had a protectionist intent."[68] NAMI appealed this decision to the Supreme Court, but the Supreme Court denied their petition.[69]

IV. Differing Approaches Amongst the States is a Problem

All fifty states have laws prohibiting animal cruelty.[70] These laws still present challenges or issues though. There are

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[63] Dan Flynn, *Solicitor General of United States Finds Prop 12 Violates Interstate Commerce Clause,* FOOD SAFETY NEWS (June 26, 2022), https://www.foodsafetynews.com/2022/06/solicitor-general-of-united-states-finds-prop-12-violates-interstate-commerce-clause/#:~:text=1%2C%202022.,bars%20their%20sale%20in%20California.

[64] Brief for Petitioners at 34, Nat'l Pork Producers Council v. Ross, No. 21-468 (U.S. argued Oct. 11, 2022).

[65] *Id.*

[66] *Id.*

[67] Complaint at 8, N. Am. Meat Inst. v. Beccerra, 420 F. Supp. 3d 1014 (C.D. Cal. 2019) (No. 2:19-CV-08569).

[68] N. Am. Meat Inst. v. Becerra, 825 Fed. Appx. 518, 520 (9th Cir. 2020).

[69] BALLOTPEDIA, *supra* note 29.

[70] *Legal Protections for Animals on Farms*, ANIMAL WELFARE INST. (Oct. 2018), https://awionline.org/sites/default/files/uploads/documents/FA-AWI-LegalProtections-AnimalsonFarms-110714.pdf.

three main issues with state cruelty laws: (1) varying definitions; (2) enforcement difficulties; and (3) certain practices being exempt from the law. Not only does the definition of animal cruelty vary by state, but so does the definition of the term animal.[71] Most states have drafted their animal cruelty laws in a specific way to exclude particular classes of animals.[72] However, there does seem to be some consistency among states which do include farm animals in their law which is the definition of "every dumb creature."[73] There is a strong majority of states who at least treat farm animals differently than companion animals under their animal cruelty laws.[74] Forty-nine of the states have statutes which are strictly criminal though, meaning the decision to prosecute is left in the hands of individual prosecutors. Broadly speaking, prosecutors have heavy caseloads already, so they are not very likely to prosecute an individual for animal cruelty unless the violation is outrageous.

The ability to gather evidence might also present another issue since the larger farming operations are located far from the public eye, making an investigation without a warrant nearly impossible. Another thing to consider is only the person violating the law is charged, allowing everyone else in the company to face no repercussions from prosecution. Removal of one bad actor does not get to the heart of the problem because those in managerial positions are not removed. Resulting in no change to company policies or compliance training. Which is a great reason to include animal cruelty statutes in a uniform code with civil penalties for those in control of the operations to face some sort of punishment.

In the same vein, numerous state animal cruelty laws create an exemption for "practices that are routinely performed on farm animals."[75] Similar to the tort law standard of a reasonable person[76], these laws "only protect farm animals from situations that no responsible farmer would defend."[77]

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[71] *Id*. at 2
[72] ANIMAL WELFARE INST., *supra* note 12 at 2.
[73] *Id.*
[74] *Id.*
[75] *Id.*
[76] Legal Info. Inst., *Standard of Care*, CORNELL L. SCH., https://www.law.cornell.edu/wex/standard_of_care (last visited Nov. 1, 2022).
[77] ANIMAL WELFARE INST., *supra* note 12 at 2.

Such as, "kicking 'downed' animals or stabbing animals with pitchforks in order to get them to move."[78] Another example of certain practices being exempted from these laws when a practice is "common or recognized animal husbandry practices . . . unless the act is specifically prohibited."[79]

V. Federal Legislation Has Proven Ineffective

The area of farm animal welfare has three notable federal laws.[80] These laws, some would argue, do not actually achieve the goals they were set out to achieve, nor the goals their names would lead someone to believe they were created for. The first law we will examine is known as the 28-Hour Law, which focuses on the health and treatment of farm animals during transport.[81] Currently, the law states any person transporting animals interstate in a carrier, "may not confine animals in a vehicle or vessel for more than 28 consecutive hours without unloading the animals for feeding, water, and rest."[82] When taken at face value, the law appears to ensure the safety of farm animals which are being transported interstate. There are two reasons why the safety and welfare of such animals actually are not being protected by this piece of legislation.

First, three federal agencies are tasked with the enforcement of the law: United States Department of Agriculture ("USDA"); Department of Transportation ("DOT"); and Department of Justice ("DOJ").[83] Secondly, the law has four exceptions, or loopholes: (1) if sheep are confined and the 28-hour period ends during the night they can be confined for 8 additional hours; (2) if there is an accident or an

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[78] *Id*. (citing Mercy for Animals, *Ohio Dairy Farm Brutality*, YOUTUBE (May 25, 2010), https://www.youtube.com/watch?v=gYTkM1OHFQg*; see also* Pamela D. Frasch et al., *State Animal Anti-Cruelty Statutes: An Overview*, 5 ANIMAL L. 69, 77-76 (1999) (explaining the state exemptions for livestock).
[79] *Id*. at 4.
[80] 49 U.S.C. § 80502 (2022); 7 U.S.C. §§ 2132-2158 (2022); 7 U.S.C. §§ 2132-2158 (2022).
[81] 49 U.S.C. 80502 (2012).
[82] *Id.*
[83] *A Review: The Twenty-Eight Hour Law and Its Enforcement*, ANIMAL WELFARE INST. (Apr. 2020), https://awionline.org/sites/default/files/uploads/documents/20TwentyEightHourLawReport.pdf [hereinafter AWI].

unavoidable circumstance, the animals can be confined longer than the 28-hour period; (3) if the owner of the animals makes a separate written request, the animals can be in confinement for a 36-hour period; and (4) if the vessel the animals are being transported in provides water, food, space, and the ability to rest the law does not apply.[84] Another factor worth noting is, there are not many areas along interstate highways which would provide adequate room for the animals to be unloaded in accordance with this law.

Having three different agencies tasked with enforcing the same law is not ideal, because their roles can be very confusing and make enforcement difficult. To make things even more challenging, neither the DOJ nor the DOT have enacted any specific regulations which would allow them to enforce the law.[85] The only regulation regarding the 28-hour law the DOJ states the Attorney General of the Criminal Division is assigned to supervising actions related to the law.[86] Unlike the other two, the USDA has authored a memo illustrating their role of enforcement, the "Statement of Policy under the Twenty-Eight Hour Law," which they codified into the federal regulations.[87] In the early years of the law, the USDA assigned the Bureau of Animal Industry ("BAI"), to handle the monitoring of animals which were being transported interstate.[88] The BAI, which is no longer an agency, between 1906 – 1917 "reported approximately 9,000 violations of the Twenty-Eight Hour Law for prosecution, which resulted in $426,818 in penalties" during that timeframe.[89] Upon the decreasing use of railroad cars to transport animals, the number of violations also decreased.[90] The second half of the Twentieth century continued the trend of decreasing reports of violations,

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[84] *Id*. at 2.
[85] *Id*. at 1.
[86] *Id.*
[87] *Id.*
[88] Michelle Pawliger & Dena Jones, *Animals in Transport Languish As Twenty-Eight Hour Law Goes off the Rails*, 25 ANIMAL LAW 1 at 6 (2018).
[89] *Id.* (citing Harry Goding & A. Joseph Raub, U.S. DEP'T OF AGRIC., BULLETIN NO. 589, THE 28-HOUR LAW REGULATING THE INTERSTATE TRANSPORTATION OF LIVESTOCK: ITS PURPOSE, REQUIREMENTS, AND ENFORCEMENT 17 (1918) https://www.nal.usda.gov/sites/default/files/28hour1918_0.pdf (accessed Sept. 11, 2018)).
[90] *Id.* (citing ANIMAL AND PLANT HEALTH INSPECTION SERV., USDA, *First Federal Law to Prevent Cruelty to Animals, Animals and Their Legal Rights,* 48, 50, ANIMAL WELFARE INST., (1990)).

"the DOJ did not bring any cases for violations of the Twenty-Eight Hour Law – on railroads or trucks."[91] One of the main reasons for the decreasing number of violations "is due in part to the fact that the USDA did not affirm that the law applied to trucks until 2003."[92] This affirmation was done via "an intra-agency memo explaining that the Statement of Policy also applies to animals shipped in trucks."[93]

The American Welfare Institute ("AWI") used the Freedom of the Information Act ("FOIA"), to request records from the USDA about the enforcement of the law and found "only 10 USDA enforcement inquiries into possible violations of the law over a 12-year period."[94] AWI conducted online research to find one additional investigation, "bringing the total number of USDA investigations to 11."[95] While the research showed six of the cases had sufficient evidence, "only one of these was reported to the DOJ to determine whether enforcement was appropriate."[96] The AWI opined that the reasoning the violations were not being submitted to the DOJ was two-fold: "(1) USDA personnel are not provided the guidance needed to understand their role in the law's enforcement, and (2) drivers are not required to provide documentation of the duration, mileage, or stops made on their trips."[97]

To make matters worse, "AWI has obtained no evidence to suggest that the DOJ has played any role in the enforcement," of the law regardless of the fact it "is codified within Title 49 of the U.S. Code, which is dedicated to transportation."[98] We are currently only seeing investigations "if it is reported that a large number of animals died during transport, and/or there is public outcry."[99] USDA has taken more initiative to enforce the law, through Food Safety and Inspection Service ("FSIS"), using "a notice to its slaughter establishment personnel informing them of [the law], and

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[91] *Id.*
[92] *Id.*
[93] AWI., *supra* note 83 at 2.
[94] *Id.* at 1.
[95] *Id.*
[96] *Id.*
[97] AWI., *supra* note 83 at 1.
[98] *Id.*
[99] *Id.*

advising inspectors to contact APHIS if they suspect a violation of the law."[100] This directive gave inspectors certain things to look for in the animals, then have the inspectors question the driver about their compliance with the law.[101] If the driver did not cooperate or the inspector felt the symptoms of the animals were caused by violating the law, they were told to let APHIS know, so APHIS could investigate.[102] While this law has been in place for decades, we can see there has been very little action taken in conjunction with it in recent years.

The second issue with the Twenty-Eight Hour law mentioned above, are the loopholes for certain practices being exempted from violating the law. Not only are there the aforementioned loopholes, but according to the USDA, poultry is also exempt from the law.[103] With so many exceptions to this law, it is easy to see how difficult enforcement would be even without three different agencies having jurisdiction. The law needs to be clarified, and enforcement placed within a single agency.

Our next piece of legislation we are going to examine is the Animal Welfare Act[104] ("AWA"). The name alone would make most people think it protects the welfare of all animals, but in reality only applies to about two percent of animals in the United States.[105] The AWA excludes any animal that is "raised for human benefit."[106] Farm animals are actually excluded in two ways: (1) certain categories are protected, and farmed animals are not one of them; and (2) the "definition of the word 'animal'" being specifically excluded.[107] The reason for this exclusion can be traced back to the origin of the AWA which "was originally the Laboratory Animal Welfare Act."[108]

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[100] *Id.*

[101] *Id.* (explaining the signs they were told to look for in the animals were exhaustion or dehydration).

[102] *Id.*

[103] Gaverick Matheny & Cheryl Leahy, *Farm-Animal Welfare, Legislation, and Trade*, 70 L. & CONTEMP. PROBS. 325, 335 (2007).

[104] 7 U.S.C. §§ 2131-2160.

[105] Matheny & Leahy, *supra* note 103 at 334.

[106] Michael McFadden et al., *Animal Welfare Act: Excluded Animals*, 25 ANIMAL L. 203, 204 (2009).

[107] *Id.* (citing *Farm Animal Statistics: Slaughter Totals*, HUMANE SOC'Y U.S., https://www.humanesociety.org/resources/farm-animal-protection-faq#what-can-i-do).

[108] *Id.* (citing *Legislative History of the Animal Welfare Act: 1960s*, USDA. NAL, https://www.nal.usda.gov/awic/legislative-history-animal-welfare-act-1960s).

When the name was changed in 1970, they attempted to change the language and definition which would have included "any warm-blooded animal."[109] The proposed language was not adopted though, so the bill remained basically unchanged except for the name.[110]

Some have argued the reason farmed animals were not included in the 1970 bill was two-fold: (1) "doing so would have been considered too costly;" and (2) "including farmed animals was seen as unnecessary."[111] In our current agricultural production environment, the argument regarding cost seems to carry the most weight. The area where most production animals are raised is not spacious, and usually requires the animals to have food brought to them.[112] Further, the genetic makeup of the farmed animals, specifically chickens have been bred and genetically modified to "grow so obese so quickly that up to a third of them can't walk correctly."[113] Due to the AWA only applying to those animals which are being raised for exhibition, research, or companion purposes we only see a small percentage of the animals in our country actually being protected by this act.[114]

The final piece of federal legislation we will examine is the Humane Methods of Slaughter Act ("HMS").[115] The HMS was designed to ensure "humane methods of slaughter to prevent the needless pain and suffering of livestock."[116] When

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[109] *Id.* (citing *Care of Animals Used for Research, Experimentation, Exhibition, or Held for Sale as Pets: Hearing on H.R. 13957 Before the Subcomm. on Livestock and Grains of the H. Comm. on Agric.*, 91st Cong. 84 (1970) (statement of Hon. G. William Whitehurst)).

[110] *Id.* at 205.

[111] McFadden et al*, supra* note 106 (citing *Care of Animals Used for Research, Experimentation, Exhibition, or Held for Sale as Pets: Hearing on H.R. 13957 Before the Subcomm. on Livestock and Grains of the H. Comm. on Agric.*, 91st Cong. 47 (1970) (statement of Dr. Charles S. Hobbs)).

[112] *Id.* (citing *Factory Farm Nation,* FOOD & WATER WATCH (2015), http://perma.cc/8KAF-9EP2 (juxtaposing natural conditions and behaviors to farming conditions and behaviors)).

[113] *Id.* (citing *An HSUS Report: The Welfare of Animals in the Chicken Industry,* HUMANE SOC'Y U.S. (2013), http://www.humanesociety.org/assets/pdfs/farm/welfare_broiler.pdf).

[114] Matheny & Leahy, *supra* note 103, at 334.

[115] Humane Methods of Livestock Slaughter, 7 U.S.C. §§ 1901 – 1907.

[116] Emma Burgess Roy, Note, *Cruelty on Your Plate: The Misadministration of the Humane Methods of Slaughter Act,* 3 MID-ATL. J. ON L. AND PUB. POL'Y 93, 95 (2015) (citing 7 U.S.C. § 1901 (1958) (Enacted for "the purpose of preventing the inhumane slaughtering of livestock.")).

enacted the HMS suggested the best way to slaughter an animal was "through a gunshot or captive bolt to the head before slaughter."[117] Similarly to the Twenty-Eight Hour Law, chickens were not explicitly mentioned in the HMS.[118] The HMS is enforced by the USDA, which has passed the baton to FSIS for enforcement purposes.[119] Until the HMS was amended in 1978, it did not apply to meat slaughtered in foreign countries and sold to the United States.[120] When considering meat slaughtered and produced in foreign countries, it is very hard to ensure those factories overseas are following the HMS because the United States does not actually inspect them.[121] The only avenue we have to investigate the slaughtering process of foreign countries is through an application "to the USDA, and undergo[ing] an audit to show that their food safety and slaughter regulatory systems are equivalent to those in the United States."[122] The only inspection for imported meat is handled at the ports where the meat is delivered.[123] So, while the meat is supposed to be from countries which follow equivalent systems, we truly have no surefire way of making sure the meat is actually slaughtered in accordance with the HMS.

While the HMS does allow for punishment to be administered in the form of civil penalties[124], we once again run into an enforcement problem. According to a study published in 2015 by the Animal Legal Defense Fund, spanning two years using documents gained through FOIA, they found "a disturbing trend of inconsistent enforcement. .

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[117] *Id.*

[118] *Humane Methods of Slaughter Ac*t, ANIMAL WELFARE INST., https://awionline.org/content/humane-methods-slaughter-act (last visited Nov. 2, 2022.

[119] Roy, *supra* note 116, at 96-97.

[120] *Humane Methods of Slaughter Ac*t., *supra* note 118.

[121] Roy, *supra* note 116.

[122] Roy, *supra* note 116, at 97 (citing FOOD SAFETY INSPECTION SERVICE, *FSIS Inspection and Grading of Meat and Poultry* (April 16, 2014), http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safetyeducation/get-answers/food-safety-fact-sheets/production-and-inspection/importing-meat-poultry-and-egg-products-to-the-unitedstates/importing-meat-poultry-egg-products-us (describing FSIS meat inspection equivalency requirements and approval process for out of country meat producers).

[123] *Id.*

[124] *Id.*

."[125] One reason for the lack of enforcement is the lack of a general enforcement provision, which was originally Section 1903, but was repealed from the law in 1978.[126]

Since we are talking about federal legislation, there is one more piece of reality that needs to be pointed out, lobbying.[127] Not only will federal legislation have to face the hurdle of winning bipartisan support, but it will also face the hurdle of lobbyists and special interest groups. For an example of this, one must look no further than the 2018 Farm Bill, where Republicans were cheering, and Democrats booed.[128] The loudest voices in the political arena were not those sitting in Congress though, but those who participate in the legislative process without ever being elected to Congress, the lobbyists.[129] Lobbyists can no longer be ignored in the political arena, we are not here to argue they are good or bad. But we must acknowledge the power and influence they hold in our legislative process. Between 2011 – 2019, an investigation by USA Today, The Arizona Republic and the Center for Public Integrity discovered that at least 10,000 bills across the country were introduced featuring almost entirely copy-and-paste legislation special interest groups had drafted.[130] Over 2,100 of the bills were signed into law.[131] Agriculture is no stranger to the power of lobbyists, in 2020 the agribusiness sector spent $142,285,917 on lobbying efforts.[132] There were 1,144 lobbyists employed by the agribusiness sector, and 58.3% of

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[125] *See Urging Enforcement of the Humane Methods of Livestock Slaughter Act*, ANIMAL LEGAL DEF. FUND, https://aldf.org/case/urging-enforcement-of-the-humane-methods-of-livestock-slaughter-act/ (last visited Nov. 1, 2022).
[126] *Id.*
[127] *See Guide to Lobbying Reporting*, N.Y. STATE JOINT COMM'N OF PUB. ETHICS (Feb. 2018), https://jcope.ny.gov/system/files/documents/2018/02/chapter-1-lobbying-overview-and-definitions_0.pdf, (This is "any attempt to influence government decision-making").
[128] *See* Katie O'Reilly, *The Draft 2018 Farm Bill is Good for Big Ag, Bad for Food Systems*, SIERRA CLUB (Apr. 27, 2018), https://www.sierraclub.org/sierra/draft-2018-farm-bill-good-for-big-ag-bad-for-food-systems.
[129] *Id.*
[130] *You Elected Them to Write New Laws. They're Letting Corporations Do It Instead*, THE CTR FOR PUB. INTEGRITY (Apr. 4, 2019), https://publicintegrity.org/politics/state-politics/copy-paste-legislate/you-elected-them-to-write-new-laws-theyre-letting-corporations-do-it-instead/.
[131] *Id.*
[132] *Agribusiness Profile Year 2020*, OPEN SECRETS, https://www.opensecrets.org/federal-lobbying/sectors/summary?cycle=2020&id=A (last visited Nov. 1, 2022).

them were former government employees.[133] So even if we could draft legislation allowing for the federal government to effectively enforce it, we would have to face reality and realize the lobbying power the regulations would be up against.

VI. What is a Uniform Act? Has it Been Done in Agriculture Before?

A uniform act has one main goal which is to "promote the uniformity of state law."[134] All uniform acts are drafted by the Uniform Law Commission, which has drafted hundreds since their inception in 1892.[135] A uniform act is defined as having "a reasonable possibility of ultimate enactment in a substantial number of jurisdictions."[136] A uniform code for farm animal welfare is not a new concept, the European Union implemented such a code in 1976.[137] The Council of Europe member states enacted the European convention for the Protection of Animals Kept for Farming Purposes.[138] All farm animals must be provided care that is "appropriate to their physiological and ethological needs."[139] The European Union did not stop there though. Next, they set the minimum standards for veal calves which prohibited the use of tether and required all units built after 1994 have at least enough room for calves to turn around.[140]

Additionally, in 1999, they passed an amendment with a delayed effective date of 2007 which explicitly prohibited confining calves, older than eight weeks, in individual pens, unless a veterinarian determined otherwise.[141] They also implemented new standards for laying hens prohibiting the construction of new barren battery cages and prohibited the use

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[133] *Id.*
[134] Deanna Barmakian, *Uniform Laws and Model Acts*, HARV. L. SCH. LIBR. (Aug. 17, 2022), https://guides.library.harvard.edu/law/unifmodelacts.
[135] *Id.*
[136] *Restatements of the Law and Uniform Laws: Uniform Laws & Model Acts; Introduction and Explanation*, CHICKASAW NATION L. LIBR. OKLA. CITY UNIV. SCH. OF L., https://libguides.okcu.edu/c.php?g=225285&p=1492987 (last visited Nov. 1, 2022).
[137] Matheny & Leahy, *supra* note 103, at 339.
[138] *Id.*
[139] *Id.*
[140] *Id.*
[141] *Id.*

of all barren battery cages after 2012.[142] Swine production was their next goal, in 2001 an amendment was passed prohibiting tethers, any new gestation creates after 2003, and eliminating the use of all gestation crates by 2013.[143] Lastly, they even require mandatory animal welfare training for all personnel involved in farm animal production.[144] The European Union has shown it is possible to create a uniform set of laws, across states, that allows for progressive changes to be made over time.

VII. Conclusion

Upon reviewing the issues with federal farm animal welfare legislation, the disparities in state laws, ballot initiatives causing more divide along with less uniformity, how a uniform code is designed, and the European Union's uniform code makes the Uniform Farm Animal Welfare Code the solution. While the language of the new code would face scrutiny from all parties involved, allowing the Uniform Law Commissioners to draft this code would be the most effective way to provide adoptable language. We cannot ignore the last hurdle in this process though, adoption would have to be at the state level. The code being drafted would be meaningless if every state does not adopt it, so the final piece of the puzzle would be garnering nationwide support to pressure state legislatures to pass it. One avenue to create such support would be to call on those who already spend billions in the agribusiness sector to help. Lobbyists are part of our legislative process, whether we like it or not, so we might as well use them to achieve the goal of farm animal welfare nationwide. Let us make all farm animals, in every state, happy. Not just the cows in California.

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[142] Matheny & Leahy, *supra* note 103, at 339.
[143] *Id.* at 340.
[144] *Id.*

The Cow Has Left the Barn: Updating Standards of Identity to Reflect Consumer Understanding of Plant-Based Foods

Nicholas G Miller*

Introduction

Have you ever seen "tofurkey" at the supermarket and thought it was a rare, delicious cousin of the turkey? The animal-based food industries, led by milk and meat producers, are claiming that the reasonable consumer might. On the other hand, the plant-based food substitutes are appearing on supermarket shelves with increasingly bold names for their products that tap into our familiarity with animal-based foods, using names like "Beyond Meat." So, who is right? Where do we draw the line on what plant-based food can be called? And who should draw that line?

This paper examines the debate surrounding the labeling of plant-based alternatives to animal-based products, and proposes a path forward, led by the Food and Drug Administration ("FDA"). Part I will describe the history of "standards of identity" (defined parameters for what a food product must contain to use a particular name) that arose in the 1900's, promoted by both consumers and well-established industries. Part I will trace the rise in labeling authority for regulatory agencies such as the FDA, along with the failure of these agencies to create adequate standards of identity to keep up with new products.

Part II will examine the decades-long war between the animal-based and plant-based food industries, which has rapidly intensified because of the recent rise in popularity of milk alternatives and meat substitutes. This part exams the two sides separately, analyzing how each side has framed the debate. The animal-based product industry models itself as an advocate for consumer protection from deceptive products, while the plant-based industry argues it is defending freedom of speech and market competition.

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Part III then proposes a reexamination of the central debate, removed from the framing of these two industry behemoths. Section A builds on the history described in Part I, to assert that the FDA is the clear authority on standards of identity for plant-based foods, rather than the U.S. Department of Agriculture ("USDA") and has preemptive authority over states and localities. Section B analyzes the existing evidence on consumer understanding of plant-based foods, and the scientific evidence on the health effects of these alternative products. This part then incorporates the burgeoning focus on sustainability that is emerging in major countries around the world, supported by expert reports on both health and the environment.

Finally, Part III concludes with proposed actions that the FDA could take, consistent with the previously summarized findings, such as allowing plant-based foods to use any food term but disallowing product names that use actual animal source terms. (e.g., "soy nuggets" are allowed, but "awesome chicken" is not).

I. Planting the Seeds for Standards of Identity

A. Pressures to Standardize

Many popular accounts of food law in the United States begin with the sensational account of the horrifically unsanitary and exploitative Chicago meat processing plants that Upton Sinclair vividly painted in his novel, *The Jungle*, published in 1906.[1] However, decades before Sinclair's exposé for the American public, industries were already organizing into the "Pure Food Movement." These industrialists sought to protect their lucrative markets from imitation products (e.g., keeping oleomargarine out of the butter market), and they sought to achieve that through standardization of the otherwise patchwork system of state regulations.[2] Their cause was aided by the advent of dubious products like "Bred Spred," which was marketed as a jelly, but contained no fruit.[3]

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[1] UPTON SINCLAIR, THE JUNGLE (Project Gutenberg 1906) (1906) (Sinclair's description, while intended to showcase the abuses suffered by a working class of mostly immigrants, was widely understood by the public and eventually by Congress as an indictment of the unseemly food production process).

[2] Wallace F. Janssen, *The Story of the Laws Behind the Labels,* FOOD & DRUG ADMIN., June 1981, https://www.fda.gov/media/116890/download (last visited September 6, 2022) (in addition to dairy, the sugar industry was involved as well, trying to keep out producers of glucose as a substitute product).

[3] RENEE JOHNSON, CONG. RSCH. SERV., IF10811, STANDARDS OF IDENTITY FOR FOODS AND PLANT-BASED FOOD PRODUCTS 1 (2018).

Their efforts began to bear fruit through increasingly protective Supreme Court decisions, and with the passage of a series of federal laws in the early 20th century, culminating in the 1938 Federal Food Drug and Cosmetics Act ("FFDCA").[4] The FFDCA updated existing federal law and gave the FDA authority to create standards of identity and quality where it deemed it necessary to "promote honest and fair dealings in the interest of consumers." The Act also gave courts the power to issue injunctive relief.[5]

B. Expansion of Regulatory Authority

While food safety responsibility is now spread over a network of federal agencies, the default agency is the Food and Drug Administration, which was empowered by the FFDCA and its subsequent amended versions.[6] The main carveout to the FDA's default authority over food is the U.S. Department of Agriculture ("USDA"), which oversees the regulation of most animal-based products such as meat and poultry.[7] The division between the FDA and USDA is longstanding and has been continually reinforced by statute, though some now question the efficiency of a bifurcated regulatory system.[8] The authority of these agencies expanded throughout the first half of the 20th century, with almost half of the U.S. food supply subject to specific standards by the 1960's.[9]

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[4] *See e.g.* United States v. Ninety-Five Barrels, 265 U.S. 438, 443 (1924) (ruling against an apple cider vinegar producer as an imitation product because "The vinegar made from dried apples was not the same as that which would have been produced from the apples without dehydration."); Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–392 (1938); *see also* United States v. Carolene Products Co., 304 U.S. 144, 154 (1938) (in which the court upheld the power of the federal government to control the shipping of adulterated "filled milk" in interstate commerce).

[5] 21 U.S.C. § 341; *Milestones in U.S. Food and Drug Law History*, FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/fdas-evolving-regulatory-powers/milestones-us-food-and-drug-law-history (last visited Sept. 11, 2022).

[6] RENEE JOHNSON, CONG. RSCH. SERV., RS22600, THE FEDERAL FOOD SAFETY SYSTEM: A PRIMER 1 (2016) (Primer from Congressional Research Service providing an overview of the regulatory bodies and legislative jurisdiction within Congress for food safety. The other primary agencies within this sprawling network include the U.S. Department of Agriculture, tasked primarily with the regulation of animal products, and the Federal Trade Commission, which regulates the advertising of all products.).

[7] Federal Meat Inspection Act, 21 U.S.C. §§ 601–695 (1906); JOHNSON, *supra* note 6, at 10.

[8] *Id.*

[9] *Part III: Drugs and Foods Under the 1938 Act and Its Amendments,* FOOD & DRUG ADMIN. (Feb. 1, 2018), https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-iii-drugs-and-foods-under-1938-act-and-its-amendments.

C. The Rise of Labeling Authority and Common Names for Products

Since the 1960's, Congress has primarily granted the FDA greater authority over labeling, through a series of acts such as the Nutrition Labeling and Education Act in 1990.[10] The Act gave the FDA's regulations preemptive power over state law in the labeling domain, and began standardizing descriptors such as "low fat," in an effort to protect consumers from being misled.[11] Thus, labeling rules promulgated by the FDA have considerable weight, such as 21 C.F.R. 101, which requires that the principal display of products contain a "statement of identity" with the name required by federal law, or if not provided, the "common or usual name of the food."[12] Unsurprisingly, the FDA has not been able to come up with standards of identity for all of the many products in the market, leaving courts to interpret whether particular names are "common or usual," per broad FDA guidelines such as the following:

> The common or usual name of a food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name.[13]

Because the FDA has thus far failed to explicitly incorporate or exclude plant-based food into the standards of identity lexicon and left courts to interpret these broad standards for common names, the result has been uncertainty and increased litigation in the disputes

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[10] Nutrition Labeling and Education Act of 1991, 21 U.S.C. §§ 301; *see also* Fair Packaging and Labeling Act, 15 U.S.C. §§ 1451-1461 (requiring products shipped in interstate commerce to be informative and fair); *see also* Food Allergy Labeling and Consumer Protection Act, Pub. L. 108-282 (amended 2004).

[11] Nutrition Labeling and Education Act § 301; *Milestones in U.S. Food and Drug Law History*, *supra* note 5.

[12] 21 C.F.R. § 101.3(a)-(b).

[13] 21 C.F.R. § 102.5(a); *See also* 21 C.F.R. 102.5(d) ("A common name or usual name of a food may be established by common usage"); *see* JOHNSON, *supra* note 3 (the FDA has come up with just over 300 standards of identity for products).

between producers of animal-based products and producers of plant-based alternatives.[14]

II. Animal-based Product Industry and the Plant-based Product Industry Spar Over Shared Terminology as the FDA Mulls New Standards of Identity

Despite its broad authority over food, the FDA has been outpaced by the food advertising industry and evolving consumer knowledge, leading to the present conflicts over the proper labeling of innovative new plant-based products. Answering the question of whether or not to restrict the naming conventions for these products to exclude historically animal-associated terms like "milk" or "meat" can depend on how the issue is framed.

A. Industry Framing of the Debate – Consumer Protection v. Free Market and Free Speech

An ongoing debate is raging between the entrenched dairy and animal-based products industries and the plant-based alternative newcomers. Usage of terms like "burger" are on the front lines of that war.[15] The resolution of these debates may be existential, particularly for the animal-based product industry, which is losing market share each year to plant-based alternatives.[16] The type of question that needs to be answered is whether enough consumers understand what a "black bean burger" contains, and if there is a less confusing way to describe it.[17]

Both sides are seeking to gain the legal high ground and attempting to galvanize consumers, judges, and lawmakers, often with reliance on the limited and constantly evolving evidence of whether consumers are being misled. The animal-based product

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[14] PERKINS COIE, FOOD LITIGATION 2019 YEAR IN REVIEW 14 (2020); *see also Guidance Documents & Regulatory Information by Topic (Food and Dietary Supplements)* FOOD & DRUG ADMIN. https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/guidance-documents-regulatory-information-topic-food-and-dietary-supplements (last visited June 19, 2022) (the FDA has yet to address the issues head on, even in their industry guidance documents).

[15] Alina Selyukh, *What Gets To Be A 'Burger'? States Restrict Labels On Plant-Based Meat,* NATL. PUB. RADIO (July 23, 2019), https://www.npr.org/sections/thesalt/2019/07/23/744083270/what-gets-to-be-a-burger-states-restrict-labels-on-plant-based-meat.

[16] *Id.*

[17] *Id.*

industry argues on the basis of protecting consumers from being defrauded by "fake meat" producers.[18] The plant-based industry and individual producers have mostly defended themselves on the basis of free speech, sometimes with the aid of advocates like the American Civil Liberties Union.[19]

i. Animal-based Food Industry and Consumer Plaintiffs Claim Deception

The animal-based food industry has taken action against plant-based alternatives in both private suits and more recently by seeking broad legislative action at the state and federal level.

1. Private Suits via State Law Bars on Unfair and Deceptive Practices

Typically, food litigation against brands is brought under state laws that prohibit deceptive or unfair business practices that mislead consumers, often mirroring the Federal Trade Commission's standards.[20] Because litigation occurs primarily in California and New York, the leading authority for the courts was set in the Ninth Circuit case *Williams v. Gerber Prods. Co., Inc.*, which ruled that disputed statements must be likely to mislead a "reasonable consumer."[21] Under this standard, falsity of the actual statement is not decisive, as the court clarifies in *Williams* that liability can be found where a statement "although true, is either actually misleading or which has a capacity, likelihood or tendency to deceive or confuse the public."[22] Even statements that are false though are still examined through the reasonable consumer lens, such as the 2021 case *Moore v. Trader Joe's Co.*, in which the Ninth Circuit found that honey advertised as "Manuka Honey" was not misleading, in

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[18] *See* NAT'L CATTLEMEN'S BEEF ASS'N, *Policy,* https://policy.ncba.org/home/issues/fake-meat (last visited June,19 2022) (The National Cattlemen's Beef Association is a leading industry group seeking policy changes to restrict plant-based products).

[19] *See, e.g., Federal Court Block 'Veggie Burger' Censorship Law*, ACLU (December 11, 2019), https://www.aclu.org/press-releases/federal-court-blocks-veggie-burger-censorship-law.

[20] *See, e.g.,* 15 U.S.C. § 52 (prohibiting false advertisements to induce the purchase of food); 15 U.S.C. § 45 (restriction against "unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices affecting commerce").

[21] Williams v. Gerber Prods. Co., 523 F.3d 934, 938 (9th Cir. 2008); Michael R. Reese, *Starting a Niche Practice in Food Law*, GP SOLO, Nov.–Dec. 2017, at 11.

[22] Williams, 523 F.3d at 938.

part because that would require a consumer to unreasonably believe that the bees had only interacted with one type of flower.[23] Such an assumption was deemed unreasonable, especially in light of the low price, and the dismissal of the complaint by the district court was affirmed.[24]

On the whole, the milk and meat industries' efforts have largely been rebuffed in court when they try to directly challenge plant-based alternatives, using laws designed to protect consumers. This may be due in part to their lack of standing to intervene on behalf of consumers.[25] Instead, the major cases against plant-based alternatives have come from consumer class action suits.[26] Class-action consumer plaintiffs have found the most success in cases where the information appears false, such as *Dumont v. Reily Foods Company*, where the First Circuit saw a plausible allegation of fraud over a label for "Hazelnut Crème" flavored coffee, that contained no hazelnuts.[27] But even those types of consumer-driven suits have had little success against plant-based products, and the animal-based industry now has placed most of their eggs in a single basket: direct lobbying for policy change.[28]

2. Legislative Action to Restrict Usage of Meat and Dairy Terms

The meat and dairy industries have both pushed aggressively for state and federal protection of their respective industries, by seeking restrictions on plant-based alternatives. For the meat industry, they have found success in several states, including Mississippi, Louisiana, Missouri, Oklahoma, and Arkansas, with

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[23] *See* Moore v. Trader Joe's Co., 4 F.4th 874 (9th Cir. 2021).
[24] *See id.*
[25] *See, e.g.,* Nat'l Milk Producers Fed'n v. Harris, 653 F.2d 339, 344 (8th Cir. 1981) (affirming dismissal of the request by the National Milk Producers Association for mandatory action against plant-based cheese alternatives).
[26] *See* Michelle E. Hoffer, *Almond Beverage, Oat Water, and Soaked Soybean Juice: How the Dairy Pride Act Attempts to Remedy Consumer Confusion About Plant-Based Milks*, 55 U. RICH. L. REV. 657, 671 (2021).
[27] Dumont v. Reily Foods Co., 934 F.3d 35 (1st Cir. 2019); *see also* Bell v. Publix Super Mkts., Inc., 982 F.3d 468, 484 (7th Cir. 2020) (finding that consumer class had adequately alleged deceptive labeling on a label that claimed to be "100% Grated Parmesan Cheese" that also contained other ingredients).
[28] *See, e.g.*, Ang v. Whitewave Foods Co., No. 13-CV-1953, 2013 WL 6492353 (N.D. Cal. Dec. 10, 2013) (dismissing claim by consumers who alleged they were deceived by Silk Products that used the word "milk" for a non-dairy product); *see also* Hoffer, *supra* note 26, at 671.

laws introduced to restrict usage of terms associated with meat.[29] However these laws have faced pushback from industry groups such as the Plant Based Food Association, in some cases leading to their withdrawal, as was the case in Mississippi.[30] Individual companies have also challenged these state restrictions with mixed results. In a 2020 case, the Tenth Circuit denied relief to a plant-based meat brand – "Upton's Naturals" – which sought to challenge Oklahoma's restrictions on its use of terms like "bacon" or "classic burger."[31] By contrast, in the 2021 case, *Turtle Island Foods SPC v. Strain*, a district court in Louisiana enjoined the state from enforcing new provisions of its Truth in Labeling of Food Products Act against the Tofurkey brand, for their use of "meat terms" on plant-based products.[32] The district court there found that "plaintiff presents compelling evidence indicating that consumers are not confused by its labeling. In response, Defendant *fails* to produce evidence indicating that consumers are confused by Plaintiffs labeling."[33]

At the federal level, the meat industry has lobbied for the "REAL Meat Act," which was introduced in the House of Representatives in 2019 to require new restrictions, such as the placement of the word "imitation" on plant-based alternatives.[34] The Act's stated goal is to "amend the Federal Food, Drug, and Cosmetic Act to ensure that consumers can make informed decisions when choosing between meat products such as beef and imitation meat products."[35] The bill has not yet advanced to a formal vote as of July 2022, and it is unclear whether it would have the requisite support.[36]

Similarly, the dairy industry has lobbied congress for the "Defending Against Imitations and Replacements of Yogurt, Milk, and Cheese to Promote Regular Intake of Dairy Everyday Act" – or its more concise name, the "DAIRY PRIDE Act," introduced in

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[29] *See* PERKINS COIE, *supra* note 14, at 14; *see also, e.g.*, Act of Mar. 12, 2019, ch. 303, § 1, 2019 Miss. Gen. Laws 303 (codified as amended at Miss. Code § 75-35-15(4) (2022)).

[30] Megan Silverman, *The FDA Should Regulate to End the Plant-Based Meat Labeling Controversy*, LEWIS & CLARK L. SCH., (Aug. 19, 2020) https://law.lclark.edu/live/blogs/136-the-fda-should-regulate-to-end-the-plant-based.

[31] Upton's Nats. Co. v. Stitt, No. CIV-20-938-F, 2020 WL 6808784, at *3 (W.D. Okla. Nov. 19, 2020) (court found that a reasonable consumer could be misled by these terms, even with qualifiers like "vegan").

[32] Turtle Island Foods SPC v. Strain, Civil Action 20-00674-BAJ-EWD, 2022 WL 909039, at 8 (M.D. La. Mar. 28, 2022).

[33] *Id.* at 19.

[34] Real MEAT Act of 2019, H.R. 4881, 116th Cong. § 403D(a) (2019); *see* Silverman, *supra* note 30.

[35] H.R. 4881.

[36] *See Id.*

2019.[37] The Act would require enforcement against plant-based products that use dairy-associated terms, calling them "misbranded milk alternatives."[38] Similar to the REAL Meat Act, the Dairy Pride Act has been referred to subcommittees on Health and Commerce, but has not been brought to a vote.[39] This kind of legislation would not be unprecedented, given previously enacted legislation such as 15 U.S.C. § 55, with its amendment passed in 1950 that prohibited advertisements that might suggest margarine was a dairy product, rather than oil-based.[40]

ii. Plant-based Producers and Free Speech Advocates Push Back

1. Anti-Competitive Argument and Voluntary Standards

Like the meat industry, the plant-based food industry has sought greater clarity from authorities like the FDA and formed their own industry group known as the Plant Based Foods Association.[41] The group is made up of several dozen brands, which have banded together to fight lawsuits and policy efforts by the meat and dairy industries. They view these efforts by the meat and dairy industries as anti-competitive measures to keep them out of the market, veiled as consumer protection.[42] Instead of the restrictions advocated by meat and dairy producers, the Plant Based Food Association has come up with their own voluntary standards to differentiate their products, using qualifiers to indicate plant-based status.[43]

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[37] *See* DAIRY PRIDE Act, H.R. 1769, 116th Cong. §1 (2019).
[38] *Id.*
[39] *See id.*
[40] 15 U.S.C. § 55(a)(2).
[41] *See* PLANT BASED FOODS ASS'N, *About* https://www.plantbasedfoods.org/about/ (last visited Sept. 13, 2022).
[42] *See e.g.*, Elaine Watson, *PBFA slams 'anti-competitive, anti-free market' Wisconsin bills targeting plant-based dairy and meat*, FOOD NAVIGATOR (April 8, 2021) https://www.foodnavigator-usa.com/Article/2021/04/08/PBFA-slams-anti-competitive-anti-free-market-Wisconsin-bills-targeting-plant-based-dairy-and-meat (arguing against proposed Wisconsin bill that would restrict use of "milk," "cheese," and "dairy" to products sourced from "hooved animals").
[43] *Voluntary Standards for the Labeling of Meat Alternatives in the United States*, PLANT BASED FOODS ASS'N, https://www.plantbasedfoods.org/wp-content/uploads/PBFA-Labeling-Standards-for-Meat-Alternatives.pdf (Last visited Sept. 13, 2022) (groups suggests disclaimers like "vegan" or "meatfree" as modifiers to go alongside traditional meat terms).

2. Protected Commercial Speech Defense Faces Uncertainty

While countering claims that their product labels are misleading consumers, the plant-based food industry has also successfully framed the new legislation that is designed to restrict them as a violation of their First Amendment right to commercial speech. Courts have found this persuasive in cases such as *Turtle Island Foods SPC v. Soman*, in 2019, where a district court awarded the maker of "Tofurkey" injunctive relief from enforcement of a restrictive new Arkansas law.[44] The court arrived at its decision using a test balancing the harm from potential deception of consumers with the harm of chilling free commercial speech, and found the latter weightier.[45] Similarly, freedom of commercial speech animated the decision of the court in the Middle District of Louisiana in 2022 where they also found for the Tofurkey brand in a suit against restrictive state labeling laws, designed to prevent the usage of meat-associated terms like "burger."[46]

The level of scrutiny to apply to restrictions on commercial speech has also been highly debated, though most courts follow the leading case, *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*.[47] In *Hudson,* the Supreme Court laid out a four-part test, which amounted to an intermediate level of scrutiny, in which the government could restrict speech only when it had a substantial interest and did so with a narrowly tailored regulation that directly and materially advanced its goal.[48]

However, *Hudson's* first factor was a threshold requirement that the speech not be "inherently misleading," which some lower courts have used to justify applying rational basis scrutiny, when the

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[44] Turtle Island Foods SPC v. Soman, 424 F. Supp. 3d 552, 579 (E.D. Ark. 2019); *see also* Anna Starostinetskaya, *Tofurky Wins Historic Free Speech Lawsuit. Can Use "Burger" and "Sausage Labels on Plant-Based Meat.*, VEGNEWS (March 29, 2022), https://vegnews.com/2022/3/tofurky-wins-historic-free-speech-lawsuit.

[45] Soman, 424 F. Supp. 3d at 579.

[46] Strain, WL 909039, at 19; *see also* Starostinetskaya, *supra* note 44.

[47] *See* Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557 (1980).

[48] *Id.* (four part test laid out by the court for restrictions on commercial speech: 1) threshold requirement that the content must not be inherently misleading; 2) government must have a substantial interest; 3) regulation must directly and materially advance the government's goal, and 4) the regulation must be narrowly tailored).

speech is "potentially misleading."[49] Thus, rational basis was applied in the 2020 case brought by *Upton's Naturals*, opposing restrictions from the Oklahoma Meat Consumer Protection Act.[50] Using this rational basis review, which follows an alternative Supreme Court case – *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio* – the district court in Oklahoma denied *Upton* injunctive relief.[51]

On the other side, some courts have employed a heightened standard, beyond intermediate scrutiny.[52] For example, some lower courts have interpreted the 2011 decision in *Sorrell v. IMS Health Inc.* to mean that heightened scrutiny can be applied whenever the state restricts commercial speech based on its content.[53] The Supreme Court in *Sorrell* made the following determination about a restriction on pharmaceutical ads: "Act 80 is designed to impose a specific, content-based burden on protected expression. It follows *that heightened judicial scrutiny is warranted."* (emphasis added).[54]

Thus, courts appear somewhat split on what level of scrutiny ought to apply for commercial speech restrictions, and cases continue to rise through the appellate pipeline. One such case, is an ongoing one between the American Beverage Association and San Francisco over an ordinance requiring warnings on sugary drink signs. In that case the Ninth Circuit ruled against the ordinance, confirming the previous reversal, in a rehearing *en banc*.[55] Without a favorable resolution on what standard to apply, the plant-based industry may face difficulty in using the First Amendment as a shield against new restrictions.

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[49] Upton's Nats. Co., No. CIV-20-938-F, 2020 WL 6808784, at *3 (relying on precedent from the 6th circuit in Int'l Dairy Foods Ass'n v. Boggs, 622 F.3d 628, 641 (6th Cir. 2010)).
[50] *Id.*
[51] Zauderer v. Off. of Disciplinary Couns. of Sup. Ct. of Ohio, 471 U.S. 626, 637 (1985) (applying the leading case for rational basis review to commercial speech).
[52] *See generally* David L. Hudson Jr., *Central Hudson Test,* THE FIRST AMEND. ENCYCLOPEDIA, (2017), https://www.mtsu.edu/firstamendment/article/1536/central-hudson-test.
[53] *See generally* Micah L. Berman, *Clarifying Standards for Compelled Commercial Speech*, 50 WASH. UNIV. J. OF L. & POL'Y 53, 54 (2016) (discussing lower court analysis of Sorrell v. IMS Health Inc., 564 U.S. 552, (2011)).
[54] *Sorrell*, 564 U.S. at 565.
[55] *See* Am. Beverage Ass'n v. San Francisco, 916 F.3d 749, 753-58 (2019).

III. A Proposed Path Forward Outside of the Industry Battle for Market Share

Both the animal-based and plant-based food industries have their own biases as self-interested competitors jockeying for market share. Therefore, in order to determine the best path forward, it is necessary to examine how the regulators see their role and how consumers can be best served, by incorporating third party experts' determinations and international standards. Then, with those considerations in mind, the proper authority – in this case the FDA – can take definitive action to settle this dispute.

A. The FDA Should Take Definitive Action to Incorporate Plant-Based Foods

i. FDA, Not USDA

As previously discussed in Part I, the FDA has default authority over foods that are not sourced from animals.[56] Thus, in the case of plant-based food, it would seem obvious that they are the proper agency to regulate. However, powerful groups such as the National Cattlemen's Beef Association have been pushing for the USDA to take primary jurisdiction.[57] In response, however, third party scientific research organizations like the Center for Science in the Public Interest have argued that the USDA has no place in regulating plant-based foods, and that the FDA is the proper authority.[58]

Finally, a recent memorandum of understanding between the FDA and the Food Safety and Inspection Service (the USDA's food health and safety regulatory division) from 2018 reinforced their discrete areas of authority and gave no indication that the USDA would have authority over meat substitutes. The memorandum once again demarcated that the USDA is limited to the authority granted under the Federal Meat Inspection Act, which carves out its authority over exclusively animal-based food products.[59]

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[56] *See generally supra* Part II.B.
[57] NAT'L CATTLEMEN'S BEEF ASS'N, *surpa* note 18.
[58] *See* Sarah Sorscher & Thomas Gremillion, *Re: Petition to Establish Beef and Meat Labeling Requirements*, CTR. FOR SCI. IN THE PUB. INT. (May 18, 2018), https://cspinet.org/sites/default/files/attachment/usca-petition-fda-2018.pdf.
[59] *See Memorandum of Understanding Between the Food Safety and Inspection Service United States Department of Agriculture and the Food and Drug Administration*, FOOD & DRUG ADMIN. (Feb. 23, 1999), https://www.fda.gov/about-fda/domestic-mous/mou-225-99-2001.

ii. Preemption Is Authorized and Will Provide Needed Uniformity

Another reason for the FDA to take action is to standardize the rules around labeling plant-based food, settling the contentious legal battle being waged across the United States.[60] The FDA has been given express preemptive authority in the area of labeling, through acts like the Nutrition Labeling and Education Act (NLEA), which ties in directly with standards of identity and the appropriate terminology for these new plant-based products.[61] Case in point, §343(1) of the NLEA amendment states that:

> *no State* or political subdivision of a state *may directly or indirectly establish* under any authority or continue in effect as to any food in interstate commerce – (1) *any requirement for a food which is the subject of a standard of identity* established under section 341 of this title that is not identical to such standard of identity or that is not identical to the requirement of section 343(g) (emphasis added)[62]

This section strongly indicates that if the FDA were to create concrete standards of identity, it would nullify any state effort to create their own restrictions, providing a uniform and standardized system of labeling, as intended by Congress. In fact, one federal court recently addressed this gap directly, when ruling on the use of the word "milk" by the Silk Products brand, writing "§131.110 pertains to what milk is, rather than what milk is not, and makes no mention of non-dairy alternatives."[63] The court then found that the local attempt to impose additional standards of identity at issue was preempted and therefore impermissible, given that "the FDA has yet to prescribe a name for the Silk Products."[64]

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[60] *See supra* Part II.
[61] *See* 21 U.S.C. § 343-1.
[62] *Id.*
[63] Ang, No. 13-CV-1953, 2013 WL 6492353; *see also* 21 C.F.R. § 131.110 ("Milk is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows.").
[64] *Id. But see* Bell v. Publix Super Mkt, Inc., 982 F.3d 468, 484 (7th Cir. 2020) (finding that "Absent contrary language in a standard of identity that protects a particular statement, § 343-1 does not expressly preempt state-law prohibitions on deceptive statements that sellers add voluntarily to their labels or advertising.").

This need for clarity is exactly what drove the early efforts to create a national regulatory framework and would presumably reduce litigation and uncertainty for both the animal and plant-based industries.[65]

B. A Closer Examination of Serving Consumer Interests

i. Consumer Perception and Interest

The meat and dairy industry have consistently argued that they are merely trying to prevent consumers from being misled, as consumers may be unable to differentiate animal-based products from plant-based substitutes. However, the evidence supporting that proposition is limited, with the majority of Americans now appearing knowledgeable about plant-based alternatives.[66] Further, 57 percent of American households are already purchasing plant-based alternatives.[67] The Center for Science in the Public Interest has also written directly to the FDA to call out beef industry groups for continuing to make the claim that consumers are confused without substantiation or rigorous evidence supporting that theory.[68]

Even more pointedly, a study of over seven thousand randomly selected public comments solicited by the FDA about the use of dairy terms found that over three-quarters of commenters favored allowing plant-based products to use dairy terms, with only 13.5 percent opposed.[69] The analysis also tracked the opinions of commenters who specified their identity (of which there were thousands), finding that 99.8 percent of commenters who identified themselves as opposed to the use of dairy terms were themselves dairy farmers.[70] This lies in stark contrast to those who identified themselves and supported the use of dairy terms, of which 97.4 percent identified themselves as consumers.[71] Thus, the animal-

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[65] *See* discussion *supra* Section II.A.

[66] Christopher Bryant, et al., *A Survey of Consumer Perceptions of Plant-Based and Clean Meat in the USA, India, and China.,* FRONTIERS SUSTAINABLE FOOD SYS (2019) (a survey in 2018 of just under 1,000 randomly selected Americans found that about two out of every three were familiar with plant-based meat).

[67] *2021 U.S. Retail Sales Data for the Plant-Based Foods Industry*, PLANT BASED FOODS ASS'N, https://www.plantbasedfoods.org/retail-sales-data/ (last visited Sept. 14, 2022).

[68] *See* Sorscher, *surpa* note 58.

[69] *Consumers Support Use of Dairy Terms for Plaint-Based Foods*, LINKAGE RSCH. & CONSULTING, https://linkageresearch.com/fda-plant-based (last viewed Sept. 13, 2022).

[70] *Id.*

[71] *Id.*

based food industry's argument about protecting consumers appears to be a flimsy façade for an anti-competitive and protectionist strategy, fueled mostly by the desire for self-preservation.

While the plant-based food market is still in its early stages, courts have already found consumers unlikely to be confused, though often based on the presiding judge's subjective personal opinion as consumers themselves. For example, in *Painter v. Blue Diamond Growers*, the Ninth Circuit affirmed dismissal of a consumer action claim against an almond milk provider. The court reasoned that the consumer class did "not plausibly allege that a reasonable consumer would be deceived into believing that Blue Diamond's almond milk products are nutritionally equivalent to dairy milk based on their package labels and advertising."[72] Thus, the consumer interest is not clearly served by restricting plant-based products from being labeled with meat and dairy terms and may in fact be harmed and lead to greater confusion.

ii. Health Effects of Reduced Meat and Dairy Consumption

Generally, to qualify for damages in federal court, one would have to allege that they suffered an injury.[73] The meat and dairy industries argue that the injury to consumers is a nutritionally inferior product.[74] But this conclusion is too sweeping, and not consistent with the evolving guidance from leading nutrition authorities. However, meat and dairy provide different nutritional benefits (or detriments) and their health effects are better discussed separately, as explained below.

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[72] Painter v. Blue Diamond Growers, 757 F. Appx 517, 518 (9th Cir. 2018); *see also* Miyoko's Kitchen v. Ross, No. 20-CV-00893-RS, 2020 WL 8361994, at *5 (N.D. Cal. Aug. 21, 2020) ("[A]s discussed above, the State's view of 'butter' stands largely by itself—unanchored by precedent, empirical research, or any other form of independently authoritative ballast—it does not disturb the weight of evidence tending to show that Miyoko's use of that word is likely not misleading. In this early phase of the litigation, it therefore appears Miyoko's decision to label its product as "butter" is entitled to First Amendment protection.").

[73] *Miyoko*, WL 8361994 at 20.

[74] NAT'L MILK PRODUCERS FEDERATION, https://www.nmpf.org/policy_priorities/dairy-labeling-food-standards; Megan Silverman, *The FDA Should Regulate to End the Plant-Based Meat Labeling Controversy*, LEWIS & CLARK L. SCH., (Aug. 19, 2020), https://law.lclark.edu/live/blogs/136-the-fda-should-regulate-to-end-the-plant-based.

1. Meat – We Overeat

There is strong evidence that a plant-based diet is more healthful than one that it is high in animal products – although there is admittedly less evidence on the effect of merely substituting meat with plant-based alternatives.[75] However, the leading authority and research body on American nutritional health is the U.S. Department of Health and Human Services, which publishes detailed guideline reports every five years. In their report for 2020 to 2025, they found that about 75 percent of Americans meet or exceed the recommendation for meat, poultry and eggs, whereas 50 percent do not get the recommended amount of nut, seed, and soy products.[76] The report states that "[s]hifts are needed within the protein foods group to add variety to subgroup intakes."[77]

These statements – made from a research arm within the USDA – demonstrate that Americans are overeating animal-sourced proteins and might actually benefit from plant-based protein in their diet, on average. The need for a more diverse source of proteins has also been advocated by global health expert panels from the United Nation, and is supported by the World Health Organization, which promotes eating animal-based foods in moderation.[78] This conclusion significantly undercuts the meat industry's argument that consumers are being given an inferior product when they buy plant-based alternatives to animal protein.

2. Milk – A Messier Story

Unlike meat, milk presents a more complicated story, as not all substitutes are nutritionally equivalent. Further, the Dietary Guidelines Report indicates that Americans consume less than the recommended amount of dairy.[79] However, the report acknowledges that to address these deficiencies most consumers would benefit from consuming either fortified plant-based milks, like soymilk, or low-fat dairy milk.[80] This means that non-fortified plant-based milks like almond, rice, coconut, and hemp milks are not encouraged, in

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[75] Rachel Tso et al, *A Critical Appraisal of the Evidence Supporting Consumer Motivations for Alternative Proteins*, FOODS – MULTIDISCIPLINARY DIGIT. PUBL'G INST., (Dec. 23, 2020) https://doi.org/10.3390/foods10010024.
[76] U.S. DEP'T. OF HEALTH AND HUM. SERVICES, DIETARY GUIDELINES FOR AMERICANS, 2020-2025, 9TH EDITION, 34 (December 2020).
[77] *Id.*
[78] *See* HLPE, NUTRITION AND FOOD SYSTEMS, 33 (2017).
[79] U.S. DEP'T. OF HEALTH AND HUM. SERVICES, *surpa* note 76 at 100.
[80] *Id.* at 33.

addition to cow milks with higher fat contents, like whole milk, that are also not encouraged.[81] Thus, the assumption that plant-based milks are nutritionally inferior is also not completely supported, with the guidelines supporting consumption of nutrient dense, low fat varieties of both plant and animal-based milks.

One solution to this problem, proposed by the Center for Science in the Public Interest, is to require front of label disclosures for any dairy substitute product which does not contain a substantially similar nutrient profile as dairy foods (e.g., oat milk). Their proposal to the FDA suggests allowing the use of dairy terms, because the evidence does not indicate consumers are unaware of what they are buying, but that they should be informed when a substitute is not nutritionally equivalent.[82]

iii. Sustainability as a Consideration in Food Policymaking

Finally, as alternative proteins begin to emerge, more people are extoling the benefits to the environment of reducing human consumption of animals. Given the precarious position we have placed ourselves in by radically altering the climate, many now consider major changes in our food system as an essential component in reversing our destructive course.[83] We now know that meat consumption alone is a key driver for emissions.[84]

Studies indicate that simply replacing animal-based food with plant-based foods would have significant positive environmental impact.[85] In fact, though there are limited studies on

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[81] *Id.*

[82] *Use of the Names of Dairy Foods in the Labeling of Plant-Based Products,* CTR. FOR SCI. IN THE PUB. INT., (Jan. 28, 2019), https://cspinet.org/sites/default/files/attachment/CSPI%20Dairy%20Alternatives%20Comment.pdf.

[83] *See* Nicole E. Negowetti, *Taking (Animal-Based) Meat and Ethics off the Table: Food Labeling and the Role of Consumers as Agents of Food System Change*, 99 Or. L. Rev. 91, 92 (2020).

[84] Fabiano DeAndrade Correa et al. *Agriculture and climate change: Law and governance in support of climate smart agriculture and international climate change goals*, FAO (2020) (legislative study from the Food and Agriculture Organization of the UN on the law and governance in support of climate smart agriculture and international climate change goals).

[85] Lukasz Aleksandrowicz et al., *The Impacts of Dietary Change on Greenhouse Gas Emissions, Land Use, Water Use, and Health: A Systematic Review,* 11 PLOS ONE, Nov. 2016, at 7-8 (systemic review of 60 studies on environmental impact of sustainable diets, concluding that there are significant environmental, and potential health benefits to shifting Western dietary patterns towards more sustainable sources, with less animals-based food); HLPE *supra* note 78.

the effect of sustainable diets on health, many report lower mortality rates and better cardiovascular health.[86] This linkage to sustainability in dietary recommendations is already being considered in major countries around the world, with Germany, Brazil, Sweden, and Qatar stressing diets lower in red meat and higher in fruits and vegetables in order to promote a sustainability as well as health.[87]

C. Proposal – Clear Guidelines That Allow Accurate and Descriptive Language

Having now established the clear authority and need for the FDA to regulate plant-based foods, the lack of consumer confusion about plant-alternatives, and the benefits of sustainable diets, I propose the FDA promulgate simple and clear-cut rules governing plant-based foods. As such, the FDA should update the outdated standards of identity for products like milk and set standards on the terminology that may be used for meat substitutes.[88]

The FDA could, for example, allow continued use of terms descriptive of shape, style, preparation, consistency, or flavor, with required modifiers indicating the source or main ingredient (e.g., soy/almond/coconut milk, black bean burger, veggie sausage, soy nugget, vegan bacon, or other similar combinations). At the same time, they could disallow the use of the actual individual animal names if the food is not literally composed of that animal (e.g., chicken, cow, pig, beef, poultry, pork, turkey, duck etc..). This would strike the balance of allowing plant-based products to describe their food using food terms without misrepresenting the origin of that food and the associated health benefits (or detriments). This kind of flexibility in the names of food products is fairly standard and intuitive. As new foods have developed, we have allowed such products, like carrot chips (rather than potato) and corn nuts (a corn product only prepared in a similar way to a toasted nut) to proliferate,

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[86] HLPE, *supra* note 78 at 61. *But see* Aleksandrowicz, *supra* note 85 (finding no statistically significant benefit to health associated with sustainable diet).
[87] Carlos Gonzalex Fisher & Tara Garnett, *Plates, Pyramids, Planet: Developments in national health and sustainable dietary guidelines: a state of play assessment*, FOOD & AGRIC. ORG. (2016) (FAO report on updating food-based dietary guidelines to promote health and environmental sustainability).
[88] 21 C.F.R. § 131.110 (2022) (existing regulation defining milk as "Milk is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows.," with no reference to milk from other animals or its common usage to describe soy and nut products).

to the benefit of consumers and new entrants to the consumer food markets.[89]

Conclusion

The regulation of food grew out of a desire to protect consumers from unseemly production conditions and adulterated products. The driving force for a national infrastructure was fueled by industries seeking standards that could be applied consistently across the country and preventing cheap knock-offs from entering lucrative markets. However, society has evolved in the intervening hundred years, with more efficient and sanitary conditions, and a rise in innovative new products meant to offer consumers new options – not trick them into buying a cheap substitute.

In response, the FDA needs to take the reins at this pivotal moment and offer clarity, with updated standards that reflect this new market of alternatives to traditional meat and dairy products. Those standards should be based on the available science pertaining to the health of the products, a rigorous survey of consumer perceptions, and consideration of the role that all consumers can have on combatting climate change through a sustainable diet.

[89] *See* Alison Spiegel, *What Exactly Are Corn Nuts, Anyway?,* HUFFPOST (Mar 6, 2015), https://www.huffpost.com/entry/what-are-corn-nuts_n_6810636.

The Cost of Compassion: Why State Ballot Initiatives Complicate Farm Animal Welfare and Overlook the True Problems in Modern Agriculture

Seth Victor

I. Introduction

Farm animal welfare is a concern for many Americans, both among those who value a higher standard of care for the animals' own sake, and those concerned with food safety.[1] Industrial agriculture has become the dominant form of animal production to satiate a daunting demand for meat, eggs, and dairy products.[2] Industrial animal-raising facilities, also known as concentrated animal feeding operations ("CAFOs"), prioritize volume and efficiency and are a key factor in keeping consumer prices low.[3] CAFOs are highly specialized and excel at production by minimizing inputs, maximizing confined animals, and externalizing environmental costs.[4] This production method comes at the cost of natural conditions, and animal welfare organizations routinely target CAFOs, depicting these operations as horrendous and inhumane.[5] Despite these concerns, federal law provides practically no protections for farm animals.[6] State laws grant greater safeguards, but protections vary greatly between jurisdictions.[7] As both federal and state governments are subject to the congressional gridlock that

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[1] *See* Marta Alonso et al., *Consumers' Concerns and Perceptions of Farm Animal Welfare*, MDPI ANIMALS, FEB. 27, 2020 at 1, 2, 4.

[2] *See* David N. Cassuto & Sarah Saville, *Hot, Crowded, and Legal: A Look at Industrial Agriculture in the United States and Brazil*, 18 ANIMAL L. 185, 188, 190 (2012).

[3] S*ee,* R. Jason Richards & Erica Richards, *Cheap Meat: How Factory Farming is Harming Our Health, The Environment, and the Economy*, 4 KY. J. EQUINE AGRIC. & NAT. RES. L. 31, 32-33 (2012).

[4] *See id.*

[5] *See Factory Farming in America: The True Cost of Animal Agribusiness for Rural Communities, Public Health, Families, Farmers, the Environment, and Animals,* HUM. SOC'Y U.S., https://www.humanesociety.org/sites/default/files/docs/factory-farming-in-america-true-cost.pdf (last visited Oct. 2, 2022).

[6] *See, e.g.,* 7 U.S.C. § 2132 (While most farm animals are exempt from the limited federal protections, laying hens are particularly vulnerable to exploitation, as they face the smallest conditions, the largest production volume, and the lowest regulations, with federal law considering chickens to be "fowl," and not "animals").

[7] *See, e.g., Farm Animal Confinement Bans by State*, ASPCA, https://www.aspca.org/improving-laws-animals/public-policy/farm-animal-confinement-bans (last visited Oct. 2, 2022).

has stimmed various legislation over the last decade, passing new welfare laws can be a herculean effort.[8]

Animal advocacy groups have responded to these legislative difficulties by increasingly focusing their efforts on individual state ballot initiatives, banking on the direct will of the people to advance welfare laws.[9] This strategy has been effective, notably with the success of California's Proposition 2 and Proposition 12, and Massachusetts's Question 3, all of which mandate larger space and better enrichment for laying hens ("layers") and sows.[10] The meat and egg industries have painted these measures as an anathema to the American food system, a subversion of American democracy, and an attack against affordable food.[11] Advocates applaud a step towards greater welfare protections, believing industrial animal production itself a crime against basic animal rights.[12] Still others believe recent ballot initiatives addressing animal welfare do not make a sufficient difference.[13]

All sides of the ballot initiative debate have failed to adequately acknowledge the impacts on independent farmers who are beholden to large-scale integrators[14] via production contracts, a

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[8] *See, e.g., A Divided Country*, THE ECONOMIST, Jul 1, 2017 at 11.

[9] *See* Joshua J. Dyck, *New Directions for Empirical Studies of Direct Democracy*, 19 CHAP. L. REV. 109 (2016) (state ballot initiatives have grown across a multitude of issues in American politics, including for farm animal welfare).

[10] *See Massachusetts Minimum Size Requirements for Farm Animals Containment, Question 3 (2016),* BALLOTPEDIA https://ballotpedia.org/Massachusetts_Minimum_Size_Requirements_for_Farm_Animal_Containment,_Question_3_(2016) (last visited Oct. 2, 2022); *see* INFORMATION GUIDE FOR 2008, GENERAL ELECTION (UC Hastings Coll. of L. 2008); *see Animal Care Program*, CAL. DEP'T OF FOOD AND AGRIC., https://www.cdfa.ca.gov/ahfss/Prop12.html (last visited Oct. 4, 2022) (As chickens and pigs have been the primary targets of recent ballot initiatives, and because poultry and pork industries are the most affected by production contracts, this paper will focus on these areas of farm animal agriculture, and not address the beef or dairy industries).

[11] *See, e.g.,* Jen Sorenson, *This Is Why California's Proposition 12 is so Unfair to Pork Producers Nationwide*, L.A. TIMES, Aug. 12, 2021.

[12] *See,* Ashley Chang, *This is What Prop 12 Means for Animals*, THE HUMANE LEAGUE (October 13, 2021), https://thehumaneleague.org/article/prop-12.

[13] *See* Tracy Reiman, *Why PETA Can't Support Proposition 12*, PETA, https://prime.peta.org/news/why-peta-cant-support-proposition-12 (last visited Oct. 4, 2022).

[14] For the purposes of this writing, the term "integrator" will mean any individual or corporation that contracts with a grower or farmer under a contract arrangement wherein the farmer raises and cares for livestock or poultry in accordance with the terms of the integrating corporation's contract. Other sources may refer to these players as "contractors," or "processors."

staple under the industrial farming model.[15] State ballot initiatives are an avenue to bypass traditional gridlocked politics to achieve welfare improvements, but this approach will not solve the economic disaster of the industrial system; the regulations required by the new state laws will ultimately not force large integrators to change their business models, but will force many independent farmers to comply with new infrastructure changes.[16] While it is easy to demonize all animal producers as part of an uncaring monolith, reality reveals an economic system that preys upon independent farmers as much as, though in different ways, the animals themselves.[17]

As the production contact model has already marginalized the ability of independent farmers to be profitable, new animal welfare laws requiring large-scale change may deter or eliminate independent producers and have the paradoxical impact of further consolidating the farm animal market in the current monopsonies decried by advocates. To break the hold of industrial agriculture equitably, animal welfare progress cannot come at the expense of independent producers if lasting reform is to occur.

Additionally, animal advocates should tread carefully in using ballot initiatives to advance welfare laws. As in traditional politics, there is a risk that the pendulum will swing in the either direction towards laws limiting farm animal welfare– indeed, there have already been successful efforts to limit the ability to pass farm animal welfare through voter initiatives.[18] While flawed, our representative democracy provides a safeguard against unrealistic or unworkable laws; by overly relying on voters to direct lawmaking without the check of legislators, unforeseen complications or misinterpretations are inevitable. Increasing farm animal welfare remains a worthy endeavor, but it is only one piece of a broken agricultural puzzle. Reforming the production contract system should also be an aim of welfare advocates so that both humans and animals can be liberated from a brutal model that rewards a select few. All players need to have a seat at the table to create a better agricultural system, and no advancements can be made at the cost of either animals or farmers.

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[15] *See* James M. MacDonald & Christopher Burns, *Marketing and Production Contracts Are Widely Used in U.S. Agriculture*, U.S. DEP'T OF AGRIC., (July 1, 2019), https://www.ers.usda.gov/amber-waves/2019/july/marketing-and-production-contracts-are-widely-used-in-us-agriculture/.

[16] *See infra* Part IX.

[17] *See* Neil Hamilton, *Broiler Contracting in the United States – A Current Contract Analysis Addressing Legal Issues and Grower Concerns*, 7 DRAKE J. AGRIC. L. 43 (2002).

[18] *See infra* Part VIII.

II. A Challenging System for Independent Farmers

The production contract model is relatively new.[19] While farmers traditionally raised animals from birth to slaughter, this method is subject to price fluctuations borne entirely by the farmer.[20] Production contracts evolved as agriculture shifted at the turn of the 20th century.[21] In the early 1900s, nearly half of U.S. labor worked in agriculture, and farm production was diverse, supplying various commodities.[22] Efficient railways and refrigerated cars expanded market options, and while market prices could fluctuate, options were plentiful.[23]

As the century continued, U.S. agriculture changed. Farm labor decreased, farm size increased, and farm production specialized into one or two outputs.[24] Simultaneously, integrators began to dominate the purchasing market.[25] Over the 1980s a trend of deregulation by the Reagan Administration, along with decisions by the Supreme Court, allowed conglomerates to effectively turn the agricultural market into a set of monopsonies.[26] By 1990, a few select companies controlled the market.[27]

In recent years, trade wars, climate change, and lower commodity prices related to globalization have all combined to weaken the financial viability of farming.[28] More than 100,000 farms disappeared between 2011 and 2018.[29] Consolidation means that small farms account for only 25% of U.S. food production, down

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[19] *See* Dean Zimmerli, *Something Old, Something New: Relying on the Traditional Agricultural Cooperative to Help Farmers Solve the Power Imbalance in Modern Meatpacker Production Contracts*, 24 SAN JOAQUIN AGRIC. L. REV. 59, 60 (2015).
[20] *See* Shi-Ling Hsu, *Scale Economies, Scale Externalities: Hog Farming and the Changing American Agricultural Industry*, 94 OR. L. REV. 23, 33-34 (2015).
[21] *See* Zimmerli, *supra* note 19, at 61.
[22] Carolyn Dimitri, et al., *The 20th Century Transformation of U.S. Agriculture and Farm Policy,* U.S. DEP'T. OF AGRIC., June 2005.
[23] *See* Zimmerli, *supra* note 19 at 62.
[24] *See id.* (Whereas half of the labor force was connected to agriculture in 1900, by 1970 only four percent of labor consisted of agricultural workers).
[25] *Id.* at 63.
[26] *See, e.g.*, Cargill, Inc. v. Monfort of Colo., Inc., 479 U.S. 104, 122 (1986) (in which the Supreme Court held that a showing of loss or damage due to decreased competition did not constitute an antitrust injury under the Clayton Anti-Trust Act); *see* Clayton Act, ch. 323, § 7, 38 Stat. 730, (1914) (current version at 15 U.S.C. § 18).
[27] *See* Lina Khan, *Obama's Game of Chicken,* WASH. MONTHLY, Nov. 9, 2012.
[28] *See* Alana Semuels, *'They're Trying to Wipe Us Off the Map.' Small American Farmers are Nearing Extinction.* TIME, Nov. 27, 2019.
[29] *Id.* ("12,000 of those between 2017 and 2018 alone.").

from 50% under two decades ago.[30] From 1987 to 2012, the number of farms with over 2,000 acres doubled, while farms with less than 1,000 acres dropped 44%.[31] Livestock concentration does not follow an exact correlation with crop land, but animal living space has nevertheless condensed dramatically since the mid-1980s.[32]

Yet while animal production has exploded, farmers have not realized more profits; in the 1970s, a farmer raising hogs received 40-60 cents for every consumer dollar spent on pig products – today, that share is down to 19 cents.[33] As a result of consolidation, the major monopsonies pushed producers into vertical integration, a system in which the buying companies[34] own the animals, supply the feed, and control the slaughter and ultimate sale through production contracts.[35] In essence farming has shifted so that a farmer is not paid for her animals, but for her labor tending to a corporate product.[36]

There are benefits to this system, the most prominent being price guarantees from the integrator laid out in the contract.[37] The relatively stable prices are attractive so farmers can better predict their expenses and earnings.[38] Broiler producers quickly converted from selling on the open market (95% of producers in 1950) to selling on contract (90% of producers in 1958).[39] Hog industries

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[30] *Id.*

[31] James M. MacDonald & Robert Hope, *U.S. Cropland is Consolidating into Larger Farms*, AMBER WAVES, Dec. 19, 2017. ("Large Crop farms (with 2,000 acres or more) accounted for 36 percent of U.S. cropland in 2012, compared to 15 percent in 1987").

[32] *See* James M. MacDonald, *Consolidation in U.S. Agriculture Continues*, AMBER WAVES, Feb. 3, 2020. (In 1987, the midpoint of a broiler flock was 300,000 animals; by 2017, it had more than doubled, at 744,000 birds. Layers jumped from 117,839 to 1,200,000 birds, while the midpoint of a team of hogs increased stupendously in the same time period, from 1,200 animals to 51,300).

[33] *Fact Sheet: The Biden-Harris Action Plan for a Fairer, More Competitive, and More Resilient Meat and Poultry Supply Chain*, THE WHITE HOUSE (Jan. 3, 2022), https://www.whitehouse.gov/briefing-room/statements-releases/2022/01/03/fact-sheet-the-biden-harris-action-plan-for-a-fairer-more-competitive-and-more-resilient-meat-and-poultry-supply-chain/.

[34] *See* Neil D. Hamilton*, State Regulation of Agricultural Production Contracts,* 25 U. MEM. L. REV 1051, 1064 (1995) (Mega-conglomerates such as Smithfield, JBS, Perdue, Tyson, and Cal-Maine Foods).

[35] *See id.* at 1055.

[36] *See generally*, OH FREEDOM AFTER A WHILE (Steven John Ross et al. 1999) (While modern farming overall remains a predominantly White occupation, the practice of using workers for labor rather than their product or directly employing them is reminiscent of the eviction crisis in the mid-west during the 1930s that predominantly affected Black sharecroppers, and reflects a troubling trend of dehumanizing the agricultural workforce.).

[37] See Hamilton, *supra* note 34, at 1099.

[38] *See id.*

[39] Khan, *supra* note 27.

joined the contract model as well.[40] The efficiency of integration does result in lower, stable prices for consumers, and less variation in the ultimate product; however, independent farmers feel the result of the intense consolidation without gaining all of the benefits.[41]

Production contracts are slanted heavily in favor of the drafting integrators, and though they do provide price stability, there is less ability for farmers to force competition in sales.[42] By obscuring the market through confidential, exclusive contacts, integrators keep individual farmers in the dark as to the true market value of their animals.[43] The animals themselves become a cog in this machine – the larger the chicken and the less feed used, the more money a farmer will be paid.[44] Integrators, however, create a zero-sum market; the total payout to all farmers contracting with an integrator remains static, and farmers compete to grab a larger percentage by maximizing their production.[45] Such a system is wonderful for efficiency, but does not incentivize farmers to prioritize animal welfare.[46]

Complicating the difficulties for farmers is the high cost of infrastructure required to raise animals. Top chicken producers can gross nearly $250,000 annually.[47] Not everyone, however, can be a top producer, and that gross does not account for construction loans, tools, repairs, and labor necessary to raise chickens, which can cost nearly a million dollars.[48] An average broiler farmer has between three and four poultry houses, each costing approximately $140,000, with an estimated $500,000 required to replace all the houses on a farm.[49] Farmers also cannot independently decide on the design of these structures; they must follow specifications detailed by the contracting company.[50]

Farmers who get into the chicken business without understanding the expense or terms of the contracts may not have a recourse to get out, as loans often involve the farmer's land or house

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[40] *Id.*
[41] *See* Zimmerli, *supra* note 19, at 59-60, 66.
[42] *See id.* at 59-60, 64-65.
[43] *See id.* at 69-70.
[44] *See* Dan Charles, *The System Supplying America's Chickens Pits Farmer Vs. Far,* NPR NEWS (Feb. 20, 2014).
[45] *See id*.
[46] *See* Zimmerli, *supra* note 19, at 66.
[47] Charles, *supra* note 44.
[48] *Id.*
[49] Hamilton, *supra* note 17, at 65.
[50] *See id.* at 73.

as collateral.[51] Those who stand up to integrators face considerable risk. Sixty-day growing contracts can be terminated unexpectedly, and integrators can punish farmers indirectly by only sending sickly chicks, poor feed, or by simply undercounting the chickens' weight when determining the payout.[52]

Integrating companies are able to do this because the contracts reserve the right to determine the number and frequency of birds delivered to the producers, and also allow delay in removing the birds.[53] A contract may include over forty separate substantive legal clauses concerning obligations and payment schedules, as well as referencing additional documents that may bind a farmer regarding complaint and arbitrations of disputes.[54] The duties of the integrator are straightforward and limited (in the example of broilers, to assign and deliver the chicks, and to compensate the farmer for them), whereas the duties of the farmer are far more explicit and demanding.[55] Even farmers who keep their heads down are at the mercy of the controlling company that determines compensation and can unilaterally change the methods for calculating payment, regardless of what the contract said when it was signed.[56] Direct or indirect retaliation from integrators is common, and exacerbating the situation, the top earners in the industry, not the consumers, benefit from pitting producers against each other.[57]

The pork industry faces the same issues. Per capita pork consumption has increased 86% since 1961, with some estimates predicting an additional increase in consumption by more than 50% by 2050.[58] This increase is sustained because of the supply shift inherent to CAFOs, wherein producers are able to generate more pork products at relatively stable prices by using fewer inputs.[59] Simultaneously, the top four hog-processing companies have increased their control over the market from 33% in 1976 to 66% in

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[51] *See* Khan, *supra* note 27.
[52] *Id.*
[53] Hamilton, *supra* note 17, at 51-52.
[54] *Id.* at 47-48.
[55] *See id.* at 48-49.
[56] *Id. at* 50 (Under the auspices of health and safety, typical production contracts prohibit a farmer from keeping birds from more than one company simultaneously. Thus, even if a farmer is in a region not dominated by a monopsony, she will still be under the yoke of a single integrator).
[57] *See* Zimmerli, *supra* note 19, at 60.
[58] Kelly Zering, *Hog Farming: Past, Present, and Future: An Economist's View*, 34 J. LAND USE & ENV'T L. 313, 315 (2019).
[59] *Id.* at 316 (the word "sustained" may be an ironic word choice, since the CAFO system is not sustainable, largely because it is able to externalize many of its market inputs and non-market outputs, such as water and waste).

2021, while earning record gross profits.[60] Independent hog farmers have dwindled, though not to the same extent as in the chicken industry.[61]

The majority of hogs are produced in CAFOs.[62] A little over 60% of this production is done through production contracts, up from approximately 35% in the mid-1990s.[63] Hog production contracts are typically structured differently than those for poultry; whereas a poultry contracts are paid on a per bird basis and influenced by ranking among other farmers, hog contracts are designed around the space of the facility regardless of whether the barn is full with pigs, with potential premiums for efficient feed but also a more standardized payment plan than chicken farmers are afforded.[64] Hog contracts also tend to be longer term, rather than year to year or flock to flock.[65] Generally U.S. pig farmers are in a slightly more favorable situation than chicken farmers, but independent farmers of both animals remain at risk of being squeezed as the market continues to consolidate, and production contracts steadily become the norm.

III. Playing Politics with Pork and Poultry

Just as legal protections for farm animals are lacking, farmers have little legal recourse against exploitative policies.

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[60] Brian Deese, et al., *Addressing Concentration in the Meat-Processing Industry to Lower Food Prices for American Families,* THE WHITE HOUSE (Sept. 8, 2021), https://www.whitehouse.gov/briefing-room/blog/2021/09/08/addressing-concentration-in-the-meat-processing-industry-to-lower-food-prices-for-american-families/.

[61] Some rare exceptions, such as Niman Ranch, offer the independent farmers with whom it contracts a guaranteed premium over market price, as well as a floor price. This is, however, the exception rather than the rule, and Niman Ranch itself, a pork, beef, and lamb supplier, was purchased by poultry giant Perdue Farms in 2015, demonstrating that even seemingly independent and innovative contractors often fall under the same corporate umbrella. *See* Marilyn Noble, *When a Big Ag Conglomerate Buys an Iconic Niche Meat Company, Who Has to Change?,* THE COUNTER (Apr. 1, 2019, 8:13 AM), https://thecounter.org/niman-ranch-perdue-farms-livestock-meat-animal-husbandry/ (Noble does note in this article that Perdue has committed to improved animal welfare conditions, better environmental stewardship, and has provided more stability for independent farmers contracting with Niman Ranch, all of which notes that the agricultural industry is complex and complicated, but that consolidation still places tremendous power and influence in the hands of a select few).

[62] Michelle B Nowlin, *Sustainable Production of Swine: Putting Lipstick on a Pig*, 37 VT. L. REV. 1079,1083 (2013).

[63] James M. MacDonald & Christopher Burns, *Marketing and Production Contracts are Widely Used in U.S. Agriculture,* AMBER WAVES, July 1, 2019.

[64]Nowlin, *supra* note 62.

[65] *Id.*

Although the Packers and Stockyards Act of 1921[66] ostensibly protects farmers from unfair competition and trade practices, its enforcement via USDA's Grain Inspection, Packers and Stockyards Administration ("GIPSA") is questionable.[67] The Biden Administration has acknowledged the inequities in the agricultural market, and noted how a select few corporations control well over half the market in poultry and pork.[68] USDA recently began work on new proposed rules to support enforcement of the Packers and Stockyards Act,[69]including better enforcement against unfair and deceptive practices and reforming the poultry grower tournament style rules.[70] In early 2022, President Biden announced that $1B of the American Rescue Plan would be dedicated to curb consolidation and encourage competition in the livestock industry.[71]

In the past, however, industry interests have tended to prevail. When the Obama Administration introduced GIPSA regulations that would have prohibited retaliation for challenging production contracts, Congress pushed back with a rider on USDA's

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[66] Packers and Stockyard Act of 1921, 85 Pub. L. No. 909, 72 Stat. 1749 (though this act has been amended or superseded with subsequent legislation several times, most recently on December 27, 2020).

[67] For example, agricultural co-operatives are exempt from many of the regulations that would otherwise apply from anti-trust laws because of the Capper–Volstead Act (P.L. 67-146.). While the intention of this act was to protect the rights of independent farmers, in modern agriculture the difference between co-operatives and mega corporations is negligible. *See* Dan Kaufman, *Is it Time to Break Up Big Ag?*, THE NEW YORKER, August 17, 2021.

[68] *See* THE WHITE HOUSE, *supra* note 33.

[69] In February 2022, USDA also released an anonymous complaint/tip website to report violations of the Packers and Stockyard Act. *Farmer Fairness,* U.S. DEP'T OF AGRIC., https://www.usda.gov/farmerfairness (Last visited Oct. 13, 2022).

[70] Press Release, U.S. DEP'T OF AGRIC., USDA to begin Work to Strengthen Enforcement of the Packers and Stockyards Act (June 11, 2021), https://www.usda.gov/media/press-releases/2021/06/11/usda-begin-work-strengthen-enforcement-packers-and-stockyards-act; The Justice Department has recently joined USDA in announcing its commitment to ensure fair competition in agriculture, but these efforts are still in preliminary stages. *See* Press Release, U.S. DEP'T OF JUST. OFF. OF PUB. AFF., Justice Department and Agriculture Department Issue Shared Principles and Commitments to Protect Against Unfair and Anticompetitive Practices (Jan. 3, 2022), https://www.justice.gov/opa/pr/justice-department-and-agriculture-department-issue-shared-principles-and-commitments-protect.

[71] Critics, however, argue that such investment is not large enough to shake up a system already rigged against small- and mid-level processors, and will instead distract from the real issue, which is scrutinizing the practice of the "Big Four," something that this administration and past ones have not achieved in practice. Jessica Fu, *Can $1 Billion Really Fix a Meat Industry Dominated by Just Four Companies?* THE COUNTER (Jan. 5, 2022), https://thecounter.org/big-four-meatpackers-antitrust-consolidation/.

funding, effectively blocking the new regulations.[72] Antitrust laws meant to protect against supermarket and food processing facility consolidation have largely gone unenforced.[73] And while returning Secretary of Agriculture Tom Vilsack has vociferously supported changes to the agriculture market, he has also been accused of allowing GIPSA to ignore enforcement of its own actions, and has been vilified as a supporter of industrial-scale farming.[74] Overall, anticompetitive behavior has not been effectively policed.[75] Although the current administration is addressing the inequities of the industrial agriculture system,[76] and bills have been introduced to limit consolidation,[77] real change is still pending.

IV. Who Ensures Farm Animal Welfare?

While farmers struggle under the production contract system, consumers increasingly demand better farm animal welfare standards.[78] The ambiguity between which animals are food versus which are friends differs between societies,[79] but the majority of Americans agree that even if farm animals are destined for dinner, they are entitled to higher care than the law generally provides.[80]

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[72] *See id.*

[73] *See* Semuels, *supra* note 28.

[74] *See* Dan Kaufman, *supra* note 67.

[75] A federal grand jury recently returned an indictment against broiler chicken producer executives on counts of price fixing and rigging bids for broilers from 2012 – 2017. While it is perhaps refreshing to see legal action against unlawful collusion, such lawsuits do little to alleviate the economic struggles of farmers and consumers who suffered under price fixing schemes. *See* Press Release, U.S. DEP'T OF JUST. OFF. OF PUB. AFF., Senior Executives at Major Chicken Producers Indicted on Antitrust Charges (June 3, 2020) https://www.justice.gov/opa/pr/senior-executives-major-chicken-producers-indicted-antitrust-charges.

[76] President Biden at least has acknowledged the difficulties of farmers, even if solutions are still forthcoming: "Consolidation in the agricultural industry is making it too hard for independent family farms to survive. Farmers are squeezed between concentrated market power in the agricultural input industries. . . and concentrated market power in the channels for selling agricultural products." Exec. Order No. 14036, 86 Fed. Reg. 36,987, (July 9, 2021).

[77] The bill did not receive a single vote and was effectively dead on arrival. *See, e.g.,* Food and Agribusiness Merger Moratorium and Antitrust Review Act of 2018, H.R. 6800, 115th Cong. (2018).

[78] *New Research Finds Vast Majority of Americans Concerned about Farm Animal Welfare, Confused by Food Labels and Willing to Pay More for Better Treatment*, ASPCA (July 7, 2016), https://www.aspca.org/about-us/press-releases/new-research-finds-vast-majority-americans-concerned-about-farm-animal.

[79] Caitlin Dewey, *Congress Doesn't Want You to Eat Your Dog or Cat*, WASH. POST, Apr. 24, 2018.

[80] A 2018 poll indicated that 67% of consumers are concerned about farm animal welfare, consistent across genders, races, and geographic location. *ASPCA Surveys,* ASPCA, https://www.aspca.org/shopwithyourheart/business-and-farmer-resources/aspca-surveys (last visited Sept. 28, 2022); *See, e.g.*, Fan Wenjiao, et al.,

Consumer opinions about food are significant; egg consumption alone represents $14.2 billion annually in consumer spending.[81] Pushed to identify whom is responsible for ensuring animal welfare, and most consumers hold distributors accountable, but with farmers a close second.[82]

Many people, however, do not understand America's food system.[83] While certain farmers may want to respond to public demand, the economic limitations of their contracts make implementing costly infrastructure improvements difficult, and belies the public's perception of what an independent farm can do.[84] Complicating the decision to invest in animal welfare is the ambiguity around whether consumers are willing to pay for it; some consumers will pay more for products with enhanced animal welfare,[85] and even support the idea of the federal government

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TBARS Predictive Models of Pork Sausages Stored at Different Temperatures, 96 MEAT SCI. 442, 443 (Jan. 2014) (69% of consumers stating animal welfare is somewhat, very, or extremely important); *Foster Farms First Major Poultry Producer in the West to Earn Humane Certification from American Humane Association™; Meets Increasing Consumer Demand for Humanely Raised Foods*, PR NEWSWIRE (Mar. 11, 2013), https://www.prnewswire.com/news-releases/foster-farms-first-major-poultry-producer-in-the-west-to-earn-humane-certification-from-american-humane-association--meets-increasing-consumer-demand-for-humanely-raised-foods-197011261.html (74% of consumers agree that they would like large producers to raise animals humanely).

[81] Yan Heng, et al., *Consumer Attitudes Toward Farm-Animal Welfare: The Case of Laying Hens*, 38 J. OF AGRIC. & RES. ECON. 418, 419 (2013).

[82] *See* World Animal Protection, *New Research Shows Major Global Supermarket Chains at Risk of Losing Customers over Poor Pig Welfare*, PR NEWSWIRE (Apr. 17, 2018), https://www.prnewswire.com/news-releases/new-research-shows-major-global-supermarket-chains-at-risk-of-losing-customers-over-poor-pig-welfare-300631690.html (89% of US consumers held supermarkets responsible for providing ethically raised products); *id.* (In one study, participants were asked to allocate 100 points across four groups (food companies, farmers, grocery stores, and restaurants), assigning points based on which group is responsible for providing information and transparency. Averaging the responses, respondents overwhelmingly attributed responsibility for animal well-being to food companies (49%), with farmers second (30%). In the same study, 47% rated humane treatment of farm animals as a high-level concern. On a rating of 0-10, 47% gave humane treatment a rating between 8-10. Comparatively, 62% gave food safety a similar rating).

[83] *See* Ronald Holden, *Do Not Underestimate the Ignorance of The American Eater*, FORBES (Jun. 15, 2017), https://www.forbes.com/sites/ronaldholden/2017/06/15/do-not-underestimate-the-ignorance-of-the-american-eater/?sh=692274c37645.

[84] World Animal Protection*, supra* note 82. (When asked if family farms would put their interests over consumer interests, 22% disagreed, and only 28% strongly agreed. Comparatively, when asked the same question about commercial farms, only 6% disagreed, and 50% strongly agreed. It is unclear from the study, however, if definitions were provided, or if participants relied on their own perceptions of "family farm" versus "commercial farms").

[85] *See* Heng, *supra* note 81.

requiring the level of farm animal care to be displayed on labels,[86] while many already find welfare claims on labels to be overly confusing.[87] In sum, while consumers may favor improved animal welfare, they are confused about how to get it, from whom to demand it, and whether it is worth the cost.

As the debate over animal welfare continues, some in the private sector have made a commitment to higher welfare standards in response to consumer demands.[88] Cargill, Smithfield, and Hormel have all made promises to phase out gestation crates and convert to group pens, and to make the same requirements of their contracted producers.[89] But producers have argued that more space for their pigs, combined with infrastructure costs, will impact their ability to be profitable, which means more cost eventually passed onto consumers.[90]

The push for better welfare standards from the private sector would be moot if there were stronger federal and state laws, but there are not. The Animal Welfare Act, the primary federal legislation aimed at animal protection, is extremely limited; it exempts farm animals from regulation and does not define chickens as "animals." [91] Specific attention is given to the transportation of farm animals under the "28 Hour Law," but adherence to and enforcement of this

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[86] *See* F. BAILEY NORWOOD & JAYSON L. LUSK, COMPASSION BY THE POUND: THE ECONOMICS OF FARM ANIMAL WELFARE 341-43 (Oxford Univ. Press 2011).

[87] Jane Black, *How One Company is Trying to Make 'Pasture-Raised' the New Egg Standard*, WASH. POST (Apr. 7, 2015) https://www.washingtonpost.com/lifestyle/food/how-one-company-is-trying-to-make-pasture-raised-the-new-egg-standard/2015/04/06/5428bf22-d275-11e4-a62f-ee745911a4ff_story.html (Less than half of consumers can identify the difference between "cage free" and "free range"); *see* Alice Mitchell, *Over 60 Per Cent of Consumers Find Chicken Labels Confusing*, THE POULTRY SITE, (Mar. 16, 2016) https://www.thepoultrysite.com/news/2016/03/over-60-per-cent-of-consumers-find-chicken-labels-confusing (Between two-thirds to three-fourths of consumers are regularly confused by labels, believing them to be misleading or meaningless); *see also US Chicken Consumption: Presentation to Chicken Marketing Summit*, NAT'L CHICKEN COUNS. (Jul. 18, 2017), https://www.nationalchickencouncil.org/wp-content/uploads/2017/07/US3002925_NCC_Consumption_Presentation_Final_170713.pdf; *see* Press Release, NEWSWIRE, USDA Natural Label Called Meaningless and Misleading to Consumers (Jan. 11, 2007) (*cited in Consumer Perceptions of Farm Animal Welfare*, ANIMAL WELFARE INST. https://awionline.org/sites/default/files/uploads/documents/fa-consumer_perceptionsoffarmwelfare_-112511.pdf (last visited Oct. 15, 2022)).

[88] *See* Mike Hughlett, *Consumer pressure leads Cargill to give pigs more room*, STAR TRIBUNE (June 8, 2014) https://www.startribune.com/consumer-pressure-leads-cargill-to-give-pigs-more-room/262257761/.

[89] *Id.*

[90] *Id.*

[91] 7 U.S.C. § 2132(g).

law is practically non-existent.[92] Once animals arrive at a slaughter facility, their deaths are regulated by the Humane Slaughter Act, but again, this law does not apply to chickens.[93]

Some state laws provide better protection, but these laws vary, and none fully ensure welfare.[94] All states have animal anti-cruelty statutes, but the animals included under these laws may not include farm animals.[95] Even if farm animals are protected, practices that are deemed "routine," "customary," or "normal animal husbandry practices" are exempt from regulation.[96] Attempts to change laws through bills have met opposition from industry and a lack of political salience, similar to attempts at the federal level to protect farmers from large integrators.[97] With legislatures unable or unwilling to advance animal welfare, advocates have turned to petitioning the people directly for change, banking that the growing prioritization of animal welfare will translate into long-lacking housing and treatment reforms.

V. State Ballot Initiatives in Massachusetts and California

Facing similar legislative obstacles at both the federal and state levels, advocate groups have embraced state ballot initiatives to work around capitol gridlock.[98] A ballot initiative is unique in that it bypasses the normal process of introducing a bill, working through subcommittees, and having to negotiate votes through both houses.[99] Rather, a ballot initiative puts the matter directly to the people of the

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[92] 49 U.S. CODE § 80502 (The 28 Hour Law was passed in 1871, originally intended for rail transportation, and did not even apply to truck transportation until 2006. The law provides that transported animals must be allowed five hours of rest for every twenty-eight hours of transportation, but there are numerous loopholes. Most significantly, there are no checkpoints or record requirements to verify if the law is being followed, and no agency (USDA, DOT, DOJ) has the means or incentive to enforce these requirements).

[93] *See* 7 U.S.C. § 1902.

[94] *See States' Animal Cruelty Statutes,* NAT'L AGRIC. L. CTR., https://nationalaglawcenter.org/state-compilations/animal-cruelty (last visited Sept. 29, 2022).

[95] *See id.*

[96] *Legal Prots. for Animals on Farms*, ANIMAL WELFARE INST., https://awionline.org/content/farm-animal-legal-protections (last visited September 22, 2022).

[97] *See, e.g.*, Assemb. B. 732, 2003-2004 Reg. Sess. (Cal. 2004); Assemb. B. 594, 2007-2008 Reg. Sess. (Cal. 2007) (which attempted to address confinement crates and similar issues reflected in Prop 2).

[98] *See* Dyck, *supra* note 9.

[99] Marvin Krislov & Daniel M. Katz, *Taking State Consts. Seriously*, 17 CORNELL J.L. PUB. POL'Y 295, 303 (2008).

state, and can be passed through a simple voter majority.[100] Advocates have used this path increasingly since 1990.[101] Of the twenty-four states that permit ballot initiatives, only California and Arizona require voter approval for legislators to significantly change or repeal citizen-initiated state statutes, and only California prohibits the legislature from making any changes without a citizen vote.[102] As such, California is a unique setting in which to evaluate the effectiveness of ballot initiatives.

Before turning to California, however, Massachusetts's recent lawmaking should be considered. Though it has not received as much press as the laws in the Golden State,[103] the Bay State has seen similar farm animal welfare initiatives pass via ballot initiative.[104] In 2016, Massachusetts became the second state, alongside California, to use a ballot question to ban the sale of eggs raised in a "cruel manner," known as Question 3.[105] The debate surrounding Question 3 focused on its potential price impact. [106]

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[100] *Id.* at 316.

[101] *Ballot Measure/Initative/Referendum Hist. – Animal Prot. Issues*, HUMANE SOC'Y U.S., https://www.humanesociety.org/sites/default/files/docs/ballot-initiatives-chart.pdf (last visited September 26, 2022).

[102] *Legislative Alteration*, BALLOTPEDIA, https://ballotpedia.org/Legislative_alteration (last visited September 26, 2022).

[103] *See California Summary*, BRITANNICA, https://www.britannica.com/summary/California-state#:~:text=Population%3A%20(2020)%2039%2C538%2C223.,400%20km)%20east%20to%20west (last visited September 26, 2022) (California represents approximately 12% of the U.S. total population, and has the largest economy of any state, which would account for its larger role in the national conversation).

[104] *Laws Governing the Initiative Process in Massachusetts*, BALLOTPEDIA, https://ballotpedia.org/Laws_governing_the_initiative_process_in_Massachusetts (last visited September 26, 2022) (Massachusetts uses an indirect initiative process, which requires a certain number of signatures to place a measure on the ballot. The legislature, however, can first consider adopting a similar law. If the legislature does not do so, then the measure goes to the ballot. The implementation of the ballot language, however, can be altered slightly before passage of the ultimate law. This distinction is important, as it gives Massachusetts more flexibility when it comes to implementing the will of the voters).

[105] *Massachusetts Minimum Size Requirements for Farm Animals Containment, Question 3 (2016)*, BALLOTPEDIA, https://ballotpedia.org/Massachusetts_Minimum_Size_Requirements_for_Farm_Animal_Containment,_Question_3_(2016) (last visited Oct. 15, 2022) (a "cruel manner" is defined as "'(i) a breeding pig in a manner that prevents the animal from lying down, standing up, fully extending the animal's limbs or turning around freely; or (ii) an egg laying-hen in an enclosure other than a cage-free housing system' or a housing system that doesn't meet the standards established by the law").

[106] Lauren Dezenski, *Both Sides of Question 3 Agree Egg Prices Will Increase*, POLITICO (Sept. 20, 2016, 6:09 PM), https://www.politico.com/states/massachusetts/story/2016/09/both-sides-of-question-3-agree-egg-prices-will-increase-105644.

Advocates touted the measure's increased animal welfare and a positive impact on food safety, while critics decried the potential increased prices for Massachusetts residents, particularly low-income residents.[107] The summary of the initiative explained to voters that the law would "prohibit any farm owner or operator from knowingly confining any breeding pig, calf raised for veal, or egg-laying hen in a way that prevents the animal from lying down, standing up, fully extending its limbs, or turning around freely."[108] Question 3 prohibits the selling of any animal product derived from animals raised in violation of these standards, with exceptions for transportation, veterinarian treatment, 4-H programs, slaughter, and certain other reasons.[109] The measure passed by a large margin, 77.6% in favor versus 22.4% against.[110] The law is slated to take effect in August 2022, though with certain delays and modifications.[111]

Within the last thirteen years, however, national attention has focused on California's state ballot initiatives, specifically regarding Proposition 2 and Proposition 12. California is an epicenter for animal welfare because of its distinct ballot initiative process and its farm animal production.[112] Over 40 million animals are raised commercially in California.[113] It is regularly a top ten producer of chicken, eggs, cattle, calves, and milk, with over 25.5 million acres devoted to farming and ranching, and a corresponding annual economy from these products near $340 billion.[114] Being such an economic goliath, changes to animal production in California have the potential to send ripples across American agriculture, and as such both Proposition 2 and Proposition 12 received significant opposition from industry leaders and continued legal challenges after their adoption.

Proposition 2 was developed by HSUS, and was approved by voters in 2008,[115] with a phase-in period allowing producers to

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[107] *Id.*
[108] *Massachusetts Minimum Size Requirements for Farm Animals Containment, Question 3 (2016)*, *supra* note 105.
[109] *Id.*
[110] *Id.*
[111] *See infra* Part VI.
[112] *See Legislative Alteration*, *supra* note 102.
[113] *Protect California's Animal Agriculture: Producer's Role in Foreign Animal Disease Prevention*, CAL. DEP'T OF FOOD & AGRIC. (May 2016), https://www.cdfa.ca.gov/ahfss/Animal_Health/pdfs/Protect_CA_Animal_Ag.pdf.
[114] *Id.*
[115] California's initiatives bookend Question 3, creating a unique timeline in which advocates and opponents in both states drew from each other's experiences. *California Proposition 2, Farm Animal Confinement Initiative (2008)*,

transition to new housing systems by 2015.[116] The measure amended the space requirements for pregnant pigs, veal calves, and layers.[117] The measure did not provide specific dimensions for prohibited confinement, but was based on the different animals' behaviors, ambiguity that would eventually lead to better definitions in Proposition 12.[118] The official California voter guide for 2008 explained the initiative as requiring "calves raised for veal, egg-laying hens and pregnant pigs be confined only in ways that allow these animals to lie down, stand up, fully extend their limbs, and turn around freely" with exceptions for "transportation, rodeos, fairs, 4-H programs, lawful slaughter, research and veterinary purposes."[119] The voter guide estimated a potential of several million dollars lost annually in farm tax revenue.[120] Specifically, the fiscal analysis stated, "Compared to current practice most commonly used by California farmers in affected industries, this measure would require more space and/or alternative methods. . . As a result, this measure would increase production costs for some of these farmers."[121] The guide noted that "higher production costs cause some famers to exit the business, or otherwise reduce overall production and profitability."[122]

After several legal challenges, advocates returned to the California ballot in 2018 with Proposition 12.[123] The measure passed with 62.66% of the vote.[124] Proposition 12 differed from Proposition 2 in several ways: Rather than restricting animal movement based on

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BALLOTPEDIA, https://ballotpedia.org/California_Proposition_2,_Farm_Animal_Confinement_Initiative_(2008) (last visited Oct. 15, 2022).

[116] *Proposition 2: Treatment of Farm Animals*, LEGIS. ANALYST'S OFF. (July 17, 2008), https://lao.ca.gov/ballot/2008/2_11_2008.aspx.

[117] Prevention of Cruelty to Farm Animals Act, CAL. HEALTH & SAFETY CODE § 25990(b) (Deering 2022) (amended 2018).

[118] *Id.* § 25991(c) (e).

[119] UC Hastings Coll. of L., *supra* note 10.

[120] *Id.* at 17.

[121] *Id.*

[122] *Id.*

[123] A full accounting of the Constitutional challenges levied against Proposition 2 would be too exhaustive for the scope of this paper, though some of the same theories raised against Proposition 2 were revived in the attacks against Proposition 12, and are discussed herein. Additionally, several excellent articles have already covered the legal battles surrounding these initiatives. *See*, *e.g.*, Sean M. Murphy, *The Chicken or the Egg: A Look at Regulating Egg-Laying Hens Through Statewide Ballot Initiatives*, 22 DRAKE J. AGRIC. L. 319, 322 (2017).

[124] Kelsey Piper, *California and Florida Both Pass Animal Welfare Laws by a Landslide*, VOX (Nov 7, 2018, 2:38 PM), https://www.vox.com/future-perfect/2018/11/7/18071246/midterms-amendment-13-proposition-12-california-florida-animal-welfare.

species' behaviors, it specified the number of square feet required for veal calves, breeding pigs, and layers;[125] additionally, Proposition 12 banned the sale in California of veal, uncooked pork, and shelled and liquid eggs (Proposition 2 only covered shelled eggs) raised in conditions that violate these space requirements.[126] Certain aspects of the law took effect in 2020, with the rest of the confinement bans, particularly concerning hog confinement, starting on January 1, 2022.[127]

Not only does this measure affect animals raised in California, but it also prevents integrators from other states from selling to California's 39 million residents, who account for approximately 12% of the nation's egg consumption, and 14% of pork consumption.[128] Proposition 12 therefore has the potential to affect nearly 40 million layers annually,[129] and could theoretically force a pig confinement revolution across the nation.[130] Animal welfare advocates have rightfully claimed the measures as a significant win for farm animals that have long suffered without strong state or federal protections, and have noted that these victories reflect the effectiveness of ballot initiatives. Yet elections have consequences, and the successes of Proposition 2 and Proposition 12 have been met with industry challenges and backlash, particularly from the pork industry.

VI. The Bacon Backlash

At the advent of 2022, much of the debate around Proposition 12 shifted to pork products.[131] While the egg market may be larger, pork has a considerable footprint in the food market.[132]

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[125] Emma Therrien, *2018 State Legislative Review*, 25 ANIMAL L. 447, 457 (2019).
[126] Prevention of Cruelty to Farm Animals Act § 25990(b).
[127] *Id.*
[128] *See* id.
[129] The combined effect of these measures and additional state laws has been a reduction of battery cage use by 26% from 2007 to 2021. *See* Samara Mendez, *US Egg Production Data Set*, THE HUMANE LEAGUE at 5 (Aug. 12, 2019), https://thehumaneleague.org/article/E008R01-us-egg-production-data.
[130] *See* Kenny Torrella, *The Fight over Cage-Free Eggs and Bacon in California, Explained,* VOX (Aug. 10, 2021, 8:10 AM), https://www.vox.com/future-perfect/22576044/prop-12-california-eggs-pork-bacon-veal-animal-welfare-law-gestation-crates-battery-cages.
[131] *See*, *e.g.*, Michael Hiltzik, *Pork Producers Are in Full Squeal Over California's Farm Animal Rules. You Should Tune Them Out*, L.A. TIMES (Feb. 23, 2022, 6:00 AM), https://www.latimes.com/business/story/2022-02-23/pork-producers-are-in-full-squeal-over-californias-farm-animal-rules-tune-them-out.
[132] *The Pork Industry,* NATIONAL PORK PRODUCERS COUN., https://nppc.org/the-pork-industry/ (last visited Oct. 15) (estimating $28.02 billion of gross output in the pork industry; NASS, POULTRY – PRODUCTION AND VALUE, 2020 SUMMARY 5

Bacon and other products derived from pigs are romanticized in restaurant and food advertising to an almost absurd degree, placing bacon on a pedestal in the public consciousness.[133] It thus comes as no surprise that pork advocates have joined the egg industry in decrying legislation aimed at increasing the size of confinement areas, particularly Proposition 12.[134] The remaining requirements under Proposition 12 took effect on January 1, 2022.[135] The National Pork Producers Council (NPPC) immediately voiced concern over anticipated devastating effects of the law, including pork shortages and skyrocketing bacon prices.[136] NPPC assistant vice president Michael Formica declared that only 4-5% of U.S. pork production is currently compliant with Proposition 12 requirements.[137]

The concern that Proposition 12 will shorten national pork supplies has echoed around the country.[138] Consumers worry that market prices will balloon at a time when prices are already high due to U.S. inflation in 2021-2022.[139] While advocates on either side overstate or downplay the potential economic impact of California's law, the true cost likely lies somewhere in the middle, and may cost consumers a few dollars more per year for similar purchases.[140] Other

(USDA 2021) (estimating the total value of chicken sales to be approximately $35.5 billion).

[133] *See* Maria Godoy, *Does Bacon Really Make Everything Better? Here's The Math*, THE SALT, (Oct. 25, 2013, 10:59 AM), https://www.npr.org/sections/thesalt/2013/10/25/240556687/does-bacon-really-make-everything-better-here-s-the-math.

[134] Hiltzik, *supra* note 131.

[135] Prevention of Cruelty to Farm Animals Act § 25990(e).

[136] Jenna Hoffman, *Prop 12: A Different Kind of California Wildfire*, FARM J., (Jan. 3, 2022) https://www.agweb.com/news/policy/politics/prop-12-different-kind-california-wildfire (The NPCC argues that Californians were misled by the language of Proposition 12, and that if they understood the potential effects to market prices, they would not have voted for it, though this reasoning does not comport with the voter's guide that did cover potential economic effects).

[137] *Id.*

[138] Hiltzik, *supra* note 131, at 17.

[139] Jackie Davalos et al., *Instacart's CEO Is 'Worried' About Inflation of Food Prices*, BLOOMBERG (Mar. 17, 2022, 4:14 PM), https://www.bloomberg.com/news/articles/2022-03-16/instacart-ceo-is-worried-about-inflation-of-food-prices?leadSource=uverify%20wall.

[140] Richard Sexton & Daniel Sumner, *California's animal welfare law caused hysteria on both sides — here are the real impacts,* THE HILL (Aug. 20, 2021, 3:00 PM), https://thehill.com/opinion/energy-environment/568762-californias-animal-welfare-law-caused-hysteria-on-both-sides-here ("Our economic study finds that the price of the fresh pork products covered under Proposition 12 (about 60 percent of the pork on a hog) will rise by about 8 percent in California. Prices of cooked pork products or pork mixed with other ingredients are not covered by the law and will be largely unaffected. Economic losses from higher prices and lower consumption are about $8 [per year] per Californian"); *see also* Natasha Daly, *California voted to improve pig welfare. The pork industry is facing a reckoning,*

estimates show Proposition 12-compliant pork products will rise on average $0.21/lb., with uncooked cuts of pork in California rising 7.7%, or about $0.25/lb.[141] While those are still significant increases, particularly for working class families, inflation unrelated to Proposition 12 increased the price of bacon 21% between November 2020 and November 2021.[142] While rising costs may price out certain buyers, at least temporarily, such increases are not unprecedented, and may be within the range of what consumers are willing to pay for enhanced welfare standards.[143]

Other concerns relate to what compliance with Proposition 12 actually looks like. Thus far the trend for pig farmers has been to adjust to group pens, creating a larger space with several animals, rather than increase the size of preexisting individual pens.[144] Some simply use existing stalls and reduce the number of animals housed.[145] Group pens have their own welfare concerns. Sows can be aggressive, and their natural tendencies in group confinement areas could lead to more fighting, and actually decrease the welfare and safety of the sows.[146] Other pork advocates have questioned the risk of food-borne illness, arguing that the interaction between sows in larger pens will increase the risk of spreading infectious diseases.[147] Industry has raised other economic questions, such as how and at what cost processing operations will keep pork destined for

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NAT'L GEOGRAPHIC (Aug. 13, 2021), https://www.nationalgeographic.com/animals/article/california-voted-to-improve-pig-welfare-the-pork-industry-is-facing-a-reckoning (stating "[b]ut the California Department of Food and Agriculture estimates that the price for pork and veal per Californian will go up by only $10 per year.").

[141] Sexton & Sumner, *supra* note 140, at 18.

[142] Taylor DesOrmeau, *Gas, Used Cars, Pork Chops: Household items push inflation to highest levels since 1982*, MLIVE.COM (Dec. 28, 2021, 10:54 AM), https://www.mlive.com/public-interest/2021/12/gas-used-cars-pork-chops-household-items-push-inflation-to-highest-levels-since-1982.html.

[143] *See generally infra* Section IV.

[144] Sexton & Sumner, *supra* note 140.

[145] *Id.* (Prop 12 will require 24 square feet per breeding sow, but. . . since the law applies to mother sows, not to the hogs actually grown for meat, less than 1 percent of America's hogs are impacted. . . about 30 percent of breeding sows are already housed in group pens which generally have about 20 square feet each — not enough to meet the 24-foot requirement. These farms will remove a few sows per group pen in order to comply with Prop 12 rule.).

[146] Hoffman, *supra* note 136, at 18; *see also* Farm Journal, *DC Signal to Noise: The Price of Prop 12*, YOUTUBE (Mar. 2, 2022), https://www.youtube.com/watch?v=jdRtnJDS6zw&list=PLvTM5d7T5l6mUXIEh8XF7pMFRMARFwwjB&index=27.

[147] *See* Jim Wiesemeyer, *California Proposition 12 Took Effect Jan. 1, But Supreme Court Action Ahead*, PORK BUS. (Jan. 2, 2022), https://www.porkbusiness.com/news/ag-policy/california-proposition-12-took-effect-jan-1-supreme-court-action-ahead.

California separate from pork for the national market, as well as compliance with labeling and packaging.[148]

While these queries remain pending, others continue to question if these measures are worth the cost.[149] If Proposition 12 will indeed force compliance with pork producers nationwide, the costs to infrastructure improvement will be significant, and will likely be passed on to consumers.[150] Even if industry can segregate pigs destined for California, the state is still looking at a $320M economic loss for what is to some a minimal animal welfare improvement.[151] PETA notably did not support Proposition 12, believing that it did not go far enough to end animal suffering.[152] There are inherent limitations to allowing natural animal behavior in a system that still considers the creatures to be commodities, and the balance between safety in the name of animal welfare versus safety for the sake of efficiency is difficult to find.

Perhaps the most legally pressing concern voiced by the NPPC is that the California Department of Food and Agriculture (CDFA) has yet to promulgate regulations defining the scope of the products and transactions covered by the law, including certification schemes, recordkeeping and documentation, and registration requirements.[153] Producers are concerned that even if they are able and willing to make infrastructure investments, they lack direction on what the regulations will require.[154] Massachusetts is facing a similar quagmire. In late 2021, Massachusetts Gov. Charlie Baker signed Question 3 into law.[155] At the same time, however, the governor signed S-2603, which delayed the implementation of Question 3 until August 15, 2022.[156] Lawmakers claimed that the delay was necessary to avoid an egg and pork shortage and a spike in prices for both, while animal advocates such as the Humane

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[148] *See id.*
[149] *See generally* Reiman, *supra* note 13, at 2.
[150] Torella, *supra* note 130, at 17.
[151] Hoffman, *supra* note 136, at 18.
[152] Reiman, *supra* note 13, at 2.
[153] Wiesemeyer, *supra* note 147, at 19.
[154] *See generally* Daly, *supra* note 140, at 18.
[155] *Massachusetts Delays Effective Date of Question 3*, NAT'L PORK PRODUCERS COUNS. (Dec. 22, 2022), https://nppc.org/massachusetts-delays-effective-date-of-question-3/.
[156] *Id.* (Additionally, the state's Department of Agricultural Resources is compelled to consult with the state's attorney general to write rules and regulations for the law by mid-2022).

Farming Association argued that the law violates the will of the voters and bows to business interests.[157]

The change in the law highlights the challenges and difference of voter initiatives. Unlike in California, the Massachusetts legislature can adapt the text of Question 3 to accommodate what some see as a logistical issue.[158] This begs the question, to what extent can the legislature adjust the law? At what point does altering a law to ease transition, or to reflect changes in best scientific practices, represent an unlawful change to the will of the people, or a practical application of their intent?[159]

VII. Challenging the Commerce Clause

Outside of the questions regarding regulations and economic impact, the largest question surrounding the welfare initiatives is whether they unconstitutionally violated the Commerce Clause.[160] Several detractors of Proposition 12 claim that the law violates the Dormant Commerce Clause because it disrupts interstate trade by forcing out-of-state producers to change their operations – in essence, that California law is unconstitutionally controlling industry in other states.[161] Protectionist measures, such as laws that attempt to help in-state business at the expense of interstate commerce, are

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[157] Chris Lisinski, *Mass. Legislature passes animal welfare law changes, set to ease egg supply fears,* GBH (Dec. 20, 2021), https://www.wgbh.org/news/politics/2021/12/20/mass-legislature-passes-animal-welfare-law-changes-set-to-ease-egg-supply-fears.

[158] *Laws Governing the Initiative Process in Massachusetts*, BALLOTPEDIA, https://ballotpedia.org/Laws_governing_the_initiative_process_in_Massachusetts (last visited Oct. 16, 2022).

[159] Consider that voters approved a measure requiring chickens and pigs to be allowed to freely turn around and have certain enrichments. In the original ballot question, this meant 1.5 square feet of "usable floor space" per hen. Advocates from both sides of the debate, however, believe that industry practices have changed in recent years. Several egg producers now use confinement measures for hens that have an aviary system, which allows more vertical space, but reduces floor space to one square foot. Would such a system still be within the intent of the law? Depending on the state and statute, some flexibility in lawmaking may be advantageous. *See,* Sarah J. Morath, *Private Governance and Animal Welfare*, 9 GEO. WASH. J. ENERGY & ENVTL. L. 21, 24, 31 (2018).

[160] As the rulings to the challenges to all three measures are somewhat similar, for brevity the focus will be on challenges to Proposition 12, as it is more timely.

[161] The Dormant Commerce Clause does not actually appear in the text of the Constitution but has long been inferred from the Commerce Clause. Simply stated, while the Commerce Clause positively grants Congress the power to regulate commerce, the Dormant Commerce Clause negatively restricts states from passing laws that grant protection or advantage to in-state producers, and from laws that discriminate or unlawfully burden interstate or international commerce. *See*, e.g. Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970); U.S. CONST. art. 1, § 8, cl. 1.

generally prohibited by the Dormant Commerce Clause.[162] Conversely, states are permitted to pass laws that promote health and safety of its citizens under its police powers that only incidentally impact interstate commerce.[163] Generally, states will permit a law that "regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental ... unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits."[164]

It is against this backdrop that the Ninth Circuit denied industry's challenge against Proposition 12. In *Nat'l Pork Producers Council v. Ross*,[165] the NPPC and American Farm Bureau Federation argued that because California does not produce nearly as much pork as it consumes, the impact of this law falls unfairly on out of state producers trying to sell in California.[166] The Ninth Circuit held that although Proposition 12 would have an impact on a national industry, such impact did not render California's law impermissibly extraterritorial.[167] Most critically, the court held that the cost increases to the market and customers were not a substantial burden to interstate commerce, and thus are not impermissible under the Dormant Commerce Clause:[168]

> Even if producers will need to adopt a more costly method of production to comply with Proposition 12, such increased costs do not constitute a substantial burden on interstate commerce. . . Nor do higher costs to consumers

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[162] *Id.*

[163] Jessica Berch, *If You Don't Have a Cow (or Chicken or Pig), You Can't Call It Meat: Weaponizing the Dormant Commerce Clause to Strike Down Anti-Animal-Welfare Legislation*. 21 UTAH L. REV. 73, 79 (2021).

[164] Pike, 397 U.S. at 142; Berch, *supra* note 163 at 82. (Laws that neutrally apply to a state purpose, such as health, are reviewed under a rational-basis scrutiny, whereas anti-protectionist laws must be reviewed under strict scrutiny. "Because of the interconnected web of commerce, many state laws - maybe most or even all - affect interstate markets in some manner, and so in assessing whether strict scrutiny or lenient balancing applies, courts consider both the effect of the law (whether the law discriminates against out-of-state business in favor of in-state interests) and its purpose (the reasons prompting the enacting state to pass the law)").

[165] Nat'l Pork Producers Council v. Ross, 6 F.4th 1021, 1025-1026, (9th Cir. 2021).

[166] Allysia Finley, *California Is Making Bacon More Expensive*, THE WALL ST. J., Dec. 30, 2021. (Californians consume approximately 13% of nationwide pork production, while California itself only produces 0.1% of U.S. pork products.); CAL. DEP'T OF FOOD & AGRIC., *California Agricultural Statistics Review 2019-2020* (Sept. 21, 2022) (California's hog and pig production is valued near $30,000,000 annually. Comparatively, the value of its cattle production, which is its largest agricultural product, is almost 100 times larger).

[167] Nat'l Pork Producers Council, 6 F.4th at 1031-1032, (2021).

[168] *Id.*

> qualify as a substantial burden on interstate commerce. . . Even though the Council has plausibly alleged that Proposition 12 will have dramatic upstream effects and require pervasive changes to the pork production industry nationwide, it has not stated a violation of the dormant Commerce Clause under our existing precedent.[169]

In late March 2022, the Supreme Court granted the petition of certiorari to review the Ninth Circuit's decision.[170]

VIII. Ballot Initiatives and the Democratic Process

As farm animal welfare advocates have increased their use of ballot initiatives in recent years, their industry opponents have been just as savvy navigating the legal landscape.[171] As organizations like HSUS declare victory at the polls in California and Massachusetts, more traditionally conservative states have pushed to restrict the ability of national NGOs to effect agricultural change using the same tactics that produced Proposition 12.[172] States have wrestled with restrictions on ballot initiatives, though the types of restrictions and reasonings vary depending on the state or reviewing circuit court. Though ballot restrictions are not exclusive to debates over farm animal welfare, the probability of such reactions in this realm loom, and could increase to counter animal welfare successes.

Returning to the Bay State, Massachusetts restricts ballot initiatives in several arenas deemed too critical to be influenced by public referendum, with the majority of these restrictions applying to certain crucial government functions.[173] Massachusetts's ability to

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[169] *Id.* at 1033-34.

[170] David G. Savage, *Supreme Court agrees to hear pork producers' challenge to California animal anti-cruelty law*, L.A. TIMES, March 28, 2022.

[171] *See, e.g.*, Initiative & Referendum Inst. v. Walker, 450 F. 3d 1082, at 1085 (10th Cir., 2006).

[172] *Id.*; Idaho recently attempted to restrict the ability to bring ballot initiatives under Senate Bill 1110, which would have required signatures from 6% of voters in all thirty-five legislative districts to bring a matter to the ballot; the bill was ultimately struck down as unconstitutional by the Idaho Supreme Court, but clearly states are reacting. *See*, Clark Corbin*, Idaho Supreme Court Says New Ballot Initiative Law Violates State Constitution*, IDAHO CAP. SUN, Aug. 23, 2021.

[173] MASS. CONST . art. 48 pt. 1 ("Legislative power shall continue to be vested in the general court; but the people reserve to themselves the popular initiative. . . and the popular referendum."); However, Sec. 2 prohibits referendums from matters related to religion, judicial appointments and removals, judicial decisions, specific appropriation of state money, and further prohibits referendum petition that is "inconsistent" with several basic rights, such as freedom of speech, freedom of

restrict types of ballot initiatives was challenged in *Wirzburger v. Galvin*, wherein a citizen group pushed to amend the state constitution via ballot initiative to allow public funds to be used for private, religiously affiliated schools.[174] Article 48 of the Massachusetts Constitution prevented such an initiative under the Anti-Aid and Religious Exclusions; the amendment was denied in the district court, and an appeal followed, wherein the First Circuit ultimately upheld the Anti-Aid and Religious Exclusions under the 14th Amendment.[175]

Addressing the concept of ballot initiatives broadly, the First Circuit held that "the primary goal of state initiative procedures is to create an avenue of direct democracy whereby citizens can participate in the generation of legislation--that is, the act of creating law," and that restricting certain matters from the initiative process does not unjustly target particular speech.[176] The circuit court elaborated, stating there is "no constitutional principle that prevents a state from determining that sensitive measures that relate to religion, religious practices, or religious institutions should not be made or initiated by the public initiative process but rather only via the legislature."[177] Applying the First Circuit's reasoning to the use of ballot initiatives in agriculture, *Wirzburger* serves as precedent that a state can keep certain issues deemed too "sensitive" off of the ballot.[178]

Other circuit courts have permitted states to remove or limit certain topics from being the subject of ballot initiatives. In *Initiative & Referendum Inst. v. Walker*, Utah amended its constitution to prevent wildlife advocates from pushing through initiatives that limited the right to hunt certain animals.[179] Ballot initiatives had been increasingly used by environmental groups in the 1990s, particularly in western states to ban hunting of certain animals, and wildlife advocates looked to use the ballot again to bypass an unfriendly Utah

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elections, freedom of the press, the right to peaceable assembly, unreasonable searches, and due process in property taking. MASS. CONST. amend. art. 48 pt. 2, § 2.

[174] Wirzburger v. Galvin, 412 F.3d 271, at 274 (1st Cir. 2005).

[175] *Id.* at 285 (finding that the exclusions did not discriminate on the basis of religious belief or status, and found that the exclusions were narrowly drawn to further a significant state interest (ensuring the Establishment Clause).).

[176] *Id*. at 277.

[177] *Id.* at 284.

[178] Although it should be noted that here the court was reviewing a "fundamental right" in religion, whereas animal welfare and farming, while both crucial, likely will not ever rise to the level of "fundamental rights." *See id.*

[179] *See, e.g.*, Initiative & Referendum Inst. v. Walker, 450 F. 3d 1082, at 1085 (10th Cir., 2006).

legislature to further more regulations.[180] Before any such measure could be presented on a ballot, hunting and fishing advocates were able to pass their own initiative, Proposition 5, which amended the Utah Constitution to require a two-thirds majority for any future ballot initiatives involving the taking of wildlife.[181] The measure passed with 58% of the vote, ironically a lower majority than what the amendment requires for the actions it limits, under the justification that it protected Utah from "East Coast interest groups."[182]

Following this amendment, wildlife advocates sued, claiming that the new amendment imposed a "chilling effect" on its First Amendment right to free speech.[183] Ultimately the 10th Circuit rejected the First Amendment argument, holding that while requesting signatures on an initiative petition involves "core political speech," and is thus subject to "exacting scrutiny," the First Amendment only protects political speech incident to an initiative campaign, not the right to make a law itself via a ballot initiative.[184] The Tenth Circuit held that a heightened requirement to pass certain ballot initiatives does not silence or restrict the speech itself, and was only a regulation of the legislative process.[185]

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[180] J. Michael Connelly, *Loading the Dice in Direct Democracy: The Constitutionality of Content – and Viewpoint-Based Regulations of Ballot Initiatives*, 64 N.Y.U. ANN. SURV. AM. L. 129, 129 (2008).

[181] *Id*;. *See* UTAH CONST. art. VI, §1(2)(a) (While the Utah Constitution provides that ballot measures may be passed simply by a majority vote, Proposition 5 added the following language: "Notwithstanding Subsection (2)(a)(i)(A), legislation initiated to allow, limit, or prohibit the taking of wildlife or the season for or method of taking wildlife shall be adopted upon approval of two-thirds of those voting.").

[182] One hunting advocate lamented that "radical groups, once they get an issue on the ballot, use emotional TV spots, such as showing an animal caught in a foot trap, to take management of wildlife away from professional state wildlife officials who use science in their work," illustrating the frustration either side of a debate feels when opposing groups are able to push through disagreeable laws. Connelly, *supra* note 180.

[183] Walker, 450 F.3d at 1086.

[184] *Id.* at 1099.

[185] The Tenth Circuit had previously ruled that abortion rights could be removed as a ballot initiative question without violating the First Amendment. *See* Skrzypczack v. Kauger, 92 F.3d 1050, 1053 (10th Cir. 1996) ("Removing [the proposal] from the ballot. . . has not prevented [the voter] from speaking on any subject. She is free to argue against legalized abortion, to contend that pre-submission content review of initiative petitions is unconstitutional, or to speak publicly on any other issue. . . moreover, she cites no law, and we find none, establishing a right to have a particular proposition on the ballot."); It is unclear how the court reasoned that a pre-submission content review might be unconstitutional, but did not find an amendment requiring a supermajority to pass laws regarding a specific issue to be content-based pre-screening. *See generally* Walker, 450 F.3d 1082.

The Tenth Circuit also drew upon a similar ruling involving a First Amendment challenge to the Barr Amendment, a federal law barring voters in the District of Columbia from passing a ballot initiative to legalize or reduce penalties associated with the possession of marijuana.[186] The D.C. Circuit found that the Barr Amendment did not infringe upon the First Amendment as it did not prohibit "speech necessary to the proper functioning" of legislation, but simply removed a subject from being discussed in that process.[187] The concern with the Tenth Circuit's reasoning is that it effectively created a viewpoint-based regulation, potentially affecting freedom of speech to debate certain topics in the political sphere; "In this sense, a viewpoint-based regulation of a ballot initiative can decrease one group's total quantity of available core political speech relative to a group on the opposite side of an issue."[188] Judge Lucreo, writing the dissent in Walker, stated, "Given that election campaigns are necessarily conducted through the medium of speech, it is no more than foolhardy formalism to say that election laws that rig the outcome of elections do not infringe on speech rights."[189]

Nationally the circuit courts are split regarding how to assess ballot restrictions in relations to the First Amendment, an issue that the U.S. Supreme Court has recently noted, but not yet addressed.[190] Yet based on the Supreme Court's brief acknowledgement of the divide, it seems that ballot restrictions will be permitted to stand, at least for the present. As such, animal welfare advocates would do well to note the Walker decision, and bear in mind that ballot initiatives and restrictions can easily swing against them.

Indeed, ballot initiatives are not restricted to interest groups attempting to work around an unfavorable legislature. In 2016, the

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[186] Marijuana Policy Project v. United States, 304 F.3d 82, 87 (D.C. Cir. 2002).
[187] *Id.* at 87.
[188] Connelly, *supra* note 180, at 155.
[189] Walker, 450 F.3d at 1112 (Lucero, J., dissenting).
[190] *See* Little v. Reclaim Idaho, 140 S.Ct. 2616, 2616 (mem.) (2020) ("Yet the Circuits diverge in fundamental respects when presented with challenges to the sort of state laws at issue here. According to the Sixth and Ninth Circuits, the First Amendment requires scrutiny of the interests of the State whenever a neutral, procedural regulation inhibits a person's ability to place an initiative on the ballot. See Thompson v. DeWine, 959 F.3d 804, 808 (C.A.6 2020) (*per curiam*); Angle v. Miller, 673 F.3d 1122, 1133 (C.A.9 2012). Other Circuits, by contrast, have held that regulations that may make the initiative process more challenging do not implicate the First Amendment so long as the State does not restrict political discussion or petition circulation. See, *e.g.,* Jones v. Markiewicz-Qualkinbush, 892 F.3d 935, 938 (C.A.7 2018); Initiative and Referendum Institute v. Walker, 450 F.3d 1082, 1099-1100 (C.A. 10 2006) (en banc); Dobrovolny v. Moore, 126 F.3d 1111, 1113 (C.A.8 1997).")

Oklahoma legislature itself placed Question 777 on the ballot.[191] The design of the proposed law was to require courts to find a compelling state interest to justify any law that regulated farming and agriculture passed after the end of 2014.[192] Supporters of the ballot believed that farmers needed the measure to protect themselves against laws that would harm the industry, while opponents countered that Question 777 would prevent the government from passing laws to protect small farmers and prevent against animal cruelty.[193] Ultimately, the measure was defeated, 60%-40%,[194] but that it reached the ballot in the first place further demonstrates the mercurial nature of relying on ballot initiatives for animal welfare reform.

IX. The Forgotten Farmers

Back in 2008, both industry and animal welfare advocates debated the merits of Proposition 2.[195] HSUS characterized the measure as preventing animal cruelty, promoting food safety, protecting the environment, and perhaps confusingly, supporting family farmers.[196] HSUS described family farmers as supporting Proposition 2 because "they believe food quality and safety are enhanced by better farming practices. Increasingly, they're supplying mainstream retailers like Safeway and Burger King. Factory farms cut corners and drive family farmers out of business when they put profits ahead of animal welfare and our health."[197] Arguments against Proposition 2 also centered on food safety, highlighting the risk of disease for birds with unnecessary outdoor access, economic loss to California, and the potential of increase

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[191] *Oklahoma Right to Farm Amendment, State Question 777 (2016)*, BALLOTPEDIA, https://ballotpedia.org/Oklahoma_Right_to_Farm_Amendment,_State_Question_777_(2016) (last visited Oct. 16, 2022).

[192] The intended effect was to restrict laws attempting to regulate the farming industry, and would have made future challenges to animal management practices difficult. *Id*.

[193] *Id.* (Article II of the Oklahoman constitution would have been amended to read: "To protect agriculture as a vital sector of Oklahoma's economy, which provides food, energy, health benefits, and security and is the foundation and stabilizing force of Oklahoma's economy, the right so citizens and lawful residents of Oklahoma to engage in farming and ranching practices shall be forever guaranteed in this state. The Legislature shall pass no law which abridges the right of citizens and lawful residents of Oklahoma to employ agricultural technology and livestock production and ranching practices without a compelling state interest.").

[194] *Id*.

[195] UC Hastings Coll. of L., *supra* note 10.

[196] *Id.*

[197] *Id.*

prices for consumers if producers were forced to incorporate infrastructure change.[198]

As the developer of the measure, it is understandable that HSUS would characterize Proposition 2 as a victory for independent farmers as well as animal welfare. Its argument, however, is reductionist and ignores the complexity of modern contract farming. While there are certainly independent producers that sell their own eggs, most are beholden to the production contracts that pit farmers against each other.[199] To portray the difficulties in animal welfare as a fight between "family farmers" and "factory farms" creates a false dichotomy. The truth of the matter, as is often the case, lies somewhere between the two sides, and is contingent on our priorities.

Advocates of the industrial model and cheap food are correct in concluding that any requirements to infrastructure overhaul will have an economic impact.[200] If our priority is affordable, readily available eggs and bacon, then initiatives like Proposition 2 do pose a threat to cheap food.[201] On the other hand, humans directed chicken into domestication and mass production not for the birds' benefit, but so they might be commodities.[202] If we prioritize welfare, then it is common sense to increase the size of cages, provide animals with enrichment, allow them to exhibit natural behaviors and have access to the outdoors, and at least attempt to decrease their suffering before they are slaughtered or age out from a lifetime of laying.[203] Sows, similarly, have an unenviable life of insemination, confinement, birth, and repetition.[204]

Of course, if the goal is to produce as many animals for market as possible, concentrated confinement make economic sense; the more room you provide for your animals, the less of them you

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[198] *Id.*

[199] *See*, Hamilton, *supra* note 17, at 84.

[200] *See*, Heng, *supra* note 81 (Higher efficiency involves management practices that protect hens, such as cutting beaks and isolating the birds from outdoor predators and disease. These measures, however, are largely viewed as cruel and brutal by the public, regardless of how effective they are).

[201] *Id.*

[202] *See*, Greger Larson & Dorian Q. Fuller, *The Evolution of Animal Domestication*, 45 ANN. REV. OF ECOLOGY, EVOLUTION, & SYSTEMATICS, 2014 at 115.

[203] Yet allowing hens unfettered outdoor access has been linked to higher amounts of environmental damage, such as more air and water pollution, and increased feed requirements, as opposed to battery-raised hens. While environmental and welfare concerns are often linked in consumers' minds, this may be an area of conflict between those two priorities. *See*, Heng, *supra* note 81.

[204] Gaveric Matheny & Cheryl Leahy, *Farm-Animal Welfare, Legislation, and Trade*, 70 L. & CONTEMP. PROBS. 325 (2007).

can have, and the higher the risk of damage or death happening to the pigs or piglets.[205] Herein lies the tension. While incremental increases to confinement spaces and added enrichments make animal advocates feel better, believing that something is better than nothing, they are still operating within a massive capitalist machine that legally considers these animals commodities whose ultimate value is related to how much food they can produce for consumption. While consumers show interest in animals that are treated better, the majority still want affordable, convenient food, and that balance is difficult to maintain.[206]

Independent farmers are problematically caught between both sides of this debate. Farming is a precarious enterprise even under optimal conditions (and conditions are seldom optimal).[207] Our modern farming system requires substantial infrastructure investments and externalized costs, and most farmers are deeply in debt and rely on a secondary source of income,[208] making the economic incentives to maximize profits not only desirable, but necessary. Changing the confinement requirements for layers and sows requires greater investments, and there is a divide between the cost of overhaul, the amount of pigs and chickens that can be raised with new space requirements, and what integrators are willing to pay.[209] One Iowan farmer estimates that to come into compliance with Proposition 12, he would need to invest $3M, and the changes would reduce his space to hold 250 pigs, down from 300.[210] To make up the difference, he would need an extra $20 per pig, a price that processors are not offering.[211] How do we balance animal welfare against farmers' livelihoods? Where do we draw the line between reforming a broken system that millions of people rely on, and rejecting it holistically because it cannot, by its nature, protect the welfare of the animals it is designed to kill? What is the cost of compassion?

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[205] *See*, Wiesemeyer, *supra* note 147.
[206] *See*, ASPCA, *supra* note 80.
[207] *See generally*, Khan, *supra* note 27.
[208] *Most farmers receive off-farm income, but small-scale operators depend on it*, U.S. DEP'T OF AGRIC. (Dec. 1, 2021), https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=58426.
[209] Scott McFetridge, *Bacon may disappear in California as pig rules take effect,* ASSOCIATED PRESS, (July 31, 2021), https://www.legalbluebook.com/bluebook/v21/rules/18-the-internet-electronic-media-and-other-nonprint-resources/18-2-the-internet#b-320154.
[210] *Id.*
[211] *Id.*

CAFOs are better equipped to absorb these costs, whereas an independent farmer may find adapting cost prohibitive.[212] Welfare measures, however, apply equally to all farmers, with no exceptions based on size or income. In the poultry industry, integrators control the purchase of birds and eggs, and affect the ultimate sale.[213] As discussed, the trend over the last forty years has been a dramatic decrease in farmers and farmland while animal production has skyrocketed. Additional welfare requirements may prove to be another nail in the coffin of independent farming, as the California voter guides warned. Ironically, while this achieves the heighten welfare that federal law has so long denied farm animals, it may be at the cost of independent farmers, which will further centralize the industry into megacorporations and CAFOs, a trend that has led to the lack of animal welfare that these measures are trying to provide.[214]

X. The Road Goes Ever On

To believe we are trapped in an unsustainable agricultural system is overly pessimistic and likely false. American agriculture has seen several revolutions in the past century,[215] and to assume it will not change again is shortsighted. Still, we find ourselves today in a system that is environmentally unsustainable and problematic. Shortcuts have been taken in the name of abundance, and while affordable food is fantastic, it cannot fly in the face of our future. American animal production in the 21st century is controlled by a powerful few companies, and farming has changed from a marriage with the land into yet another industrial arm of the capitalist machine. Farmer have become cogs, their actions dictated by contracts designed to keep them competing with each other for small capital increases, most of them not making enough to survive on farming alone.

Adding to the complications of this exploitative system is that the commodities being traded are living animals who deserve, at the bare minimum, certain welfare guarantees. Farm animal

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[212] *See*, Hamilton, *supra* note 34.
[213] *See*, *supra* Part II.
[214] Wiesemeyer, *supra* note 147 (Per American Farm Bureau Federation President Zippy Duvall, "small family farms well beyond California's boarders will be hit hardest as they are forced to make expensive and unnecessary changes to their operations. This will lead to more consolidation in the pork industry and higher prices at the grocery store, meaning every family in America will ultimately pay the price for Prop 12.").
[215] *See, e.g.*, Jim Chen, *Of Agriculture's First Disobedience and Its Fruit*, 48 VAND. L. REV. 1261 (1995).

advocates fight for small, but significant, increases in the welfare of the creatures fueling this enterprise. With federal and state laws mostly heeding to industry that would rather not endure laws that slow down efficiency, advocates have turned to ballot initiatives, asking voters to directly push for welfare reform in specific states, particularly in California and Massachusetts. While Propositions 2, 12, and Question 3 have been landmark results, their success has brought considerable scrutiny, and may paradoxically pave the way for ballot initiatives that shut down welfare reform, or call into question the constitutionally of the entire system. Lost is all of this are the farmers who are stuck in a production contract system that has only gotten worse in the last few decades.

While welfare advocates should not retreat from ballot initiatives, these measures need to consider the difficulties facing farmers. Historically progress is never equally realized if all stakeholders do not have a seat at the table, and the economic reality of independent farmers needs to be addressed, lest the solution becomes more difficult than the problem it attempts to solve. Animal welfare advocates need to continue to do what often seems monumental in modern politics and reach across the aisle. In this instance, that means recognizing potential allies in independent farmers who may well want to ensure farm animal welfare and return to better stewardship relationship between animals and nature, but who are unable to see a path to do so. While some welfare advocates may bristle at the compromise of not realizing a world without animal exploitation, such conversations are crucial; our modern farming system is not going to be tossed aside at once, lest we throw out the hog with the hogwash. The achievable goal of both advocates and independent farmers is the dissolution of the conglomerated industrial system that has evolved throughout the 20th century. The recent overtures from the Biden Administration are encouraging and necessary, hopefully harbingers of real change in American agriculture. Rather than watching the pin-pong of issues being raised in various ballot initiatives throughout the states, advocates and farmers should focus on overhauling the economic hold industry has placed on the nation. Through that avenue, we can find a road down which both animals and farmers can thrive.

Federal Food Safety Framework: Where does Seaweed Fit in?

Catherine M. Janasie*

I. Introduction

When one mentions seaweed as food, what do you think of? The dried nori used to wrap your sushi roll or perhaps the seaweed salad on the side? In fact, seaweed has many uses, including as both a food source in its own right and as a food additive. A quick Google search of "seaweed as a food source" generates a multitude of results touting seaweed's nutritional benefits and many claiming that it is a food of the future. While the seaweed market has been dominated by East Asian countries, seaweed is cultivated in about 50 countries, and the U.S. seaweed industry is steadily growing.[1] The global seaweed industry is currently worth about $6 billion annually.[2] Food products for human consumption account for about 85% of this value.[3]

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[1] FOOD AND AGRIC. ORG., REPORT OF THE EXPERT MEETING ON FOOD SAFETY FOR SEAWEED 6 &10 (2021), https://www.fao.org/3/cc0846en/cc0846en.pdf [hereafter *FAO Report*].

[2] Fatima Ferdouse et al., *The Global Status of Seaweed Production, Trade, and Utilization*, FAO GLOBEFISH RSCH. PROGRAMME 1 (2018), https://www.fao.org/3/ca1121en/CA1121EN.pdf.

[3] *Id.* at 1-2.

Seaweed can either be wild harvested or cultivated at an aquaculture farm.[4] In the United States, seaweed is produced on both the East and West coasts and in Hawaii and Alaska. Maine and Alaska currently lead production in the U.S. Seaweed farmers in Maine harvested 500,000 lbs of seaweed in 2020, and there are over 30 active seaweed farms in the state.[5] Maine is also a leader in wild harvest, where the industry harvested over 16 million lbs in 2020. In Alaska, seaweed farms sold 536,390 lbs of seaweed in 2021, which is over double the amount of 231,015 lbs sold in 2020.[6] Alaska is also a good example of the types of seaweed operations that exist in the United States. Of its active farms in 2021, there were 5 seaweed only farms and 14 multi-trophic farms growing both shellfish and seaweed.[7]

Seaweed operations in other states also help to show the diversity of businesses in the United States. Washington, Oregon, and California all have land-based, tank culture operations, though in 2021 Blue Dot Sea Farms became the first open-water, commercial seaweed farm in Washington in 30 years.[8] New Hampshire, Massachusetts, Rhode Island, and Connecticut all have multiple permitted seaweed farms, and New York has a couple of research sites. However, due to a lack of processing facilities in these states, the seaweed produced is often sold raw or dried to restaurants or consumers, or to processors in other states.[9]

Maine and Alaska provide examples of the wide variety of processed seaweed food products produced in the United States, such as seaweed salsas, hot sauces, kimchi, snack bars, teas and smoothie cubes, and spice mixes. Other examples of processed foods include seaweed farmers in New Hampshire selling some of their harvested seaweed to breweries to create

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[4] *See Id.*
[5] Jaclyn Robidoux & Meg Chadsey, *State of the States: Status of U.S. Seaweed Aquaculture*, SEA GRANT (Mar. 29, 2022), https-seaweedhub-org-wp-content-uploads-2022-03-state-of-the-states_forposting_mar2022-1-pdf/.
[6] *Id.*
[7] *Id.* (A total of 11 seaweed-only farms have been issued permits by the state, and 17 multi-trophic farms have been permitted).
[8] *Id.*
[9] *Id.*

kelp beer, while seaweed from a Washington state farm is used to make Seacharrones[10], a vegan kelp snack puff.[11]

While the U.S. seaweed industry continues to grow, so do concerns about seaweed food safety. In 2016, a Salmonella outbreak was linked to seaweed from a farm in Oahu, Hawaii.[12] Researchers in New England are studying how to reduce pathogens in seaweed by using different drying and storage methods.[13] A recent literature review identified some potential food safety hazards, such as arsenic, iodine, heavy metals like lead, cadmium, and mercury, and biological hazards like pathogenic bacteria and viruses.[14] The species of seaweed, water quality, and harvesting, storage, processing, and transportation methods can all affect the food safety concerns in a batch of harvested seaweed.

Food safety risks necessarily raised the need for regulation to prevent food-borne illnesses. But from a regulatory standpoint, what is seaweed? Scientifically speaking, it is macroalgae that are classified into three major groups: brown algae (*Phaeophyceae*), green algae (*Chlorophyta*), and red algae (*Rhodophyta*).[15] Legally, it is unclear. Legal definitions do not always track scientific ones. For instance, the U.S. Supreme Court once ruled that a tomato could be treated as a vegetable for regulatory purposes, even though scientifically it is a fruit.[16] Seaweed is not a plant in biological terms, but at least one state defines seaweed as a "marine aquatic plant."[17] Further, while the Food and Drug Administration (FDA) does not consider seaweed to be a

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[10] For more information on this packaged snack, visit the Seacharrones website. SEACHARRONES, https://www.seacharrones.com/ (last visited Oct 24, 2022).
[11] Robidoux & Chadsey, *supra* note 5 .
[12] *Salmonella Outbreak in Hawaii Linked to Seaweed in Raw Fish,* FOOD SAFETY NEWS (Nov. 8, 2016), https://www.foodsafetynews.com/2016/11/salmonella-outbreak-in-hawaii-linked-to-seaweed-in-raw-fish/.
[13] *More Food Uses for Seaweed Sparks Food Safety Research*, FOOD SAFETRY NEWS (June 2, 2022), https://www.foodsafetynews.com/2022/06/more-food-uses-for-seaweed-sparks-food-safety-research/.
[14] J.L. Banach et al., *Seaweed Value Chain Stakeholder Perspectives for Food and Environmental Safety Hazards*, 11 FOODS 1514 (May 23, 2022), https://www.mdpi.com/2304-8158/11/10/1514/htm.
[15] FAO Report, *supra* note 1 at 1-4.
[16] Nix v. Hedden, 149 U.S. 304, 307 (1893).
[17] WASH. REV. CODE § 79.135.400 (1993).

"plant" or "produce,"[18] the U.S. Department of Agriculture (USDA) has referred to seaweed as an aquatic plant.[19]

With respect to food safety, there is no federal definition directly related to seaweed. Seaweed does not clearly fit into the FDA's definition of "fish or fishery product," which would subject it to Seafood Hazard Analysis and Critical Control Points (HACCP) requirements, or the definition of produce, which would subject it to the Produce Safety Rule. Seaweed clearly is not a shellfish, but the National Shellfish Sanitation Program could be a potential model in considering the health risks of seaweed related to water quality and cultivating, harvesting, processing, shipping, or handling of seaweed products.

Even if seaweed does not fit neatly into the definition of fish, produce, or shellfish, it can be classified generally as food. On the federal level, all food for human consumption is subject to the Federal Food, Drug, and Cosmetic Act (FDCA), including the prohibition on introducing adulterated food into interstate commerce.[20] The adulterated food prohibition applies to harvested seaweed intended for consumption as food, including that it not be "prepared, packed, or held under insanitary conditions."[21]

In February 2021, the FDA, in a response to a request from the Association of Food & Drug Officials, stated that harvested seaweed is a raw agricultural commodity.[22] Like other raw agricultural commodities, the FDA therefore considers the growing and harvesting of seaweed to be "farm" activities.[23] This distinction is important because activities that

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[18] Emanuel Hignutt, Jr., Off. of Food Safety, FDA Ctr. for Food Safety and Applied Nutrition, FSMA Preventive Controls for Human Foods (PCHF) with Emphasis on Seaweed, NSGLC Seaweed Food Safety Webinar Series: Federal Considerations (Aug. 27, 2020).

[19] USDA NAT'L ORGANIC PROGRAM, USDA NOP 5027, GUIDANCE: THE USE OF KELP IN ORGANIC LIVESTOCK FEED (2013) (stating that "[s]eaweeds are simple, saltwater-dwelling algae that can be referred to as aquatic plants).

[20] 12 U.S.C. § 321(f).

[21] 21 U.S.C. § 342(a)(4).

[22] Email on file with author. The FDCA defines a raw agricultural commodity as "any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing." 21 U.S.C. § 321(r).

[23] 21 U.S.C. § 321.

fit within FDA's definition of a "farm" are not considered food processing that would be subject to further requirements besides the adulteration prohibition mentioned above.[24] Some activities that may be thought of as processing can still fall within the farm definition, such as drying.[25] If an operation goes beyond harvesting and drying, such as by blanching, freezing, or cutting the seaweed, it would be considered a "food facility."[26]

Under the Food Safety Modernization Act (FSMA), certain food facilities need to register with the FDA and are subject to 21 CFR Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Rule.[27] However, due to certain exemptions to these requirements, few seaweed operations in the United States are subject to the full requirements of Part 117.[28] For instance, businesses that sell only raw seaweed are completely exempt, while those businesses with less than $1 million in sales a year are exempt from the Preventive Controls requirements.[29]

Further, while the FDA has wide authority to regulate food that circulates in interstate commerce, states have the authority to regulate food sold in restaurants and retail stores found within the state. Thus, states have options in deciding how to approach the regulation of seaweed when grown and sold for human food in intrastate sales. However, when developing food safety rules, states often rely on the FDA Food Code, which is a guidance document updated every four years. The most recent version was released in 2017, but it does not address seaweed.[30]

Without federal guidance, states are independently developing regulatory programs to address the emerging industry needs in their states. Rooted in this uncertainty, is the decision state agencies must make regarding whether to

[24] *Id.*
[25] 21 C.F.R. § 1.227.
[26] *Id.*
[27] 21 U.S.C. § 117.3.
[28] *Id.* § 117.5.
[29] *Id.* § 117.3.
[30] FOOD & DRUG ADMIN., FOOD CODE (2017).

regulate seaweed on the state-level as a raw agricultural commodity, seafood (like fish or shellfish), or as a plant. This decision has regulatory implications, as it may affect which governmental entity regulates the seaweed product. Regulatory authority for food safety may be shared or split among several agencies within a state, and, therefore, oversight responsibility for different food categories may fall to different agencies. For example, the Connecticut Department of Agriculture (DOAG), Bureau of Aquaculture regulates kelp intended to be sold as a *raw agricultural commodity* under a *seaweed producer license*.[31] The DOAG also implements the Produce Safety Rule in the state under FSMA. However, the Connecticut Department of Consumer Protection Food and Standards Division (DCP) regulates kelp that is *packaged or processed* under a *food manufacturing license*.[32] Therefore, how and when a state classifies seaweed can drive the regulatory agency in charge of the food source.

As Connecticut shows, states have already taken steps in regulating seaweed as a food source. While Connecticut has chosen to apply Seafood HACCP, Alaska has chosen to regulate seaweed under its general food provisions.[33] These choices have an effect on the relevant state agencies and the regulated community. For instance, Maine takes a mixed approach, with the Maine Department of Marine Resources regulating seaweed as seafood up until the point of harvest and the Maine Department of Agriculture, Conservation and Forestry regulating it as a produce for post-harvest activities, including handling, processing, distribution, and sale.[34] While these choices are not set in stone, experiences with these regulatory models can be useful for states as they collaborate in discussing the next steps forward for seaweed food safety regulation.

The following sections explore the legal framework governing the sale of food products in the United States and how that framework applies to seaweed. Topics covered

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[31] ANOUSHKA CONCEPCION ET AL., SEAWEED PRODUCTION AND PROCESSING IN CONNECTICUT: A GUIDE TO UNDERSTANDING AND CONTROLLING POTENTIAL FOOD SAFETY HAZARDS 12 (Connecticut Sea Grant et al. 2020).
[32] *Id.* at 1.
[33] *See generally* ALASKA ADMIN. CODE tit. 18, §31 (2022).
[34] Private Communication with Maine Sea Grant Staff on file with author.

include the FDA framework for regulating food and FDA's current regulatory standards for seaweed in its use as an additive.

II. The FDA Framework for Regulating Food

States and the federal government have split authority when it comes to regulating food safety. Under the U.S. Constitution, the federal government has the authority to regulate interstate commerce.[35] Known as the Commerce Clause power, this is the legal basis for FDA to regulate food under the FDCA and the FSMA.

A. Federal Food, Drug, and Cosmetic Act (FDCA)

The FDCA prohibits activities involving the movement of adulterated food[36] in interstate commerce. The statute lists the different circumstances where a food could become adulterated.[37] Relevant to seaweed is the category of poisonous or unsanitary ingredients in food, which includes, among other items, the following:

- Poisonous or deleterious substances that make the food injurious to health, though a food is not adulterated if the potentially harmful substance is not added to the food and the amount is not usually injurious to health.

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[35] U.S. CONST. art. 1 § 8, cl. 3.

[36] 21 U.S.C. § 331 (defines food as "means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.").

[37] *Id.* § 342 (Other categories of adulterated food that are not discussed in this paper include color additives that do not meet the standards of the FDCA, confections containing alcohol or nonnutritive substances, oleomargarine that is unfit as food, limits on dietary supplements or ingredients, and certain imported food that does not meet the standards of the FDCA. Additional adulterated food categories include food "(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.").

- Added poisonous or deleterious substance, pesticide chemical residue, unsafe food additives, or new animal drugs that are unsafe under the Act.
- Food that consists in whole or in part of filthy, putrid, or decomposed substances, or is otherwise unfit to be eaten.
- Food that is prepared, packed, or held in conditions where it can become "contaminated with filth" or rendered injurious to health."
- Food that is held in a container that could be injurious to health.[38]

Finally, food is adulterated if it is transported in a way that does not comply with the regulations for sanitary transportation practices, which can be found at 21 CFR Sections 1.900-1.934.[39] This standard could be important when considering the transportation of seaweed from the farm to a farmer's market, restaurant, or similar location.

B. Food Safety Modernization Act (FSMA)

FSMA was enacted in 2011 as a way to strengthen food safety regulation in the United States. The law is structured to prevent food safety issues before they occur, instead of reacting to problems after the fact. New authorities given to the FDA under FSMA include a legislative mandate to prevent food safety issues, mandatory inspection and testing protocols, and enhanced response authority.[40] Under FSMA, the responsible agent of a food processing facility is required to analyze potential hazards and create a written plan that includes preventative control measures for each potential hazard. Since FSMA was enacted, the FDA has finalized seven major rules to implement the Act, including rules related to (1) Good Manufacturing Practice, Hazard Analysis, and Preventive

[38] *Id.* § 342(a)(6).
[39] *Id.* § 342(i).
[40] FDA Food Safety Modernization Act, Pub. L. No. 353.

Controls and (2) Produce Safety, which are discussed in more detail below. [41]

Importantly, FSMA is applicable only to food facilities that "engaged in manufacturing, processing, packing, or holding food for consumption…".[42] The FDA has published detailed definitions for each of these terms in the agency's regulations implementing FSMA.

Manufacturing/Processing: Making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients.

- Examples include: baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, *drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins)*, evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing.
- For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.[43]

Packing: Placing food into a container other than packaging the food. The definition also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)). It

[41] 21 U.S.C. § 321(gg) (the FDCA defines processed food as "any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.").
[42] *See Id.* § 350d.
[43] 21 C.F.R. § 1.227.

does not include activities that transform a raw agricultural commodity into a processed food.[44]

Holding: Storage of food and activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)).[45]

- Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but it does not include activities that transform a raw agricultural commodity into a processed food.
- Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.[46]

Domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States have to register with the FDA.[47] Certain entities are exempt from the facility registration process, including farms, retail food establishments, and restaurants.[48]

C. Current Regulatory FDA Standards for Seaweed

With respect to the sale of seaweed in its whole form as a food product, there are no federal regulations or guidance. There are, however, federal regulations and actions related to other uses of seaweed. The FDA's current regulations apply to seaweed farmers and processors who sell their product for use as a food additive, but the regulations are limited to certain

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[44] *Id.*
[45] *Id.*
[46] *Id.*
[47] *Id.* § 350d.
[48] 21 U.S.C. § 350d.

marine algae species and do not encompass the sale of seaweed in its whole form.[49]

The FDA currently has several regulations controlling the legal consumption of seaweed and kelp products in the United States, but *only* when used in other foods as an additive. A "food additive" legally refers to any substance the intended use of which results or may reasonably be expected to result—directly or indirectly—in its becoming a component or otherwise affecting the characteristics of any food.[50] Food additives are subject to FDA's premarket review and approval, unless the substance is given a "generally recognized as safe" (GRAS) designation.[51]

The FDA has made a GRAS determination for certain seaweeds when they are used as additives.[52] The FDA has set forth maximum daily amounts of kelp additive (including Giant Kelp (*Macrosystis pyrifera*), Oarweed (*Laminaria digitata*), and Sugar Kelp (*Saccharina latissima*)) that certain subsets of people should be able to ingest without consuming too much iodine. For most people, the daily amount is 225 micrograms.[53] For infants, the maximum amount is 45 micrograms, while the limit for pregnant or lactating women is 300 micrograms. Additionally, the agency notes that its GRAS determination and regulations apply generally to certain species of dehydrated, ground kelp, including giant kelp, oarweed, sugar kelp, and cuvie (*Laminaria cloustoni*).[54]

Besides these general regulations, the FDA adopted specific regulations for brown and red algae.[55] These regulations list the names of applicable GRAS species, and note both brown and red algae's functional uses include "flavor enhancer" and "flavor adjuvant."[56] Listed brown and red algae species may be considered GRAS, whether or not they are

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[49] FOOD & DRUG ADMIN., GENERALLY RECOGNIZED AS SAFE (GRAS) (Sept. 6, 2019), https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras.
[50] 21 U.S.C. § 321(s).
[51] FOOD & DRUG ADMIN., *supra* note 49.
[52] 21 C.F.R. § 172.365.
[53] *Id.*
[54] *Id.*
[55] *Id.* §§ 184.1120, 1121.
[56] *Id.*

meant to impart any of their own taste to the food to which they are added. GRAS determinations do not apply to singular products such as kelp or seaweed in its whole raw, cooked, or dried forms.[57] Until the FDA promulgates relevant regulations to that effect, commercial aquaculturists and harvesters could experience complications when trying to get such products to market.

D. Raw Agricultural Commodity Determination

In February 2021, the FDA released a statement in response to a question from the Association of Food and Drug Officials (AFDO).[58] In the statement, FDA clarified that raw seaweed is not a seafood or plant, but rather, a raw agricultural commodity.[59] On the federal level, food that is not a fish or fishery product, shellfish, or produce is regulated under 21 CFR Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Rule (Part 117), which is discussed in the next section.[60]

III. Treating Seaweed as a General Food Product under 21 CFR Part 117 - Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Rule

On the federal level, food that is not a fish or fishery product, shellfish, or produce is regulated under 21 CFR Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Rule (Part 117).[61] There are two important parts of the rule as it applies to seaweed operations: requirements for Current Good Manufacturing Practices (CGMPs) and requirements for Hazard Analysis/Preventive Controls (HA/PC).[62] CGMPs aim

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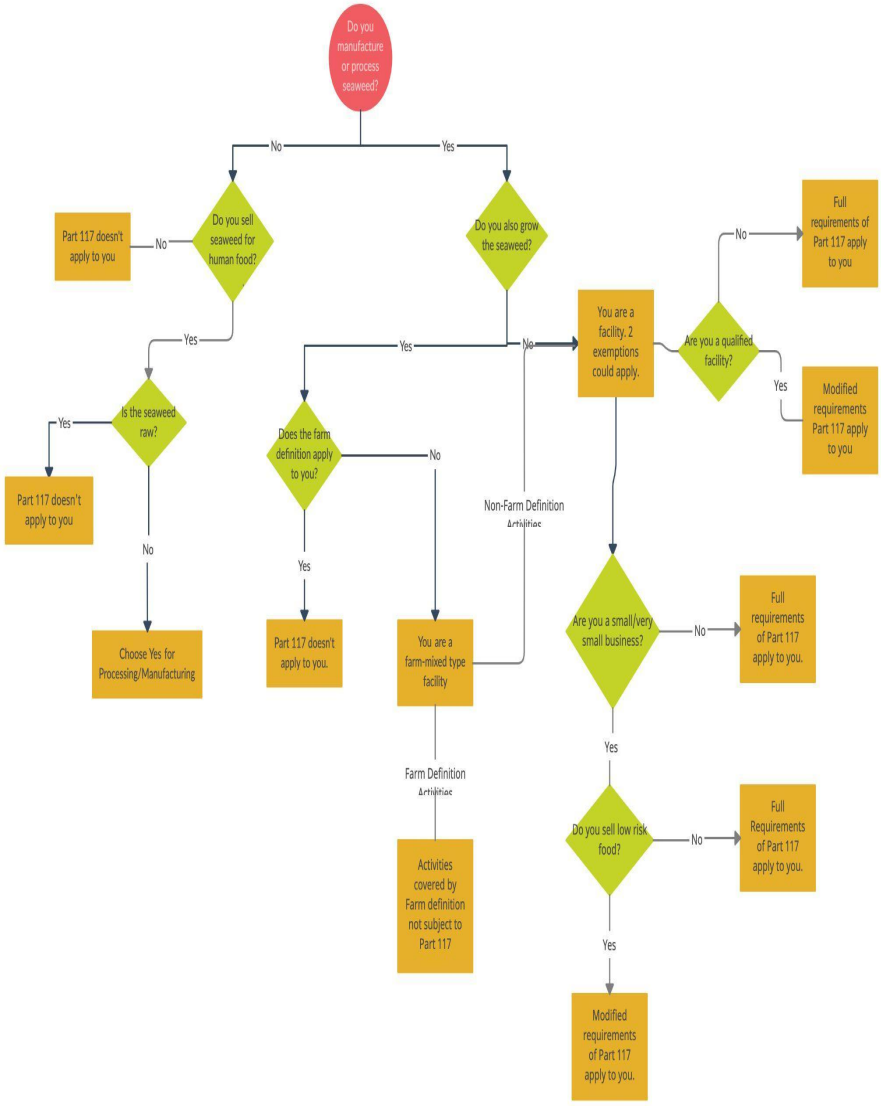
[57] 21 C.F.R. § 170.3(o)(11) (definition of flavor enhancer- Flavor enhancers: Substances added to supplement, enhance, or modify the original taste and/or aroma of a food, without imparting a characteristic taste or aroma of its own.").
[58] Email on file with the author.
[59] *Id.*
[60] 21 C.F.R. § 117.
[61] *Id*. §§ 117.4, 117.5.
[62] *Id.*

to ensure food safety by addressing matters like "personal hygienic practices, design and construction of a food plant and maintenance of plant grounds, plant equipment, sanitary operations, facility sanitation, and production and process controls during the production of food."[63] HA/PC requires food facilities to have a food safety plan in place that includes an analysis of hazards and risk-based preventive controls to minimize or prevent the identified hazards.[64] However, as discussed more below, there are some major exemptions to the rule.

Many seaweed growers in operation in the United States today are not subject to Part 117 due to the small size of their operations and type of products sold.[65] In particular, Part 117 does not apply to: 1) seaweed that is a raw agricultural commodity; 2) seaweed subject to certain exempt on-farm manufacturing, process, packing, or holding activities; or 3) seaweed operations below certain size thresholds (modified requirements).[66] Figure 1 shows the overall framework for determining which parts of Part 117 apply to a facility. The details of the framework are discussed more fully later in this section.

[63] FOOD & DRUG ADMIN., CURRENT GOOD MANUFACTURING PRACTICES (CGMPS) FOR FOOD AND DIETARY SUPPLEMENTS (Jan. 31, 2020), https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/current-good-manufacturing-practices-cgmps-food-and-dietary-supplements.
[64] 21 C.F.R. § 117.126.
[65] *Id.* § 117.5.
[66] *Id.*

Figure 1. Overview of Part 117.



A. Applicability

The application of the CGMPs and HA/PC depends on whether the operation needs to register as a facility under FSMA.[67] Facilities, mixed-type facilities, and qualified facilities all need to register. However, depending on the characteristics of the operation, the registered facility may only be subject to modified CGMP and HA/PC requirements. Farms and retail food establishments are not required to register, and thus, are not subject to the CGMPs and HA/PC.[68] The meaning of these terms is therefore very important. The difference among these categories is discussed below, as well as how seaweed operations might fit into each category.

i. Full Applicability

Facilities are subject to all the requirements of CGMPs and HA/PC.[69] Part 117 defines a facility as simply "a domestic facility or foreign facility that is required to register" under FDCA Section 415.[70] The FDA's regulations for facility registration more fully define what constitutes a facility:

> any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility….[71]

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[67] *Id.* § 117.1.
[68] *Id.* § 117.5
[69] 21 C.F.R. § 117.1.
[70] *Id.* § 117.3.
[71] *Id.* § 1.227.

ii. Full Exemption

Farms are exempt from Part 117.[72] The definition of farm is complicated and divided into two subcategories: "primary production" farms and "secondary activities" farms.[73] The definition of farms in Part 117 includes some manufacturing and processing activities. Farms that engage in manufacturing or processing activities beyond those listed in the farm definition are classified as a mixed-type facility, discussed more below.

A primary production farm includes operations "under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities."[74] A secondary activities farm is "an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm."[75] Table 1 provides a summary of the activities included in the farm definition.

When reviewing these activities, it becomes clear that seaweed that is sold raw or is dried in accordance with farm definition is exempt from Part 117. Further, many of the seaweed producing states in the U.S. produce only raw or dried seaweed, meaning these operations are not subject to regulation under Part 117, leaving space for the respective states to step in and fill the regulatory gap.

[72] *Id.* § 117.5.
[73] *Id.* § 1.227.
[74] 21 C.F.R. § 1.227.
[75] *Id.*

Table 1: Manufacturing and Processing Activities Included Within the Farm Definition in 21 C.F.R. § 1.227

Activity	**Requirements to Meet Farm Definition**
Pack/Hold Raw Agricultural Commodities	None
Pack/Hold Processed Food	● All processed food is either consumed on the farm or another farm under the same management; OR ● processed food is a dried or dehydrated raw agricultural commodity that created a distinct product (ie. drying grapes to make raisins) and the packaging and labeling of the new product occurred without any additional manufacturing or processing.

Manufacture/Process Food	● All food is consumed on the farm or another farm under the same management; OR ● it is one of the following: ○ a dried or dehydrated raw agricultural commodity that created a distinct product (ie. drying grapes to make raisins) and the packaging and labeling of the new product without any additional manufacturing or processing; ○ treating a raw agricultural commodity to manipulate its ripening and packaging or labeling it without any additional; or manufacturing or processing; or ○ packaging or labeling a raw agricultural commodity without any additional manufacturing or processing.

Retail food establishments are also exempt from Part 117.[76] Retail food establishments are businesses whose primary function is to sell food directly to consumers. Included in the definition of retail food establishment are establishments that sell "food products directly to consumers as its primary function."[77] Consumers do not mean businesses, and a "retail food establishment" can be a grocery store, convenience store, or vending machine location. Retail food operations also include facilities:

> that manufacture, process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures, processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers.[78]

In terms of seaweed operations, growers and harvesters who sell directly to consumers or produce value-added products could fit within the retail food establishment definition. The farm-operated business simply has to make a majority of its sales directly to the consumers.

iii. Partial Applicability

Qualified facilities face modified requirements under Part 117.[79] There are two ways to be deemed a qualified facility. The first is to be a "very small business," which is a business that grossed less than $1 million a year for the previous three years in its sales of human food, including food it held for a fee.[80] The second route is based on direct sales to consumers and other "qualified end users," which includes restaurants and retail food establishments in the same state or

[76] *Id.* § 117.1
[77] *Id.* § 1.227.
[78] *Id.* § 1.227.
[79] 21 C.F.R. § 117.5.
[80] *Id.* § 117.3.

within 275 miles that sell food directly to consumers.[81] To meet this requirement, the value of the food sold to consumers and other qualified end users in the previous three years must be greater than the value of the food sold to other purchasers and less than $500,000 per year.[82]

Mixed-type facilities are establishments that engage in a mix of activities, some of which are exempt from registration and others that require registration.[83] For instance, a "farm mixed-type facility" "is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered."[84]

There is a partial exemption for farm mixed-type facilities if the facility is a small or very small business and the only manufacturing/processing it engages in are considered low-risk for certain foods.[85] The FDA's list for these activities and foods is extensive.[86] If a mixed-type facility does not fall within this exemption, it is subject to the full requirements of Part 117. Table 2 summarizes these exemptions.

Seaweed operations which qualify as a Qualified Facility are put in an interesting situation- the business is currently exempt from Hazard Analysis and Preventive Controls, but could be subject to those requirements should the business grow in the future. Thus, it may make sense for the business to begin to follow Hazard Analysis and Preventive Controls while it is still currently exempt. However, further complicating matters is that some states such as New York are encouraging seaweed Qualified Facilities to develop a HACCP Plan- and not follow Hazard Analysis and Preventive Controls.[87]

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[81] *Id.*
[82] *Id.*
[83] *Id.* § 117.3.
[84] 21 C.F.R. § 117.3.
[85] *Id.*
[86] FOOD & DRUG ADMIN., WHAT YOU NEED TO KNOW ABOUT THE FDA REGULATION: CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (21CFR PART 117): GUIDANCE FOR INDUSTRY (2006).
[87] *Food Safety: Seaweed*, N.Y. DEP'T OF AGRIC. AND MKT., https://agriculture.ny.gov/food-safety/seaweed (last visited Oct. 24, 2022).

Table 2: Applicability of FSMA Requirements

Type	**Registration**	**Current Good Manufacturing Practices**	**Hazard Analysis/Preventive Controls**
Facility	Yes	Yes	Yes
Qualified Facility	Yes	Yes	Modified Requirements
Farm	No	No	No
Retail Food Establishment	No	No	No
Farm Mixed-Type Facility	Yes	Depends on Characteristics of the Operation	Depends on Characteristics of the Operation

B. Part 117 Requirements

Because of the small scale of most seaweed farms and operations in the United States, Part 117 is not currently widely applicable to the seaweed industry. However, the structure and requirements of Part 117 may be helpful for state agencies considering potential food safety models to regulate the industry in their states.

i. Good Manufacturing Practices

The FDA first established CGMPs for food in the Federal Register in 1969.[88] The CGMPs were modernized in

[88] FOOD & DRUG ADMIN., *supra* note 63.

2015 following the passage of FSMA. Brief summaries of the CGMP categories are provided below.

Personnel: These CGMPs require employees who are visibly ill to be excluded from operations, unless the illness, like open wounds or lesions, can be adequately covered. An additional requirement for cleanliness mandates that "[a]ll persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of food."[89]

Plants and Grounds: These CGMPs require that grounds under the operator's control be kept in a condition that prevents the contamination of food. Further, "[t]he plant must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes."[90]

Sanitary Operation: These CGMPS include requirements for the general maintenance of the facility, cleaning materials (including the storage of toxic chemicals), sanitizing food and non-food contact surfaces, and storing and handling utensils and portable equipment.[91]

Sanitary Facilities and Controls: These CGMPS include requirements for water supply, plumbing, sewage disposal, toilet and hand-washing facilities, and rubbish disposal.[92]

Equipment and Utensils: These CGMPS include requirements for equipment and utensils that are cleanable, avoid adulteration, and able to be kept in a sanitary condition. Food-contact surfaces must be made of corrosion resistant and non-toxic materials, maintained to protect against allergen cross contamination or any other type of contamination, and kept to avoid the build-up of dirt and organic matter.[93]

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[89] 21 C.F.R. § 117.10.
[90] *Id.* § 117.20.
[91] *Id.* § 117.35.
[92] *Id.* § 117.37.
[93] *Id.* § 117.40.

Processes and Controls: These CGMPS include general requirements for the manufacturing, processing, packing, and holding of food that will ensure adequate sanitation and ensure the food is suitable for human consumption. There are additional requirements for raw materials.[94]

Warehousing and Distribution: These CGMPS include requirements for storing and transporting food "under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container."[95]

Defect Action Levels: These CGMPS include requirements for "quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible" and prohibits the mixing of defected, adulterated food with another lot of food.[96]

ii. Hazard Analysis and Preventive Controls

Under the Hazard Analysis and Preventive Controls requirements, the agent in charge of the facility must prepare a food safety plan.[97] A food safety plan is a written plan that documents all of the procedures by which the facility complies with the HA/PC requirements.[98] The required contents of the food safety plan are summarized in Table 3. The document must be available to the FDA by oral or written request. A "preventive controls qualified individual" must write or oversee the preparation of the food safety plan.[99] Who this person or persons can be depends upon the following definitions:

- *Preventive controls qualified individual*: a qualified individual who has successfully completed training in the development and application of risk-based

[94] 21 C.F.R. § 117.80.
[95] *Id.* § 117.93.
[96] *Id.* § 117.110.
[97] *Id.*
[98] *Id.*
[99] 21 C.F.R. § 117.126.

preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.[100]

- *Qualified Individual*: a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.[101]

[100] *Id.*
[101] *Id.* § 117.3.

Table 3: Contents of Food Safety Plan	
Component	**Description**
Hazard Analysis	Must be written and must include natural, unintentional hazards as well as hazards that may be intentionally introduced.
Preventive Controls	Must have the effect of minimizing or preventing the named hazards and assuring that the food processed in the facility will not be adulterated.
Procedures for Monitoring the Implementation of Preventive Controls	The required monitoring should assure the preventive controls are achieved.
Supply Chain Program	Required for processing facilities that receive from a supplier raw materials/ingredients for which the facility has identified a hazard.
Recall Plan	A recall plan is required for identified foods with hazards that require preventive controls.
Corrective Action Procedures	The agent in charge of the facility shall have corrective action procedures in the case that the preventative controls are not implemented or are ineffective, ensuring that the controls are put back in place, the affected food is evaluated for safety, and the affected food is not put into commerce if the agent cannot ensure safety.
Verification Procedures	The agent in charge of the facility must personally verify that the control measures are adequate, effective,

	documented, and in accordance with these provisions.

It should be noted that facilities are required to reanalyze hazards whenever significant changes are made in the facility's activities or once every three years, whichever is earlier.[102] Further, FSMA provides for the Secretary of the U.S. Department of Health and Human Services to work in coordination with the USDA to review new health science at least every two years and release new guidance documents and regulations to help prevent the adulteration of food.[103] In conjunction with 21 U.S.C. § 350g(i), this section implies that the issuance of a guidance document might be a cause for a food facility to reanalyze potential hazards.

1. Hazard Analysis

Through Hazard Analysis, a facility must identify and evaluate "known or reasonably foreseeable hazards" that require preventive controls.[104] All facilities must complete a written hazard analysis, even if the facility ultimately determines that there are no hazards that require implementing preventive controls.[105]

The analysis must be "based on experience, illness data, scientific reports, and other information" for all the food the facility manufactures, processes, packs, or holds.[106] The facility must consider both biological hazards, like parasites and pathogens; chemical hazards, like pesticide residue, unapproved food additives, and food allergens; and physical hazards, like fragments of stone, metal, or glass.[107] Finally, the facility must consider any hazards that naturally occur or are

[102] *Id.* § 117.150.
[103] 21 U.S.C. § 2201.
[104] 21 C.F.R. § 117.130(a).
[105] *Id.*
[106] *Id.*
[107] *Id.*

introduced unintentionally or intentionally for economic gain.[108]

Once the facility identifies the relevant hazards, it needs to evaluate them "to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls."[109] The evaluation must consider effects of the following factors on the finished product's safety for the consumer:

> (i) The formulation of the food;
>
> (ii) The condition, function, and design of the facility and equipment;
>
> (iii) Raw materials and other ingredients;
>
> (iv) Transportation practices;
>
> (v) Manufacturing/processing procedures;
>
> (vi) Packaging activities and labeling activities;
>
> (vii) Storage and distribution;
>
> (viii) Intended or reasonably foreseeable use;
>
> (ix) Sanitation, including employee hygiene; and
>
> (x) Any other relevant factors, such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of some natural toxins).[110]

2. Preventive Controls

If required by the facility's hazard analysis, the facility must create and implement written preventive controls.[111] The preventive controls must ensure that the hazards "will be significantly minimized or prevented" and the food will not be

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[108] *Id.* § 117.130(b).
[109] 21 C.F.R. § 117.130(c).
[110] *Id.*
[111] *See id.* (part 117 does provide circumstances for when a facility is not required to implement preventive controls).

adulterated.[112] Preventive controls can include controls at any critical control points (CCPs) and other controls that are necessary for food safety.[113] There is flexibility in developing preventive controls, which can include:

- Process controls;
- Food allergen controls;
- Sanitation controls;
- Supply-chain controls;
- A recall plan; and
- Other controls needed to minimize or prevent hazards, such as hygiene training or other current good manufacturing practices.[114]

IV. Treating Seaweed as Seafood: Seafood HACCP and National Shellfish Sanitation Program

While seaweed is a macroalgae that does not fit into the FDA's definition of "fish or fishery product," Seafood Hazard Analysis Critical Control Point (Seafood HACCP) may still be instructive when considering possible regulatory models for states to adopt when regulating seaweed as a human food product. For instance, in Connecticut, state regulators are currently treating raw seaweed sold in its whole form like seafood and requiring seaweed growers to comply with the Seafood HACCP.[115] While seaweed is clearly not shellfish, the National Shellfish Sanitation Program could be a potential model in considering the health risks of seaweed related to water quality and cultivating, harvesting, processing, shipping, or handling of seaweed products.

A. Seafood Hazard Analysis Critical Control Point (Seafood HACCP)

[112] *Id.* § 117.135(a).
[113] *Id.* § 117.135(b).
[114] 21 C.F.R. § 117.135(c).
[115] CONCEPCION, *supra* note 31 at ii.

The FDA issued regulations in 1995 that require processors of fish and fishery products to develop and implement HACCP systems for their operations.[116] Under the Seafood HACCP regulations, a seafood processor must identify "food safety hazards that are reasonably likely to occur for each kind of fish and fishery product produced by" the processor and "identify the preventative measures that the processor can apply to control those hazards."[117] Food safety hazards are defined as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption."[118] Additional information about the Seafood HACCP risk management process and requirements can be found in the FDA's Fish and Fishery Products Hazards and Control Guidance.[119]

The Seafood HACCP regulation applies to processors, where processing means the "[h]andling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding" of a fish or fishery product.[120] Specifically, processing does not mean: "(i) Harvesting or transporting fish or fishery products, without otherwise engaging in processing; (ii) Practices such as heading, eviscerating, or freezing intended solely to prepare a fish for holding on board a harvest vessel; (iii) The operation of a retail establishment."[121]

A seafood processor's failure to have and implement a compliant Seafood HACCP plan renders that processor's products adulterated under the FDCA. HACCP plans are also

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[116] Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, 60 Fed. Reg. 65096 (December 18, 1995) (to be codified 21 C.F.R. parts 122, 1240).
[117] 21 C.F.R. § 123.6.
[118] *Id.*
[119] FOOD & DRUG ADMIN., *Fish and Fishery Products Hazards and Controls Guidance,* CTR. FOR FOOD SAFETY AND APPLIED NUTRITION, OFF. OF FOOD SAFETY, June 2022.
[120] *Id.*
[121] *Id.*

required for juice processors and encouraged for dairy plants and retail and food service.[122]

Seaweed is not included in the FDA's definition of "fish" or "fishery product." Fish is defined as "fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption."[123] A fishery product is defined as "any human food product in which fish is a characterizing ingredient."[124]

i. State Approaches

Although the FDA does not consider seaweed a "fish or fishery product," states may choose to extend the Seafood HACCP requirements to seaweed as Connecticut has done. In addition to adopting the Seafood HACCP model, Connecticut has developed a guide examining the potential food safety hazards present in the production and processing of seaweed in the state.[125]

Other states are also treating seaweed as a seafood, but have not gone as far as Connecticut in requiring Seafood HACCP. New York encourages seaweed growers who qualify as Qualified Facilities to use HACCP, stating "while food safety science for seaweed is still developing applying the principles included in a HACCP plan could ensure that all potential hazards are eliminated or controlled to acceptable levels."[126] For example, there are no seaweed processors in Massachusetts, so seaweed is a seasonal commodity sold raw and fresh.[127] Under the Department of Public Health's food protection and the Division of Marine Fisheries regulations, kelp is required to be sold directly to a wholesale seafood

[122] *Hazard Analysis Critical Control Point (HACCP)*, FOOD & DRUG ADMIN., (Jan. 29, 2018).
[123] 21 C.F.R. § 123.3.
[124] *Id.*
[125] CONCEPCION, *supra* note 31.
[126] N.Y. DEP'T OF AGRIC. AND MKT., *supra* note 91.
[127] Robidoux & Chadsey, *supra* note 7.

dealer. From there, the wholesalers distribute the seaweed to restaurants.[128]

ii. Foreign HACCP Models

HACCP has been used in other parts of the world as a method to ensure seaweed food safety. Included below are brief overviews of the use of HACCP in the European Union, Ireland, and Japan.

1. European Union

Under the EU legal system, treaties are the primary source of law. Among other things, treaties detail the objectives of the European Union, the rules for EU institutions (*e.g.*, the European Commission, the European Parliament, and the European Council), and the rules for decision-making. Regulations, in turn, are legal acts by EU institutions that are binding in their entirety on all EU countries, applying automatically and uniformly as soon as they enter into force without needing to be transposed into national law.

Article 5 of European Commission Regulation (EC) No. 852/2004 requires all food business operators (FBOs) to implement and maintain permanent procedures based on HACCP principles.[129] FBOs include any entity carrying out production, processing, or distribution of food at any stage of the food chain after primary production and associated activities.[130] The Regulation highlights the need to provide flexibility to small FBOs in complying with the requirement, specifically indicating:

> It is necessary to recogni[z]e that, in certain food businesses, it is not possible to identify critical control points and that, in some cases, good hygienic practices can replace the monitoring of critical control points. Similarly, the requirement of establishing "critical limits" does not imply that it is necessary to fix a

[128] *Id.*
[129] EUR. PARL. DOC. (NO 852) (2004).
[130] *Id.*

> numerical limit in every case. In addition, the requirement of retaining documents needs to be flexible in order to avoid undue burdens for very small businesses.[131]

The Commission has published a guidance document on implementing procedures based on the HACCP principles, particularly in certain food businesses.[132] Likewise, sector-specific guides developed by the EU and a register of available national guides to good hygienic practices (GHP) are also available.[133] Although seaweed is not mentioned in the European Commission guidance document and seaweed does not appear to have its own GHP guide at present, the guidance document and national guides represent a model that could be adapted for U.S. markets should policymakers have concerns about the burden that a HACCP requirement might impose on small businesses that handle raw seafood sold for human consumption.

2. Ireland

A HACCP-based food safety management system has been a legal requirement for all food businesses in Ireland since 1998.[134] The term "food business" is defined rather broadly under current legislation as, "…any undertaking, whether for profit or not and whether public or private, carrying out any or all of the following: preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling or offering for sale or supply of foodstuffs." This definition pertains to seaweed harvesters and cultivators.

The Ireland-based Irish Seaweeds company states on its website that the company has a HACCP system in place, with the company explicitly indicating that this is a legal

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[131] *Id*. at 15.
[132] *See Food Hygiene*, EUROPEAN COMM'N, https://food.ec.europa.eu/safety/biological-safety/food-hygiene_en (last visited Nov. 9, 2022).
[133] *See Guidance Platform*, EUROPEAN COMM'N, https://food.ec.europa.eu/safety/biological-safety/food-hygiene/guidance-platform_en (last visited Nov. 9, 2022).
[134] FOOD SAFETY AUTH. OF IR., https://www.fsai.ie/faq/haccp.html (last visited Dec. 23, 2022).

requirement for any registered food facility or manufacturer in Ireland.[135] Emerald Isle Seaweed, a different Irish seaweed operation focusing on organic products, also has a HACCP system in place, but their materials are silent with respect to a legal mandate.[136]

3. Japan

Under Japan's Food Sanitation Act (FSA), a seaweed operation's legal obligations will ultimately depend on whether that operation qualifies as a food business operator (FBO).[137] The FSA defines an FBO as anyone who (1) engages in collecting, producing, importing, processing, cooking, storing, transporting, or selling food or additives or (2) provides food to the public on an ongoing basis at schools, hospitals or other facilities.[138] The term "food business operator" is likely interpreted quite broadly under the FSA, as the Japanese government announced the mandatory adoption of HACCP "by all FBOs in the food chain" in anticipation of the 2020/2021 Tokyo Olympics.[139] However, small-scale FBOs are afforded flexibility in complying with this requirement, with a greater emphasis on utilizing guidance issued by the appropriate industry association as long as that guidance is HACCP-based.[140]

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[135] *See About Us*, IRISH SEAWEEDS, https://irishseaweeds.com/about-us/ (last visited Nov. 12, 2022).
[136] *See* EMERALD ISLE ORGANIC IRISH SEAWEED, https://emeraldisleseaweed.com/ (last visited Nov. 9, 2022).
[137] *See* 食品衛生法 [Food Sanitation Act] Act No. 233 of 1947, (Japan), *amended by* Act No. 46 of 2018 art 3 para 1.
[138] *Id.*
[139] *Summary of the Final Report on the Implementation of Mandatory HACCP Program in Food Industry adopted by the ad hoc Panel on International Standardization of Food Hygiene Control*, MINISTRY OF HEALTH, LABOUR, AND WELFARE https://www.mhlw.go.jp/english/topics/foodsafety/consideration/dl/summary_of_the final report.pdf (December 2016) [hereinafter *Summary of the Final Report*]; *see* Tingmin Koe, *International requirements: How Japanese food manufacturers can benefit from global food safety guidelines*, FOODNAVIGATOR-ASIA (Jan. 9. 2019), https://www.foodnavigator-asia.com/Article/2019/01/09/International-requirements-How-Japanese-food-manufacturers-can-benefit-from-global-food-safety-guidelines.
[140] Summary of the Final Report, *supra* note 139; 21 U.S.C. § 321(r).

B. National Shellfish Sanitation Program

Here in the United States, states ensure that molluscan shellfish (oysters, clams, mussels, and whole or roe-in scallops) are safe for human consumption through participation in the National Shellfish Sanitation Program (NSSP).[141] The NSSP is a cooperative program recognized by the FDA and the Interstate Shellfish Sanitation Conference (ISSC) for the sanitary control of bivalve molluscan shellfish produced and sold for human consumption.[142] The NSSP offers guidance to states through a Model Ordinance that "establishes the minimum requirements necessary to regulate the interstate commerce of molluscan shellfish and to establish a program to protect the public health of consumers by assuring the sale or distribution of shellfish from safe sources and assuring shellfish have not been adulterated during cultivating, harvesting, processing, shipping, or handling."[143] States participating in the NSSP agree to adopt and enforce the Model Ordinance.[144]

The NSSP Model Ordinance requires states to conduct sanitary surveys of shellfish growing areas to assess water quality and determine their suitability for harvest.[145] Growing areas may be classified as Approved, Conditionally Approved, Restricted, Conditionally Restricted, or Prohibited. Each of these classifications has different implications regarding whether shellfish can be harvested from the area and how the shellfish can be used after harvest. In growing areas where harvest is approved, other NSSP Model Ordinance requirements for biotoxin control and management must still

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[141] *National Shellfish Sanitation Program (NSSP)*, FOOD & DRUG ADMIN. (Oct. 29, 2020), https://www.fda.gov/food/federalstate-food-programs/national-shellfish-sanitation-program-nssp.
[142] *Id.*
[143] FOOD & DRUG ADMIN., GUIDE FOR THE CONTROL OF MOLLUSCAN SHELLFISH (2019), https://www.fda.gov/media/143238/download.
[144] Lisa Schiavinato & Catherine Courtier, *Molluscan Shellfish Aquaculture in Federal Waters of the Exclusive Economic Zone (EEZ): Agencies, Industry, and Academia Working Together on Compliance and Permitting Requirements*, SEA GRANT CAL. (Jan. 01, 2019), https://caseagrant.ucsd.edu/our-work/e-documents/molluscan-shellfish-aquaculture-in-federal-waters-of-the-us-exclusive-economic-zone.
[145] *Id.*

be met before harvest.[146] The NSSP Model Ordinance also establishes specific regulations regarding the shipping and handling of molluscan shellfish, including specific time and temperature requirements for safe transport.[147]

Unlike shellfish, seaweed is not a particulate filter feeder, and different water quality characteristics and considerations to ensure seaweed food safety likely exist. However, a similar approach could be applied to seaweed, especially seaweed that is grown on shellfish farms. For instance, states could identify growing waters for seaweed and establish regulations regarding the harvest, shipment, and sale of the state's seaweed.

As an example, in Maine, seaweed is treated as seafood up until the point of harvest.[148] The Maine Department of Marine Resources approves the cultivation of kelp for human consumption in waters that are classified as Approved or Conditionally Approved for shellfish, controlling water quality at the source by identifying suitable growing areas and monitoring for bacterial contaminants. However, seaweed farmed in Maine is not regulated as seafood for post-harvest activities, including handling, processing, distribution, and sale. Farmed seaweed is regulated as produce by the Maine Department of Agriculture, Conservation and Forestry.[149] The next chapter provides an overview of the FDA's Produce Safety Rule.

V. Treating Seaweed as a Plant: the Produce Safety Rule

In 2019, the Maine Supreme Court likened rockweed, a kind of seaweed, to a plant.[150] In the decision, the Maine Supreme Court refused to consider harvesting seaweed in the intertidal zone as a form of fishing, citing the fundamental

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[146] *See* FOOD & DRUG ADMIN., *supra* note 23.
[147] Schiavinato & Catherine Courtier, *supra* note 144, at 14.
[148] ME. STAT. tit. 12, §6001 (2021) (The Maine Department of Marine Resources also regulates seaweed aquaculture in Maine. Aquaculture is defined to mean the cultivation of marine organisims, which defined to include "any animal, plant or other life that inhabits waters below head of tide.").
[149] Private Communication with Maine Sea Grant Staff on file with author.
[150] Ross v. Acadian Seaplants, 206 A.3d 283 (Me. 2019).

biological differences between fish and rockweed, as rockweed draws nutrients from the air and seawater using a photosynthetic process and, once attached to the intertidal substrate, does not move."[151] Although this case involved legal issues outside the food safety context, the Court's analysis provides an opportunity to explore what food safety regulation would look like if seaweed was classified as a plant, or more specifically in the food safety context: produce.

While seaweed is a macroalgae that does not fit into the FDA's definition of "plant" or "produce," the Produce Safety Rule may still be instructive for states looking at regulatory models for regulating seaweed as a food product. In 2015, the FDA adopted Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, known as the Produce Safety Rule (PSR).[152] The PSR, which went into effect in 2016, establishes mandatory science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption.[153] The FDA issued the PSR as part of the agency's efforts to implement the Food Safety Modernization Act of 2011.

Generally, the PSR is intended to apply to produce that will be eaten raw. The FDA provided a list of produce that is covered by the rule.[154] Produce included on this list is not

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[151] *Id.* at 291.

[152] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. 74353 (Nov. 27, 2015) (to be codified at 21 C.F.R. §112) [hereinafter *Produce Safety Rule*].

[153] *Id.*

[154] 21 C.F.R. §112.1. (Covered produce includes: Fruits and vegetables such as almonds, apples, apricots, apriums, Artichokes-globe-type, Asian pears, avocados, babacos, bananas, Belgian endive, blackberries, blueberries, boysenberries, brazil nuts, broad beans, broccoli, Brussels sprouts, burdock, cabbages, Chinese cabbages (Bok Choy, mustard, and Napa), cantaloupes, carambolas, carrots, cauliflower, celeriac, celery, chayote fruit, cherries (sweet), chestnuts, chicory (roots and tops), citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and uniq fruit), cowpea beans, cress-garden, cucumbers, curly endive, currants, dandelion leaves, fennel–Florence, garlic, genip, gooseberries, grapes, green beans, guavas, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydew, huckleberries, Jerusalem artichokes, kale, kiwifruit, kohlrabi, kumquats, leek, lettuce, lychees, macadamia nuts, mangos, other melons (such as Canary, Crenshaw and Persian), mulberries, mushrooms, mustard greens, nectarines, onions, papayas, parsnips, passion fruit, peaches, pears, peas, peas-pigeon, peppers (such as bell and hot), pine nuts, pineapples, plantains, plums,

subdivided into different categories (i.e., fruits, vegetables, tree nuts, etc.). Only two categories of produce exist: (1) produce covered by the PSR; and (2) foods that are not. In practical terms, this just means that the same rules apply to greens as would apply to tree nuts.[155]

Neither seaweed nor algae is currently on the list of produce covered by the PSR, although the list could be amended in the future. In fact, the FDA explicitly addressed the inclusion of seaweed within the scope of the PSR when responding to public comments as part of the PSR rulemaking process. While it was drafting the PSR, the FDA received comments inquiring whether the term "produce" included a list of other commodities, including algae.[156] In response, the FDA defined produce to include, "fruits (the harvestable or harvested part of a plant developed from a flower) and vegetables (harvested part of any plant or fungus), which by definition does not include algae."[157] The agency went on to discuss how algae differ from and are not considered produce.[158] The agency does provide an example which references seaweed stating, "the blue-green algae, also known as cyanobacteria, are generally considered to be bacteria, but because blue-greens are aquatic and possess photosynthetic pigments like seaweeds, they are still called algae."[159] However, the agency mentioned that algae that are used for food will continue to be covered under the FDCA and its applicable implementing regulations.[160] As mentioned in previous chapters, the FDA has asserted that seaweed sold in its whole form will be regulated as a raw agricultural commodity under the FDCA.[161] The agency left open the opportunity to address algae in the future, stating, "[a]s appropriate, we may consider issuing guidance on

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plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, soursop, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), sweetsop, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons, and yams).

[155] *Id.*

[156] Produce Safety Rule, *supra* note 152.

[157] *Id.* at 74385.

[158] *Id.*

[159] *Id.*

[160] *Id.*

[161] Produce Safety Rule, *supra* note 152.

the topic of algae production for human food use in the future."[162]

A. Produce Safety Rule Requirements

The PSR standards are designed to work effectively for food safety across the wide diversity of produce farms.[163] Generally, the PSR requires produce growers to "take appropriate measures to minimize risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated."[164] In other words, farms covered by the rule are held to certain standards designed to reduce the presence of potentially dangerous bacteria in the food supply, with the ultimate goal of reducing the number of illnesses caused by contaminated produce. Key elements of the PSR include:

- Qualifications and training requirements for personnel who handle/contact covered produce or food contact surfaces. (Subpart "C").
- Specific measures farms must take to reduce potential contamination of covered produce by personnel and other visitors, as well as hygienic practices that must be followed by personnel. (Subpart "D").
- Requirements for agricultural water quality and testing designed to detect contamination. (Subpart "E").
- Requirements related to domestic and wild animals in instances where a covered activity takes place outdoors or in a partially enclosed building. (Subpart "I"). *Note that these requirements do not apply when a covered activity takes place in a fully-*

[162] *Id.*
[163] *Id.*
[164] 21 C.F.R. §112.11.

enclosed building or to fish used in aquaculture operations.

- Requirements governing growing, harvesting, packing and holding activities. (Subpart "K").
- Equipment, tools, buildings, and standards and requirements regarding operation, maintenance, and sanitation. (Subpart "L").[165]

In terms of handling produce under PSR Subpart K, immediately prior to and during harvesting activities, growers must take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including animal excreta.[166] Further, during covered activities, growers must handle harvested covered produce in a manner that protects against contamination with known or reasonably foreseeable hazards.[167] During packaging, covered produce must be packaged in a manner that prevents the formation of *Clostridium Botulinum* toxins if such toxin is a known or reasonably foreseeable hazard.[168]

If seaweed were to be regulated under the PSR, the agricultural water provisions could play a significant role. First, per this rule, "agricultural water" is defined as:

> Water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce).[169]

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[165] *Id.* § 112.
[166] *Id.* § 112.113.
[167] *Id.*
[168] *Id.* § 112.115.
[169] 21 C.F.R. §112.3.

The general requirement under this subpart is that "all agricultural water must be safe and of adequate sanitary quality for its intended use."[170] To ensure this requirement is met, all agricultural water systems must be inspected at the beginning of a growing season. In addition, all agricultural water distribution systems and agricultural water sources must be maintained to prevent the contamination of "covered produce, food contact surfaces, areas used for a covered activity, or water sources, including by regularly inspecting and adequately storing all equipment used in the system for continued compliance with the safety and sanitary standards."[171]

In regard to water treatment, any method used to treat agricultural water must be effective to make the water safe and of adequate sanitary quality for its intended use and/or meet the relevant microbial quality criteria. There must be no detectable generic *E. coli* in 100 milliliters of agricultural water, and untreated surface water cannot be used for any following purposes:

- Sprout irrigation water;
- Water applied in any manner that directly contacts covered produce during or after harvest activities;
- Water used to contact food surfaces; and
- Water used for washing hands during and after harvest activities.[172]

In addition, when agricultural water is used during growing activities, using a direct water application method, the following criteria must be met:

- A geometric mean of grower's agriculture water samples of 126 or less colony forming units of general *E. coli* per 100 milliliters of water; and

[170] *Id.* §112.41.
[171] *Id.* §112.42.
[172] *Id.* §112.44(a).

- A statistical threshold value of grower's agricultural water samples of 410 or less colony forming units of generic *E. coli* per 100 milliliters of water.[173]

Each source of water must be tested. This testing comes in the form of an initial survey to develop the microbial water quality profile of the source. This profile must be updated annually. Other requirements include establishing a water changing schedule and monitoring water temperature.[174]

B. Produce Safety Rule Application to Aquaponics or Hydroponics

Although seaweed and algae are not currently covered by the PSR, the FDA has commented on the applicability of some of the PSR requirements to listed produce grown in aquaponic or hydroponic systems. Similar requirements could serve as a model for seaweed grown in tanks. For instance, the FDA has stated that aquaponic farms should *not* be excluded from the PSR requirements for agricultural water. The agency reasoned that,

> [T]he routes of contamination we considered for covered produce under this rule are applicable to aquaponic farming and covered produce grown in aquaponic systems is subject to the same potential for contamination from agricultural water, biological soil amendments of animal origin, and animals as covered produce grown using non-aquaponic systems.[175]

The agency did however make a distinction regarding the use of agricultural water. The agency stated, "when covered produce is grown in an aquaponic system in which the water is not intended or likely to contact the harvestable portion of the produce, that water is *not* agricultural water for purposes of this rule."[176] In contrast, "when covered produce is grown in an

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[173] *Id.* §112.44(b).
[174] 21 C.F.R. §112.48.
[175] Produce Safety Rule, *supra* note 152, at 74366.
[176] *Id.* (emphasis added).

aquaponic system in which water is intended or likely to contact the harvestable portion of the produce, that water *is* agricultural water for purposes of this rule and must meet the applicable standards."[177]

However, aquaponic and hydroponic systems used to grow covered produce other than sprouts are not subject to the requirements under Subpart M. The FDA has not established additional standards applicable to aquaponic or hydroponic production of crops other than sprouts.[178]

VI. Conclusion

The growth of the seaweed aquaculture industry in the United States is raising challenging questions about how to ensure products are safe to eat when most operations are exempt from the federal framework. States are taking action to fill the gaps, but they are pursuing different approaches. This could make it difficult for products to cross state lines and cause problems as businesses grow. There is a need for states and federal governments to work together.

There are multiple factors that states must consider when adopting a regulatory model. First, seaweed is biologically very different from fish, shellfish, and produce. However, the regulatory models used to ensure that those products are safe to eat may be informative from a regulatory perspective as state frameworks are developed to govern the emerging seaweed industry.

Second, states must consider which agency or agencies should have authority for implementing the seaweed food safety program. Importantly, the model a state chooses to implement can vastly affect which state agency is in charge of licensing or approving the sale of seaweed as a food source. Regulatory authority for food safety may be shared or split among several agencies within a state, and, therefore, oversight responsibility for different food categories may fall to different agencies.

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[177] *Id.* (emphasis added).
[178] *Id.*

Third, states must consider the regulatory burden associated with implementing the chosen seaweed food safety framework. States may choose particular paths because they are familiar with a regulatory framework, even if that framework is not the best option scientifically. For instance, if many seaweed growers in a particular state are diversifying their shellfish farms by adding seaweed, then both the farmer and the regulator are already familiar with Seafood HACCP and the National Shellfish Sanitation Program.

Fourth, states must consider how their chosen model will affect businesses as they grow and expand. How hard would it be for a qualified facility following Seafood HACCP pursuant to state regulation to shift to Hazard Analysis and Preventive Controls if the business sells enough product to lose their qualified facility exemption?

Finally, food safety hazards are being actively researched. States will have to do a delicate balance to not provide overly-burdensome regulations while the science is still developing while also providing for food safety protocols. Likewise, states will have the burden of updating their regulations as the science on seaweed food safety continues to emerge.

Following the Framework: Intentional Genomic Alterations in Animals

Sarah Copper

Intentional genomic alterations in animals or genetically engineered animals have existed in their modern form since the 1980s. However, the introduction of these animals into our food supply has been a more recent development. The federal government has taken steps in an attempt to regulate these products in a streamlined and efficient manner but has faced criticism in their approach. While the Food and Drug Administration ("FDA") is currently responsible for the regulation of intentional genomic alterations ("IGAs") in animals, there is significant effort behind transferring that oversight to the United States Department of Agriculture ("USDA"). However, in the meantime, there are products currently approved and on the market. These products are facing legal hurdles as well as consumer backlash. This paper will address what intentional genomic alterations in animals are, the framework that established the regulatory structure surrounding these products, the current relevant regulatory guidance, the IGA products currently on the market and the legal issues facing these products.

I. Defining Intentional Genomic Alterations in Animals

The FDA defines animals with intentional genomic alterations as animals whose genomes have been intentionally altered using modern molecular technologies.[1] These technologies can include random or targeted DNA sequence changes including nucleotide insertions, substitutions, or deletions, or other technologies that introduce specific changes to the genome of the animal.[2] Traditionally, recombinant DNA ("rDNA") technology has been used in plants and animals to create genetic modifications. rDNA techniques involve splicing DNA sequences from various sources and introducing them into animals via techniques that result in random integration events.[3] Animals whose genomes have been intentionally altered by rDNA technology have been produced since the early 1980s when two scientists at the University of Washington, Ralph Brinster and Richard Palmiter, reported on the development of

[1] *See* FOOD & DRUG ADMIN., REGULATION OF INTENTIONALLY ALTERED GENOMIC DNA IN ANIMALS: DRAFT GUIDANCE (2017).
[2] *See id.*
[3] *See id.*

mice altered in this manner.[4] Not long thereafter, Robert Hammer, a scientist at the University of Pennsylvania demonstrated that rDNA techniques could be used to intentionally alter the genomes of rabbits and pigs.[5]

More recently, newer more precise technologies have been developed. Some of these include the use of "nucleases" or "genome editing technologies" including engineered nuclease/nucleotide complexes such as zinc finger nucleases ("ZFN"), transcription activator-like effector nucleases ("TALENs"), and the clustered regulatory interspersed short palindromic repeats ("CRISPR").[6] These nucleases are intended to introduce alterations at specific sites in the genome, rather than the more random changes associated with rDNA technology, resulting in more predictable alterations.[7]

These intentional genetic alterations can be heritable or non-heritable. A heritable genetic alteration will be passed on to the animal's offspring while a non-heritable genetic alteration will not be passed on and is generally used as gene therapy.[8] This distinction between heritable and non-heritable is an important consideration in how FDA currently regulates intentional genomic alterations in animals. All of the product currently approved as food contain heritable intentional genomic alterations.

Some animals with intentional genomic alterations are intended to produce medical products, such as human drugs or medical devices. While the FDA's Center for Veterinary Medicine ("CVM") is responsible for oversight of the IGA in the animal, the products derived from that animal are subject to regulation by other FDA centers such as the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, or the Center for Food Safety and Applied Nutrition.[9]

II. Regulation of IGA in Animals

Animals with intentional genomic alterations are regulated as new animal drugs under section 201 of the Food, Drug, and

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[4] *See* Ralph L. Brinster et al., *Somatic Expression of Herpes Thymidine Kinase in Mice Following Injection of a Fusion Gene into Eggs*, HSS PUB. ACCESS, Nov. 1981 at 223.
[5] *See* Robert E. Hammer et al., *Production of Transgenic Rabbits, Sheep, and Pigs by Microinjection*, 315 NATURE 680 (June 20, 1985).
[6] *See* FOOD & DRUG ADMIN., *supra* note 1.
[7] *See id.*
[8] *See id.*
[9] *See id.*

Cosmetic Act. A "drug" under the relevant section includes: "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals"; and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." The definition of "new animal drug" in section 201(v) of the FD&C Act includes "any drug intended for use in animals that is not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in the drug's labeling, or that is so recognized but has not been used to a material extent or for a material time." So, the genomic alteration itself is considered the new animal drug because the alteration of the animal's genetic makeup affects the structure or function of the animal. For example, a genomic alteration that enables a fish to grow at a faster rate is regulated as an animal drug. However, arriving at this regulatory framework was not an easy task and continues to be a subject of concern.

III. History of Regulation of Intentional Genomic Alterations in Animals and Interagency Collaboration

In June of 1986, the White House released the Coordinated Framework for the Regulation of Biotechnology. This framework laid out a comprehensive Federal regulatory policy for ensuring the safety of biotechnology products. The framework stated that "the application of traditional genetic modification techniques is relied upon broadly for enhanced characteristics of food (e.g., hybrid corn, selective breeding), manufactured food (e.g., bread, cheese, yogurt), waste disposal (e.g., bacterial sewage treatment), medicine (e.g., vaccines, hormones), pesticides (e.g., Bacillus thuringiensis) and other uses."[10] To ensure the safety of these types of products, Congress charged various Federal agencies with implementing an array of laws.[11] However, recognizing that there might gaps in regulations given the discovery and use of rDNA and cell fusion, the Reagan Administration formed an interagency working group to address the matter.[12] The working group concluded that the current law adequately addressed regulatory needs.[13] However, "For certain microbial products, however, additional regulatory requirements, available under existing statutory authority, needed to be

[10] Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg 23302 (June 26, 1986).
[11] *See id.*
[12] *See id.*
[13] *See id*.

established."[14] The working group also established that the three primary regulatory agencies responsible for these genetically engineered products were the U.S. Environmental Protection Agency ("EPA"), the Food and Drug Administration ("FDA"), and the U.S. Department of Agriculture ("USDA").[15] The framework was "expected to evolve in accord with the experiences of the industry and the agencies, and, thus, modifications may need to be made through administrative or legislative actions."[16] It described a risk-based, scientifically sound basis for the oversight of activities that introduce biotechnology products into the environment.[17]

This framework was first updated in 1992 to outline the appropriate agencies and authorities for the exercise of authority and oversight under the current regulations.[18] The 1992 update reaffirmed that federal oversight "focuses on the characteristics of the biotechnology product and the environment into which it is being introduced, not the process by which the product is created" and clarified that "[e]xercise of oversight in the scope of discretion afforded by statute should be based on the risk posed by the introduction and should not turn on the fact that [a biotechnology product] has been modified by a particular process or technique."[19] Moreover, the 1992 Update to the Coordinated Framework stated that "[i]n order to ensure that limited federal oversight resources are applied where they will accomplish the greatest net beneficial protection of public health and the environment, oversight will be exercised only where the risk posed by the introduction is unreasonable."[20] The 1992 update likely was spurred by the progress that AquaBounty was making with their genetically engineered salmon that was created to develop an Atlantic salmon that grows faster during the earlier stages of growth.[21] AquaBounty's website states that in 1989 the genetically engineered salmon was created and in 1991 the company was founded to commercialize the innovation.[22]

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[14] *Id.*
[15] U.S. DEP'T OF AGRIC., MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS (2017), https://usbiotechnologyregulation.mrp.usda.gov/2017_coordinated_framework_update.pdf.
[16] Coordinated Framework for Regulation of Biotechnology § 23303.
[17] 1992 Update to the Coordinated Framework, 57 Fed. Reg. 6663, 6753 (Feb. 27, 1992).
[18] MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS, s*upra* note 15.
[19] *Id.*
[20] *Id.*
[21] *About Us*, AQUABOUNTY, https://aquabounty.com/about-us (last visited Nov. 28, 2022).
[22] *Id.*

This product was the first genetically engineered animal that was intended for human consumption.

The FDA first released draft guidance on the regulation of genetically engineered animals containing heritable recombinant DNA constructs on September 18, 2008.[23] The document was titled, Guidance for Industry #187 "Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs."[24] The purpose of the draft guidance was to clarify that the new animal drug provisions of the Federal Food, Drug and Cosmetic Act ("FFDCA") applied to the rDNA constructs in genetically engineered animals.[25] This guidance defined genetically engineered animals as "animals modified by recombinant DNA ("rDNA") techniques. The term GE animal can refer to both animals with heritable rDNA constructs and animals with non-heritable rDNA constructs."[26] This guidance laid out important principles regarding FDA oversight and regulation of genetically engineered animals. First, the FDA stated that they would be exercising enforcement discretion with regard to genetically engineered animals of non-food-species that are regulated by other government agencies or entities and genetically engineered animals of non-food-species that are raised and used in contained and controlled conditions.[27] The FDA states that the factors they consider when choosing to exercise enforcement discretion is the potential for human, animal or environmental risk; potential for greater environmental risk than a non-genetically engineered counterpart; human, animal, or environmental concerns over disposition of genetically engineered animal; or other safety questions not adequately addressed by the sponsor.[28] The guidance then goes through the requirements of a new animal drug application, the approval process and post approval requirements.[29]

This first draft guidance was met with a staggering response. There were over 28,000 comments that were mostly statements

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[23] FOOD & DRUG ADMIN., RESPONSE TO PUBLIC COMMENTS ON DRAFT GUIDANCE FOR INDUSTRY #187 (2008).
[24] FOOD & DRUG ADMIN., INTENTIONAL GENOMIC ALTERATIONS (IGAS) IN ANIMALS (2022).
[25] MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS, *supra* note 15.
[26] FOOD & DRUG ADMIN. CTR. FOR VETERINARY MED., GUIDANCE FOR INDUSTRY 187, REGULATION OF GENETICALLY ENGINEERED ANIMALS CONTAINING HERITABLE RECOMBINANT DNA CONSTRUCTS, (2009).
[27] *Id.*
[28] *Id.*
[29] *Id.*

opposing genetic engineering in animals.[30] However, the substantive comments that the FDA addressed in their response contained concerns, analysis, recommendations, and opinions regarding a variety of topics related to genetic engineering in animals. Some of the important issues raised were the adequacy of the new animal drug application ("NADA") in regulating these products, interagency collaboration, animal health and safety, food safety, food labeling, and environmental safety. Importantly, the FDA's response to the thousands of comments made it clear that they did not intend to promulgate any new regulations regarding genetically engineered animals. The final guidance was published in January of 2009.

The next regulatory update went back to the coordinated framework. The framework was further updated starting in 2015 by the EPA, FDA and USDA at the behest of the Executive Office of the President.[31] The purpose of this update was to clarify the roles and responsibilities of the subject agencies in the regulation of biotechnology products, to develop a long-term strategy that would ensure the federal regulatory system is prepared for future biotechnology products and commission an independent, expert analysis of the future landscape of biotechnology products.[32] Specifically, the memorandum requesting this update established four objectives:

i. clarifying which biotechnology product areas are within the authority and responsibility of each agency;
ii. clarifying the roles that each agency plays for different product areas, particularly for those product areas that fall within the responsibility of multiple agencies, and how those roles relate to each other in the course of a regulatory assessment;
iii. clarifying a standard mechanism for communication and, as appropriate, coordination among agencies, while they perform their respective regulatory functions, and for identifying agency designees responsible for this coordination function; and

[30] *Id.*
[31] MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS, s*upra* note 15.
[32] *Id.*

> iv. clarifying the mechanism and timeline for regularly reviewing, and updating as appropriate, the Coordinated Framework to minimize delays, support innovation, protect health and the environment and promote the public trust in the regulatory systems for biotechnology products.[33]

In looking specifically at genetic engineering in animals in the update, the FDA addresses "GE Animals" in a separate section.[34] The update details that FDA regulates GE animals under the NADA provisions of the FFDCA. Specifically, the update details that the rDNA construct will be overseen by the Center for Veterinary Medicine ("CVM"), including the safety of any food derived from the GE Animal and the validity of the claims by the sponsor.[35] Essentially, the CVM will ensure that GE Animals are safe for consumption by humans and that they work as intended. The update goes on to detail that GE animals producing substances to be used in or as drugs, biologics, or medical devices for use in humans, FDA's Center for Drug Evaluation and Research ("CDER"), Center for Biologics Evaluation and Research ("CBER"), or Center for Devices and Radiological Health ("CDRH") has responsibility for reviewing those products that are produced by GE animals under their respective purview.[36]

The USDA also claims responsibility for animal health in the update. Under the Animal Health Protection Act ("AHPA"), the Animal and Plant Health Inspection Service ("APHIS") will conduct an animal health risk assessment to determine if the genetically engineered animal poses a risk to livestock.[37] If such a risk is found, the genetically engineered animal would be subject to import or transport restrictions to minimize the risk.[38] This second update to the coordinated framework for the regulation of biotechnology was finalized in 2017.[39]

Also in 2015, the FDA updated the guidance document titled, "GFI #187, Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs." This document was further edited and released for public comment in

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[33] *Id.*
[34] *Id.*
[35] *Id.*
[36] MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS, s*upra* note 15.
[37] *Id.*
[38] *Id.*
[39] *Id*.

2017 under the title "Guidance for Industry #187 Regulation of Intentionally Altered Genomic DNA in Animals." FDA stated that the draft revised Guidance for Industry was being released "to clarify its approach to the regulation of intentionally altered genomic DNA in animals. This guidance addresses animals whose genomes have been intentionally altered using modern molecular technologies, which may include random or targeted DNA sequence changes including nucleotide insertions, substitutions, or deletions, or other technologies that introduce specific changes to the genome of the animal.[40] At this time, the FDA changed the nomenclature surrounding genetically engineered animals to animals with intentional genomic alterations. This change clarifies the article that is being regulated. The FDA expands on this point, stating:

> *A specific DNA alteration is an article that meets the definition of a new animal drug at each site in the genome where the alteration (insertion, substitution, or deletion) occurs. The specific alteration sequence and the site at which the alteration is located can affect both the health of the animals in the lineage and the level and control of expression of the altered sequence, which influences its effectiveness in that lineage. Therefore, in general, each specific genomic alteration is considered to be a separate new animal drug subject to new animal drug approval requirements.*[41]

The 2017 draft guidance also restated the agency's position on enforcement discretion. However, the 2017 draft guidance has not yet been finalized. This is likely due to the comments received and the continued fight for oversight responsibilities between agencies. Several actions have been taken since the release of this draft guidance to further change the regulatory landscape regarding intentional genomic alterations in animals.

On June 11, 2019, President Trump signed an Executive Order on "Modernizing the Regulatory Framework for Agricultural Biotechnology Products." This Executive Order calls for, among other things, regulatory streamlining in order to facilitate the innovation of agricultural biotechnology to the market efficiently, consistently, and safely under a predictable, consistent, transparent, and science-based regulatory framework.[42] In response to the

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[40] FOOD & DRUG ADMIN. CTR. FOR VETERINARY MED., *supra* note 26.
[41] *Id.* at 7.
[42] U.S. DEP'T OF AGRIC., *Memorandum of Understanding Between the United States Department of Agriculture and the Food and Drug Administration*, DEP'T

objectives laid out in this Executive Order, on December 28, 2020, the USDA issued an advanced notice of proposed rulemaking addressing the possibility of transferring jurisdiction over some genetically engineered animals from FDA to USDA.[43] Following this advanced notice of proposed rulemaking, on January 13, 2021, the USDA and Department of Health and Human Services signed an agreement that the USDA would take over portions of the FDA's oversight of genetic modifications in agricultural animals and biotechnology for agricultural animals.[44] One key aspect of this agreement was the FDA's commitment to "immediately implement a streamlined, risk-based approach to oversight of intentional genomic alterations in animals."[45] The agreement goes to state, "FDA and USDA will work on a communication plan to explain FDA's involvement with agriculture amenable species developed using genetic engineering."[46]

Under this framework, "USDA would safeguard animal and human health by providing end-to-end oversight from pre-market reviews through post-market food safety monitoring for certain farm animals modified or developed using genetic engineering that are intended for human food," a USDA announcement states.[47] The FDA would retain authority over genomic alterations for nonagricultural purposes and over dairy products, eggs, some meat products, and animal feed derived from modified animals.[48] The agreement also states that the FDA would implement a streamlined risk-based approach to oversight of intentional genomic alterations in animals.[49] Previously, the USDA had authority over genetic engineering of plants, while the FDA regulated all genetic engineering of animal species.

The FDA adamantly opposed this transition at the time. Former FDA Commissioner Stephen Hahn voiced some of his concerns regarding the advanced notice of proposed rulemaking via

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OF HEALTH & HUM. SERVS., at 1 (Jan. 13, 2021) https://www.aphis.usda.gov/biotechnology/downloads/mou-usda-fda.pdf.

[43] U.S. DEP'T OF AGRIC., *Secretary Perdue Announces Groundbreaking Proposal to Transfer Agricultural Animal Biotechnology Regulatory Framework to USDA*, (Dec. 21, 2020), https://www.usda.gov/media/press-releases/2020/12/21/secretary-perdue-announces-groundbreaking-proposal-transfer.

[44] *Secretary Perdue Statement on MOU on Animal Biotechnology*, U.S. DEP'T OF AGRIC. (Jan. 19, 2021), https://www.usda.gov/media/press-releases/2021/01/19/secretary-perdue-statement-mou-animal-biotechnology.

[45] *Memorandum of Understanding, supra* note 42.

[46] *Id.*

[47] *Secretary Perdue Statement on MOU on Animal Biotechnology, supra* note 44.

[48] *Id.*

[49] *Id.*

Twitter.[50] Hahn stated that the FDA did not support the MOU and had no intention of abdicating its public health mandate.[51] USDA officials announced March 7 they were reopening the proposal's comment period, which had expired in February of 2021.[52] The agency accepted comments through May 7, 2021.[53] However, no action has been taken as a result of those comments.

However, most recently, on April 14, 2022, eleven agricultural institutions have penned a letter to Secretary Vilsack supporting the agency's advance notice of proposed rulemaking and calling for change in the federal regulation of gene editing in livestock.[54] The letter stated that the current FDA regulatory approach stifles innovation in the livestock sector, citing the decades long regulatory process.[55] The letter states that:

> *Gene editing technology offers livestock producers the opportunity to address the serious sustainability, animal health, and food security challenges facing our food supply in the 21st century. However, this potential can only be achieved if we have federal policies that are risk and science-based, and that permit the meaningful adoption of these products by producers, supply chains, and consumers.*[56]

However, at this time, neither the FDA nor the USDA have come out with any new regulations regarding intentional genomic alterations in animals. Therefore, the controlling regulations are the new animal drug application rules governed by the FDA.

IV. Investigational New Animal Drug Application

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[50] Michael Mezher, *HHS, FDA Dispute Spills Out Onto Twitter*, REGUL. FOCUS (Jan. 19, 2021), https://www.raps.org/news-and-articles/news-articles/2021/1/hhs-fda-dispute-spills-out-onto-twitter.
[51] *Id.*
[52] Steve Davies, *USDA Reopens Comment Period On Animal Biotech Regulatory Overhaul*, AGRIPULSE (Mar. 5, 2021, 12:13 PM), https://www.agri-pulse.com/articles/15457-usda-reopens-comment-period-on-animal-biotech-proposal.
[53] *Id.*
[54] Letter from Nat'l Ass'n of State Dep'ts of Agric. to U.S. Dep't of Agric. Sec'y Tom Vilsack (Apr. 14, 2022), https://www.nasda.org/wp-content/uploads/2022/07/4.14.22_Gene_Editing_Livestock_Letter.01.pdf.
[55] *Id.*
[56] *Id.*

A new animal drug is "deemed unsafe" prior to FDA's approval of said animal drug.[57] Therefore, the regulations surrounding new animal drugs place restrictions on interstate shipment of these products prior to opening an investigational new animal drug file.[58]

During the investigational stage of developing a new intentional genomic alteration, the FDA recommends opening an investigational new animal drug file before shipping the products for any purpose.[59] Commonly these products need to be shipped to and from different laboratories. All shipments must bear labeling that clearly identifies that edible products derived from investigational animals are not to be used for food without prior authorization from the FDA.[60] The regulations surrounding investigational new animal drug files specify labeling and record-keeping requirements, animal disposition, and conditions under which food from animals used for clinical investigations can be introduced into the food supply.[61] The FDA recommends a disposition plan for these investigational products as they want to ensure that these products do not enter the market before they are approved.[62] If a sponsor wishes to introduce investigational animals or animal products into the food supply, they must request an Investigational Food Use Authorization.[63] Actions on investigational new animal drug applications are considered major federal actions under the National Environmental Policy Act ("NEPA"), and as such may require preparation of an environmental assessment ("EA") and a finding of no significant impact ("FONSI") or an environmental impact statement ("EIS").[64]

V. Low Risk Products

FDA has stated that for products that are low risk, the Agency may not expect developers to seek approval of these intentional genomic alterations. The FDA will conduct a risk-based review to determine if a product is low risk. If the review finds the

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[57] MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS, *supra* note 15.
[58] 21 C.F.R § 511.1 (2022).
[59] MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS, *supra* note 15.
[60] 21 CFR § 511.1 (2022).
[61] MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS, *supra* note 15.
[62] *See* 21 C.F.R. § 511.1(b)(5) (2022).
[63] *Id.*
[64] 21 C.F.R. § 511.1(b)(10) (2022); 21 C.F.R. § 25.15 (2022); 21 C.F.R. § 25.22 (2022).

intentional genomic alteration to be low risk, the FDA will not require developers to seek approval for the alteration.[65] FDA will publish a summary of their risk-based review to increase transparency into the approval process. [66] There is currently only one intentional genomic alteration approved for use in animals intended for food use, the PRLR-SLICK cattle. The alteration found in this cow is intended to create a short slick haircoat allowing for greater heat tolerance.[67] Review for low-risk alterations includes a review of molecular characterization, phenotypic data and animal safety, human food safety and environmental risk.

VI. Intentional Genomic Alterations in Animals Review Process

The FDA's draft guidance establishes a recommended process for completing the pre-approval assessments for intentional genomic alterations. The first three steps focus on the establishing and characterizing the altered genomic DNA in the resulting animals, specifically: product identification; the molecular characterization of the altered genomic DNA; and the molecular characterization of the lineage of animals whose genomes have been intentionally altered.[68]

The product identification or definition encompasses the specific lineage of animals whose genomes have been intentionally altered, that is, the altered genomic DNA as well as the animals containing it, and the purpose of the altered genomic DNA that is the subject of the new animal drug application.[69]

The molecular characterization of the altered genomic DNA serves to describe the components and composition of the product. The FDA recommends that a sponsor provides information for identifying and characterizing the altered genomic DNA that will be introduced into the progenitor of the animal to be marketed. – this is the first step in the hazard identification component of the safety review of the new animal drug application.

The molecular characterization of the lineage of animals whose genomes have been altered serves as the second part of the

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[65] U.S. DEP'T OF AGRIC., *Intentional Genomic Alterations (IGAs) in Animals: Low Risk IGAs*, (Jun. 1, 2022), https://www.fda.gov/animal-veterinary/intentional-genomic-alterations-igas-animals/intentional-genomic-alterations-igas-animals-low-risk-igas.
[66] *Id.*
[67] FOOD & DRUG ADMIN., RISK ASSESSMENT SUMMARY – V-006378 PRLR-SLICK CATTLE 1.
[68] *Id.*
[69] *Id.*

hazard identification by continuing the analysis of the intentionally altered genomic DNA and the location of the genomic alteration in the resulting animal as well as the production of the animal(s) intended to be used in commerce and any potential hazards that may be introduced into those animals as part of their production.

Information gathered in the following steps helps establish whether the genomic alteration poses any risks to humans, the health of the animal or the environment. In the phenotypic characterization of animals whose genomes have been intentionally altered, the FDA is looking for data regarding the target animal safety requirements and whether the genomic alteration or its expression product cause any direct or indirect toxicity.

As part of the genotypic and phenotypic durability assessment, FDA requires information to ensure that the altered genomic DNA in the animal resulting from the specific alteration event is durable. There is a reasonable expectation that the altered genomic DNA is stably inherited, and the phenotype is consistent and predictable. This would include developing a sampling plan.

As part of the food safety and environmental safety assessment, the sponsor must look at direct and indirect toxicity including allergenicity, via food consumption of the intentional genomic alteration in the animal and the potential for indirect toxicity or unintended food consumption hazards. For the environmental safety assessment, most applications for animals whose genomes have been intentionally altered would have to be evaluated to determine whether such an approval will individually or cumulatively result in significant environmental impact.

Lastly, for effectiveness and claim validation, the sponsor must show the they have validated the claims for the characteristics that the animals whose genomes have been intentionally altered are intended to exhibit. For example, in the case of animals whose genomes have been intentionally altered that are intended to resist disease, the sponsor should demonstrate that those animals are indeed resistant to that disease.

Again, each genomic alteration is an individual new animal drug, that is each specific genomic alteration is considered to be a separate new animal drug subject to new animal drug approval requirements.[70] If a sponsor wishes to introduce multiple genomic alterations resulting in one final animal lineage, the FDA

[70] REGULATION OF INTENTIONALLY ALTERED GENOMIC DNA IN ANIMALS: DRAFT GUIDANCE, *supra* note 1.

recommends that the sponsor contact the agency to discuss regulatory options and the kinds of scientific questions that would have to be addressed in an application.[71] In the research phase, an Investigational new animal drug file may be created to research several different types of alterations. [72] Each new animal drug approval covers all animals containing the same genomic alteration derived from the same alteration event.[73] Animals containing the genomic alteration as a result of breeding between an intentionally altered animal and its non-intentionally altered counterpart animal are covered by the new animal drug approval.[74]

VII. Products currently approved for human consumption by FDA

A. AquAdvantage Salmon

AquAdvantage Salmon contains an intentional genomic alteration that causes the salmon to grow at a rapid rate.[75] AquAdvantage Salmon was developed by the company AquaBounty in 1989.[76] The heritable intentional genomic alteration was introduced to the parent stock of fish and continually bred to create the AquAdvantage school that is being harvested today.[77] According to the FDA, AquAdvantage is able to grow at a faster rate than conventional salmon because "it contains an rDNA construct that is composed of the growth hormone gene from Chinook salmon under the control of a promoter, which is a sequence of DNA that turns on the expression of a gene, from ocean pout."[78] These salmon grow twice as fast as wild salmon, reaching eight to twelve pounds within 18 months instead of thirty-six months.[79] AquaBounty has facilities in Canada, Panama, and two facilities in the US, one currently in

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[71] *Id.*
[72] *Id.* at 7-8
[73] *Id.* at 8.
[74] *Id.*
[75] *AquAdvantage Salmon Fact Sheet*, FOOD & DRUG ADMIN. (April 28, 2022), https://www.fda.gov/animal-veterinary/aquadvantage-salmon/aquadvantage-salmon-fact-sheet.
[76] AQUABOUNTY, *supra* note 21.
[77] *Our Salmon*, AQUABOUNTY, https://aquabounty.com/our-salmon (last visited Nov. 28, 2022).
[78] *AquAdvantage Salmon Fact Sheet supra* note 75.
[79] Casey Smith, *First shipments of genetically modified salmon go to restaurants in eastern U.S.*, ACHORAGE DAILY NEWS, June 1, 2021, https://www.adn.com/business-economy/2021/06/01/genetically-modified-salmon-head-to-restaurants-in-eastern-us/.

operation in Indiana and the other potentially in Kentucky.[80] All of the AquaBounty facilities are enclosed and on land in an effort to mitigate the risk of AquAdvantage escaping into the ocean.[81]

AquAdvantage has been approved by the FDA as food for human consumption. The FDA states "the salmon are safe to eat, the introduced DNA is safe for the fish itself, and the salmon meet the sponsor's claim about faster growth."[82] However, this product has faced significant opposition from consumers. Consumer groups have pressured major retailers from selling AquAdvantage in their stores.[83] AquAdvantage was first harvested for sale in May of 2021.[84] However, because of the consumer response, the product is only available in select restaurants.[85]

B. GalSafe Pig

In December of 2020, the FDA approved a first of its kind intentionally altered genomic line of domestic pigs which may be used for human food or human therapeutics.[86] The pigs were originally created to potentially provide a source of porcine-based materials to produce human medical products that are free of detectable alpha-gal sugar.[87] The FDA states that as an example, "GalSafe pigs could potentially be used as a source of medical products, such as the blood-thinning drug heparin, free of detectable alpha-gal sugar. Tissues and organs from GalSafe pigs could potentially address the issue of immune rejection in patients receiving xenotransplants, as alpha-gal sugar is believed to be a cause of rejection in patients."[88]

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[80] *Our Farms,* AQUABOUNTY, https://aquabounty.com/our-farms (last visited Dec. 2, 2022).
[81] *AquAdvantage Salmon Fact Sheet supra* note 75.
[82] *Id.*
[83] Dan Flynn, *AquaBounty salmon is what's for dinner if you can find it*, FOOD SAFETY NEWS (Sept. 4, 2020), https://www.foodsafetynews.com/2020/09/aquabounty-salmon-is-whats-for-dinner-if-you-can-find-it/.
[84] Smith, *supra* note 79.
[85] *Id.*
[86] FOOD & DRUG ADMIN., *FDA Approves First-of-its- Kind Intentional Genomic Alteration in Line of Domestic Pigs for Both Human Food, Potential Therapeutic Uses,* FDA NEWS RELEASES, (Dec. 14, 2020), https://www.fda.gov/news-events/press-announcements/fda-approves-first-its-kind-intentional-genomic-alteration-line-domestic-pigs-both-human-food#:~:text=Today%2C%20the%20U.S.%20Food%20and,for%20food%20or%20human%20therapeutics (last visited Nov. 29, 2022).
[87] *Id.*
[88] *Id.*

In determining that the meat from the GalSafe pigs is safe for human consumption, the FDA not only looked at the safety of the intentional genomic alteration, but also at the product developer's intention to market the product for its ability to eliminate alpha-gal sugar on pigs' cells.[89] The FDA determined that food from GalSafe pigs is safe for human consumption. The FDA also focused on ensuring the effectiveness of the intentional genomic alteration through the evaluation of data demonstrating that there is no detectable level of alpha-gal sugar across multiple generations of GalSafe pigs.[90] The FDA found no greater environmental risk, or antimicrobial resistance risk than is found with conventional pigs.[91] However, the product developer's new animal drug application did not include data regarding food allergies, the FDA's review process did not evaluate food safety specific to allergies related to alpha-gal sugar.[92] Anecdotally, the meat resulting from the intentional genomic alteration found in the GalSafe pigs is safe for individuals who suffer from alpha-gal syndrome, an allergy to alpha-gal sugar that is spread through lone star tick bites.[93] While GalSafe pigs are approved by the FDA for human consumption, they have not yet been approved for their biomedical uses.[94] Once approved, the intentional genomic alteration could produce organs that are viable for human transplant. So far, doctors have transplanted a kidney and a heart from these pigs to humans under special authorizations from FDA.[95]

C. PRLR-SLICK Cattle

Approved as a low-risk intentional genomic alteration, the PRLR-SLICK cattle have been altered to present with a short, slick haircoat.[96] The cattle with the IGA are referred to as PRLRSLICK cattle. This heritable intentional genomic alteration was introduced using a genome editing technique known as CRISPR in two

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[89] *Id.*
[90] *Id.*
[91] *Id.*
[92] *FDA Approves First-of-its- Kind Intentional Genomic Alteration in Line of Domestic Pigs for Both Human Food, Potential Therapeutic Uses supra* note 86.
[93] Chris Clayton, *FDA Approves Biotech Swine: Pigs Become First Genetically Altered Animals Approved for Food, Medical Use in US*, PROGRESSIVE FARMER (Dec. 21, 2020, 7:58 AM CST), https://www.dtnpf.com/agriculture/web/ag/livestock/article/2020/12/14/pigs-become-first-genetically-food.
[94] *Id.*
[95] Roni Caryn Rabin, *Patient in Groundbreaking Heart Transplant Dies*, N.Y. TIMES (Mar. 9, 2022), https://www.nytimes.com/2022/03/09/health/heart-transplant-pig-bennett.html.
[96] RISK ASSESSMENT SUMMARY – V-006378 PRLR-SLICK CATTLE, *supra* note 67.

"founder" beef calves.[97] Because this alteration is heritable, it is can be passed on to offspring, only requiring introduction to the parent stock, similar to the AquAdvantage salmon.[98] The PRLR-SLICK alteration is equivalent to a naturally occurring mutation that occur in several breeds of conventionally raised cattle that have adapted to warmer climates.[99] The FDA's risk assessment summary states "the slick mutations confer a short, 'slick' haircoat, and cattle with the slick phenotype have been reported to be better at withstanding hot weather."[100]

Acceligen, the company sponsoring the application for the PRLR SLICK cattle, submitted genomic data and other information to FDA to demonstrate that the intentional genomic alteration present is genetically equivalent to naturally occurring mutations with a history of food safety.[101] Essentially, the data provided shows that the genetic pattern created by the intentional genomic alteration has been present in food used for human consumption safely.

These three products all present different goals by producers: faster growing proteins; food products aimed at solving allergen issues and being used in medical products, and lastly a product addressing animal welfare concerns and allowing for cattle ranching in harsher weather climates. These products all have very different goals, are part of different industries and therefore require different considerations in how they should be regulated. The types of issues these products are facing now are only going to compound as technologies advance and more diverse products are brought to market.

VIII. Regulatory Hurdles facing IGA in Animals - Labeling

Animals containing intentional genomic alterations are subject to the Bioengineered Foods Disclosure Standard. This standard was created by the USDA and is administered through the Agricultural Marketing Service ("AMS").[102] Prior to the Bioengineered Foods Disclosure Standard, the FDA had released

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[97] *Id.*
[98] *Id.*
[99] *Id.*
[100] *Id.*
[101] RISK ASSESSMENT SUMMARY – V-006378 PRLR-SLICK CATTLE, *supra* note 67.
[102] U.S. DEP'T. OF AGRIC. MARKETING SERVICE, *Agricultural Mktg. Serv.* https://www.ams.usda.gov/rules-regulations/be (last visited Dec. 1, 2022).

guidance that did not require labeling on genetically engineered salmon because it was not materially different from other Atlantic Salmon and met the regulatory standard for Atlantic Salmon.[103] The FDA supported voluntary labeling of non-genetically engineered products while cautioning against deceptive mislabeling products. For comparison, the FDA's approach to labeling this genetically engineered salmon was similar to their approach to labeling for Genetically Modified Organisms.

Again, when looking specifically at genetically engineered salmon, as a result of FDA's decision regarding voluntary labeling, language was added to the 2016 federal budget requiring labeling for genetically engineered Atlantic salmon before it could be imported into the United States.[104] This back and forth on the labeling requirements caused many issues for AquaBounty, as its grow out facility was located in Indiana while their salmon eggs were cultivated in Canada.[105] The import alert blocked AquaBounty from bringing its eggs to the Indiana facility for growing.[106]

In December of 2018, the USDA passed the National Bioengineered Food Disclosure Standard.[107] This USDA-developed standard regulates the labeling of foods that are genetically engineered. According to the National Bioengineered Food Disclosure Standard, a bioengineered food, "contain[s] detectable genetic material that has been modified through certain lab techniques and cannot be created through conventional breeding or found in nature."[108] USDA maintains the List of Bioengineered Foods which includes AquAdvantage Atlantic salmon.[109] Therefore, products that contain AquAdvantage must be appropriately labeled under the National Bioengineered Food Disclosure Standard as

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[103] FOOD & DRUG ADMIN., *Draft Guidance for Industry: Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived From Genetically Engineered Atlantic Salmon* (March 2019), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-voluntary-labeling-indicating-whether-food-has-or-has-not-been-derived.

[104] Christine Blank, *New Labeling Rule Paves Way for GM Salmon to Enter US Market* (December 21, 2018), https://www.seafoodsource.com/news/supply-trade/new-labeling-rule-paves-way-for-gm-salmon-to-enter-us-market.

[105] *Id.*

[106] *Id.*

[107] U.S. DEP'T OF AGRIC., *BE Disclosure*, https://www.ams.usda.gov/rules-regulations/be (last visited Dec. 1, 2022).

[108] *Id.*

[109] Scott Gottlieb, *Statement from FDA Commissioner Scott Gottlieb, M.D., on Continued Efforts to Advance Safe Biotechnology Innovations, and the Deactivation of an Import Alert on Genetically Engineered Salmon* (April 8, 2019), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-continued-efforts-advance-safe-biotechnology.

bioengineered with one of the four disclosure options: on-package text stating "bioengineered food"; the USDA approved symbol for bioengineered food; an electronic or digital link, such as a QR code; or a text message disclosure prompt.[110] Once the National Bioengineered Food Disclosure Standard was enacted, the labeling requirement for genetically engineered salmon was met and the import alert was lifted.[111] This legislative effort was spearheaded by Alaska Senator Lisa Murkowski in an effort to protect the salmon industry in Alaska.[112] However, even though FDA now refers to these products as intentional genomic alterations in animals, they are still subject to the National Bioengineered Food Disclosure Standard.

IX. Legal Hurdles – NEPA lawsuit

AquAdvantage has been in development and in the market for over thirty years. Given this presence and novelty as the first entrant into this market, it has faced greater scrutiny from consumer and advocacy groups. Most notably, the Institute for Fisheries Resources commenced an action against the FDA relating to the environmental analysis the agency conducting in reviewing AquaBounty's new animal drug application for AquAdvantage. The case challenged FDA's authority to regulate the altered salmon and questioned the agency's decision to regulate the salmon as a drug instead of a food.[113] The court found that FDA did have the authority to regulate genetically engineered salmon to avoid a regulatory gap and ensure proper oversight of the food derived from the animal.[114] However, the environmental claims warranted greater consideration.

As part of the FDA's analysis of AquAdvantage, they conducted an environmental review under the National Environmental Policy Act ("NEPA").[115] At the time of this review,

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[110] U.S. DEP'T OF AGRIC. AGRIC. MKTG. SERV., NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD, 2 (2019).
[111] Statement from FDA Commissioner Scott Gottlieb, M.D., on continued efforts to advance safe biotechnology innovations, and the deactivation of an import alert on genetically engineered salmon, FOOD & DRUG ADMIN., April 08, 2019, https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-continued-efforts-advance-safe-biotechnology.
[112] Press Release, Lisa Murkowski Campaign for U.S. Senator, *Murkowski Statement on New U.S. Genetically Engineered Salmon Facility*, (May 1, 2018), https://www.murkowski.senate.gov/press/release/murkowski-statement-on-new-us-genetically-engineered-salmon-facility-.
[113] Brigit Rollins, *Fish Fumbles: GE Salmon Faces Uncertainty*, THE NAT'L AGRIC. LAW CTR. (Feb. 5, 2020), https://nationalaglawcenter.org/fish-fumbles-ge-salmon-faces-uncertainty/.
[114] *Id.*
[115] *Id.*

AquaBounty was only utilizing facilities in Canada and Panama at the time it applied to FDA.[116] The company's United States based facilities were not yet operational. Therefore, the agency only conducted an environmental review on the foreign facilities when making its decision to approve AquAdvantage.[117] FDA conducted the environmental assessment as required by NEPA and made a finding of no significant impact.[118] That is, FDA determined that AquAdvantage posed no environmental or ecological risks due to the containment measures in place at the facilities in Canada and Panama. As a result, no further assessment was needed by either Fish and Wildlife Service (FWS) or National Marine Fisheries Service (NMFS).

The plaintiffs challenge both of FDA's conclusions.[119] They alleged that FDA violated federal law by failing to conduct an appropriate review under either NEPA or the Endangered Species Act (ESA).[120] First, the plaintiffs aver that by only drafting an Environmental Impact Statement, FDA violated NEPA's provisions regarding the environmental assessment.[121] Second, the plaintiffs argued by not conferring with FWS or NMFS regarding potential harms to endangered wild salmon, FDA was in further violation of the ESA.[122]

In deciding the motion for summary judgment, the court stated that because the FDA did not conduct an analysis of "what might happen to normal salmon in the event the engineered salmon did survive and establish themselves in the wild," the FDA had violated NEPA and the ESA in approving the original application for the AquAdvantage facilities in Canada and Panama.[123] The case was "remanded to the FDA without vacatur for reconsideration of the environmental assessment under NEPA and the ESA analysis."[124] Therefore, the opinion orders the FDA to reanalyze the possible

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[116] *Id.*
[117] *Id.*
[118] *Q&A on FDA's Approval of AquAdvantage Salmon*, FOOD & DRUG ADMIN., https://www.fda.gov/animal-veterinary/aquadvantage-salmon/qa-fdas-approval-aquadvantage-salmon (last visited Dec. 2, 2022).
[119] Rollins, *supra* note 113.
[120] *Id.*
[121] Plaintiffs' Motion For Summary Judgment at 1, Inst. for Fisheries Res. v. Hanh, Case No. 3:16-cv-01574-VC (N.D. Cal. May 13, 2020).
[122] *Id.*
[123] Order Granting in Part and Denying in Part Plaintiffs' Motion for Summary Judgment at 16, Inst. for Fisheries Res. v. U.S. Food & Drug Admin., Case No. 16-cv-01574-VC (N.D. Cal. Nov. 5, 2020).
[124] *Id.*

escape by the salmon that are then able to survive and thrive in the wild.

However, the court order does not revoke the approval of AquAdvantage and the facilities in Canada, Panama, and Indiana that are currently in place. In fact, in response to the court's order, AquaBounty CEO, Sylvia Wulf stated in a statement, "The focus of this decision was on the potential environmental impacts, and the judge confirmed the 'low' threat to the environment of our salmon . . . [t]his decision will not have an impact on our on-going operations on Prince Edward Island, Canada to produce eggs or in the raising and selling of AquAdvantage salmon from our farm in (Albany) Indiana. We are committed to working with FDA on next steps and continue to evaluate the legal decision."[125] As a result, AquAdvantage was made available in May of 2021 at select restaurants.[126] Again there has been more pushback from advocacy groups including the Center for Food Safety regarding AquaBounty's compliance with the court's order. In March of 2022 the Center filed a Freedom of Information Act Lawsuit against the FDA for unlawfully withholding records regarding FDA's environmental assessment of genetically engineered (GE) salmon and a planned Ohio-based production facility.[127]

X. Conclusion

The regulatory and overall legal landscape surrounding animals with intentional genomic alterations or genetically engineered animals is complex and evolving rapidly. While the ultimate goal is to ensure the safety of the animals subjected to the alteration, the food or biomedical products produced from that animal, and the environment, it is clear that no one can agree on how to achieve that safety. This is exemplified by the agencies' difficulty in determining what to call these products – IGAs in animals, GE

[125] Sam Hill, *Federal judge rules FDA must reevaluate effects of potential GE salmon escape*, SEAFOOD SOURCE (Nov. 9, 2020), https://www.seafoodsource.com/news/food-safety-health/federal-judge-rules-fda-must-reevaluate-effects-of-potential-ge-salmon-escape.
[126] Smith, *supra* note 79.
[127] *FDA Sued Over Failure to Release Documents Regarding Approval of Genetically Engineered Salmon, Planned Ohio Production Facility*, CTR. FOR FOOD SAFETY (Mar. 10, 2020), https://www.centerforfoodsafety.org/press-releases/6589/fda-sued-over-failure-to-release-documents-regarding-approval-of-genetically-engineered-salmon-planned-ohio-production-facility.

animals, bioengineered animals, or something different. In order to adequately regulate these products and ensure safety, a unified regulatory structure surrounding these products needs to be developed.

Do States Prefer Alcohol Over Marijuana? A Look at Labeling Regulatory Differences Between the Alcohol and Edibles Industries

McKinley H. Groves*

I. Introduction

In the children's book *Through the Looking Glass and What Alice Found There*, Alice interacts with Humpty Dumpty. During their conversation, Humpty notes that he, alone, can decide the meaning of words.[1] Even Alice, at the young age of seven, casts doubt on this idea.[2] Definitions of words and phrases play an important role in human interactions and even more so when the words and phrases defined are within a statute. In the United States, Congress and state legislatures play the role of Humpty Dumpty by coming up with meanings of important words and phrases found in the laws they write. This is an important role of the legislatures to ensure the clarity of the law. While sometimes it is necessary to give different meanings to the same word, when the legislature uses unique phrases such as "appealing to children," one would expect the legislature to use the same meaning, given the limited applicability of the phrase. However, this phrase appears to have two different meanings when it comes to states that prohibit labels on marijuana edibles ("edibles") and alcohol that appeal to children. Regulations in the states that regulate such labels on both alcohol and edibles have been shown to have stricter standards for edible labels, even when the language of the regulations is nearly identical.

This note is not advocating for edible manufacturers to target children through advertising. Such advertising would likely lead to more small children accidentally ingesting edibles, which should be avoided. Rather, this note is arguing for state governments to cease violating the constitutional rights of edible manufacturers, given the labeling practices of the alcohol industry.

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[1] LEWIS CARROLL, THROUGH THE LOOKING-GLASS AND WHAT ALICE FOUND THERE 81 (1871).

[2] *Id.*

As of 2021, 18 states and Washington D.C. have legalized marijuana for recreational use.[3] In 2022, it is expected that number will increase to 25, assuming there are no setbacks to obtaining petition signatures like there were in 2020.[4] With this increasing number of states legalizing marijuana likely comes an increasing number of regulations prohibiting edibles from having labels that appeal to children. While the edibles industry is and will continue to be affected by these regulations, the alcohol industry is often not subject to such regulations. It is this lack of uniformity in regulation of mind-altering substances, particularly in regulations that prohibit labels that are appealing to children, that is the subject of this note. By setting one standard for edibles and another standard for alcohol, the states enacting these regulations have violated edible manufacturers' First Amendment rights. This note discusses the "cannot appeal to children" regulations on both marijuana and alcohol and the constitutional implications of such regulations. This note serves as a guide to both states that have already implemented these regulatory schemes, as well as states who will soon be legalizing recreational marijuana and will look for ways to best regulate their new industry.

In analyzing this topic, it is important to first grasp an understanding of the current regulatory schemes, looking at how the edibles industry have been scrutinized and also how the alcohol industry has been given free reign when it comes to labeling design choices. From there, one should understand the First Amendment implications of these regulatory schemes, especially those which prohibit labels from appealing to children.

II. Background

Before looking at the regulations prohibiting labels that appeal to children on both alcohol and edibles, one must compare the two products to understand why they should be regulated similarly. While alcohol and marijuana have different effects, both are mind-

[3] Casey Liens et al., *States Where Recreational Marijuana is Legal*, U.S. NEWS & WORLD REP. (Nov. 9, 2022), https://www.usnews.com/news/best-states/slideshows/where-is-pot-legal (Alaska, Arizona, California, Colorado, Connecticut, Illinois, Maine, Maryland, Massachusetts, Michigan, Missouri, Montana, Nevada, New Jersey, New Mexico, New York, Oregon, Rhode Island, Vermont, Virginia, Washington, and Washington D.C. have enacted marijuana legalization measures).

[4] Jon Campbell, *These States Could Legalize Cannabis Next in 2022*, LEAFLY (Oct. 25, 2021), https://www.leafly.com/news/politics/these-states-could-legalize-cannabis-next (Arkansas, Florida, Ohio, Oklahoma, and Pennsylvania are all expected to have ballot initiatives to legalize marijuana in 2022).

altering substances that have serious effects on children. Alcohol can slow down the breathing and heart rate of a small child while also lowering their blood pressure to dangerous levels, causing seizures or even death.[5] However, when a child ingests marijuana they will most likely suffer a state of lethargy, dizziness, increased heart rate, and in rare cases seizures.[6] Even in children, death from a marijuana overdose is extremely rare.[7] This article is not asserting marijuana is safer than alcohol, but rather arguing that the two substances are, at the very least, similar and should be regulated accordingly.

A. States Prohibit Edible Labels that Appeal to Children

First, to get a sense of the problem, it is important to look at the marijuana industry. While edibles have been around for centuries, in 2012 Colorado and Washington legalized marijuana for recreational use, which marked the beginning of the measurable U.S. edibles market, worth billions.[8] In recent years, these edibles have gone from simple "special" brownies to complex candies that resemble their non-marijuana infused counterparts.[9] Although this is quickly becoming a national issue, marijuana remains illegal under federal law as a Schedule I drug and the Food and Drug Administration (FDA) has refused to regulate recreational marijuana as a result.[10] This deferral leaves regulation to the states. In recent years, state legislatures justifiably began enacting regulations prohibiting labels that appeal to children.[11] Overall, these regulations have not led to the intended result of protecting children from

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[5] Rose Ann Gould Soloway, *Alcohol: A Dangerous Poison for Children*, POISON CONTROL NAT'L CAP. POISON CTR., https://www.poison.org/articles/alcohol-a-dangerous-poison-for-children (last visited Nov. 15, 2022).

[6] Linda Carroll, *Doctors Debate Whether Baby Died from Marijuana Overdose*, NBC NEWS (Nov. 17, 2017) https://www.nbcnews.com/health/kids-health/doctors-debate-whether-baby-died-marijuana-overdose-n821801.

[7] *Id.*

[8] *See* Colleen Fisher Tully, *A Global History of Cannabis Edibles*, LEAFLY (Dec. 4, 2019), https://www.leafly.com/news/canada/canada-world-history-cannabis-edibles; *see also Cannabis Edibles Expected to be a $4.1 Billion Business by 2022*, FOODABLE NETWORK INC., (Oct. 16, 2018), https://www.foodabletv.com/blog/cannabis-edibles-expected-to-be-a-41-billion-industry-in-the-us-and-canada-by-2022.

[9]Tori B. Powell, *State Attorneys General Warn of Cannabis Edibles that Look Like Snacks and Candy Ahead of Halloween*, CBS NEWS (Oct. 28, 2021), https://www.cbsnews.com/news/halloween-candy-snacks-cannabis-edibles-warning/.

[10] *See* 21 C.F.R. § 1308.11 (2022); Sheryl C. Cates & Jenny L. Wiley, *Marijuana Edibles and Labeling*, RTI INT'L, https://www.rti.org/impact/marijuana-edibles-and-labeling (Last visited Nov. 15, 2022).

[11] *See* 1 COLO. CODE REGS. § 212-3:3-1010; MICH. ADMIN. CODE r. 420.403; OR. ADMIN. R. 845-025-7000 (2018).

accidental ingestion and some have even cost manufacturers hundreds of thousands of dollars.

In 2016, Colorado enacted a regulation prohibiting the word "candy" or "candies" from appearing on edible labels.[12] Colorado later prohibited labels appealing to children in 2020.[13] This regulation prohibited manufacturers from "plac[ing] any content on a Container or the Marketing Layer in a manner that reasonably appears to target individuals under the age of 21, including but not limited to, cartoon characters or similar images."[14] Although these measures were taken to protect children from unintentionally ingesting marijuana, the numbers prove the opposite is true. Since the first regulation passed in 2016, accidental marijuana ingestion in children age 0-5 years old has more than tripled, jumping from 33 cases in 2016 to 127 in 2020.[15] While the observed increase in accidental ingestions may be indicative of the increase in marijuana availability in the state, it is important to note the regulations prohibiting labels that appeal to children have had little if any effect on curbing the increase in accidental marijuana ingestion among small children. Not only are these regulations ineffective, but they also have cost manufacturers hundreds of thousands of dollars in modifying their products to comply with the law.[16] This is in addition to the $100,000 fine and suspended license manufacturers suffer if they fail to comply with the regulations.[17]

While Colorado was one of the first states to adopt regulations prohibiting edibles with labels that appeal to children, in recent years more states have been following this approach. In Michigan, "cartoons, caricatures, toys, designs, shapes, labels, or packaging that would appeal to minors," are prohibited from edible labels.[18] Moreover, Michigan also prohibited edible manufacturers from using images of animals, humans, or fruit on their labels.[19] Like

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[12] Press Release, Colo. Dept. of Rev. & Colo. Dept. of Pub. Health & Env't, New Colorado Rules Make Marijuana Packaging Safer for Adults, Less Appealing to Children (Sept. 2016).
[13] 1 COLO. CODE REGS. § 212-3:3-1010.
[14] *Id.*
[15] Rocky Mountain Poison & Drug, *Reported Marijuana Exposures in Colorado,* COLORADO DEP'T OF PUB. HEALTH & ENV'T, https://marijuanahealthinfo.colorado.gov/health-data/poison-center-data (last visited Nov. 21, 2022).
[16] John Schroyer, *New Colorado Edibles Rules: Major Cost for Producers, 'Blip on the Radar' for Others*, MJBizDaily (Sept. 26, 2016), https://mjbizdaily.com/new-co-edibles-rules-major-cost-producers-blip-radar-others/.
[17] 1 COLO. CODE REGS § 212-3:8-235 (2020).
[18] MICH. ADMIN. CODE r. 420.403.
[19] *Id.*

Colorado, Michigan also prohibits the use of the word "candy" or "candies" on edible labels, but Michigan takes this a step further by prohibiting "words that are commonly used in commercial candy such as milk chocolate, peanut butter, gummies, or chews without using the words THC, marijuana, or cannabis as modifiers."[20]

> In Oregon, edible labels may not show:
>
> cartoons, a design, brand, or name that resembles a non-cannabis consumer product of the type that is typically marketed to minors, symbols or celebrities that are commonly used to market products to minors, images of minors, words that refer to products that are commonly associated with minors or marketed by minors.[21]

While these requirements appear similar to the ones in effect in Colorado, in actuality, manufacturers selling in both states must use different labels on the same product. One example of this is Wana's Watermelon-flavored Sour Gummy edibles, which in Colorado bear a label with the words "Sour Gummies" and pictures of watermelon wedges, but in Oregon, the same product bears the words "Cannabis Infused Sour Gummies" with a very prominent warning label.[22] Were the product to be sold in Michigan, the company would have to remove the images of fruit and the word "gummies" from its label to comply with that state's regulations.[23] Do children in different regions have such different preferences that the regulations intended to prevent them from ingesting harmful substances should be different? Or are the labels the result of a lack of uniformity in regulation that harms both edible manufacturer and consumers? Table 1 shows the similarities and differences in the language of the state regulations prohibiting edible manufacturers from using labels that are appealing to children.

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[20] *Marijuana Infused Edibles: Enforcement Guide*, MICH. MARIJUANA REGUL. AGENCY (Aug. 2, 2021), https://www.michigan.gov/documents/mra/Marijuana-Infused_Edibles_Bulletin_-_080221_731636_7.pdf.
[21] OR. ADMIN. R. 845-025-7000 (2018).
[22] Valeriya Safronova, *Big Candy is Angry*, N.Y. TIMES (May 22, 2021), https://www.nytimes.com/2021/05/22/style/edibles-marijuana.html.
[23] MICH. ADMIN. CODE r. 420.403.

Table 1

State	Regulation	Regulation Language
California	4 CA ADC § 15040	(a)(3) – (a) Any advertising or marketing, as defined in Business and Professions Code section 26150, that is placed in broadcast, cable, radio, print, and digital communications: (3) Shall not use any images that are attractive to children, including, but not limited to: (A) Cartoons; (B) Any likeness to images, characters, or phrases that are popularly used to advertise to children; (C) Any imitation of candy packaging or labeling; or (D) The terms "candy" or "candies" or variants in spelling such as "kandy" or "kandeez."
	4 CA ADC § 17408	(a)(2) – (a) Cannabis goods labeling shall not contain any of the following: (2) Content that is, or is designed to be, attractive to individuals under the age of 21, as specified in section 15040(a)(2) and (3).

Colorado	1 CO ADC 212-3:3-1010	(B)(2) - Labels Shall Not Be Designed to Appeal to Children. A Regulated Marijuana Business shall not place any content on a Container or the Marketing Layer in a manner that reasonably appears to target individuals under the age of 21, including but not limited to, cartoon characters or similar images. (B)(8)(a) - Licensees shall not use the word(s) "candy" and/or "candies" on the label of any Container holding Regulated Marijuana, or of any Marketing Layer.
Illinois	IL ST CH 410 § 705/55-21	(f)(5) – (f) Packaging must not contain information that: (5) includes any image designed or likely to appeal to minors, including cartoons, toys, animals, or children, or any other likeness to images, characters, or phrases that are popularly used to advertise to children, or any packaging or labeling that bears reasonable resemblance to any product available for consumption as a

		commercially available candy, or that promotes consumption of cannabis
Maine	28-B M.R.S.A. § 701	(4)(B) and (D) - Adult use marijuana and adult use marijuana products to be sold or offered for sale by a licensee to a consumer in accordance with this chapter: (B) May not be labeled or packaged in a manner that is specifically designed to appeal particularly to a person under 21 years of age; (D) May not be sold or offered for sale using a label or packaging that depicts a human, animal or fruit;
Massachusetts	935 MA ADC 500.105	(6)(b) – Packaging for Marijuana or Marijuana Products sold or displayed for Consumers, including any label or imprint affixed to any packaging containing Marijuana, Marijuana Products or any exit packages, may not be attractive minors. Packaging is explicitly prohibited from: 1. Using bright colors, defined as colors that are "neon" in appearance; 2.

		Imitating or having a semblance to any existing branded consumer products, including foods and Beverages, that do not contain marijuana; 3. Featuring cartoons; 4. Featuring a design, brand or name that resembles a non-cannabis consumer product of the type that is typically marketed to minors; 5. Featuring symbols or celebrities that are commonly used to market products to minors; 6. Featuring images of minors; and 7. Featuring words that refer to products that are commonly associated with minors or marketed to minors.
Michigan	MI ADC R. 420.403	(9)(a) and (b) - (a) Edible marihuana product packages shall not be in a shape or labeled in a manner that would appeal to minors aged 17 years or younger. Edible marihuana products shall not be associated with or have cartoons, caricatures, toys, designs, shapes, labels, or packaging that would appeal to minors. (b) Edible marihuana products shall not be easily

		confused with commercially sold candy. The use of the word candy or candies on the packaging or labeling is prohibited. Edible marihuana products shall not be in the distinct shape of a human, animal, or fruit, or a shape that bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings. Edible marihuana products that are geometric shapes and simply fruit flavored are permissible.
Montana	MT ADC 42.39.319	(1)(c) – All packaging of marijuana and marijuana products shall: (c) not primarily appeal to children. Packaging that primarily appeals to children includes but is not limited to packaging that: (i) depicts a child; (ii) portrays objects, images, celebrities, or cartoon figures that primarily appeal to children or are commonly used to market products to children; or (iii) otherwise has special

		attractiveness for children beyond the general attractiveness for adults;
Nevada	NV ADC 453D.805	(1)(b) – (d) – Any edible product containing marijuana must: (b) Be packaged in a manner which is not modeled after a brand of products primarily consumed by or marketed to children; (c) Be presented in packaging which does not contain an image of a cartoon character, mascot, action figure, balloon or toy, except that such an item may appear in the logo of the marijuana product manufacturing facility which produced the product; and (d) Not be packaged or marketed as candy.
New Jersey	24 N.J.S.A. § 6I-35	(7)(a)(iv) - Cannabis items and cannabis paraphernalia are not packaged, branded, or marketed using any statement, illustration, or image that: (iv) Includes objects, such as toys, characters, or cartoon characters suggesting the presence of a person under the legal age to purchase cannabis items, or any other depiction

		designed in any manner to be especially appealing to persons under the legal age to purchase cannabis items;
New Mexico	NM ADC 7.34.4.16	(A) A package containing usable cannabis shall not display any content that reasonably appears to target minors, including but not limited to, cartoon characters or similar images. A product name or package shall not be modeled after a brand of product that is traditionally marketed toward children.
Oregon	OAR 845-025-7000	(3) "Attractive to minors" means packaging, receptacles, inhalant delivery devices, labeling and marketing that features: (a) Cartoons; (b) A design, brand or name that resembles a non-cannabis consumer product of the type that is typically marketed to minors; (c) Symbols or celebrities that are commonly used to market products to minors; (d) Images of minors; and (e) Words that refer to products that are

		commonly associated with minors or marketed by minors. (12) "Cartoon" means any drawing or other depiction of an object, person, animal, creature or any similar caricature that satisfies any of the following criteria: (a) The use of comically exaggerated features; (b) The attribution of human characteristics to animals, plants or other objects, or the similar use of anthropomorphic technique; or (c) The attribution of unnatural or extra-human abilities, such as imperviousness to pain or injury, X-ray vision, tunneling at very high speeds or transformation.
	OAR 333-007-0090	(8)(b) – A label may not be attractive to minors, as that is defined in OAR 845-025-7000.
Washington	WAC 314-55-105	(1)(c) - "Especially appealing to persons under the age of twenty-one" means a product or label that includes, but is not limited to: (i) The use of cartoons;

		(ii) Bubble-type or other cartoon-like font; (iii) A design, brand, or name that resembles a noncannabis consumer product that is marketed to persons under the age of twenty-one; (iv) Symbols or celebrities that are commonly used to market products to persons under the age of twenty-one; (v) Images of persons under the age of twenty-one; or (vi) Similarities to products or words that refer to products that are commonly associated or marketed to persons under the age of twenty-one. (1)(g)(iv) - Labels for marijuana edibles in solid form may not contain any statement, depiction, or illustration that: Depicts a person under the age of twenty-one consuming marijuana, or is especially appealing to persons under twenty-one years of age as defined in subsection (1)(c) of this section.

While the reasons given by state legislators in prohibiting edible manufacturers from using labels that appeal to children are seemingly valid, when one compares these regulations to similar ones applicable to the alcohol industry, they can see the unfairness and resulting violations of edible manufacturers' First Amendment rights.

B. Labels that Appeal to Children are Prohibited from Alcohol Labels. Or are They?

Before discussing the regulations prohibiting alcohol labels from appealing to children, it is important to understand how the alcohol industry is regulated. At the federal level, alcohol labels are regulated by the Alcohol and Tobacco Tax and Trade Bureau (TTB).[24] However, these regulations are concerned with the label's description of the container's contents and any health claims made by the label instead of whether the label makes the product appealing to children.[25] So, if the federal government does not prohibit alcohol labels from appealing to children, who does? The states? No. Most states take a similar approach to alcohol labeling as the federal government. In fact, as discussed further, of the 18 states that have legalized marijuana for recreational use, only two prohibit alcohol labels that appeal to children.[26] In actuality, the alcohol industry is largely self-regulated when it comes to the advertising content of alcohol labels.[27]

Three institutes are mostly responsible for regulating the alcohol industry and prohibiting labels that appeal to children, the Beer Institute (BI), Distilled Spirits Council of the United States (DISCUS), and the Wine Institute (WI).[28] Each institute has its own set of guidelines for members to follow when participating in advertising activities, which includes the alcohol's labeling.[29]

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[24] *See* 27 C.F.R. § 4.39 (2006); *see also* 27 C.F.R. § 5.42 (2020); *see also* 27 C.F.R. § 7.29 (2020); *see also* 27 C.F.R. § 25.142 (2006).
[25] *See* 27 C.F.R. § 4.39; *see also* 27 C.F.R. § 5.42; *see also* 7 C.F.R. § 7.29; *see also* 27 C.F.R. § 25.142.
[26] WASH. ADMIN. CODE § 314-20-020 (2018); MONT. ADMIN. R. 42.13.201 (2019).
[27] *See* Fed. Trade Comm'n, Self-Regulation in the Alcohol Industry, 1–2 (Mar. 2014).
[28] *Id.* at 1.
[29] *See* Beer Inst., Advertising/Marketing Code and Buying Guidelines (2018); *see also Wine Institute's Code of Advertising Standards,* WINE INST. (June 2011), https://wineinstitute.org/our-work/responsibility/social/ad-code; *see also*

Before considering whether self-regulation is a workable alternative to the status quo of edible labeling regulation, one should examine the impact this scheme has on the alcohol industry. The emergence of microbreweries in recent years has proved that self-regulation does not stop alcohol labels that appeal to children.[30] For example, Fossil Cove Brewing Co. in Fayetteville, Arkansas sells cans of beer featuring cartoon images of dinosaurs riding skateboards, T-Rexes eating peaches, and sasquatches wearing boxers while eating a popsicle.[31] Fossil Cove's approach is not uncommon among local breweries. One can find cartoons appearing on the labels of local brewery beer cans in liquor stores from coast to coast.[32] In California, Paperback Brewing Co. sells cans featuring bunnies with chainsaws and other comic book-like art; while in New York penguins in spacesuits decorate the cans of Kings' County Brewers Collective.[33] Not only that, but breweries are discovering that cartoons on beer labels can significantly boost sales.[34] One example of this is New Belgium's Voodoo Ranger, a beer that has become the most popular Imperial IPA since its debut in 2017 and was the top beer launch in the United States and increased New Belgium's IPA sales by 45%.[35] Voodoo Ranger features a cartoon skeleton on its label which was awarded the second best beer label in 2017 according to USA Today, other beer labels on the list include Three Heads Brewing's Captain Banana Unfiltered Wheat Beer, which depicts a monkey in an Evel Knievel-like jumpsuit; Red Cypress Brewery's Devil's Chair IPA which features a cartoon devil lounging in a chair while drinking a glass of beer; and Laughing Dog Brewing's Dogzilla Black IPA which features a cartoon dog resembling Godzilla.[36] Given these labels listed and the similar ones that can be found throughout the country, it can be concluded that

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Distilled Spirits Council of the U.S., Code of Responsible Practices for Beverage Alcohol Advertising and Marketing (Mar. 2021).

[30] *See generally* Dan Fox, *Irresponsible Marketing and Craft Beer*, THE DRINKS BUS. (Mar. 11, 2014), https://www.thedrinksbusiness.com/2014/03/irresponsible-marketing-and-craft-beer/.

[31] *Our Beers,* Fossil Cove Brewing Co., https://www.fossilcovebrewing.com/beers (last visited Nov. 15, 2022).

[32] Joshua M. Bernstein, *Cartoons Are Becoming the Beer Industry's Best New Sales Tool*, SevenFiftyDaily (Aug. 30, 2021), https://daily.sevenfifty.com/cartoons-are-becoming-the-beer-industrys-best-new-sales-tool/.

[33] *Id.*

[34] *Id.*

[35] *Voodoo Ranger*, Frost Motion, https://frostmotion.com/project/voodoo-ranger/ (last visited Nov. 17, 2022).

[36] *10 Best Beer Labels of (2017)*, USA TODAY, https://www.10best.com/awards/travel/best-beer-label-2017/ (last visited Nov. 17, 2022).

self-regulation in the alcohol industry has not led to a decrease in the number of labels that appeal to children.

The problem is not unique to small craft breweries, but in the liquor industry as well. One example of this is UV's Sugar Crush Vodka, which features a cartoon image of candy on the top of its bright purple bottle.[37] In his article "Limp DISCUS—How Alcohol Lacks a Watchdog," Geoff Kleinman discusses his experience in filing a complaint with DISCUS regarding Sugar Crush's label.[38] Even after pointing out the issue to DISCUS, DISCUS found that, because the primary target is adults, not children, the label did not violate regulations even though it had images of cartoon candy on the label, which would, presumably, be a violation of DISCUS's self-imposed regulation to not allow images on labels which may appeal to children.[39] The alcohol industry's label regulatory system shines a light on the problem of self-regulation in industries intended to target adults only; while also emphasizing the fact that the edibles industry is treated unconstitutionally regarding labeling regulations.

Remember that two states, Montana and Washington, prohibit labels that appeal to children on both alcohol and marijuana edibles.[40] While these states do not allow unbridled self-regulation in the alcohol industry, they seem to do little to reduce the number of alcohol labels that appeal to children. While Montana's regulations are shown below and in Table 1, this note will focus only on Washington's labeling regulations for edibles and beer.

First, looking at Montana's edibles labeling regulation, one can tell that it resembles those regulations in effect in Colorado and Oregon. Montana's labeling regulation reads:

> All packaging of marijuana and marijuana products shall: (c) not primarily appeal to children. Packaging that primarily appeals to children includes but is not limited to packaging that: (i) depicts a child; (ii) portrays objects, images, celebrities, or cartoon figures that primarily appeal to children or are commonly used to market products to children; or

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[37] Geoff Kleinman, *Flavored Vodka Goes Too Far: UV Sugar Crush Vodka*, DRINK SPIRITS (Jul. 21, 2014), https://www.drinkspirits.com/vodka/flavored-vodka-goes-far-uv-sugar-crush-vodka/.

[38] Geoff Kleinman, *Limp DISCUS–How Alcohol Lacks a Watchdog*, DRINK SPIRITS (Jan. 13, 2015), https://www.drinkspirits.com/general-spirits/limp-discus-alcohol-lacks-watchdog/.

[39] *See id.*

[40] WASH. ADMIN. CODE § 314-20-020 (2018); *See* Mont. Admin. R. 42.13.201 (2019).

> (iii) otherwise has special attractiveness for children beyond the general attractiveness for adults.[41]

The only noticeable difference in this regulation compared to other regulations is the prohibition on labels that have "special attractiveness for children beyond the general attractiveness for adults."[42] This inclusion allows a little more breathing room for edible manufacturers to argue that their designs, which do not fall into the other prohibited categories are attractive to both children and adults.

Montana's alcohol labeling regulation is not near as detailed as its edibles labeling regulation. The alcohol labeling regulation reads:

> The department [of revenue], in its discretion and on a case-by-case basis, will not approve a beer, wine, or hard cider label or primary package that . . . (c) contains graphics or elements that: (i) are designed to target or particularly appeal to underage persons.[43]

This regulation, like the edibles labeling regulation, allows for manufacturers to use labels that are appealing to both adults and children, so long as the label is not "designed to target or particularly appeal to underage persons."[44] However, there are two main differences between the alcohol labeling regulation and the edibles labeling regulation. The first is that the department of revenue uses its discretion in deciding whether to approve the alcohol labels that conflict with the regulation, whereas edible labels are strictly prohibited from using labels that contradict the regulation. The other difference is that, unlike the edibles labeling regulation, this regulation does not go further to prohibit certain images that would be appealing to children like cartoons, children, etc. As this note will discuss in detail below, this is a content preference for alcohol labels and should be subject to strict scrutiny.

Washington's edibles labeling regulation is similar to that of other states discussed above. Washington's regulation prohibits labels that are "Especially appealing to persons under the age of twenty-one," which includes:

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[41] MONT. ADMIN. R. 42.39.319(1)(c) (2022).
[42] *Id.*
[43] MONT. ADMIN. R. 42.13.201(c)(i).
[44] *Id.*

> (i) The use of cartoons; (ii) Bubble-type or other cartoon-like font; (iii) A design, brand, or name that resembles a noncannabis consumer product that is marketed to persons under the age of twenty-one; (iv) Symbols or celebrities that are commonly used to market products to persons under the age of twenty-one; (v) Images of persons under the age of twenty-one; or (vi) Similarities to products or words that refer to products that are commonly associated or marketed to persons under the age of twenty-one.[45]

The statute also defines cartoon as:

> any drawing or other depiction of an object, person, animal, creature, or any similar caricature that meets any of the following criteria: (i) The use of comically exaggerated features; (ii) The attribution of human characteristics to animals, plants, or other objects; (iii) The attribution of animal, plant, or other object characteristics to humans; (iv) The attribution of unnatural or extra-human abilities.[46]

The Washington State Liquor and Cannabis Board (WSLCB) went a step further to clarify exactly what is prohibited from appearing on labels when it published its Packaging and Labeling Guide for Medically Compliant and Recreational Marijuana. The guide shows examples of the cartoon definition including, but not limited to, a gorilla smoking a pipe and a singing marijuana leaf.[47]

Comparing Washington's edibles label regulation with its beer label regulation, one can see many similarities. The beer label regulation states:

> No beer shall be imported or sold within the state of Washington until the licensed brewery, or certificate of approval holder, submitted to the board, one copy of the federal certificate of label approval for such beer, issued by the Bureau of Alcohol, Tobacco, and Firearms, U.S. Treasury Department . . . No label will be approved which is designed to be especially

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[45] WASH. ADMIN. CODE § 314-55-105(c)(2022).
[46] *Id.* § 314-55-105(a).
[47] WASH. STATE LIQUOR & CANNABIS BD., Packaging and Labeling Guide for Medically Compliant and Recreational Marijuana 16 (2019).

> appealing to children or other persons under legal age to consume.[48]

The use of the same "especially appealing to children" language implies that the Washington legislature intended there to be no use of cartoons on labels of beer sold within the state. However, as this note will show, beer labels featuring cartoons and other graphics that appeal to children are common in the state. It is this disparity that gives rise to a potential First Amendment claim on behalf of edible manufacturers.

III. Constitutional Implications of State Regulations on Edibles Labels

The information on a product's label is considered commercial speech.[49] As the Supreme Court first held in *Central Hudson*, commercial speech is protected under the First Amendment.[50] Before delving into whether Washington's edibles regulation violates the First Amendment, it is important to understand what level of scrutiny the court views regulations limiting commercial speech.

In *Central Hudson*, the court developed a four-prong test to determine whether commercial speech is protected by the First Amendment. This four-prong test asks whether (1) "the commercial speech concerns a lawful activity and is not misleading," (2) "the asserted governmental interest is substantial," (3) "the regulation directly advances the governmental interest asserted," and (4) "whether [the regulation] is not more extensive than necessary to serve that interest."[51] If the second, third, or fourth prong of the test fails, then the commercial speech is protected under the First Amendment.[52] Intermediate scrutiny is the standard utilized by the courts when using the *Central Hudson* test to decide most commercial speech cases, meaning that the court looks at the government restriction to determine if it is substantially related to an important governmental interest.[53]

Having determined the test and level of scrutiny applicable to regulations like the one in Washington, the next question is whether the regulation would survive the *Central Hudson* test. Given

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[48] WASH. ADMIN. CODE § 314-20-020(5)(2022).
[49] Rubin v. Coors Brewing Co., 514 U.S. 476 (1995).
[50] Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 566 (1980).
[51] *Id.*
[52] *Id.* at 569–71.
[53] *Id.*

the lack of litigation regarding this law, it is easiest to make this determination after presenting a hypothetical set of facts and applying the *Central Hudson* test to that scenario.

The first obstacle an edible manufacturer would have to overcome to satisfy the *Central Hudson* test is the requirement that the label not be misleading.[54] One could argue that placing cartoons or other designs that appeal to children on edibles or other products not meant for children would be misleading even to the most reasonable consumer, especially if those labels resemble the labels of other, non-cannabis products consumed by children. Such products have been the subject of recent intellectual property litigation between candy manufacturers and edible manufacturers.[55] Moreover, an edibles package in compliance with Washington law, would have prominent warning labels showing that it is a marijuana product.[56] Thus, it is likely the label of an edible would satisfy the first requirement of *Central Hudson* to be protected by the First Amendment.

The next prong of *Central Hudson* is more easily determined. The government's asserted interest in protecting children from accidentally ingesting potentially harmful substances is a substantial interest as required by *Central Hudson*'s second prong. Thus, this prong is satisfied, and the analysis can move to the third prong.

For Washington's labeling regulation to satisfy the third prong of the *Central Hudson* test, it must directly advance the government's asserted interest.[57] The Supreme Court has stated that "the third step of *Central Hudson* requires that the government demonstrate that the harms it recites are real and that its restriction will, in fact, alleviate them to a material degree."[58] The Court has repeatedly held that evidence of alleviation is required to satisfy the third prong of *Central Hudson*, although this evidence may simply be a reference to studies affirming the government's position.[59] While the WSLCB relied on studies stating children are attracted to colorful packages with cartoons or other graphics appealing to children, those studies also point out many other factors that appeal

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[54] *Id.*
[55] *See* WM. Wrigley Jr. Co. v. Terphogz, LLC, No. 21 C 2357, 2021 WL 5356229 (E.D. Ill. Nov. 17, 2021); *see also* Ferrara Candy Co. v. Inland Empire 420 Supply, Case No. EDCV 20-2357 JGB (KKx), 2021 WL 2915086 (C.D. Cal. Jun. 23, 2021).
[56] *See* WASH. ADMIN. CODE § 314-55-105 (2020).
[57] Central Hudson, 447 U.S. at 566.
[58] Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 555 (2001) (quoting Greater New Orleans Broad. Ass'n v. United States 527 U.S. 173, 188 (1993)).
[59] *Id.*

to children, such as odor, color, and shape of the food itself.[60] Those studies do not argue that removing colorful labels viewed as appealing to children would reduce the number of small children who accidentally ingest edibles. The evidence shows the opposite is true.

In the first nine months of 2020, Washington Poison Control received 139 reports of children under 12 accidentally ingesting marijuana.[61] That is 19 more cases than the total number of marijuana incidents in that age group reported to Washington Poison Control in 2019.[62] To prove the regulation alleviates the harm to a material degree, Washington would have to provide evidence proving that the labeling regulation has helped to curb the problem of small children accidentally ingesting marijuana.[63] However, the labeling regulation prohibiting edibles from using labels that appeal to children has proven ineffective as accidental ingestion of edibles among children has increased not decreased. Thus, a court would likely find Washington's regulation fails to satisfy the third prong of the *Central Hudson* test, thereby violating the First Amendment. For the sake of argument, however, this note's analysis will continue to the fourth prong.

The fourth prong of *Central Hudson* Washington's labeling regulation would have to satisfy is that it must not be more extensive than necessary to serve the asserted interest.[64] If there are less restrictive methods to satisfy the government's interest, the fourth prong is not satisfied and the regulation violates the First Amendment.[65] As the earlier referenced Washington University School of Law study notes, one of the main factors attracting children to food is the shape of the food.[66] While Washington regulates the labeling and packaging of edibles sold in the state, it leaves the edible itself unregulated. Cannabis retailers in Washington have menus featuring edibles that resemble baked goods, candy, chips, and other items on which children would normally snack. Regulating the shape and type of edibles able to be sold in Washington is a type of regulation that would be less restricting of edible manufacturers' First Amendment rights than the current labeling regulation. Thus,

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[60] SEAN O'CONNOR ET. AL., CONCERNING CANNABIS INFUSED EDIBLES: FACTORS THAT ATTRACT CHILDREN TO FOODS (Univ. of Wash. Sch. Of L., Cannabis L. & Pol'y Project 2016).
[61] WASH. POISON CTR., EXPOSURE TRENDS DURING THE COVID-19 PANDEMIC, SPECIAL FOCUS: CANNABIS (THC) (2020).
[62] *Id.*
[63] Lorillard Tobacco Co., 533 U.S. at 555.
[64] Central Hudson, 447 U.S. at 566.
[65] 44 Liquormart v. R.I., 517 U.S. 484, 487 (1996) (citing Bd. of Trs. v. Fox, 492 U.S. 469, 480 (1989)).
[66] *See* O'Conner, *supra* note 60.

because of the existence of less restrictive alternatives, the Washington regulation fails to satisfy the fourth prong of *Central Hudson*, thereby violating the First Amendment.

As the above analysis concludes, because the Washington regulation would likely fail to satisfy the third and fourth prongs of the *Central Hudson* test the regulation likely violates the First Amendment. *Central Hudson* requires courts to employ intermediate scrutiny in deciding commercial speech cases.[67] However, it is likely the Court would hold that government actions like the Washington edibles labeling regulation should be subject to strict scrutiny.

Recent cases have suggested that strict scrutiny, not intermediate scrutiny is the right standard to decide commercial speech cases, particularly those concerning commercial speech regulations demonstrating a preference for certain content.[68] As the Supreme Court has stated, "laws favoring some speakers over others demand strict scrutiny when the legislature's speaker preference reflects a content preference."[69] This content preference rule has been employed by the Court in several cases involving commercial speech. *Rubin v. Coors Brewing, Inc.* is an example of this. In *Rubin*, the Court held a ban against beer labels that listed the alcohol by volume content on the label was irrational deferential treatment given the fact that wine labels were not subject to such restriction.[70] Another example of the court employing strict scrutiny in cases involving a content preference is *Reed v. Town of Gilbert, Ariz.*, which held that a city sign code imposing stricter restrictions on directional signs for nonprofit groups than on those conveying other messages did not survive strict scrutiny.[71]

An individual can observe a clear disparity when looking at Washington's labeling regulations of both edibles and beer. One example of the disparity is Fort George Brewery's 3-Way IPA. Fort George Brewery, which is located in Astoria, Oregon but sells in Washington stores is one example of this.[72] Like most breweries, Fort George has year-round beers as well as seasonal beers. One of Fort George's seasonal beers is the 3-Way IPA which features a peacock, turkey, and penguin playing a violin, guitar, and drum set

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[67] *See* Central Hudson, 447 U.S. at 568-572.
[68] *See* Reed v. Town of Gilbert, 576 U.S. 155, 170 (2015); *See* Rubin v. Coors Brewing Co., 514 U.S. 476, 490-91 (1995).
[69] Barr v. Am. Ass'n of Political Consultants, 140 S. Ct. 2335, 2347 (2020) (quoting Reed, 576 U.S. at 170).
[70] Rubin, 514 U.S. at 483, 488–89.
[71] Reed, 576 U.S. at 170-71.
[72] *Distribution,* FORT GEORGE BREWERY, https://fortgeorgebrewery.com/beers/fort-george-distribution/ (Last visited Nov. 17, 2022).

respectively on its 2021 edition can.[73] Previous versions of 3-Way IPA have featured images of cats wearing clothes and playing instruments as well as a gorilla, dragon, and armadillo playing instruments.[74] Recall that, for beer to be sold in Washington, the label must be approved by the WSLCB, meaning that Fort George annually gets its cartoonish labels approved whereas edible manufacturers are punished for similar conduct.

Since the regulation prohibiting labels that appeal to children on edibles went into effect in 2019, eight edible manufacturers have been issued written warnings for violating the regulation.[75] While this number may seem insignificant, it should be noted that the marijuana industry has a 95% compliance rate according to the WSLCB.[76] Further, the written warnings are a precursor to an Administrative Violation Notice ("AVN") which would impose a penalty on the manufacturer, meaning that if the manufacturers do not change their labels, they will be forced to pay penalties for violating the regulation, both avenues are a significant cost to the manufacturer. Further, the eight written warnings are eight more than Washington breweries received for labels appealing to children during the same period.[77]

Washington is not the only state that seems to favor the alcohol industry through labeling regulations. In its advisory bulletin, Michigan's Marijuana Regulatory Agency (MRA) gives several examples of what it considers labels that are appealing to children and thus, illegal under Michigan Law.[78] One example of a label that allegedly appeals to children is the label of Fireball's Cinnamon Cannabis Gummies which bears the same fire-breathing demon Fireball uses on its whiskey bottles.[79] In its bulletin, the MRA states that the label is appealing to children because it features an "image[] of [an] animal/caricature."[80] The MRA stated that the removal of

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[73] *3-WAY IPA 2021*, Fort George Brewery, https://fortgeorgebrewery.com/beer/3-way-ipa-2021/ (Last visited Nov. 17, 2022).

[74] *3-WAY IPA Series*, Fort George Brewery, https://fortgeorgebrewery.com/beers/3-way-series/ (Last visited Nov. 17, 2022).

[75] *Cannabis Violations*, WASH. STATE LIQUOR & CANNABIS BD (2021), https://lcb.wa.gov/records/frequently-requested-lists).

[76] WASH. STATE LIQUOR & CANNABIS BD, Annual Report Fiscal Year 2021 6 (2021).

[77] *Liquor Violations*, WASH. STATE LIQUOR & CANNABIS BD (2021), https://lcb.wa.gov/records/frequently-requested-lists.

[78] Ad*visory Bulletin, Marijuana Infused Edibles: Enforcement Guidance*, MICH. MARIJUANA REGUL. AGENCY (Aug. 2, 2021) https://www.michigan.gov/documents/mra/Marijuana-Infused_Edibles_Bulletin_-_080221_731636_7.pdf.

[79] *Id*. at 11.

[80] *Id.*

Fireball's fire-breathing demon is necessary to make the product compliant under Michigan law.[81] The MRA claims the logo is appealing to children even though the logo does not appear on any other product besides Fireball Whiskey.[82] This is a blatant content preference for alcohol and should also be subject to strict scrutiny.

Like the prohibition on labels showing alcohol content of beer at issue in *Rubin*, Washington's current regulatory scheme is a clear example of a regulation on commercial speech showing a content preference. Thus, because the Washington edibles statute would most likely be classified as showing a content preference for alcohol manufacturers, the Court would likely apply strict scrutiny in a case brought before it regarding Washington's edibles labeling regulation rather than the *Central Hudson* test. This means Washington would have to prove the regulation is narrowly tailored to meet a compelling government interest. Since, as outlined above, Washington's regulation would fail to survive the intermediate scrutiny standard required by *Central Hudson*, the chances of the same regulation surviving strict scrutiny are remote.

IV. Conclusion

States with regulations prohibiting edibles from having labels that are appealing to children display a preference for the alcohol industry. This preference violates the First Amendment rights of edible manufacturers. Not only that, but they have also failed to protect children from accidentally ingesting edibles. This will soon become a national issue. More and more states are legalizing recreational marijuana and are adopting similar regulations prohibiting what edible manufacturers may put on their labels. These regulations show a preference for alcohol manufacturers and are subject to strict scrutiny which they do not satisfy. Because of this, states should stop showing a preference for the alcohol industry and remove regulations that prohibit edible labels that appeal to children.

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[81] *Id.*
[82] *Id*.