

ANIMAL LAW FUNDAMENTALS

Cutting Edge Issues in 21^{st} Century Animal Food Product Labeling

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Why do we as a 21st century society label goods, including food products and specifically animal food products? To what end(s)? Perhaps because there is a goal and an expectation that the public purchasing those goods will make better, more informed decisions if they have information with which to make them. That is, labels empower consumers with accurate information, and informed consumers are essential to a fair and efficient market economy. Further, perhaps not only can more informed decisions lead to a more efficient marketplace, but also a better society overall, with "better" quantified in some health, environmental, socioeconomic, or other terms. And, perhaps there is a related goal: to increase transparency and accountability on producers, as a form of regulation or standardization, towards similar societal ends. Indeed, maybe such disclosures are best viewed as not merely optional, but rather as part of a fundamental "right to know" about products in certain ways—such as representations being accurate and not misleading or how a product is made—thus entitling the public to such labeling. For these reasons, the goal is to provide people information and give them the right to choose how they spend their money, to decide what they eat and feed their families. Accordingly, as a society we demand (through government regulation or market effects) a shift in the social contract, to require producers to provide this information. Product labels are a key means by which the public receives this information, because labels make it available at the time and place of the purchasing decision.

These goals still beg the question of <u>what</u> information we should provide on food labels. Should label laws just prohibit misleading and false claims, ensuring accuracy? Should they go further and mandate some information about either the final product or its production process? Ingredients and name, quantity and weight, amount? Food safety information? Health information, like nutrition and allergies? Broader societal effects, like worker conditions, animal welfare, environmental footprint, climate effects of the production or shipping, environmental justice considerations? In a democracy, laws (should) reflect society's views, which can and do

shift over time. And our society's "appetite" for a food label's role and purpose has similarly grown over time.

Finally, there are the questions of <u>who</u> requires labeling and <u>how</u> it is done. Should the government decide what information is provided, or the marketplace? If the former, which level of government, federal, state, both, other? And how should that label information be prioritized and provided? On the package or elsewhere? In text, symbols, or smartphone "QR Code" scans? Keep in mind the above overarching purpose questions throughout this article and apply them to the examples given and the story told.

This Article is a critical discussion of the U.S. animal food labeling laws and regulations. **Section I** provides an overview of federal standards. It discusses what labeling is; details the dizzying array of federal agencies and subagencies involved in food labeling, their differing roles, uneven statutory authority and jurisdiction, and implementing regulations; and illustrates the many types of labeling. While the entire food labeling system is necessarily analyzed for context, particular emphasis is given to animal food labeling jurisdiction and legal standards, given that is the article's focus.

Section II explains the state role in food labeling. Prior to the creation of federal food safety laws at the turn of the last century, states were the primary regulators of food and food labeling. But their powers are constrained by our federal system. This Section provides an overview to the constitutional doctrine of federal preemption and how it limits states' authority when the federal government has already acted in a given field, and then specifically applies preemption to food labeling regulation. It covers both proscriptive state enactments of labeling law and regulation as well as state-law based labeling litigation. It closes with a discussion of 21st century state law unknowns.

Section III recounts several "ripped from the headlines" animal food labeling law controversies. Each of these microcosms are 21st century "process" labeling examples, where society is demanding further labeling information about how an animal food product is

produced. *First*, the section discusses USDA-certified organic food labeling, its special role among the federal schemes, and in particular the ongoing litigation over the implementation of the organic label's livestock animal welfare standards. The controversy's outcome will largely determine how much integrity organic labeling will have for those who care about animal welfare. *Second*, the section explains the 2016 "Bioengineered" food disclosure law, the first-ever U.S. federal labeling law for genetically engineered foods, and its implementation. It focuses on what the new federal standard does (and does not) provide, why it may be a harbinger of electronic "QR code" disclosure forms to come, and what it means for the labeling of any future genetically engineered livestock used in factory farming. *Third*, the section covers "Country of Origin Labeling" (COOL), the labeling of food based on its country of production, as applied to animal food labeling and the controversy surrounding COOL meat labeling. *Fourth* and finally, the section discusses the rising weaponization by corporations of the First Amendment's freedom of speech protections as applied to commercial speech. As a result, even when governments are able to pass labeling disclosure requirements, such laws face commercial speech challenges in the courts, where it is increasingly difficult to pass constitutional muster.

Finally, the article concludes by taking a step back to provide some overarching themes throughout the past, present, and future of animal food labeling, as well as applying the first principles noted in this introduction.

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Federal Food Labeling Regulation

At best, the United States' method for food regulation, and thus food labeling, could be described as dizzying and byzantine. Overall there are fifteen different agencies and subagencies involved in some aspect of food regulation, acting pursuant to thirty different statutes, all with different implementing regulations and guidance, covering different types of food labeling.¹

How and why did we get here? In part because the history of our federal food system is a history of waves, waves of lawmaking layers, one on top of another. 116 years of such layers, from 1906 to the present, to be exact. Over the many decades, new laws followed public demand of the time, or scientific advancement, or both. But unfortunately, policymakers made little effort to centralize,, or in some cases even harmonize, food regulation.

And the result? The system's hallmarks include uneven and inefficient oversight, loopholes, gaps, gray areas, and a lack of transparency and cohesion. It is difficult even for legal experts to navigate, let alone the shopper in the grocery store. It can be hard to decide which agency has authority over which products, and for what purposes. Take the classic frozen pizza example: compare two frozen pizzas from the exact same brand, one cheese and one pepperoni. Yet those two products transverse two different regulatory universes, with different agencies in charge, applying different legal standards, with different inspection standards and resulting in different product labeling standards. How does that make sense? It does not. And among other things, it begs the question of why our government does not have a single agency entrusted with overseeing food, food safety, and food labeling, based on a unified law and legal standards.

¹ Renée Johnson, Cong. Research Serv., The Federal Food Safety System: A Primer (2016), available at https://sgp.fas.org/crs/misc/RS22600.pdf; GAO, Overseeing the U.S. Food Supply (2005), available at https://www.gao.gov/assets/gao-05-549t.pdf.

A Very Brief History

The call for improved food industry reform and food safety regulation was part of the broader Progressive movement at the turn of the 20th Century, pushing back against the Gilded Age.² At the time, food regulation happened only at the state level and food contamination was rampant.³ Dairy producers thinned milk with water and recolored it with chalk; to keep it from turning sour sooner they added formaldehyde, which had a disguising sweet taste.⁴ Formaldehyde was also used commonly by the meat-packing industry, causing routine outbreaks of illnesses from "embalmed meat."⁵ Canned food had borax and copper sulfate. Fraudulent products of "honey" were actually corn syrup; there were no legal consequences for false labeling.⁶

Three individuals were primarily responsible for the enactment of our country's first federal food safety and food labeling laws. First, Upton Sinclair, the progressive movement muckraking journalist who wrote The Jungle, the excoriating exposé of the meatpacking industry. Sinclair's focus was the plight and horrific, dehumanizing conditions endured by the workers and immoral treatment of the livestock in those factories. But he also included a chapter on the rotting and diseased meat, contaminated and doctored with chemicals, and mislabeled for sale, which he saw there. And this was the portion of the book that hit home,

² Jaya Saxena, We Owe Food Regulation to a 19th-Century Chemist Who Poisoned His Colleagues, Eater (Jan. 28, 2020), https://www.eater.com/2020/1/28/21112258/pbs-the-poison-squad-documentary-food-regulation-history-deborah-blum-interview.

³ Id.

⁴ Deborah Blum, The 19th-Century Fight Against Bacteria-Ridden Milk Preserved with Embalming Fluid, Smithsonian Mag. (Oct. 5, 2018), https://www.smithsonianmag.com/science-nature/19th-century-fight-bacteria-ridden-milk-embalming-fluid-180970473/. 5 Id.

⁶ Saxena, supra note 2.

⁷ Upton Sinclair, The Jungle (1906); https://www.nytimes.com/interactive/projects/cp/obituaries/archives/upton-sinclair-meatindustry; see Peter B. Hurt & Peter B. Hurt II, A History of Government Regulation of Adulteration and Misbranding of Food, 39 Food. Drug Cosmetic L.J. 2, 53-54 (1984); U.S. Food & Drug Admin., Part I: The 1906 Food and Drugs Act and Its Enforcement, http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucmo54819.htm

 $^{8\} Daniel\ E.\ Slotnik,\ Upton\ Sinclair,\ Whose\ Muckraking\ Changed\ the\ Meat\ Industry,\ NY\ Times\ (June\ 30,\ 2016),$

https://www.nytimes.com/interactive/projects/cp/obituaries/archives/upton-sinclair-meat-industry.

⁹ Constitutional Rights Found., Upton Sinclair's The Jungle: Muckraking the Meat-Packing Industry (2008), https://www.crf-usa.org/bill-of-rights-in-action/bria-24-1-b-upton-sinclairs-the-jungle-muckraking-the-meat-packing-industry.html.

causing a public outcry, increasing calls for legislation action and reform. As Sinclair himself famously said, "I aimed for the public's heart" but "by accident I hit it in the stomach." Congress had introduced food safety legislation for several decades prior, but it failed to pass prior to the Jungle.¹¹

And those activated by Sinclair's efforts found a President ready to champion the legislative reform of the food system in Teddy Roosevelt. Roosevelt was an antimonopoly trustbuster, including of the meat industry, but he had also personally seen the problem years before, when as Colonel Roosevelt in the Spanish American war of 1898, he had seen his "Rough Riders" felled by their own rations, in what became known as the "embalmed beef" scandal. More men were said to have died from their adulterated, rotting meat rations than were killed by Spanish bullets. Roosevelt testified before U.S. Army inquiry boards the following year that he would "sooner eat his hat" than the rations. Roosevelt put his full weight behind the legislative efforts, pushing Congress to act.

Finally, there was Dr. Harvey Wiley, a U.S. Department of Agriculture chemist. Wiley spent years researching mislabeled food, and went so far as to ask unanimous volunteers (young USDA clerks) to eat food that Wiley had reason to believe was adulterated, in order to analyze

¹⁰ Slotnik, supra note 8.

¹¹ Emily M. Broad Leib, Margot J. Pollans, The New Food Safety, 107 Cal. L. Rev. 1173, 1195 (2019).

¹² Constitutional Rights Found., supra note 9; Roger Roots, A Muckraker's Aftermath: The Jungle of Meat-Packing Regulation After A Century, 27 Wm. MITCHELL L. REV. 2413, 2418 (2001).

¹³ Swift & Co. v. United States, 196 U.S. 375 (1905) (applying the Sherman Antitrust Act to allow the government to regulate the meat industry and prevent meatpackers from fixing prices); Robert B. Shepherd, Jr., What Roosevelt Thought: A Rough Rider's Guide to the USTEA, 23 QUINNIPIAC PROB. L.J. 311, 314 (2010) (explaining progressive politicians concerned over corporate abuses and seeking to regulate trusts).

¹⁴ Andrew Amelinckx, Old Time Farm Crime: The Embalmed Beef Scandal of 1898, MODERN FARMER (Nov. 8, 2013), https://modernfarmer.com/2013/11/old-time-farm-crime-embalmed-beef-scandal-1898/.

¹⁵ Deborah Blum, "Gloom and Horror Unrelieved", PBS (Jan. 27, 2020),

https://www.pbs.org/wgbh/americanexperience/features/poison-squad-gloom-horror-unrelieved/.

¹⁶ NY Times, Roosevelt on Army Beef (Mar. 26, 1899),

https://timesmachine.nytimes.com/timesmachine/1899/03/26/102531710.pdf?pdf_redirect=true&ip=o.

the effects.¹⁷ The brave volunteers—known as "the Poison Squad"—became a public sensation, splashed across the nation's newspapers to great acclaim.¹⁸ Chemicals used in the experiments included salicylic acid, sulfuric acid, sodium benzoate and formaldehyde, borax, boric acid, saccharin, and others, and Wiley medically monitored the clerks before, during, and after the experiments.¹⁹ Wiley's Poison Squad, and his published findings over five years embarrassed corporate and political actors; the ills of the squad inspired the public to demand regulation.²⁰

Accordingly, in the culmination of these efforts Congress passed our first two federal food safety and food labeling laws, the Pure Food Act of 1906, also known as the Wiley Act, the Federal Meat Inspection Act of 1907.²¹

But that was just the first wave; the decades that followed brought new laws, amending and supplementing the old in layers, and usually reactive to then-recent current events. In 1938, Congress amended the Wiley Act to create the Federal Food, Drug, and Cosmetic Act and creating the Food and Drug Administration.²² While the 1906 Act had focused more on prohibiting fraud and misbranding, the new law included more safety protections and followed on the heels of a 1937 drug scandal that had killed over a hundred people, including many children.²³ Post-World War II, the Agricultural Marketing Act of 1946 reflected the changing future goals of U.S. agricultural production and improving the marketing of U.S. agricultural products.²⁴ The 1950s brought a wave of new chemical additives being used in food and

 $^{^{\}scriptscriptstyle 17}$ Saxena, supra note 2.

¹⁸ Alexa Lim, Borax: It's What's For Dinner, SCIENCE FRIDAY (Oct. 5, 2018), https://www.sciencefriday.com/segments/the-chemist-and-the-poison-squad-that-fought-for-food-safety/; Deborah Blum, The Pursuit of 'Pure' Food, SCIENCE FRIDAY (Oct. 5, 2018), https://www.sciencefriday.com/articles/the-search-for-pure-food/; Library of Cong., The Washington Times, December 14, 1902, https://chroniclingamerica.loc.gov/lccn/sn84026749/1902-12-14/ed-1/seq-14/.

 $^{^{19}\} Stirling, Profiles\ in\ Toxicology:\ Harvey\ W.\ Wiley,\ 67\ Toxicological\ Sciences\ 157-158,\ Society\ of\ Toxicology\ (2002).$

²⁰ Marissa Fessenden, Early Food Safety Workers Tested Poisons by Eating Them, SMITHSONIAN MAG. (Jan. 9, 2015), https://www.smithsonianmag.com/smart-news/early-food-safety-workers-us-tested-poisons-eating-them-180953864/.

²¹ Johnson, Cong. Research Serv., supra note 1.

²² Id

²³ U.S. FOOD & DRUG ADMIN., Part II: 1938, Food, Drug, Cosmetic Act, https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-ii-1938-food-drug-cosmetic-act

²⁴ Johnson, Cong. Research Serv., supra note 1.

Congress passed the Food Additives Amendments to the FFDCA in 1958 to address concerns about their health risks.²⁵ At the time of the 1906 FMIA, poultry was a minor meat product, bought locally and eaten far less frequently; small-scale farmers were able to meet the demand. But by the 1950s poultry demand had greatly increased and Congress passed the Poultry Products Inspection Act of 1957, the sister statute of the FMIA.²⁶ As advertising and product packaging grew more sophisticated in the 1960s, Congress passed the Fair Packaging and Labeling Act of 1967.²⁷ In 1990 came the food labeling law culmination of several decades for two issues. First, Congress passed the Nutrition Labeling and Education Act, which reflected the maturation of nutrition food science and thus for the first time both required mandatory nutrition labeling as well as permitted limited health claims on food.²⁸ Also in 1990 Congress passed the Organic Foods Production Act (OFPA), federalizing the growing organic farming certification seal that had proliferated with state labels since the birth of the environmental movement.²⁹ Finally, in 2004 Congress passed the Food Allergen Labeling and Consumer Protection Act, which for the first time required the labeling of major allergens on food products, based on studies and increased concern over unlabeled allergy risks and food recalls.³⁰ Notably this list only illustrates these waves of legislation but is not comprehensive.

²⁵ Id.; Leib & Pollans, supra note 11 at 1195 (2019) (citing legislative history and testimony); U.S. FOOD & DRUG ADMIN., Part III: Drugs and Foods Under the 1938 Act and Its Amendments, https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-iii-drugs-and-foods-under-1938-act-and-its-amendments.

²⁶ Johnson, Cong. Research Serv., supra note 1; NATIONAL RESEARCH COUNCIL, POULTRY INSPECTION, Chapter 2: Poultry Inspection in the United States: History and Current Procedures, Nat'l Acad. Press (1987), https://www.ncbi.nlm.nih.gov/books/NBK218008/. ²⁷ Johnson, Cong. Research Serv., supra note 1.

²⁸ Johnson, Cong. Research Serv., supra note 1; Sandy Skrovan, The Origins and Evolution of Nutrition Facts Labeling, FOOD DIVE (Oct. 16, 2017), https://www.fooddive.com/news/the-origins-and-evolution-of-nutrition-facts-labeling/507016/.

²⁹ 7 U.S.C. Ch. 94; see supra Section III.

 $^{^{30}}$ U.S. Food & DRUG ADMIN, Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), $\underline{\text{https://www.fda.gov/food/food-allergensgluten-free-guidance-documents-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-falcpa}.$

What Is Food Labeling?

To begin, what qualifies as a food "label" and "food labeling" is defined broadly, essentially "any display of written, printed or graphic material" on the actual food article package, as well as any materials "accompanying" the article, qualify.³¹ As such, federal regulation applies to product labels, but also materials not attached, but accompanying a product, such as point-of-purchase materials,³² or other product explanatory materials that are separate in time and space from the food product itself.³³ Further, as will be discussed infra, food advertising is also subject to federal regulation.

Agencies and their Areas of Labeling Oversight

Multiple federal agencies have jurisdictions over different and overlapping aspects of food product labeling, including the Food and Drug Administration (FDA),³⁴ the U.S. Department of Agriculture (USDA),³⁵ including and in particular USDA's subagency, the Food Safety and Inspection Service (FSIS),³⁶ and the Federal Trade Commission (FTC).³⁷ Each of these agencies derives its authority from different statutes, principally the Federal Food Drug and Cosmetic Act

https://www.fsis.usda.gov/sites/default/files/media file/2020-10/Label-Approval-Guide.pdf.

 $^{^{31}}$ This definition is consistent throughout the various statutes covering different food labeling. See, e.g., 21 U.S.C. § 601(0) and (p) (meat); 21 U.S.C. § 453(s) (poultry); 21 U.S.C. § 321(k) &(m) (FFDCA covering FDA's jurisdiction).

 $^{^{32}}$ 21 U.S.C. \S 607; 21 U.S.C. \S 457.

³³ See, e.g., Kordel v. U.S., 335 U.S. 345 (1948) (interpreting the FFDCA's definition of label and labeling to include false and misleading literature about the product but shipped separately and later in time from the product); see also, e.g., U.S. v. Jorgensen, 144 F.3d 550, 558 (S.D. Cal. 1998) (brochures accompanying meat products are labeling); U.S. v. Sene X Eleemosynary Corp., Inc., 479 F. Supp. 970, 979 (S.D. Fla. 1979) (neither physical attachment nor concurrent shipment is required to establish FDA misbranding authority under FFDCA).

³⁴ U.S. FOOD & DRUG ADMIN., Food Labeling & Nutrition, https://www.fda.gov/food/food-labeling-nutrition; U.S. FOOD & DRUG ADMIN., Guidance for Industry: Food Labeling Guide, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-labeling-guide.

 $^{{\}tt 35~U.S.~DEP'T~OF~AGRIC.}, Labeling~and~Label~Approval,~https://www.fsis.usda.gov/inspection/compliance-guidance/labeling.$

 $^{{\}it 36}\ FOOD\ SAFETY\&\ Inspection\ SERV.,\ Labeling\ Policies,\ https://www.fsis.usda.gov/inspection/compliance-guidance/labeling-policies;\ FOOD\ SAFETY\&\ INSPECTION\ SERV.,\ FSIS\ Compliance\ Guideline\ for\ Label\ Approval\ (July\ 2020),$

³⁷ FEDERAL TRADE COMM'N, Fair Packaging and Labeling Act: Regulations Under Section 4 of the Fair Packaging and Labeling Act, https://www.ftc.gov/enforcement/rules/rulemaking-regulatory-reform-proceedings/fair-packaging-labeling-act-regulations-o

(FFDCA),³⁸ the Federal Meat Inspection Act (FMIA),³⁹ the Poultry Products Inspection Act (PPIA),⁴⁰ the Egg Products Inspection Act (EPIA),⁴¹ the Agricultural Marketing Act (AMA),⁴² and the Fair Packaging and Labeling Act (FPLA).⁴³ More recent and specific legislative enactments covering various aspects of food labeling, including but not limited to those listed above such as the Nutritional Labeling and Education Act, the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), have supplemented the authorities established by the above statutes.

THE FOOD SAFETY AND INSPECTION SERVICE (FSIS)

The USDA is charged by Congress with ensuring that food products under its jurisdiction are wholesome, not adulterated, and properly marked, labeled, and packaged.⁴⁴ In turn a USDA subagency, the FSIS, implements this mandate for meat and poultry products, labeling standards and oversight, with authority derived from the FMIA and the PPIA, respectively, and delegated by the USDA.⁴⁵

The FMIA established federal standards for slaughtering, processing, inspecting, and labeling meat products,⁴⁶ with an aim to "prevent the shipment of impure, unwholesome, and unfit meat and meat-food products."⁴⁷ While the FMIA authorized USDA as the monitoring entity, as noted USDA has delegated this authority to FSIS. The FMIA covers myriad animals

 $^{^{38}}$ 21 U.S.C. §§ 301 et seq.

^{39 21} U.S.C. §§ 601 et seq.

 $^{^{40}}$ 21 U.S.C. §§ 451 et seq.

^{41 21} U.S.C. §§ 1031 et seq.

^{42 7} U.S.C. §§ 1621 et seq.

⁴³ 15 U.S.C. §§ 1451 et seq.

⁴⁴ See generally 21 U.S.C. §§ 601 et seq. (Chapter 12, meat); 21 U.S.C. §§ 451 et seq. (Chapter 10, poultry).

⁴⁵ 21 U.S.C. §§ 601 et seq.; 21 U.S.C. § 451; 9 C.F.R. 300.2(a).

⁴⁶ 60 Fed. Reg. 6775-76.

⁴⁷ Pittsburgh Melting Co. v. Totten, 248 U.S. 1, 4-5 (1918).

commonly raised for meat, including cattle, sheep, swine, goats, horses, mules, and other equines.⁴⁸

The PPIA's regime was modeled after the FMIA,⁴⁹ and like the FMIA requires that slaughterhouses be inspected,⁵⁰ establishes sanitation and labeling standards,⁵¹ and prohibits the sale of adulterated or misbranded poultry products.⁵² It mandates USDA oversight over birds (namely, chickens, turkeys, ducks, geese, guineas, ratites [ostrich, emu, and rhea], and squab [pigeons up to one month old]) intended for human consumption.⁵³ Like the FMIA, USDA has delegated the PPIA implementing authority to FSIS.

Pursuant to these Congressional mandates, FSIS develops labeling standards governing whether or not a meat or poultry product is misbranded or adulterated.⁵⁴ Both the FMIA and PPIA set forth detailed guiding commands for when food products are "misbranded," the most relevant and broadest being when its label is "false or misleading in any particular way" or does not contain the required labeling features.⁵⁵ Manufacturers are then responsible for compliance with FSIS labeling rules and processes, including the FSIS process for evaluating and approving meat and poultry product labels. If FSIS deems a meat or poultry product as misbranded, the manufacturer can face numerous penalties, including recension of the labeling; prohibition on shipping and/or sale; product recall and/or fines; and criminal prosecution.⁵⁶

USDA and its subagencies have other, more discrete food labeling authority, discussed infra, but first it is helpful to cover the other main agency, FDA.

⁴⁸ Johnson, Cong. Research Serv., supra note 1, at 5.

⁴⁹ 60 Fed. Reg. at 6775.

^{50 21} U.S.C. § 455.

⁵¹ 21 U.S.C. §§ 456, 457.

^{52 21} U.S.C. § 458.

⁵³ Johnson, Cong. Research Serv., supra note 1, at 6.

⁵⁴ "Misbranded" food is food with a label that is, inter alia, "false or misleading in any particular," 21 U.S.C. § 601(n), whereas "adulterated" food is food that, inter alia, contains a poisonous substance or otherwise poses a health risk to consumers, id. § 601(m); see also 21 U.S.C. § 453(g), (h) (same).

^{55 21} U.S.C. § 601(n), 21 U.S.C. § 453(g).

⁵⁶ 21 U.S.C. §§ 672—73; 21 U.S.C. § 467.

THE FOOD AND DRUG ADMINISTRATION (FDA)

USDA regulates approximately 20% of domestic and imported food supply, while FDA regulation covers the remaining 80%.⁵⁷ Essentially, if USDA does not regulate a food's labeling under a particular statutory scheme, the default is that FDA does. Examples of FDA-regulated and labeled foods (discussed in further detail infra) include packaged foods, nearly all seafood, bottled water, dairy, and eggs.⁵⁸

FDA establishes its labeling requirements and oversight for food products under its FFDCA purview.⁵⁹ As with FSIS's statutory authorities, the FFDCA sets forth a similar core "misbranded" standard under which FDA governs, including if its label is "false or misleading in any particular."⁶⁰ Also similar to the FSIS's governing statutes, the FFDCA defines what constitutes a "label" and "labeling" broadly.⁶¹ FDA can sanction manufacturers several ways for violations of labeling requirements, including seeking court order preventing production and sale, confiscation of the product, and criminal sanctions.⁶²

FDA: NUTRITION, HEALTH CLAIMS, ALLERGY LABELING, PACKAGING

As discussed above, history shows that as society's interests in labeling have grown over time, Congress has accordingly amended the FFDCA to address the demand and need for more types of labeling. For example, in response to the rise of nutrition science and the public interest in it, in 1990 Congress amended the FFDCA with the Nutrition Labeling and Education Act (NLEA),⁶³

⁵⁷ FOOD & DRUG ADMIN., Fact Sheet: FDA at a Glance (Nov. 2020), https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance; Johnson, Cong. Research Serv., supra note 1, at 4 n. 7.

⁵⁸ Except under the EPIA, providing FSIS oversight over some egg products, as discussed infra.

 $^{^{59}}$ 21 U.S.C. §§ 301 et seq.

^{60 21} U.S.C. § 343(a).

^{61 21} U.S.C. § 321(k) &(m).

^{62 21} U.S.C. § 332-33.

⁶³ Pub. L. No. 101-535, 104 Stat. 2353 (codified as amended in scattered sections of 21 U.S.C.).

which was intended "to clarify and to strengthen the [FDA's] legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about nutrients in foods." That is, the NLEA amended the FFDCA to grant the FDA authority to require uniform national standards for nutrition labeling of foods and to regulate the health claims that may be made about nutrients in foods. Although the NLEA only mandated nutrition labeling for FDA regulated foods, USDA has also established nutrient labeling requirements for meat and poultry. 66

The NLEA established the first nutrition label, with which the public is now familiar. It required foods "intended for human consumption to be labeled with a serving size, the number of servings in a container, the total calories in each serving size, the calories derived from fat in each serving size, and the total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein contained in each serving size. . ."⁶⁷ Certain foods are exempt from the nutrition labeling requirements such as restaurant and medical foods.⁶⁸

Additionally, in response to the proliferation of unfounded health claims being made on food products, the NLEA established restrictions on nutrient content and health claims.⁶⁹

Nutrient content claims are those claims made on a label that "expressly or implicitly characterize[] the level of any nutrient" required to be in the nutrition label (ex. "low sodium").⁷⁰

The NLEA granted FDA authority to promulgate regulations detailing how manufacturers can characterize the food nutrient content.⁷¹ Today regulations exist defining when it is to

⁶⁴ H.R. Rep. No. 101-538 at 7 (1990), reprinted in 1990 U.S.C.C.A.N. 3336, 3337.

 $^{^{65}\} Remarks\ of\ Rep.\ Waxman,\ 136\ Cong.\ Rec.\ 5840\ (daily\ ed.\ July\ 30,\ 1990)\ [debate\ on\ H.R.\ No.\ 3562,\ 101st\ Cong.,\ 2d\ Sess.].$

⁶⁶ U.S. DEP'T OF AGRIC., A GUIDE TO FEDERAL FOOD LABELING REQUIREMENTS FOR MEAT, POULTRY, AND EGG PRODUCTS 53 (2007), available at https://www.fsis.usda.gov/sites/default/files/import/Labeling Requirements Guide.pdf.

^{67 21} U.S.C. § 343(q)(1)).

^{68 21} U.S.C. § 343(q)(5).

^{69 21} U.S.C. § 343(r)(1).

^{70 21} U.S.C. § 343(r)(1)(a).

⁷¹ Public Law 101-535, § 3(b).

appropriate use basic terms like "free," "good source," "high," "more," and "low," with reference to nutrients.⁷² Disclaimers are required when a nutrient claim is made that is not consistent with FDA definitions (ex. "only 200 mg sodium per serving, not a low sodium food").⁷³

Similarly, health claims are those that "expressly or by implication characterize[] the relationship of any nutrition label required nutrients to a disease or health-related condition,"⁷⁴ (ex. "adequate calcium throughout life may reduce risk of osteoporosis").⁷⁵ Health claims are routinely made through third party reference, symbols, or written statements.⁷⁶ The NLEA authorizes FDA to issue regulations authorizing health claims after reviewing and evaluating scientific evidence.⁷⁷ FDA will promulgate regulations authorizing a health claim only when it "determines, based on the totality of publicly available scientific evidence . . . that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence."⁷⁸ To provide an opportunity for health claims when there is only emerging evidence of a relationship between a food and a health-related condition, FDA also allows for qualified health claims.⁷⁹ Qualified health claims do not need to meet the "significant scientific agreement" standard, however, they must contain disclaimers to ensure consumers are aware of the limited evidence supporting their health claims.⁸⁰

Similar to the NLEA, as more awareness of food allergies and related health risks became commonplace and properly understood by the scientific community, the Food Allergen Labeling

 $^{^{72}}$ See generally 21 C.F.R. \S 101.13.

^{73 21} C.F.R. § 101.13 (i)(2) (emphasis added).

^{74 21} U.S.C. § 343 (r)(1)(b).

⁷⁵ Food & Drug Admin., Label Claims for Conventional Foods and Dietary Supplements (June 19, 2018),

https://www.fda.gov/food/food-labeling-nutrition/label-claims-conventional-foods-and-dietary-supplements.

⁷⁶ 21 C.F.R. § 101.14(a)(1).

⁷⁷ Label Claims for Conventional Foods and Dietary Supplements, supra note 75.

⁷⁸ 21 U.S.C. 343 (r)(1)(3)(B)(i); see also 21 C.F.R. 101.14(c).

⁷⁹ Label Claims for Conventional Foods and Dietary Supplements, supra note 75.

⁸⁰ Id.

and Consumer Protection Act of 2004 (FALCPA)⁸¹ amended the FFDCA to require that most foods containing one or more major food allergens be labeled to clearly identify the name of the allergen(s).⁸² Under the FFDCA, products that fail to provide this allergy information are deemed "misbranded." ⁸³ The eight major allergens include wheat, soy, tree nuts, peanuts, as well as the animal food products of eggs, milk, fish, and crustacean shellfish.⁸⁴ The allergens can be listed two ways—(1) in the ingredient statement, after the common or usual name (e.g., "whey (milk)"); or (2) or in a separate "contains" statement after or adjacent to the ingredients (e.g., "Contains Peanuts"). FALCPA requirements apply to all FDA-regulated food products.⁸⁵

Unfortunately, the FALCPA only applies to products under FDA's jurisdiction, as it only amended the FFDCA, not the USDA statutes (FMIA, PPIA, EPIA). This is another example of a problem with such divergent food regulation and standards. Instead, FSIS has guidance⁸⁶ that urges industry to disclose voluntarily as consistent with FALCPA any allergens in its products through labeling when it seeks approval for such labeling.

Finally, in addition to its FFDCA authority, FDA also has authority under the Fair Packaging and Labeling Act (FPLA), which sets out the requirements for package labels of all commodities, including most foods.⁸⁷

⁸¹ Pub. L. 108-282, Title II.

⁸² See generally U.S. FOOD & DRUG ADMIN., Food Allergen Labeling and Consumer Protection Act of 2004 Questions and Answers (July 18, 2006), https://www.fda.gov/food/food-allergensgluten-free-guidance-documents-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-questions-and-answers.

^{83 21} U.S.C. § 343(w).

⁸⁴ FALCPA §202(2).

⁸⁵ 21 U.S.C. § 323(w) (1)(A)-(B); see generally U.S. FOOD & DRUG ADMIN., Allergy Labeling Guidance Documents (Nov. 10 2020), https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/food-allergensgluten-free-guidance-documents-regulatory-information#labeling.

⁸⁶ FOOD SAFETY & INSPECTION SERV., Allergens - Voluntary Labeling Statements (June 2013),

https://www.fsis.usda.gov/guidelines/2013-0010.

⁸⁷ 15 U.S.C. 1451 et seq.; id. § 1459(b) (defining "package" to include, inter alia, any "container or wrapping" of "any consumer commodity" for use in the "delivery or display" of the commodity to retail purchasers).

FSIS AND FDA: DIFFERENT APPROACHES AND JURISDICTION,
OVERLAP, FOOD SAFETY OF INGREDIENTS, STANDARDS OF
IDENTITY

Before going further, it is helpful to explore some of the important differences and relationships between FSIS and FDA labeling regulations.

First, one crucial difference is that FSIS requires pre-market approval of labels, whereas FDA does not. Specifically, applying its FMIA and PPIA authority, FSIS requires that meat and poultry labels be pre-approved by the agency before they are used in commerce. Reference is The FMIA and PPIA provide that no food under its jurisdiction "shall be sold ... under any name or other marking or labeling ... but established trade names and other marking and labeling ... which are not misleading and which are approved by the Secretary." FSIS's implementing regulations establish the specific requirements for meat and poultry labeling, including ensuring that they are accurate and not misleading. FSIS has similar authority over egg products under the EPIA, as discussed infra. In contrast to FSIS, FDA does not require prior label approval for products under its jurisdiction, as neither the FFDCA nor the FPLA has similar authority language to that relied upon by FSIS for its premarket review power.

This FSIS-FDA difference has positive and negative outcomes for animal food labeling.

On the positive side, theoretically it should make FSIS labels, which are most meat labels, more accurate and trustworthy, as they are pre-approved before use. On the negative side, it increases the likelihood and strength of federal preemption for FSIS regulated products, meaning that

⁸⁸ See 21 U.S.C. § 607(d) (FMIA: "No article subject to this subchapter shall be sold or offered for sale by any person, firm, or corporation, in commerce, under any name or other marking or labeling which is false or misleading, or in any container of a misleading form or size, but established trade names and other marking and labeling and containers which are not false or misleading and which are approved by the Secretary are permitted."); 21 U.S.C. § 457(c)(PPIA, same language).

⁸⁹ Id. (emphasis added).

^{90 9} C.F.R. Part 317 et seq. (meat); 9 C.F.R. 381.115 et seq. (poultry).

^{91 21} U.S.C. § 1036(b) (similar language).

other levels of government have less leeway to improve upon the federal system should they choose, as discussed in Section II *infra*.

Second, as to overlapping and confusing jurisdiction between the agencies, while *most* common meat and poultry falls under FSIS labeling jurisdiction, there are some exceptions. While FSIS has authority over labeling foods products containing meat and poultry, its statutes authorize the agency to exempt from its coverage products that contain "only a relatively small portion" of meat or poultry, or products that "historically have not been considered by consumers as products of the meat food industry." Further, and somewhat confusingly, FDA—not FSIS—has oversight over the products of "exotic" species of livestock and poultry, such as deer, elk, boar, and pheasant. This is due to the fact that the FMIA and PPIA statutory definitions of meat, livestock, and poultry do not include these "exotic" species.93

Third, when a product's jurisdiction is unclear, the agencies determine proper jurisdiction via an "amenability" decision, a decision based on a products formulation and the finished product. For example, under USDA rules any food product containing very small amounts of meat or poultry—such as 3% or less raw or less than 2% cooked—is not subject to FSIS oversight. Some common examples would be meat spaghetti sauces, cans of pork and beans, soup, broth, and gravy mixes. These products would instead be subject to FDA labeling regulations.

<u>Fourth</u>, the agencies work together to determine a food product's "standard of identity," that is defining what a given food product is, its common name, and the ingredients which must

^{92 21} U.S.C. § 601(j).

^{93 21} U.S.C. §§ 601(j) & 453(f); 9 C.F.R. §§ 301.2 & 381.1 (covering, inter alia, chickens, turkeys, ducks, geese).

⁹⁴ FOOD SAFETY & INSPECTION SERV., FOOD STANDARDS AND LABELING POLICY BOOK 8 (2005),

https://www.fsis.usda.gov/sites/default/files/import/Labeling-Policy-Book.pdf.

⁹⁵ Id.; see also 9 C.F.R. § 381.15 (exemption from the definition of "poultry product" of certain human food products containing poultry).

⁹⁶ Id.

^{97 9} C.F.R. § 381.15(e).

or may be used and declared on the label. 98 USDA makes this determination for products under its jurisdiction, but its decision is tied to FDA's standards of identity under the FFDCA, as both the FMIA and the PPIA establish that FSIS's standards must be consistent with those set by FDA under the FFDCA. 99

<u>Finally</u>, with regard to food safety of ingredients in animal food products labeled under FSIS jurisdiction, only FDA-approved ingredients (e.g., food additives, color additives, and substances "generally recognized as safe" known as GRAS substances)¹⁰⁰ are permitted.¹⁰¹ That is, FDA is charged with assuring the food safety of these substances, but once it does, they are allowed in USDA regulated and labeled foods.

FSIS: A MORE DETAILED BREAKDOWN OF FSIS REGULATION AND LABELING

Because FSIS covers most animal food labeling, a more detailed look at its labeling scheme is helpful. FSIS's implementing FMIA and PPIA regulations establish the specific requirements for meat and poultry labeling, including ensuring that they are accurate and not misleading. Recall that all FSIS labels require review and preapproval. In decades past, each individual label on meat and poultry products had to be submitted to FSIS for review and approval. But as the number of submissions grew over time, the regulatory process changed. Today, "sketch" approval is given when labels are submitted, and a "final" approval is given prior to product

^{98 21} U.S.C. § 607(c); 21 U.S.C. § 457(b). See 9 C.F.R. 381.155—174 (standards for poultry products); 9 C.F.R. Part 319 (meat products). FDA has 300 identity standards for 20 categories of food. See 21 C.F.R. Parts 130—69. For example, the standard for "turkey ham" includes that it must be made from boneless turkey thigh meat with skin removed; the product name on the label shall show the word "Turkey" in the same size and style as the word "Ham," and it can be may or may not be smoked, see 9 C.F.R. §381.171.

⁹⁹ Id.

¹⁰⁰ U.S. FOOD & DRUG ADMIN., Determining the Regulatory Status of a Food Ingredient (Sept. 20, 2018),

https://www.fda.gov/food/food-ingredients-packaging/determining-regulatory-status-food-ingredient.

¹⁰¹ 21 U.S.C. § 348; 21 U.S.C. § 601(m)(2); § 453(g)(2).

 $^{^{102}}$ 9 C.F.R. Part 317 et seq. (meat); 9 C.F.R. 381.115 et seq. (poultry).

^{103 9} C.F.R. §§ 412.1, 412.2, 590.411

distribution in commerce. A "temporary" approval can be granted for up to six months while final approval is pending.¹⁰⁴

Further, FSIS also now allows "generic labels" to be applied to some meat and poultry, circumventing entirely the premarket approval requirement.¹⁰⁵ To be generically approved all mandatory labeling features must conform with FSIS regulations and the FSIS Food Standards and Labeling Policy Book.¹⁰⁶ The rules provide specific types of labels that are generically approved, and the FSIS guidance document, Food Standards and Labeling Policy Book, addresses many products and is designed to help producers prepare product labels that are truthful and not misleading.¹⁰⁷ If a product's label bears a term from the Policy Book, and the product complies with the Policy Book's definition, the label may be treated as "generically approved."108 For example, the Policy Book states that a product labeled "Chicken Patty Fritter" must contain at least 35% chicken patty, and a product may be labeled "Italian style" only if it contains anise, fennel, certain "Italian type cheese[s]," or at least three of basil, garlic, marjoram, olive oil, and oregano. 109 Detailed (and periodically updated) lists of special statements and claims requiring FSIS approval and examples of claims eligible for generic approval are available on the FSIS website. 110 A standard of identity sets the manner of preparation and the ingredients of a product that is labeled with a particular name. FSIS has prescribed definitions and standards of identity or composition for some products in its regulations.111

¹⁰⁴ 9 CFR 412.1(f)(1); FOOD SAFETY & INSPECTION SERV., Protecting Public Health and Preventing Foodborne Illness (Sept. 25, 2019), https://www.fsis.usda.gov/sites/default/files/media_file/2021-02/generic-labeling-webinar.pdf.

^{105 9} C.F.R. § 412.2.

 $^{^{\}rm 106}$ Id.; Food Standards and Labeling Policy Book, supra note 94.

¹⁰⁷ FOOD STANDARDS AND LABELING POLICY BOOK, supra note 94, at 2.

^{108 9} C.F.R. 412.2(a)(1) and (b).

¹⁰⁹ FOOD STANDARDS AND LABELING POLICY BOOK, supra note 94, at 57, 75.

¹¹⁰ FSIS Compliance Guideline for Label Approval, supra note 35.

¹¹¹ See, e.g., 9 C.F.R. 381.164 (defining "barbecued" poultry).

To be approved, there are specific requirements for each product label, including the placement and prominence in the principal display panel¹¹² and the information panel of certain features.¹¹³ The required label features include (1) product name, (2) inspection legend and establishment number,¹¹⁴ (3) handling statement,¹¹⁵ (4) net weight statement,¹¹⁶ (5) ingredients statement,¹¹⁷ (6) address,¹¹⁸ (7) nutrition facts,¹¹⁹ and (8) safe handling instructions.¹²⁰

Finally, like FDA, USDA implemented nutrition labeling regulations for products under its jurisdiction in 1994.¹²¹ This move resulted largely thanks to the 1990 NLEA, despite the statute not actually mandating such changes for the USDA. The nutrition labeling regulations are comprehensive and require the inclusion of the product's nutrition information, including topics such as total calories, calories from fat, saturated fat, trans fat, cholesterol, sodium, dietary fiber, sugars, protein, and vitamins.¹²² This includes nutrition topic metrics such as daily reference values, serving size, as well as nutritional content claims and the standards for them, such as "high," "good source," "light," "lean," "low sodium" or "low fat," "sugar free," to give some examples.¹²³

OTHER AGENCIES: THE FEDERAL TRADE COMMISSION (FTC)

In addition to FDA and USDA, the Federal Trade Commission (FTC) also plays a supplemental role in overseeing food product labeling. The Federal Trade Commission Act (FTCA) charges

^{112 9} C.F.R. § 317.2(d) (meat); 9 C.F.R. § 381.116(b) (poultry).

^{113 9} C.F.R. §§ 317.2(m), 381.116(c).

^{114 9} C.F.R. §§ 312, 381.96.

^{115 9} C.F.R. §§ 317.2(k), 381.125(a).

^{116 9} C.F.R. §§ 317.2(h), 381.121.

^{117 9} C.F.R. §§ 317.2, 381.118.

¹¹⁸ 9 C.F.R. §§ 317.2(c)(3) & (g), 381.122.

^{119 9} C.F.R. Subpart B, 317.300 (meat) & 381.400 (poultry).

^{120 9} C.F.R. §§ 317.2(l), 381.125(b).

¹²¹ Golan et al., Economics of Food Labeling, (Table 1)

 $[\]underline{https://www.ers.usda.gov/webdocs/publications/41203/18887\ aer793a.pdf?v=o.}$

¹²² USDA, Food Labeling Guide, supra note 66 at 75.

¹²³ Id. at 75-95.

FTC with prohibiting the false advertising of foods, drugs, and cosmetics. ¹²⁴ This includes advertisements on TV, the internet, social media, and similar. While "advertisements" are defined separately from "labeling," the FTCA grants FTC the authority to prevent "unfair or deceptive" actions affecting commerce, ¹²⁵ including unfair business practices such as the false and misleading labeling of foods. ¹²⁶ Thus, FTC is responsible for regulating advertising claims and certain labeling. Among other things, the FTCA makes it unlawful for any company to "disseminate ... any false advertisement ... for the purpose of inducing, or which is likely to induce, directly or indirectly the purchase ... of *food*. ⁷¹²⁷ Accordingly, FTC uses its broad FTCA mandate to apply its authority to food advertising. ¹²⁸

FTC has advertising guidelines¹²⁹ under which it can classify an advertising claim as false and misleading, if it is not adequately substantiated.¹³⁰ Similar again to the core "false and misleading" standards in the FFDCA, the FMIA, and the PPIA, the FTCA prohibits "false advertisements" that are "misleading in a material respect."¹³¹ Companies must have a "reasonable basis" for claims in their ads, meaning "objective evidence that supports the claim," with the kind of evidence required dependent on the type of claim.¹³² When determining if an ad is deceptive the agency will use the point of view of a "reasonable consumer," i.e., the typical

^{124 15} U.S.C. § 52.

^{125 15} U.S.C. § 45(a)(1).

¹²⁶ Fresh Grown Preserve Corp. v. FTC, 125 F.2d 917 (2d Cir. 1942) (holding FTC jurisdiction to prevent unfair competition through false labeling and/or misbranding regardless the kind of product, including there for fruit preserves).

^{127 15} U.S.C. § 52(a) (emphasis added).

¹²⁸ FED. TRADE COMM'N, Enforcement Policy Statement on Food Advertising (May 13, 1994), https://www.ftc.gov/public-statements/1994/05/enforcement-policy-statement-food-advertising.

¹²⁹ FED. TRADE COMM'N, Policy Statement on Deception (Oct. 14, 1983), https://www.ftc.gov/public-statements/1983/10/ftc-policy-statement-deception; FED. TRADE COMM'N, Advertising FAQ's: A Guide for Small Business, https://www.ftc.gov/tips-advice/business-center/guidance/advertising-faqs-guide-small-business [hereinafter Advertising FAQ's].

¹³⁰ Advertising FAQ's, supra note 129; see FED. TRADE COMM'N, Policy Statement on Advertising Substantiation, 48 Fed. Reg. 10, 471 (1984).

¹³¹ 15 U.S.C. §§ 45, 52, 55.

¹³² Advertising FAQ's, supra note 129.

person looking at the ad, viewing it in context.¹³³ A deceptive claim can be either express or implied.¹³⁴ The representation, omission, or practice must also be a "material" one that is likely to mislead the consumer.¹³⁵ In sum, FTC finds an ad deceptive and therefore unlawful, if it (1) contains a representation or omission of fact that is (2) likely to mislead consumers acting reasonably under the circumstances, and (3) the representation or omission is material.¹³⁶

However, similar to FDA and food labels, food advertisements do *not* require preapproval by FTC.¹³⁷ Instead, FTC only has the authority to engage in enforcement action if it determines an advertisement is deceptive. As to remedies, FTC has the authority to obtain injunctive relief, and in some cases damages, as well as rescission and corrective advertising to remedy past deception, and civil and/or criminal penalties.¹³⁸

OTHER AGENCIES: AGRICULTURAL MARKETING SERVICE (AMS)

Another USDA subagency also covers certain aspects of meat labeling. Pursuant to the Agricultural Marketing Act of 1946 (as also subsequently amended),¹³⁹ the USDA's Agricultural Marketing Service (AMS),¹⁴⁰ sets and regulates quality and marketing "grades" and standards for many foods, standards that are part of the food products' labels. These include several well-known voluntary or optional labeling programs, including the National Organic Program,¹⁴¹ the Process Verified Program,¹⁴² and the Grademark Program.¹⁴³

¹³³ Advertising FAQ's, supra note 129; see also Policy Statement on Deception, supra note 129.

¹³⁴ Advertising FAQ's, supra note 129.

¹³⁵ Policy Statement on Deception, supra note 129.

 $^{^{\}scriptscriptstyle 136}$ Enforcement Policy Statement on Food Advertising, supra note 128.

¹³⁷ Advertising FAQ's, supra note 129.

 $^{^{138}}$ 15 U.S.C. §§ 52, 53(a), 57(b)(b), 45(m) (civil penalties), 54(a) (criminal penalties if a violation was committed with intent to defraud or expose consumers to health and safety risks).

^{139 7} U.S.C. §§162-1627.

¹⁴⁰ U.S. DEP'T AGRIC., Agricultural Marketing Service, https://www.ams.usda.gov/.

¹⁴¹ U.S. DEP'T AGRIC., National Organic Program, https://www.ams.usda.gov/about-ams/programs-offices/national-organic-program.

¹⁴² U.S. DEP'T AGRIC., Process Verified Program, https://www.ams.usda.gov/services/auditing/process-verified-programs

¹⁴³ U.S. DEP'T AGRIC., USDA Shell Egg Grading Service, https://www.ams.usda.gov/publications/qa-shell-eggs

The National Organic Program and its labeling is discussed in detail in Section III infra. As to the other AMS labeling "grading" programs, these include dairy products, fruits and vegetables, livestock, meat, poultry, seafood and shell eggs. 144 AMS standards are about a product's quality, uniformity, and/or consistency, rather than safety, and are generally user feefunded. 145 An example would be the meat grading labels of "USDA Prime" or "USDA Choice" used to indicate quality. Also pursuant to the AMS, the National Marine Fisheries Service (NMFS), part of the Department of Commerce, provides a fee-based, voluntary seafood grading inspection program for marketing and quality aspects of fish and shellfish. 146

Some Specific Animal Food Labeling Instances

SEAFOOD

Unlike animal food labeling of beef and poultry products, FDA, not USDA, oversees the safety and labeling of fish, shellfish, and other seafood under the FFDCA, with only one notable exception (discussed infra).¹⁴⁷ With regard to labeling, FDA has a guidance known as "the seafood list"¹⁴⁸ setting forth the FDA-approved acceptable market names for all seafood sold.¹⁴⁹ These are the labeling names FDA recognizes as suitable "statements of identity" for the labeling of the species that would not be misleading and generally consists of the "common or usual"

 $^{^{\}scriptscriptstyle{144}}$ Johnson, supra note 1, at 8.

¹⁴⁵ Id.

¹⁴⁶ NAT'L MARINE FISHERIES SERVS., NOAA's Seafood Inspection Program, https://www.fisheries.noaa.gov/insight/noaas-seafood-inspection-program; see 50 C.F.R. Part 260.

¹⁴⁷ See FOOD & DRUG ADMIN., Seafood,

https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/default.htm. See generally U.S. FOOD & DRUG ADMIN., Seafood Guidance Documents and Regulatory Information (June 12, 2020),

https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/seafood-guidance-documents-regulatory-information; 21 C.F.R. Part 123 (fish and fishery products).

¹⁴⁸ U.S. FOOD & DRUG ADMIN., The Seafood List (July 2021), https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=SeafoodList.

¹⁴⁹ U.S. FOOD & DRUG ADMIN., Guidance for Industry: The Seafood List – FDA's Guide to Acceptable Market Names for Seafood Sold in Interstate Commerce (July 2012), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-seafood-list.

name established by a history of use or regulation. ¹⁵⁰ Many processed products are set by specific regulation, such as canned salmon, tuna, and oysters. ¹⁵¹

More generally, seafood labeling follows the same FFDCA "misbranded" standards as all other foods under FDA's jurisdiction, meaning that the labels cannot be "false and misleading in any particular." And like FDA's other foods, seafood labels are not approved pre-market, only policed by FDA afterwards. They must include all the standard package display requirements discussed above as well (nutrition fact label, allergen disclosure, ingredients, quantity, and so forth). ¹⁵³

However despite FDA having jurisdiction over all other seafood, USDA has jurisdiction over farmed catfish, pursuant to 2008 and 2014 Farm Bill amendments to the FMIA. ¹⁵⁴ These amendments transitioned from FDA to FSIS the primary regulatory responsibilities for siluriformes (catfish) fish and fish products. The U.S. domestic catfish industry successfully lobbied Congress to make this change, believing USDA labeling and inspection would give them a market advantage over their foreign competitors. ¹⁵⁵ Thus, catfish production and labeling proceeds akin to that described above for labeling of meat and label approval under FMIA.

 $^{^{\}scriptscriptstyle 150}$ Id.; see also 21 CFR \S 101.3.

^{151 21} C.F.R. § 161.145 (canned oysters), 21 C.F.R. § 161.170 (canned pacific salmon), 21 C.F.R. § 161.190 (canned tuna).

^{152 21} U.S.C. § 343(a)(1).

¹⁵³ See supra.

¹⁵⁴ See 2008 Farm Bill (Pub. L. 110-246, §4(a), title XI, §11016(b)(1)(A), June 18, 2008; 1221 Stat. 1664, 2130), and further amended by the 2014 Farm Bill (Pub. L. 113-79, title XII, §12106(a)-(c), February 7,2014; 128 Stat. 980-982). See also FDA-FSIS Memorandum of Understanding regarding Fish and Fish Products, April 30, 2014, available at

https://www.fsis.usda.gov/sites/default/files/media_file/2020-11/MOU-FSIS-FDA-Fish-Products.pdf.

¹⁵⁵ Dan Flynn, The New Reality of USDA Catfish Regulation, FOOD SAFETY NEWS (Aug. 17, 2021),

https://www.foodsafetynews.com/2021/08/the-new-reality-of-usda-catfish-regulation/.

EGGS

FDA and USDA share oversight of egg production and egg labeling.¹⁵⁶ USDA is in charge of the inspection and labeling of egg products, such as packaged egg whites or powdered eggs for food processing. Specifically, the Egg Products Inspection Act (EPIA) of 1970¹⁵⁷ provides USDA (then delegated to FSIS) oversight and labeling authority over liquid, frozen, or dried egg products.¹⁵⁸ These egg products have a labeling regime akin to that of FSIS's other meat and poultry products, with label pre-approval required, as well as substantiation of approved label claims, as discussed above.¹⁵⁹

The EPIA delegates FSIS authority over egg products, but not shell eggs. ¹⁶⁰ Because shell eggs are not covered by any of USDA's more specific statutes, their labeling regulation falls to FDA under its general FFDCA "misbranding" authority; as such, these labels are not preapproved and instead the general FDA food product labeling standards discussed above apply. ¹⁶¹ These standards do not include FDA review of "animal-raising" claims, like "cage-free" or "free-range."

However, back at USDA, the AMS has a voluntary size and quality grading program that applies to shell eggs. ¹⁶² As such, these grademarks/shields generally apply to quality and processing (USDA Grade AA, A, or B). ¹⁶³ However, some do include production method ("free range" and "cage free"), with established requirements, all of which require pre-approval by

 $^{^{156}}$ E.g., Daniela Galarza, USDA vs. FDA: What's the Difference?, THE EATER (Mar. 24, 2017),

https://www.eater.com/2017/3/24/15041686/fda-usda-difference-regulation.

 $^{^{157}}$ 21 U.S.C. \S Chapter 15, 1031 et seq.

¹⁵⁸ U.S. DEP'T AGRIC., Egg Products Inspection Act, https://www.fsis.usda.gov/policy/food-safety-acts/egg-products-inspection-act.

¹⁵⁹ See supra; FSIS Compliance Guideline for Label Approval, supra note 35; see also generally NAT'L AGRIC. LAW CTR., Putting All the Eggs in One Basket: FSIS Updates Egg Products Inspection Regulations (Sept. 22, 2020),

https://nationalaglawcenter.org/putting-all-the-eggs-in-one-basket-fsis-updates-egg-products-inspection-regulations/.

^{160 21} U.S.C. §§ 1031, 1033(f).

¹⁶¹ JOHNSON, supra note 1, at 4-5.

¹⁶² 7 C.F.R. Part 56; U.S. DEP'T AGRIC., Questions and Answers – USDA Shell Egg Grading Service, at https://www.ams.usda.gov/publications/qa-shell-eggs.

¹⁶³ U.S. DEP'T AGRIC., Shell Egg Grades, https://www.ams.usda.gov/grades-standards/egg/grade-shields.

AMS prior to use. 164 These claims, if included, must be source-verified by USDA. 165 The AMS also houses the National Organic Program and organic certified label, which applies to eggs, and which is discussed in detail in Section III infra.

DAIRY

FDA (not USDA) also regulates milk and dairy (e.g., yogurt, cheese, and ice cream). ¹⁶⁶ Milk is defined as "the lacteal secretion . . . obtained by the complete milking of one or more healthy cows." ¹⁶⁷ Milk products must contain a label identifying the product as "milk," declaring the presence of any "characterizing flavoring" (ex. vanilla), and identifying, in font not less than half the height of the product name, any added vitamins or extra pasteurization. ¹⁶⁸ Other labels, such as "pasteurized," are optional. ¹⁶⁹ Additionally, milk product labels must contain "each of the ingredients used in the food." ¹⁷⁰ Most milk byproducts are subject to similar requirements. ¹⁷¹ Labels must indicate the appropriate product name (ex. yogurt, sour cream, etc.) and the composition of the product must meet the detailed description provided in the regulations. ¹⁷² Optional ingredients are also detailed, allowing for some flexibility in what any given milk

¹⁶⁴ U.S. DEP'T AGRIC., Questions and Answers – USDA Shell Egg Grading Service, https://www.ams.usda.gov/publications/qa-shell-eggs; see also U.S. DEP'T AGRIC, USDA Grade A Certified Cage Free,

https://www.ams.usda.gov/sites/default/files/media/ShellEggAGradeCageFree.png.

¹⁶⁵ Craig Morris, USDA Graded Cage-Free Eggs: All They're Cracked Up to Be, U.S. DEP'T AGRIC. (Feb 21, 2017),

https://www.usda.gov/media/blog/2016/09/13/usda-graded-cage-free-eggs-all-theyre-cracked-be ("For AMS approval, cage-free eggs must be produced by hens housed in a way that allows for not only unlimited access to food and water, but, unlike eggs from caged hens, also provides them the freedom to roam during the laying cycle." ... We also know some consumers prefer their eggs to come from "free range" hens. For those eggs, we verify they are produced by hens that are not only housed in a way that allows for unlimited access to food and water and provides the freedom to roam within the area like cage-free hens but also gives the hens continuous access to the outdoors during their laying cycle.").

¹⁶⁶ Milk and Cream, 21 C.F.R. § 131 (2021); Cheeses and Related Cheese Products, 21 C.F.R. 133 (2021).

¹⁶⁷ 21 C.F.R. § 131.110a.

¹⁶⁸ § 131.110e; see also § 101.22i.

^{169 § 131.110}e

¹⁷⁰ § 131.110f. See also § 101.4 (explaining the process for designation of ingredients).

¹⁷¹ See § 131.111 - § 131.200.

¹⁷² See § 131.111 - § 131.200.

product can contain.¹⁷³ Certain products, like yogurt, are subject to additional label disclosure requirements based on their content. (ex. "sweetened" if sweetener is added).¹⁷⁴

Cheese products are subject to similar labeling requirements. Cheese product names are required to be displayed in full on the label, with all words being given "equal prominence," or more simply put, the same font size. (Ex. an asiago medium cheese product must read asiago medium cheese in the same font, not simply asiago cheese in large font and medium in smaller font). Like milk products, each of the ingredients used in cheese products must be declared on the label. (Certain cheese products contain an additional label guideline, clarifying how dairy ingredients are to be listed. Additionally, like many milk products, many cheese products contain optional ingredients.

Conclusion

To summarize in closing, let's review just a few of the illustrative weird product splits between the agencies. This section started with the frozen pizza example, which is really just a specific example of a broader category: processed foods with meat in them, where the answer depends on the amount and ratio. USDA handles raw produce, but once an apple becomes apple sauce or apple juice FDA is in charge. While USDA is considered the "meat" agency, FDA has its own meats, called exotic meats, plus animal products like milk and cheese. FDA also has seafood, except for catfish, which is USDA. Shell eggs go through FDA, but egg products are USDA. Clear as mud.

¹⁷³ See, e.g., § 131.110c; see also § 131.111c.

¹⁷⁴ § 131.200f.

 $^{^{175}}$ § 133.10.

¹⁷⁶ § 133.10e.

¹⁷⁷ See § 133.133d2 ("The dairy ingredients may be declared, in descending order of predominance, by use of the terms "milkfat and nonfat milk" or "nonfat milk and milkfat", as appropriate.")

¹⁷⁸ See § 133.138.

Accordingly within the past few decades there has been a push to streamline government regulation of food, repeated calls for reform and a unified system.¹⁷⁹ The Government Accountability Office (GAO) has found that the current approach to food regulation, a confusing patchwork of approximately thirty different laws and fifteen federal agencies, "has caused inconsistent oversight, ineffective coordination, and inefficient use of resources."¹⁸⁰ The National Research Council and the National Academies of Sciences have similarly called for a single food safety agency, and U.S. Representative Rosa DeLauro (D-CT) and Senator Dick Durbin (D-IL) have introduced numerous bills over the years seeking to create a single food safety agency.¹⁸¹ Both Presidents Obama and Trump promoted reorganizing food safety regulation into a single agency but took no action.¹⁸² Proponents of a consolidated agency believe a single agency "would reduce duplication of inspection at some food processing facilities, improve outreach to consumers and industry, and achieve savings over time while ensuring robust and coordinated food safety oversight."¹⁸³ One agency, one legal standard, better food safety, and better labeling, including the labeling of what people care about in the 21st century.

¹⁷⁹ David Nakamura & Ed O'Keefe, Obama Seeks More Power to Merge Agencies, Streamline Government, Wash. Post (Jan. 13, 2012), https://www.washingtonpost.com/politics/obama-to-propose-combining-agencies-to-shrink-federal-government/2012/01/13/gIQAHsLqvP_story.html; Richard Raymond, Single Food Safety Agency: It's Déjà Vu All Over Again, FEEDSTUFFS (Jun. 27, 2019), https://www.feedstuffs.com/commentary/single-food-safety-agency-its-deja-vu-all-over-again; Shook, Hardy, & Bacon L.L.P., Proposal Would Move Food Regulation To USDA, FOOD & BEVERAGE LITIG. & REGULATORY UPDATE (June, 22, 2018); Judith McGeary, One Federal Agency?, Weston A. Price Found. (July 2, 2015), https://www.westonaprice.org/one-federal-agency/; Dan Flynn, Trump Wants a Single Federal Food Safety Agency Put Under USDA, FOOD SAFETY NEWS (Jun. 22, 2018), https://www.foodsafetynews.com/2018/06/president-trump-wants-the-single-federal-food-safety-agency-put-under-usda/; News Desk, Congressional Duo Continues Push for Switch to Single Food Safety Agency, FOOD SAFETY NEWS (Jun. 21, 2019), https://www.foodsafetynews.com/2019/06/congressional-duo-continues-push-for-switch-to-single-food-safety-agency/; see generally Timothy M. Hammonds, It is Time to Designate a Single Food Safety Agency, 59 FOOD & DRUG L.J. 427 (2004); see generally Richard J. Durbin, Food Safety Oversight for the 21st Century The Creation of a Single, Independent Federal Food Safety Agency, 59 FOOD & DRUG L.J. 383 (2004).

¹⁸⁰ Shook, Hardy, & Bacon L.L.P., supra note 179; McGeary, supra note 179.

¹⁸¹ Id.; see, e.g., Safe Food Act of 2019, H.R. 4755, 116th Cong. (1st Sess. 2019); see also Raymond, supra note 1; see also News Desk, supra note 1.

¹⁸² Flynn, supra note 179

 $^{^{183}}$ Shook, Hardy, & Bacon L.L.P., supra note 179.

Animal Food Labeling Jurisdiction, Table 1

Product Type	Authorizing Statute	Authorized Agency	Subagency Delegated Authority (if applicable)	Notes
Meat	FMIA	USDA	FSIS	Covers beef, lamb, pork
Poultry	PPIA	USDA	FSIS	Covers chicken, turkey, duck, goose
"Exotic" Meats	FFDCA	FDA		Covers deer, elk, boar, and pheasant
Canned meat and poultry products	FMI/PPIA	USDA	FSIS	Provided meat is over certain established percentages of product
Seafood	FFDCA	FDA		Covers all fish and shellfish except farmed catfish
Catfish	FMIA (as amended by 2008 & 2014 Farm Bills)	USDA	FSIS	
Milk and Dairy	FFDCA	FDA		Milk, cheese, yogurt, ice cream
Processed Foods	FFDCA	FDA		Processed Foods
Eggs	FFDCA/EPIA	FDA/USDA	FSIS	FDA: shell eggs USDA (through FSIS): egg products
Food Allergies	FALCPA	FDA		Applied to USDA- regulated products through guidance
Nutrition Labeling	NLEA	FDA		Applied to USDA- regulated products through guidance
Voluntary Marketing Grades	AMA	USDA	AMS	Meat, eggs, seafood
Organic	OFPA	USDA	NOP	Organic certification

The State Role in Animal Food Labeling

American federalism has a long history of individual states being the "laboratories" of governance, ¹⁸⁴ stepping into the breach when there is an absence of federal action, leading the way in testing solutions to address new and developing social challenges. As relevant here, states handled nearly all food and food labeling regulation prior to the birth of federal food law. And even now that we have nearly 120 years of complex, interwoven federal regulation of food labeling, state governments still can and do regulate food labeling in various ways. Take California's "Prop 65" product warning labels, for example, which require warnings for exposures linked to cancer, birth defects, or other reproductive harm, ¹⁸⁵ including on food products such as mercury in fish like tuna or swordfish. ¹⁸⁶ Or Vermont's state labeling requirements for pure maple syrup "produced in Vermont." Or New Mexico's similar mandate that only pine nuts from native pinon trees can carry the "pine nut" label. ¹⁸⁸ And states are even more active through their consumer protection laws and "regulation through litigation" of food labels.

There are limits, however. And while there are other constitutional limits on states' powers to regulate the food system—prominently among them, the dormant commerce clause¹⁸⁹—this section will focus on state limitations and opportunities based on their authority interplay with federal law via preemption.

¹⁸⁴ See e.g., Oregon v. Ice, 555 U.S. 160, 170–71 (2009) ("We have long recognized the role of the States as laboratories for devising solutions to difficult legal problems."); United States v. Oakland Cannabis Buyers' Co-op., 532 U.S. 483, 502 (2001) (Stevens, J., concurring) (citation omitted).

¹⁸⁵ What Is Proposition 65?, CA.Gov, https://www.p65warnings.ca.gov/.

¹⁸⁶ Food, CA.Gov, <u>https://www.p65warnings.ca.gov/products/food.</u>

¹⁸⁷ Vt. Stat. tit. 6 §481.

¹⁸⁸ Nm. Stat. § 25-10-2 (2018).

¹⁸⁹ See generally Kimbrell and Paulsen, The Constitutionality of State-Mandated Labeling For Genetically Engineered Foods: A Definitive Defense, 39 VERMONT LAW REVIEW 342, 373–87 (2014) (explaining dormant commerce clause standards as applied to state food labeling laws in the context of genetically engineered food labeling); Association des Eleveurs de Canards et d'Oies du Quebec v. Harris, 729 F.3d 937, 947–53 (9th Cir. 2013) (holding California law prohibiting sale of foie gras not a dormant commerce

Preemption Doctrine

The United States' Constitution is a two-part system that at its core establishes that, while federal law is limited, where it is established and there is a conflict with state law, federal law trumps state law. That is, under the Constitution's supremacy clause, state laws that conflict with federal laws are "without effect" and preempted.¹⁹⁰

The touchstone of all preemption analysis is identifying Congress's preemptive purpose, 191 which can be shown three ways: express preemption, field preemption, and conflict preemption. 192 Express preemption is preemption via an express textual clause; however even in express cases, the inquiry must continue to determine what the contours of the state law displacement are in substance (what topics) and scope (how far). 193 Field preemption is just what it sounds like, federal occupation of the legal "field": when there is shown to be congressional intent for federal oversight to occupy an entire field of regulation so comprehensively that there is no room for state participation. 194 Finally, conflict preemption comes in two forms, impossibility and obstacle. Impossibility is when there is an actual conflict, making it impossible for a regulated entity to comply with both federal and state law. Obstacle is much more abstract, sweeping, and subject to interpretation, requiring a finding that a state law "stand[s] as an obstacle" to the "purposes and objectives" of Congress in a given federal law. 195

clause violation); North American Meat Inst. v. Becerra, 825 F. App'x 518 (9th Cir. 2020) affirming 420 F. Supp. 3d 1014 (C.D. Cal. 2019) (holding that California law prohibiting the sale of veal and pork meat from confined crates did not violate the dormant commerce clause).

¹⁹⁰ Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1678 (2019); see, e.g., M'Culloch v. Maryland, 17 U.S. (4 Wheat.) 316, 427 (1819) ("It is of the very essence of supremacy to remove all obstacles to [a supreme government's] action within its own sphere").

 $^{^{\}rm 191}$ Altria Group, Inc. v. Good, 555 U.S. 70, 76 (2008).

¹⁹² Holk v. Snapple Beverage Corp., 575 F.3d 329, 334 (3d Cir. 2009) (citing Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc., 471 U.S. 707, 713 (1985)); Hillsborough Cnty., Fla., 471 U.S. at 713 (citing Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977), Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)); see id. (reviewing the forms of preemption which arise under the Supremacy Clause).

¹⁹³ Altria Group, Inc., 555 U.S. at 76.

¹⁹⁴ Pacific Gas and Electric Co. v. State Energy Resources Conserv. & Development Com'n, 461 U.S. 190, 204 (1983).

¹⁹⁵ Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996).

Importantly, only federal action with the force of law has the power to preempt; this can take the form of statutes or binding regulations, ¹⁹⁶ but cannot be softer federal actions such as agency guidance or policy. ¹⁹⁷

Preemption analysis is not undertaken on a clean slate. First, there is a "presumption against" preemption. ¹⁹⁸ If a court confronts two plausible views, they have a duty to accept the reading that disfavors preemption. ¹⁹⁹ The presumption applies to both express and implied preemption, ²⁰⁰ and to both its existence and its scope. ²⁰¹ And second, in areas of traditional state regulation, the federal law cannot supplant state law unless Congress's intention is "clear and manifest." ²⁰²

Health and safety issues, which encompass food regulation, are core traditional areas of the states' general policy power.²⁰³ More specifically and as most relevant here, the same is true of the regulation of food labeling, an area "historically governed by state law."²⁰⁴ As the Supreme Court explained in 1894: "If there be any subject over which it would seem the states ought to have plenary control ... it is the protection of the people against fraud and deception in the sale of food products."²⁰⁵ That is because, as discussed *supra*, the federal government did not begin to start regulating food products and food labeling until the early 1900s, with the passage of the

¹⁹⁶ Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 153 (1982) ("Federal regulations have no less pre-emptive effect than federal statutes.").

¹⁹⁷ Holk, 575 F.3d at 342 (FDA policy on "natural" labeling did not have the force of law and therefore could not preempt state-law based challenges to "natural" labeled product as misleading).

¹⁹⁸ Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992).

¹⁹⁹ Bates v. Dow Agrosciences, 544 U.S. 431, 449 (2005).

²⁰⁰ See Wyeth, 555 U.S. at 565–66 n.3 (2009) ("The presumption thus accounts for the historic presence of state law but does not rely on the absence of federal regulation.").

²⁰¹ Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996).

²⁰² Wyeth, 555 U.S. at 565-66 n.3.

²⁰³ Medtronic, Inc. v. Lohr, 518 U.S. 470, 475 (1996).

²⁰⁴ Holk v. Snapple Beverage Corp., 575 F.3d 329, 335 (3d Cir. 2009).

²⁰⁵ Plumley v. Massachusetts, 155 U.S. 461, 472 (1894); see Plumley, 155 U.S. at 472 ("[I]f there be any subject over which it would seem the states ought to have plenary control ... it is the protection of the people against fraud and deception in the sale of food products.").

FMIA and the first version of the FFDCA, the Food and Drugs Act of 1906.²⁰⁶ Similarly, state consumer production laws, such as the prevention of false advertising and deceptive sales practices, fall within the states' historic police powers.²⁰⁷

Preemption Doctrine as Applied to Federal Food Labeling Law

The next question is how these standards apply in the food labeling context, and specifically with animal food labeling. In sum, applying preemption doctrine to state law efforts at food labeling regulation has led to mixed results, depending on the context.

FDA-REGULATED FOOD LABELING

Turning first to FDA-regulated and labeled foods: Recall that this is 80% of all food products, all plant-based food products and animal products including nearly all seafood, "exotic" meats, dairy, milk, some egg products, and mixed processed goods with some meat, depending on the ratio and amount.²⁰⁸ First, the original FFDCA (and as repeatedly amended up through 1990) lacked an express preemption provision at all, showing the lack of any intent to preempt state authority.²⁰⁹ And second, while Congress did include an express preemption provision in amending the FFDCA with the Nutrition Labeling and Education Act (NLEA) of 1990,²¹⁰ it limited that clause in several important ways. The provision provides 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... any requirement for the labeling of food *of the*

²⁰⁶ Part I: The 1906 Food and Drugs Act and Its Enforcement, U.S. FOOD & DRUG ADMIN. (Apr. 24, 2019), https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-i-1906-food-and-drugs-act-and-its-enforcement.

²⁰⁷ Florida Lime & Avocado Growers v. Paul, 373 U.S. 132, 144 (1963).

 $^{^{\}scriptscriptstyle 208}$ See supra Section I.

 $^{^{209}}$ See 21 U.S.C. §§ 301–399f; Grocery Mfrs Ass'n v. Sorrell, 102 F. Supp. 3d 583, 611 (D. Vt. 2015).

²¹⁰ 21 U.S.C. § 343-1.

type required by section ... of this title that is not identical to the requirement of such section"
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Thus, even for the preemption covered categories, states are preempted from requiring any labeling only "not identical" to that required by FDA. States may establish their own labeling requirements in those areas so long as they are identical to that required by FDA regulation.²¹² Further, not all state labeling requirements providing more or different information from the FFDCA are preempted. Instead, in order for preemption to apply, the FFDCA must already require the labeling information at issue. The labeling categories covered by the NLEA's preemption provision are expressly listed and include a food's "standard of identity,"²¹³ imitation of another food,²¹⁴ package form,²¹⁵ common or usual name,²¹⁶ allergen labeling requirements,²¹⁷ product name,²¹⁸ misleading container,²¹⁹ prominence of information on the label,²²⁰ standards of quality and fill,²²¹ artificial flavoring, coloring, or preservatives,²²² nutrition labeling information for retail products (but not restaurants),²²³ and nutrition level and health-related claims.²²⁴ Thus where FDA has acted to establish categories of labeling for a particular food in these ways, states are not at liberty to establish their own labeling "not identical" to them.²²⁵ However the absence of a federal standard obviates any preemptive claim that a state

²¹¹ 21 U.S.C. § 343-1 (emphases added).

²¹² In re Farm Raised Salmon Cases, 42 Cal 4th 1077, 1086 (2008).

 $^{^{213}}$ 21 U.S.C. \S 343-1(a) (1) (referencing 21 U.S.C. \S 343(g)).

 $^{^{214}}$ 21 U.S.C. \S 343-1(a) (2) (referencing 21 U.S.C. \S 343(c)).

²¹⁵ 21 U.S.C. § 343-1(a) (2) (referencing 21 U.S.C. § 343(e)).

²¹⁶ 21 U.S.C. § 343-1(a) (2) (referencing 21 U.S.C. § 343(i)(1)-(2)).

²¹⁷ 21 U.S.C. § 343-1(a) (2) (referencing 21 U.S.C. § 343(w) & 21 U.S.C. § 343(x)).

²¹⁸ 21 U.S.C. § 343-1(a) (3) (referencing 21 U.S.C. § 343(b)).

²¹⁹ 21 U.S.C. § 343-1(a) (3) (referencing 21 U.S.C. § 343(d)).

²²⁰ 21 U.S.C. § 343-1(a) (3) (referencing 21 U.S.C. § 343(f)).

²²¹ 21 U.S.C. § 343-1(a) (3) (referencing 21 U.S.C. § 343(h)).

²²² 21 U.S.C. § 343-1(a) (3) (referencing 21 U.S.C. § 343(k)).

^{223 21} U.S.C. § 343-1(a) (4) (referencing 21 U.S.C. § 343(q)) (exempting restaurants and other retail establishments).

²²⁴ 21 U.S.C. § 343-1(a) (5) (referencing 21 U.S.C. § 343(r)(1)).

^{225 21} U.S.C. § 343-1.

requirement is "not identical" to it. For example, FDA has not promulgated "standards of identity" for all foods.²²⁶

Third, Congress also instructed that the preemptive scope of the NLEA was to sweep no further than the plain language of the statute itself, stating that "[t]he [NLEA] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [section 343–1] of the [FDCA]."²²⁷ That is, Congress said limited express preemption was the *only* type of NLEA preemption available, and that the statute should not be interpreted by the Courts to implicitly preempt beyond that scope.²²⁸ Thus if courts were to hold any type of implied preemption it must find its home from other provisions of the FFDCA or other law, not the NLEA.²²⁹ Overall, Congress showed it was aware of the operation of state law and regulation in the food regulation and labeling field, and enacted limited exceptions in the NLEA, strongly cutting against implied preemption arguments.²³⁰

Accordingly, the courts' application of these standards has left room for plenary state operation with regard to FDA-labeled food. For example, when Vermont passed the first-ever state law requiring the mandatory labeling of genetically engineered foods, ²³¹ the court reviewing the food industry's challenge to the state law rejected their NLEA preemption arguments, because genetically engineered ingredients was not a category established by FDA and the state's labeling requirements did not change any of the existing FDA label categories

²²⁶ See 21 C.F.R. § Parts 130-169 (identifying 300 standards in 20 categories of food); compare 21 C.F.R. § 150.110 (fruit butter) with 150.140 (fruit jelly).

 $^{^{227}}$ Pub. L. No. 101–535, 6(c)(1) (Nov. 8, 1990), 104 Stat. 2364.

²²⁸ New York State Rest. Ass'n v. New York City Bd. of Health, 556 F.3d 114, 123 (2d Cir. 2009) ("Helpfully, the NLEA is clear on preemption, stating that it 'shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [21 U.S.C. § 343–1(a)] of the [FDCA].").

²²⁹ Holk v. Snapple, 575 F.3d 329, 336 (3d Cir. 2009).

²³⁰ Wyeth v. Levine, 555 U.S. 555, 575 ("[t]he case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them.")

²³¹ 2014 Vt. Acts & Resolves 120,

https://legislature.vermont.gov/Documents/2014/Docs/ACTS/ACT120/ACT120%20As%20Enacted.pdf.

(such as common name or standard of identity); the state law requirement existed independent of them.²³² And because the term "genetically engineered" was not then federally regulated or defined by federal law, the court similarly held there was no implied conflict or obstacle preemption. Namely, FDA's policy on the labeling of GE foods was only a policy—and as such, without the force of law—thus there was no relevant federal "law" to which Vermont's law could present a conflict or be an obstacle for preemptive purposes.²³³ Finally even that FDA policy allowed for voluntary GE food labeling, showing that it could co-exist and not conflict with general federal "false and misleading" labeling standards.²³⁴

THE "FOOD COURT"

While there are proscriptive state laws addressing and supplementing federal food labeling standards, many state legislatures have strong agricultural lobbying interests, making it difficult to pass state disclosure or right to know laws that might be perceived as contrary to their interests. Hence the main state battleground has been consumer protection statutes and false and misleading labeling. Recall that court challenges to food labeling as false and misleading are brought under *state* consumer protection laws, state laws that generally prohibit deceptive trade practices.²³⁵ Thus the same preemption questions apply to these cases as if the state enacted a new labeling law on a particular food topic.

The result has been an explosion of state-based consumer protection "false and misleading" food labeling cases over the past decade-plus.²³⁶ Class action cases against food and

 $^{^{232}}$ Grocery Mfs Ass'n v. Sorrell, 102 F. Supp. 3d 583, 613-615 (D. Vt. 2015). This state law was later expressly preempted by Congress in the National Bioengineered Food Disclosure Act of 2016. See infra.

²³³ Id. at 615-17.

²³⁴ Id. at 615.

²³⁵ Carolyn L. Carter, A 50-State Report on Unfair and Deceptive Acts and Practices Statutes, NATIONAL CONSUMER LAW CENTER (Nov. 2009), https://www.nclc.org/images/pdf/car_sales/UDAP_Report_Febog.pdf.

²³⁶ See, e.g., Andrew Jacobs, Lawsuits Over 'Misleading' Food Labels Surge as Groups Cite Lax U.S. Oversight, N.Y. TIMES (Sept. 7, 2021), https://www.nytimes.com/2021/09/07/science/food-labels-lawsuits.html.

beverage companies reached a record high of 220 separate litigations in 2020, up from 45 such cases a decade before.²³⁷ It even has a catchy name: the "Food Court."²³⁸ These cases are borne of frustration by advocates in convincing federal and state regulators to require better regulation through labeling, who see these cases as an effective tool for holding companies accountable.²³⁹

The quintessential example of such litigation is the "natural" litigation: state false and misleading labeling cases over the use of the term "natural" on food products or its various iterations, "all natural," "100% natural," "made with all natural ingredients." FDA has never defined the term nor established standards for its use on food labeling, leaving it open for companies to use—and exploit—for virtually whatever products on which they conclude they can get away with using it.

In general the theory of these cases is that products with synthetic ingredients nonetheless labeled as "natural" are false and misleading to consumers' reasonable expectations of what natural means (or should mean). These cases generally have included allegedly unnatural things like: the use of synthetic or artificial additives or ingredients, the use of genetically engineered ingredients, or pesticide residues in food.

For example, the first and most well-known natural case was a challenge to the use by the beverage company Snapple, which claimed to be "made with the best stuff on earth," including labeling its products as having "all natural" ingredients, despite them being made with high fructose corn syrup (also made from genetically engineered corn).²⁴⁰ In a detailed analysis, the reviewing court of appeals rejected all of Snapple's FFDCA preemption arguments, permitting the case to go forward.²⁴¹ Among other holdings, the court explained that the NLEA

²³⁷PERKINS COIE, FOOD & CONSUMER PACKAGED GOODS LITIGATION, 2020 YEAR IN REVIEW (2021),

https://www.perkinscoie.com/images/content/2/4/241153/2021-Food-CPG-Litigation-YIR-Report-v4.pdf,

 $^{^{238}}$ Institute for Legal Reform, The Food Court: Trends in Food and Beverage Class Action Litigation (2017),

https://instituteforlegalreform.com/research/the-food-court-trends-in-food-and-beverage-class-action-litigation/.

²³⁹ Jacobs, supra note 236.

²⁴⁰ Holk v. Snapple, 575 F.3d 329, 332 (3d Cir. 2009).

²⁴¹ Id. at 337-42.

and FFDCA anticipate the operation of state regulation (and litigation) within the federal sphere, with the enumerated NLEA category exceptions.²⁴² And FDA has categorically declined to establish a definition or standards for "natural" labeling.²⁴³ Thus, its regulation is left to the states, until and unless FDA acts to establish federal natural labeling standards.²⁴⁴

Over the past decade dozens of other cases followed the Snapple litigation model.²⁴⁵ Consumers have filed similar false and misleading "natural" cases with regard to all sorts of food products: cooking oils, chips, granola bars, breakfast cereals, soups, cookies, tea, crackers, pasta sauces, sodas, to name a few.²⁴⁶ To be sure, the *results* of these cases have been mixed on the merits of what a reasonable person would believe was a natural ingredient or production method, or not.²⁴⁷ But the courts have overwhelmingly held that the cases are categorically not preempted by federal food law.²⁴⁸

Consumers have lodged other types of similarly misleading labeling cases as well: In the same vein as the "natural" litigation are challenges to other food labeling claims and deceptive

²⁴² Id. at 334-40.

²⁴³ Id. at 340-44.

²⁴⁴ FDA has held public comment on so defining the term, however it has never proposed nor completed that process. Use of the Term Natural on Food Labeling, U.S. FOOD & DRUG ADMIN. (Oct. 22, 2018), https://www.fda.gov/food/food-labeling-nutrition/use-term-natural-food-labeling.

²⁴⁵ See generally Food Court, supra note 238; e.g. at 2 (claims challenging products advertised as "natural" are the most frequent food class action cases).

²⁴⁶ See, e.g., Lee v. Conagra Brands, 958 F.3d 70 (1st Cir. 2020) ("100% all natural" cooking oil made with genetically engineered ingredients challenged under Massachusetts unfair or deceptive practices law, rejecting preemption challenges); Garcia v. Kashi Co., 43 F. Supp. 3d 1359 (S.D. Fla. 2014) ("all natural" cereals and snack bars made with numerous synthetic ingredients and genetically engineered corn and soy); Ault v. J.M. Smucker Co., 2014 WL 1998235 (S.D.N.Y. May 15, 2014); In re Frito-Lay N. Am., Inc. All Nat. Litig., 2013 WL 4647512 (E.D.N.Y. Aug. 29, 2013) ("all natural" chips).

²⁴⁷ E.g., Axon v. Florida's Natural Growers, 813 F. App'x 701 (2d Cir. 2020) (affirming dismissal of challenge to "natural" orange juice that had trace amounts of pesticide residues because not plausible to allege that a reasonable consumer would interpret the brand label as meaning that the product was completely free of any trace amounts of pesticides); Yu v. Dr. Pepper Snapple Group, 2020 WL 5910071 (N.D. Cal 2020) (trace amounts of pesticide did not render "natural" claim on apple juice misleading).

²⁴⁸ Barnes v. Campbell Soup Co., ²⁰¹³ WL 5530017 (N.D. Cal ²⁰¹³) ("100% natural" vegetable soup label challenges for use of genetically engineered corn not preempted); Lockwood v. Conagra Foods, ⁵⁹⁷ F. Supp. ^{2d} 1028, ¹⁰³²⁻³⁴ (N.D. Cal. ²⁰⁰⁹) (misleading label challenge to "all natural" pasta sauce using high fructose corn syrup not preempted); Astiana v. Ben & Jerry's Homemade, ²⁰¹¹ WL ²¹¹¹⁷⁹⁶, *8 (N.D. Cal. ²⁰¹³) (misleading label challenge to "all natural" ice cream containing synthetic substance (alkalized cocoa) not preempted); Hitt v. Arizona Beverage Co., ²⁰⁰⁹ WL ⁴⁴⁹¹⁹⁰ (S.D. Cal. ²⁰⁰⁹) (misleading label challenge to "100% Natural" tea drinks with artificial ingredients not preempted).

imagery implying a products healthy nature (ex. "nothing artificial," "no preservatives," and "nutritious").²⁴⁹ Others include claims of "no antibiotics" on cheese made from milk sourced from cows raised with antibiotics;²⁵⁰ the use of "sustainable" on Red Lobster seafood that are sourced from suppliers using harmful and inhumane industrial aquaculture practices;²⁵¹ and cases challenging the depiction of "happy cows" on ice cream from milk sourced largely from factory style dairy farms.²⁵² Other cases challenging products as misleading have focused on the use of deceptive ingredient names, such as evaporated cane juice (as opposed to sugar),²⁵³ and the amount of empty space in food containers.²⁵⁴ As such, and as most relevant here, these cases challenging labels can, and in some cases already do, encompass the types of animal food labeling overseen by FDA, including labeling for fish, shellfish, "exotic" meats, dairy, milk, and processed goods with some meat, depending on the ratio and amount.

²⁴⁹ See In re Ferroro Litigation, 794 F.Supp.2d. 1107 (S.D. Cal. June 30, 2011) (challenging promotion of Nutella as healthy and beneficial to children despite its dangerous levels of fat and sugar). See Cruz Acevedo v. ConAgra Fods Inc., No. 3:15-cv-02307 (D. P.R. Sept. 20, 2015) (misleading label challenge to Chef Boyardee products containing citric acid but claiming "no preservatives.")

²⁵⁰ Quynh Phan v. Sargento Foods Inc., No. 5:20-cv-09251 (N.D. Cal. Dec. 12, 2020) (bringing suit for deceptive labeling, marketing, and sale over Sargento's use of "no antibiotics" on cheese products as they are made from milk sourced from cows raised with antibiotics and on products that sometimes contain antibiotics).

²⁵¹ Dezzi Rae Marshall v. Red Lobster Management LLC., No. 2:21-cv-04786 (C.D. Cal. Jun. 6, 2021) (bringing suit for deceptive marketing and sale over the use of the term "sustainable" on Red Lobster's lobster and shrimp products as they are sourced from suppliers using environmentally harmful and inhumane practices).

²⁵² James Ehlers v. Ben & Jerry's Homemade Inc., No. 2:19-cv-194, 2020 WL 3642976 (D. Vt. Jan. 13, 2020) (serving as the impetus for the discontinuation of the term "happy cows on Ben & Jerry's ice cream. This decision followed a suit for deceptive labeling and marketing over the use of "happy cows" on ice-cream made from milk sourced largely from factory style dairy farms).

²⁵³ See Sue Werstak et al., Cane Juice Litigation Shows no Signs of Evaporating, Food SAFETY MAG. (Feb. 7, 2017),

https://www.food-safety.com/articles/5180-cane-juice-litigation-shows-no-signs-of-

evaporating#:~:text=Much%20of%20the%20evaporated%20cane%20juice%20labeling%20litigation,However%2C%20plaintiffs%2 oare%20also%20filing%20in%20other%20venues; see, e.g., Grindel v. Mondelez Int'l Inc., No. 1622-CC-11518 (Nov. 16, 2016); Kane v. Chobani, Inc., No. 12-cv-2425, (N.D.Cal. May 14, 2012); Melvin v. Blue Diamond Growers, No. 8:13-cv-1746 (C.D. Cal. Nov. 5, 2013).

²⁵⁴ Izquierdo v. Mondelez Int'l Inc., No. 16-cv-4697 (S.D.N.Y. Oct. 26, 2016) (alleging false marketing of Sour Patch Watermelon Candy based on the significant percentage of box that is left empty).

FSIS-REGULATED FOOD LABELING

Turning next to those food labels regulated by USDA (mostly through FSIS): Recall that this is approximately 20% of food products, but most of the meat (beef and pork) and poultry products. First, unfortunately for state labeling authority, unlike FDA and the FFDCA, the FMIA and PPIA administered by USDA do include broad (substantially identical) express preemption clauses. The twin meat laws permit some concurrent state enforcement, but expressly declare that state laws regulating the labeling of meat and poultry products "may not be imposed by any State" if they set forth "marking, labeling, packaging, or ingredient requirements in addition to, or different than, those made under this Act."²⁵⁵ The Supreme Court characterized the preemption from these clauses as one that "sweeps widely" and "prevents a State from imposing any additional or different—even if non-conflicting—requirements that falls within the scope of the Act."²⁵⁶

Thus, state efforts to regulate meat and poultry labels directly run into some preemption difficulties. For example in *Jones v. Rath Packing Co.*, a 1977 Supreme Court case, several companies challenged a California removal order of their bacon products for having net weight different than the net weight stated on their packages.²⁵⁷ However the bacon came from plants already subject to USDA inspection and labeling under the FMIA, with which they were in compliance.²⁵⁸ The Supreme Court held that the California state code provision also addressing the weight and measure of the bacon packages was "different than" the same established federal weight requirement and thus preempted.²⁵⁹ Similarly, in *National Broiler Council v. Voss*, the

²⁵⁵ 21 U.S.C. 678 (meat); 21 U.S.C. 467e (poultry) (emphases added).

 $^{^{256}}$ National Meat Ass'n v. Harris, 565 U.S. 452, 459 (2012) (holding as preempted a California penal code provision that prohibited the sale of meat from "nonambulatory" animals because it attempted to impose on slaughterhouses additional and different requirements from those established by USDA under FMIA).

²⁵⁷ Jones v. Rath Packing Co., 430 U.S. 519, 522-23 (1977).

²⁵⁸ Id. at 528-30.

²⁵⁹ Id. at 532; see also, e.g., Grocery Manufacturers of America v. Gerace, 755 F.2d 993, 1002-03 (2d Cir. 1985) (New York state law requiring certain products be labeled imitation was preempted as applied to any meat and poultry products covered by FMIA and PPIA).

Ninth Circuit later held preempted a California law that prohibited using the word "fresh" on previously frozen poultry product labels, because the state law set a different labeling standard than those already defined by FSIS as to what "fresh" could mean for poultry labels. ²⁶⁰ In short, it was true that the chickens had been previously frozen—not fresh—as a reasonable person would interpret the term, but USDA's regulatory label standard had nonetheless approved the practice as still "fresh," and California was preempted from requiring otherwise.

The forementioned state-based consumer protection act "natural" litigation also provides an illuminating contrast. Namely, unlike the misleading "all natural" cases brought against FDA-regulated products—in which courts have almost uniformly denied preemption challenges—courts have held that similar "natural" challenges aimed specifically at meat product labels under USDA's purview *are* preempted.²⁶¹ Unlike FDA, USDA requires preapproval by FSIS before the term can be used on product labels, including for "natural" claims. Because USDA previously approved the "natural" meat labels in question, the courts have held that as a matter of law, they cannot be false or misleading.

SILVER LININGS

While States have less non-preempted room to regulate FSIS-regulated meat labels than with other food product labels overseen by FDA, there are at least three silver linings.

<u>First</u>, as explained in Section I, FSIS does have to pre-approve a meat and poultry product labels and their terms before their market use.²⁶² This includes approval for all the standard mandatory product information, but as most relevant here, also include negative or

²⁶⁰ National Broiler Council v. Voss, 44 F.3d 740 (9th Cir. 1994).

²⁶¹ E.g., Phelps v. Hormel Foods, 244 F. Supp. 3d 1312, 1317 (S.D. Florida 2017) (challenge to "100% natural" deli meat label preempted); Barnes v. Campbell Soup Co., 2013 WL 5530017, *5 (N.D. Cal. 2013) (challenge to "100% Natural" chicken soup label preempted); Meanurit v. ConAgra Foods Inc., 2010 WL 2867393, *7 (N.D. Cal. 2010) (challenge to chicken pot pie labels preempted).

²⁶² See supra Section I.

"absence" claims, such as "no hormones added," and broader process-based and animal-raising claims, like "cage free" and "free range." ²⁶³ In contrast for FDA-regulated labels, when FDA has not expressly enacted standards for a certain part of the label, manufacturers are left to their own devices to try whatever claims they think they can get away with without drawing FDA enforcement warning letters or state consumer protection challenges. ²⁶⁴ So *in theory*, because FSIS's labels require premarket review and agency approval, those product labels should be better than FDA's labels for the public, being less misleading and thus requiring less state supplementation.

However, in practice this silver lining fizzles. While FSIS does pre-approve labels, FSIS standards for what those labels mean are not as rigorous or meaningful as what many food advocates would prefer, or the reasonable consumer would arguably think.²⁶⁵ For example, for claims that meat came from animals that are "cage-free," or "free range," FSIS has not defined the terms by regulation, nor established specific raising standards for them.²⁶⁶ Instead the claims are to be described by the producer on the label, such as, "Cage free. Chickens were never confined to cages during raising."²⁶⁷ Similarly for "free range" or "free roaming," the producer must show that the animal had "continuous, free access to the outside through the normal growing cycle," but what qualifies as "access" is not defined.²⁶⁸ Other claims, such as "grass-fed" are in contrast more well defined and can only be applied to meats from cattle that are fed solely

²⁶³ U.S. DEP'T OF AGRIC., FSIS COMPLIANCE GUIDELINE FOR LABEL APPROVAL (2020),

https://www.fsis.usda.gov/sites/default/files/media file/2020-10/Label-Approval-Guide.pdf; see also U.S. DEP'T OF AGRIC., FOOD STANDARDS AND LABELING POLICY BOOK (2009), https://www.fsis.usda.gov/sites/default/files/import/Labeling-Policy-Book.pdf.

²⁶⁴ See Warning Letters, U.S. FOOD & DRUG ADMIN. (Nov. 2, 2021), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters.

²⁶⁵ See generally Sutherland & Craig, Oversight of Animal Raising Claims on Product Packaging: A Review of Jurisdiction and Challenges to Label Claims, 26 ANIMAL L. 271 (2020).

²⁶⁶ U.S. DEP'T OF AGRIC., FOOD SAFETY AND INSPECTION SERVICE LABELING GUIDELINE ON DOCUMENTATION NEEDED TO SUBSTANTIATE ANIMAL RAISING CLAIMS FOR LABEL SUBMISSIONS 10 (2019), https://www.fsis.usda.gov/sites/default/files/media-file/2021-02/RaisingClaims.pdf [hereinafter Food Safety and Inspection Service Labeling Guideline].

²⁶⁷ Id.

²⁶⁸ Id. at 11.

grass or forage and never grain, and must have continuous access to pasture (e.g., not confined to a feedlot).²⁶⁹ Similarly negative input claims "no hormones added" or "no antibiotics added" are also defined to mean what they sound like—that the animals were raised without them.²⁷⁰

Unfortunately, as far as claim substantiation, FSIS only undertakes limited document review of affidavits and descriptions of farm conditions and practices; it does not actually inspect farms to ensure accuracy and compliance.²⁷¹ And even for the documentation required, outside investigations have shown a significant percentage are missing substantiating documentation.²⁷² If there is an additional third-party private certification requested to be also included on the label, all that is required by FSIS is a copy of the certificate from the certifying organization.²⁷³ While some are rigorous, these private certifications have varying levels of integrity and may easily sow confusion or mislead uninformed shoppers.²⁷⁴

Further, for many broad claims—like "raised with care," "humanely raised," "sustainable," "pasture raised," or "environmentally friendly"—things are even more vague: FSIS approves claims, but has never set definitions or identified acceptable standards for review and approval.²⁷⁵ Instead, FSIS guidance instructs the producer to *self*-define what it means by the term, which often devolves into vague, bootstrapping, feel-good jargon, such as approving "humanely raised" based on this production definition: "meets Empire Kosher's humane policy for raising chicken on family farms in a stress-free environment" (without defining "stress free"

²⁶⁹ Id. at 9.

²⁷⁰ Id. at 13–14. One complication however is that federal law prohibits the use of hormones in poultry completely, so the use of the label "no hormones" on poultry must be supplemented with a qualifying statement such as "federal regulations prohibit the use of hormones in poultry." Id.

²⁷¹ Sutherland & Craig, supra note 265 at 276; FOOD SAFETY AND INSPECTION SERVICE LABELING GUIDELINE, supra note 266. FSIS likely lacks the authority for such on-farm inspections to evaluate animal raising or environmental practice claims, even if it had the regulatory bandwidth and budget.

²⁷² Sutherland & Craig, supra note 265 at 277; see also Animal Welfare Institute, Label Confusion 2.0 (2019), https://awionline.org/sites/default/files/publication/digital_download/19LabelConfusionReport.pdf.

²⁷³ FOOD SAFETY AND INSPECTION SERVICE LABELING GUIDELINE, supra note 266.

²⁷⁴ Stephanie Strom, What to Make of Those Animal-Welfare Labels on Meat and Eggs, N.Y. TIMES (Jan. 31, 2017), https://www.nytimes.com/2017/01/31/dining/animal-welfare-labels.html?referringSource=articleShare.

²⁷⁵ FOOD SAFETY AND INSPECTION SERVICE LABELING GUIDELINE, supra note 266, at 7.

or what "humane policy" entails).²⁷⁶ Effectively, all these claims mean is what the producer suggests they do, so long as FSIS determines the claim is not misleading. Finally, all of this is set out by guidance—not binding regulation—leaving agency discretion and a lack of standardization in individual label approval.²⁷⁷ Consequently, consumer watchdog and nonprofit attempts to force FSIS (and other agencies) to improve food labeling definitions and standards face high hurdles of judicial review in the courts.²⁷⁸

Second, federal meat and poultry labeling law's preemption of state law is limited to the four corners of the label approved by FSIS, and does not include any surrounding meat product advertising.²⁷⁹ While preempting the label, the courts have held that "nothing in the text of the FMIA [or PPIA] indicates an intent to preempt state unfair-trade-practice laws in general."²⁸⁰ Indeed neither federal meat law even mentions advertising, beyond the label itself. And the "presumption against preemption" beyond the label applies with particular force here, because the regulation of advertising is a field the states have traditionally occupied.²⁸¹ Indeed, when Congress amended the FMIA and PPIA to include the express preemption provisions in the 1960s, states had long had regulated advertising, showing Congress's awareness and a lack of intent to preempt.²⁸² The aforementioned Ninth Circuit decision in Voss crystalized this

 $^{^{\}rm 276}$ Sutherland & Craig, supra note 265 at 276.

²⁷⁷ FOOD SAFETY AND INSPECTION SERVICE LABELING GUIDELINE, supra note 266.

²⁷⁸ Compassion over Killing v. FDA, 849 F.3d 849 (9th Cir. 2017) (holding, inter alia, that numerous agencies including FSIS did not act arbitrarily and capriciously in denying organizations' rulemaking petition requesting improvement to "free-range" and "cage-free" egg labeling standards).

²⁷⁹ E.g., ALDF v. Hormel Foods Corp., 258 A.3d 174, 191 (D.C. Ct. App. 2021) ("States are free to regulate advertisements without regard to whatever terms the USDA approves as appropriate for labeling, so long as they do not encroach on the labeling itself."); Sanderson Farms v. Tyson Foods, 549 F. Supp. 2d 708, 720 (D. Md. 2008) (PPIA and FMIA do not govern "non-label advertising" of meat products, including whether they are false or misleading).

²⁸⁰ U.S. v. Stanko, 491 F.3d 408, 418 (8th Cir. 2007).

²⁸¹ Florida Lime & Avocado Growers v. Paul, 373 U.S. 132, 144 (1963); Medtronic, 518 U.S. at 485; In re Farm Raised Salmon Cases, 42 Cal.4th 1077 (2008).

²⁸² Hormel, 258 A.3d at 193; Wyeth, 555 U.S. at 575 ("the case for federal preemption is particularly weak" where Congress is aware "of the operation of state law in a field ... and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them.").

distinction: while California's attempt to change the poultry label's definition of "fresh" was preempted, California was not powerless. "California stores can still be required by state law to tell the truth in advertising and to display frozen chickens for what they are—'frozen'—even though the labels on the chickens themselves are required by federal law to say 'fresh'. ... The States are not without devices of their own to protect their citizens."²⁸³

This second silver lining has shown more promise. In recent years consumer protection cases alleging false and misleading advertising practices in animal food labeling have proliferated;²⁸⁴ these cases forming a separate wave of state-based litigation.²⁸⁵ For example, a 2021 case against Hormel Foods alleged their deli meat "natural choice" advertising campaign falsely conveyed to consumers that their animals were treated humanely and that their products were free from preservatives.²⁸⁶ Where an earlier case challenging the Hormel FSIS-approved "natural" *label* fell to preemption,²⁸⁷ in this challenge—not to the label but to the surrounding print and video *advertising campaign*—the court rejected Hormel's preemption arguments.²⁸⁸ Similarly, a 2017 case challenged the major poultry company Sanderson over its "100% Natural" advertising campaign despite their chicken products testing positive for antibiotics, pharmaceuticals, and other unnatural substance residues.²⁸⁹ The court rejected Sanderson's preemption arguments since the false and misleading allegations addressed the broader print and video advertising, not the FSIS label.²⁹⁰

²⁸³ Voss, 44 F.3d at 749 (O'Scannlain, J., concurring).

²⁸⁴ See, e.g., Andrew Jacobs, Lawsuits Over 'Misleading' Food Labels Surge as Groups Cite Lax U.S. Oversight, N.Y. TIMES (Sept. 7, 2021), https://www.nytimes.com/2021/09/07/science/food-labels-lawsuits.html.

²⁸⁵ Id.

²⁸⁶ ALDF v. Hormel Foods Corp., 258 A.3d 174, 179 (D.C. Ct. App. 2021).

²⁸⁷ Phelps v. Hormel Foods, 244 F. Supp. 3d 1312, 1317 (S.D. Florida 2017) (challenge to "100% natural" deli meat label preempted).

²⁸⁸ ALDF v. Hormel Foods Corp., 258 A.3d at 179-180, 191-195.

²⁸⁹ Organic Consumers Ass'n v. Sanderson, 284 F.Supp.3d 1005 (N.D. Cal. 2018).

²⁹⁰ Id. at 1013–14. While the case was later dismissed on standing grounds and affirmed on appeal, Friends of the Earth v. Sanderson Farms, 992 F.3d 939 (9th Cir. 2021), these did not alter the court's earlier preemption analysis.

Legal actions have targeted other similar false or misleading advertising about animal welfare, environmental impacts, or worker conditions. In addition to those noted above, other examples include: Cargill turkeys ads as being raised by "independent family farmers" despite these contract poultry farmers having nearly zero control over the means of the production, including the poultry they raise for Cargill brands; and Tyson, for its claims of "humane production" for its poultry and "safe work environment" for its workers, despite its chickens being raised in inhumane confined animal feeding operations and dozens of its workers were killed by COVID (and thousands more infected) during the 2020-2021 pandemic;²⁹¹ the use of terms like "pasture-raised" on advertisements for eggs raised in cramped barns;²⁹² the use of *American Humane Certified* certification on Foster Farm advertisements despite Foster Farms inhumane practices;²⁹³ the use of "natural" and "containing no nitrates or nitrites"²⁹⁴ and the depiction of idyllic, free range chicken life in advertisements despite chickens actually residing in barns.²⁹⁵ Since 2013, over two dozen cases have been brought challenging false and misleading animal raising claims.²⁹⁶

Third and finally, with regard to future state action addressing on-farm, animal welfare standards established through the passage of state laws, the preemptive reach of FSIS-label regulation appears unclear and may well leave plenary room.²⁹⁷ Imagine a state law that categorically defined a "humanely raised" meat product label, for example.

²⁹¹ Food & Water Watch v. Tyson Foods, No. 2019-CA-004547 (D.C. Super. Ct. July 7, 2019) (arguing that Tyson's marketing and advertising of its products under the label "all natural" is deceptive and misleading as their operations are contaminated by antibiotic resistant pathogens, use numerous environmentally damaging chemicals, and employ inhumane animal husbandry practices); Family Farm Action Alliance v. Cargill, Inc. (F.T.C. Nov. 23, 2020) (urging the FTC to investigate false and misleading representations made by Cargill about its turkeys being raised in independent family farms).

²⁹² Handsome Brook Farm, LLC v. Humane Farm Animal Care, Inc., 193 F.Supp.3d 556 (E.D. Vir. June 15, 2016) (bringing suit for false advertising over Handsome Brook's claim of "pasture-raised" chickens when many were being raised within barns with no outdoor access).

²⁹³ Leining v. Foster Poultry Farms, BC588044 (Cal. Super. Ct. July 13, 2015).

²⁹⁴ Animal Legal Def. Fund v. Hormel Foods, 2016-CA-004744 B (D.C. Super. Ct. Sept. 20, 2017)

²⁹⁵ Lugones v. Pete & Gerry's Organics, No. 19-cv-02097 (S.D.N.Y. Mar. 6, 2019).

²⁹⁶ Sutherland & Craig, supra 265 at Table 1 (compiling litigation as of 2020 as well as administrative actions).

²⁹⁷ See generally Bruce Friedrich, Meat Labeling Through the Looking Glass, 20 ANIMAL L. 79 (2013).

To be sure, where FSIS has affirmatively acted to set a general meat labeling standard by regulation, as in *Voss* with regard to the meaning of "fresh," or in *Jones* as to what weight measurements are permitted, *see supra*, state laws attempting to establish different standards are preempted. But as explained *supra* there are many aspects of labeling in which FSIS acts on a case-by-case, label-by-label approval basis, including broader process-based and on-farm animal-raising claims. And for those claims, FSIS has not set by regulation categorical standards with the force of law, which is what type of agency action is required to preempt;²⁹⁸ instead instructions for producers is set forth by non-binding *guidance*.²⁹⁹ And within FSIS's guidance, at best, there is only general instruction from FSIS on what the label means or should include, and producers are told to self-define the rest. The guidance acknowledges that, with regard to "animal welfare and environmental stewardship" claims, "FSIS has not defined these claims in regulations or policy guidelines."³⁰⁰ In preemption terms, there is no federal "law" on these topics with to conflict, or to which a state law would present an obstacle. Nor has FSIS comprehensively regulated the whole field of this type of labeling, instead declining to so act.

Beyond the label submission guidance, FSIS does affirmatively approve individual product labels with many such claims, and those individual product approvals do have the force of law. But they are individualized: while that might preempt a false and misleading state consumer protection *case* brought against that *particular* meat product label, it would be passing strange if an individual product label approval could preempt a categorical state law in an area. Nor do these individual approvals have the hallmarks of broader agency rulemaking preemptive actions, like public notice and comment.

²⁹⁸ Holk v. Snapple, 575 F.3d 329, 340-44 (3d Cir. 2009).

 $^{^{299}}$ FOOD SAFETY AND INSPECTION SERVICE LABELING GUIDELINE, supra note 266, at 7.

³⁰⁰ Id. at 7.

More fundamentally, labels regarding on-farm treatment of animals, like humane livestock issues, appear beyond the scope of FMIA as mandated by Congress.³⁰¹ *Jones* addressed the labeling of meat weight, a core part of the FMIA's food safety and health focus;³⁰² in contrast there is nothing in the FMIA or the PPIA regarding humane considerations pre-slaughter and on-farm conditions. As mentioned above, FSIS does not inspect farms to ensure compliance with labels, including humane claims. It would seemingly be difficult to find congressional intent—the touchstone of preemption analysis—to preempt given the meat laws' scope and focus.

On the other hand, there is still the broad express preemption clause of the FMIA and PPIA to grapple with, which declares that state laws regulating the labeling of meat and poultry products "may not be imposed" if they set forth "marking, labeling, packaging, or ingredient requirements in addition to, or different than, those made under this Act."303 Based on its plain language, not just different requirements appear preempted but also any "in addition to" FSIS requirements. However even an express preemption provision must be framed by intent, e.g., "the question of the substance and scope of Congress's displacement of state law,"304 as well as the presumption against preemption, particularly in areas of traditional state regulation like food labeling. Finally, an argument can be made that any such state law would not be additional or different than the federal regime; instead it would only be applying the same core "misbranded" standard in prohibiting any false and misleading labels. In the pesticide context the Supreme Court has analyzed similar preemption language regarding state law "in addition to or different from" federal pesticide standards and held that not all state causes of action were preempted; it was not the precise wording of the state law or cause of action that mattered, but

³⁰¹ Friedrich, supra note 297 at 88-90.

³⁰² Jones, 430 U.S. at 528.

^{303 21} U.S.C. 678 (meat); 21 U.S.C. 467e (poultry) (emphases added).

³⁰⁴ Altria Group, 555 U.S. at 76.

the rather whether the state law was "equivalent to and fully consistent with" the federal law.³⁰⁵ A state law establishing humane standards and prohibiting labeling that would be considered misleading under FMIA and the PPIA "would seem to aid, rather than hinder" federal law.³⁰⁶

Conclusion

Like so many areas of our law, when it comes to food labeling, states have an important role to play. In fact, as the laboratories of our democracy, states often lead the way in improving labeling standards, as some examples in Section III *infra* illustrate. While the limits of state involvement are not crystal clear, the last decade-plus of litigation has clarified a good deal of that scope. Frustrated with the lack of leadership by federal agencies, advocates have had some success in state-based litigation in addressing false and misleading food labeling and food advertising. State-based litigation can be an effective tool to hold companies accountable and it is open season on false and misleading FDA-product label claims. And while more difficult, challenges to FSIS product advertising are increasing too. But whether these advances can be turned into improvements of federal and/or state labeling standards more generally is still to be determined.

Important Developing Areas in Animal Food Labeling Law

The maze that is food labeling regulation now navigated, federal and state, what follows are several microcosms of the underlying themes of this article, of how and why we label food, how that shifts over time, and what the hidden drivers of those shifts are.

³⁰⁵ Bates, 544 U.S. at 447; Friedrich, supra 297 at 98-99 (discussing Bates).

³⁰⁶ Bates, 544 U.S. at 450-51.

Organic Food Labeling

One current landscape for animal food labeling that is particularly important for consumers and stakeholders that care about livestock production conditions—and in particular the animal welfare of farm animals—is organic food labeling.³⁰⁷ While "certified organic" labeling has been around for several decades, how meaningful that labeling may be as to animal welfare for the organic livestock may well be decided by currently pending agency rulemaking and court decisions.³⁰⁸

USDA's organic program is one of the voluntary labeling programs housed in the AMS, overseen by another USDA subagency, the National Organic Program (NOP).³⁰⁹ It has its own statute, the Organic Foods Production Act of 1990 (OFPA).³¹⁰ However, organic agriculture began long before that. In a sense, until the widespread introduction of synthetic fertilizers, herbicides, and pesticides in the mid-twentieth century, all agriculture was "organic" because it relied upon natural biological processes for the successful propagation of crops for food. But modern industrial agriculture began with the post-World War II introduction of chemical technologies in agricultural production,³¹¹ and the organic farming movement of the 1960s-1970s was a reaction to that so-called "green revolution" and rapidly industrializing agriculture as part of the larger environmental movement. The growth of organic farming and its principles—to produce food sustainably, not in a damaging fashion—were closely tied to the environmental movement of the time. Indeed Rachel Carson, the mother of the environmental

³⁰⁷ USDA Organic, U.S. DEP'T OF AGRIC., https://www.usda.gov/topics/organic.

³⁰⁸ USDA to Reinstate Vital Organic Animal Welfare Protections Gutted by Trump Administration, CTR. FOR FOOD SAFETY (June 17, 2021), https://www.centerforfoodsafety.org/press-releases/6390/usda-to-reinstate-vital-organic-animal-welfare-protectionsgutted-by-trump-administration.

³⁰⁹ National Organic Program, U.S. DEP'T OF AGRIC., https://www.ams.usda.gov/about-ams/programs-offices/national-organic-program.

 $^{^{\}scriptscriptstyle 310}$ 7 U.S.C. § 6501 et seq.

³¹¹ Mary Jane Angelo & Seth Hennes, The Environmental Impacts of Industrial Fertilizers and Pesticides, in FOOD, AGRICULTURE, AND ENVIRONMENTAL LAW 35, 35–36 (Mary Jane Angelo et al. eds., 2013).

movement, wrote her seminal work, *Silent Spring*, about agricultural pesticides and their impacts on songbirds.³¹²

Without a federal organic labeling standard in place, states filled the breach and led the way, starting with Oregon in 1973³¹³ and California in 1979;³¹⁴ by 1990, 22 states had separate organic regulation and labeling of some kind,³¹⁵ and what had been a tiny percentage of the food market had become the fastest growing sector of the U.S. agricultural economy.³¹⁶

State organic standards differed however and in 1990 Congress passed OFPA with stated goals including to create national, uniform organic standards that would assure consumers that organically produced products met a consistent standard.³¹⁷ The statute set up a broad new regulatory regime establishing federal standards, such as that organic products cannot be produced using synthetic chemicals; substances would be approved through a national list of substances; and farming would be certified pursuant to an organic plan.³¹⁸ USDA (through NOP) was charged with writing the implementing regulations, with guidance from a congressionally created advisory body of experts, the National Organic Standards Board (NOSB).³¹⁹

³¹² Pesticide Early Warnings/Rachel Carson, Public Broadcasting Station, https://opb.pbslearningmedia.org/resource/amex29rcsoc-pesticide/american-experience-rachel-carson-pesticide-early-warnings/; Rachel Carson, Silent Spring 103 (First Mariner Books ed., 2002) (1962) ("Over increasingly large areas of the United States, spring now comes unheralded by the return of the birds, and the early mornings are strangely silent where once they were filled with the beauty of bird song.").

³¹³ Or. Rev. Stat. § 632.925.

³¹⁴ Cal. Health & Safety Code § 26569.13.

³¹⁵ Proposed Organic Certification Program: Joint Hearing Before the Subcommittee on Domestic Marketing, Consumer Relations, and Nutrition and the Subcommittee on Department Operations, Research, and Foreign Agriculture of the Committee on Agriculture, 101st Cong., 2 (1990).

³¹⁶ Carolyn Dimitri & Catherine Greene, Recent Growth Patterns in the U.S. Organic Foods Market, U.S. DEP'T OF AGRIC., https://www.ers.usda.gov/webdocs/publications/42455/13377 aib777c 1 .pdf?v=o; Organic Market Overview, ORGANIC TRADE ASSOCIATION, https://ota.com/resources/market-analysis.

³¹⁷ 7 U.S.C. § 6501 (1)-(3) (OFPA's purposes).

³¹⁸ Id.§§ 6501; 6503, 6504, 6508, 6513, 6517; 7 C.F.R. Part 205.

³¹⁹ Id. § 6518.

Notably, while elsewhere recognizing and infusing organic's original environmental and socioeconomic origin,³²⁰ the statute's stated goals only state its purpose as to be a "marketing" standard setting a consistent standard for consumers³²¹ and giving USDA significant discretion in how to implement the statute. This dichotomy set in place an inherent tension that continues to the present and has increased as the organic market and industry has grown exponentially.

Congress set out requirements for organic livestock production in OFPA Section 6509.

Because the organic livestock industry was still nascent when OFPA was passed,³²² Congress was far less detailed about animal agriculture than it was about the very thorough crop agriculture standards. OFPA set forth mainly that organic livestock had to be fed only organic feed, and that producers could not use growth promoters, hormones, or subtherapeutic antibiotics;³²³ then, OFPA directed USDA, in consultation with NOSB and through notice and comment, to flesh out the remaining standards "for the care" of livestock standards beyond those spelled on in the statute to ensure that livestock were organically produced.³²⁴

Those first OFPA-implementing regulations took a very long time—over ten years—finally promulgated in 2000.³²⁵ However much like the 1990 statute most of the new labeling rules dealt with crops; when it came to livestock, the first rules offered far less, despite organic consumer expectation for livestock to have very high levels of welfare. For example, the original

³²⁰ E.g., 7 CFR § 205.2 (defining organic production as "Organic Production. A production system that is managed in accordance with the Act and regulations in this part to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity.").

 $^{^{321}}$ 7 USC §§ 6501(1)-(3) (note no enviro/socio purpose).

³²² Indeed, the 1990 Senate Report that accompanied OFPA stated that, while organic livestock production was a small industry in the U.S. at the time, "[w]ith additional research and as more producers enter into organic livestock production, the [Senate Committee on Agriculture, Nutrition, and Forestry] expects that USDA, with the assistance of the National Organic Standards Board will elaborate on livestock criteria." Senate Report 101-357 at 292 (July 6, 1990).

^{323 7} U.S.C. § 6509.

³²⁴ Id. § 6509(d), (g). Rather than limit livestock standards to what was known in 1990, Congress, decided to "require[] the Secretary to hold hearings and develop regulations regarding livestock standards in addition to those specified in [the OFPA]." H.R. Rep. 101-916, at 1777-78 (1989).

 $^{3^{25}}$ 65 Fed. Reg. 13512 (March 13, 2000); 7 C.F.R. § 205.239 (2000); id. §§ 205.237; 205.239; 205.240 (2010).

2000 rules only said that organic livestock had to have "access" to organic pasture and forage,³²⁶ but did not define what that vague standard meant. The 2000 rules also required "[t]he producer of an organic livestock operation must establish and maintain livestock living conditions which accommodate the health and natural behavior of animals,"³²⁷ but again without defining the requirement.

This livestock ambiguity was an invitation for producers to cheat the standard but still gain the organic price premium mark-up, and it took a scandal to raise public awareness: a few years later an organic watchdog organization's undercover investigation revealed that an 'organic' dairy in Colorado supposedly with "access to pasture" was actually just a confined animal feeding of 5,600 cows on 250 acres of dry lot.³²⁸ When the formal complaint lodged with USDA only resulted in a sweetheart, slap-on-the wrist consent agreement allowing Aurora to keep their organic certification, false and misleading class action litigation ensued over the resulting milk being labeled as 'organic' despite the feedlot conditions.³²⁹

But beyond the litigation, more broadly the *Aurora* controversy eventually resulted in the first major and overdue organic livestock rulemaking, the 2010 access to pasture rule, 330 which finally set detailed, concrete livestock access standards, fulfilling congressional intent and bringing the standard in line with what consumers already expected. These rules included quantifiable portions of feed and time from/in pasture, including that livestock had to have

^{326 7} CFR 205.237(a)).

³²⁷ 7 C.F.R. § 205.239. The first set of livestock standards went on to establish "[a]nimals . . . must be maintained under conditions which provide for exercise, freedom of movement, and reduction of stress . . . all physical alterations performed on animals . . . must be conducted to promote the animals' welfare and in a manner that minimizes stress and pain." 65 Fed. Reg. 80,548, 80,560 (Dec. 21, 2000).

 $^{^{328}}$ Complaint Concerning Violation of the NOP Pasture Rule by the Aurora Organic, The Cornucopia Instit. (Jan. 10, 2005), https://www.cornucopia.org/aurora_complaint/.

³²⁹ In re Aurora Dairy, 621 F.3d 781 (8th Cir. 2010). And as relevant to Section II above, the 8th Circuit eventually ruled that some of the state law based misleading labeling claims were preempted by OFPA and could not be sustained. Namely, challenges could not be brought as to the certification alone itself being misleading, but challenges could be sustained as to its underlying facts of the certification, or to other, related labeling representations (e.g., pastoral scenes of cows grazing in pastures, etc) being made. Id. at 797-800.

³³⁰ Access to Pasture, 75 Fed. Reg. 7154 (February 17, 2010) (codified at 7 C.F.R. §§ 205.237; 205.239; 205.240).

pasture for not less than 120 days, receive at least 30% of their feed from pasturing, and have year-round access to the outdoors.³³¹ However the 2010 pasture rule only addressed organic dairy and other ruminants (the immediate topic of the *Aurora* scandal). Another NOP rulemaking was needed in order to apply that level of detail and clarity to all organic livestock, especially poultry, and ensuring that organic standards covered entire lifecycles.

Accordingly, after ten years in the making, in January 2017 NOP issued the Organic Livestock and Poultry Practices Rule (OLPP),³³² which built on the earlier rulemakings and set further standards for the care of livestock under OFPA.³³³ Specifically, the Rule added new standards for livestock handling, transport for slaughter, and avian living conditions, and clarified standards covering livestock care, production practices, and mammalian living conditions, furthering the OFPA purpose of providing specific and consistent standards for organic animal care.³³⁴ It addressed topics such as closing the "porch" loophole for poultry,³³⁵ limited stocking densities, provided for the natural behavior of livestock animals, and put in place prohibitions/restrictions on physical alterations. ³³⁶ Additionally, the rule included new requirements for humane transport and slaughter. ³³⁷ Finally, the rule set numerous improvements to living conditions for both mammals and birds, adding significant details to

³³¹ Id. Notably, the Access to Pasture rule made clear that "[o]ne of the tenants [sic] of organic production is that animals are able to express their natural behaviors, and exercise and move freely." Id. at 7171.

^{332 82} Fed. Reg. 7042 (2017).

³³³ Organic Livestock and Poultry Practices Final Rule, 82 Fed. Reg. 7042, 7082 ("In 2010, AMS published a final rule (75 FR 7154, February 17, 2010) clarifying the pasture and grazing requirements for organic ruminant livestock, which partially addressed OFPA's objective for more detailed livestock standards. This rule extends that level of detail and clarity to all organic livestock and poultry, and would ensure that organic standards cover their

entire lifecycle, consistent with recommendations provided by USDA's Office of Inspector General and nine separate recommendations from the NOSB.").

³³⁴ Id.

 $^{^{335}}$ Prior to OLPP, poultry outdoor access practices varied widely, with some operations providing "large, open-air outdoors areas, while others provide[d] minimal outdoor space or use[d] screened covered enclosures commonly called "porches" . . ." Id. The Organic Livestock Rule clarifies the impropriety of enclosed porches as outdoor access. Id.

³³⁶ Id.

³³⁷ Id.

indoor shelter and outdoor access requirements.³³⁸ These animal welfare requirements are inextricably linked to animal health: animal welfare reinforces animal health, and animal health reinforces animal welfare. These changes would also ensure that consumer expectations—that livestock and poultry products labeled as organic are raised with a high level of welfare—were being met. They also would fulfill the statutory goal of a consistent, uniform standard for consumers,³³⁹ protecting producers practicing humane animal husbandry from being undercut in the marketplace from those skirting the standard. The final rule acted upon six dozen unanimous recommendations from the agency's congressionally created expert body, the NOSB, and garnered near unanimous support from organic producers and consumers.³⁴⁰

However, before the OLPP rule could go into effect in spring 2017, and following the change in Presidential Administration, the then-incoming Trump administration's USDA stayed the rule three times before eventually withdrawing it entirely in 2018.³⁴¹ The Trump USDA premised the OLPP withdrawal rule on two new rationales. First and most relevant here,³⁴² despite having otherwise interpreted its OFPA authority consistently since its enactment as including animal care and welfare standards, USDA for the first time claimed OFPA' scope *prohibited* it from issuing the Rule.³⁴³ Specifically, USDA argued that OFPA's mandate was cabined to regulating livestock synthetic inputs like feed and drugs, and did not include other on-farm, process-based concerns like animal welfare and care standards for handling, transport,

³³⁸ Id.

^{339 81} Fed. Reg. at 21980. Specifically, USDA recognized that "[t]he current practices of organic poultry operations to provide outdoor access and minimum indoor and outdoor space per bird vary widely. This disparity causes consumer confusion about the meaning of the USDA organic label, threatens to erode consumer confidence in the organic

label more broadly and perpetuates unfair competition among producers." Id.

^{340 81} Fed. Reg. at 21981.

³⁴¹ 82 Fed. Reg. 9967; 82 Fed. Reg. 21677; 82 Fed. Reg. 21742; 82 Fed. Reg. 52643; 82 Fed. Reg. 59988; 83 Fed. Reg. 10775 (March 18, 2018 withdrawal rule).

³⁴² USDA's second rationale was based on a lack of "material market failure to justify prescriptive regulatory action," and USDA's concern that the Organic Livestock Rule "may hamper market driven innovation and evolution and impose unnecessary regulatory burdens." 82 Fed. Reg. at 59990; 83 Fed. Reg. at 10779-80. This rationale was based on both a reliance on extra-statutory economic factors (i.e., a "market failure") and a flawed assessment of the impacts of the original OLLP rule.

³⁴³ 83 Fed. Reg. at 10775-6.

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and living conditions as detailed in the Rule.³⁴⁴ USDA provided no reasoning or support for its total reversal of interpretation of OFPA, and failed to reconcile the contrary OFPA legislative history, plain language, or USDA's own regulatory history. The agency also refused to again consult its expert body, the NOSB, which strongly disagreed with its new withdrawal decision.

As such, the Trump administration's withdrawal decision rationale—that OFPA did not give NOP the authority to implement rules that address animal welfare—had far-reaching ramifications and created an *existential* threat, not just the current vital rule, but also previous (and any future) rules for organic farm animals when it came to care and handling.³⁴⁵ In effect, if left in place it would make the organic label meaningless for consumers that cared about animal welfare and purchased organic food based on those concerns (which is the vast majority of them).

Organic stakeholders and animal welfare advocates immediately filed legal challenges to the OLPP withdrawal rule and subsequently defeated a motion to dismiss.³⁴⁶ However just as the case was reaching the merits, the incoming Biden administration sought a voluntary remand, indicating its intent to do a further rulemaking re-affirming the original OLPP rule, but without giving much in the way of details or any assurances as to the content of this OLPP 2.0. Whether the Biden administration will reinstate or improve the original OLPP—and repudiate the withdrawal decision's rationale—is unclear at the time of writing. But the result will go a long way towards whether organic labeling will finally live up to public expectations and its original principles as providing humane animal welfare standards.

^{344 83} Fed. Reg. at 10776.

³⁴⁵ In the withdrawal rule USDA also admitted its new interpretation was contrary to prior governing 2000 and 2010 regulations on animal care and stated that it "may seek comment in the future regarding whether the cited regulations are in accordance with AMS' statutory authority"— essentially threatening to undo decades of organic standards, upon which both producers and consumers have long relied. Id. at 10779.

³⁴⁶ Center for Environmental Health et. al. v. Perdue, 2018 WL 9662437 (N.D. Cal. 2018).

In conclusion, the organic food label is an important one in and of itself, but also for what it represents: it was the first time that society said "enough!" to industrial agriculture and rejected it, creating a grassroots movement and alternative food system that eventually led to Congress being forced to create the first federal food label that encompasses broad production concerns like externalized environmental impacts and animal welfare considerations. Organic labeling is not just about what is in the final product—its ingredients—it is about the process of how it was made and the integrity of that process. And that's a hugely important precedent to safeguard for any future process-based labeling. It is true that there are private, market-based certifications for animal welfare and for environmental concerns. But whatever their merit, for good governance supporters, a market-based system can never entirely substitute for actual law. Private systems are not overseen by government officials that have a duty to act in the public interest and established by legal code. Organic is far from perfect, but it is transparent and it is law: the standards are there for all to see, set forth in published rules and guidance, with lots of public process. But as this story illustrates, the industry's continued growth is a blessing and a curse, requiring constant vigilance and a continued battle to protect its soul, to retain the integrity of its original ethos and protect against those who would water it down.

Country of Origin Labeling

Another question that 21st century consumers ask is "where did this food come from?" People might want to know foods' geographic origin for any number of reasons. Some consumers might have patriotic or jingoistic rationales ("buy American"), or domestic industry might see a market "home field" advantage to such labeling. There could be a food safety or foodborne illness concern about a particular region. Environmentally conscious consumers might be worried about the climate impacts of global shipping and wish to buy food with a lower carbon footprint (e.g., food miles, in season or out of season; is an organic apple still environmentally positive if it

traveled all the way from New Zealand?). While still others might be worried specific location conditions of some food production, whether that be worker conditions, animal welfare, or environmental damage. Think sweatshop factory conditions or a fish from an overfished, deplete fishery. Location disclosure can enlighten directly or indirectly on these and other topics. And where in the past technological and market limitations would have naturally limited options, the more globalized and interdependent our food economy has become, the more material this information has become for consumers.

Country of origin labeling (COOL) requires that a label include the source location of the food.³⁴⁷ The first wave of country-of-origin labeling was actually during the past century, in the Tariff Act of 1930.³⁴⁸ This is why you see country of origin on lots of imported retail goods if they arrive at the U.S. border in retail-ready packaging. The 1930 Act exempts articles shipped to U.S. processes that are slated to undergo substantial transformation before sale, even if no new or different product is produced.³⁴⁹ And importantly certain classes of goods were exempted, and food products were among those.³⁵⁰ The FMIA and PPIA also require country of origin on containers of imported meat and poultry but this is limited to those already packaged for consumers (i.e. canned ham).³⁵¹

Congress first enacted modern 21st century COOL requirements in the 2002 Farm Bill,³⁵² which was elaborated on in the 2008 Farm Bill.³⁵³ USDA oversees COOL labeling, through its Agricultural Marketing Service (AMS).³⁵⁴ Food products covered by COOL

³⁴⁷ See generally Peter Chang, Country of Origin Labeling: History and Public Choice Theory, 64 FOOD DRUG L.J. 702 (2009). ³⁴⁸ 19 U.S.C. § 1304.

³⁴⁹ Id.

 $^{^{350}}$ 19 C.F.R. § 134.33 (known as the "J-List" and exempting, inter alia, "Natural products, such as vegetables, fruits, nuts, berries, and live or dead animals, fish and birds").

^{351 9} C.F.R. § 327.14; 9 C.F.R. § 381.205.

³⁵² Farm Security and Rural Investment Act of 2002, Pub. L. No. 107-171, § 10816, 116 Stat. 134, 533 (codified at 7 U.S.C. §§ 1638 et seq.); 7 C.F.R. §§ 60, 65 (implementing regulations).

³⁵³ Food, Conservation, and Energy Act of 2008, Pub. L. No. 110-234, § 11002, 122 Stat. 923, 1352, 1354 (codified at 7 U.S.C. §§ 1638 et sea.).

³⁵⁴ USDA, Country of Origin Labeling, at https://www.ams.usda.gov/rules-regulations/cool.

requirements are called "covered commodities," ³⁵⁵ and must have COOL information at the point of sale. ³⁵⁶ Retailers like grocery stores, supermarkets, and club warehouses stores are the regulated entities subject to COOL requirements; ³⁵⁷ other institutions that provide ready-to-eat food, such as restaurants, bars, hotels, farmers markets, are exempt. ³⁵⁸ The COOL information of covered commodities can be provided on a store sign or on the package itself, so long as it is at the point of sale, ³⁵⁹ and normally is in the form of a statement like "Product of USA" or "Grown in Mexico." ³⁶⁰

The covered commodities subject to COOL requirements are: fresh and frozen fruits and vegetables; wild and farm-raised fish and shellfish; chicken, lamb, and goat meat; raw peanuts, pecans, macadamia nuts; honey; and ginseng.³⁶¹ Processed foods are exempt.³⁶² Finally, what else is missing? In the original COOL legislation, beef and pork *were* included, but now they are *no longer* included. And the controversy of why that came to be is a story of Big Ag exceptionalism, pitting small ranchers against the industrial agriculture system.

Originally, the COOL implementing regulations had several labels for meat. "U.S. origin" was for meat born, raised, and slaughtered in the U.S. However given the global reach of our meat industry and the multi-national corporations holding consolidated control over it, often livestock can be born in one country, raised in another, and slaughtered in a third. It is common for meat products, especially ground beef, to be mixed with meat products from different countries. In these instances, multiple countries would be listed on the COOL label. The first

^{355 7} U.S.C. § 1638(1).

³⁵⁶ Id. § 1638(a)(1).

^{357 7} C.F.R. § 65.300

³⁵⁸ Id. § § 65.140; 65.300(b).

³⁵⁹ Id. § 65.400.

³⁶⁰ Labeling Options, U.S. DEP'T OF AGRIC. (Apr. 10, 2018),

https://www.ams.usda.gov/sites/default/files/media/COOL_Labeling_Options.pdf.

³⁶¹ 7 C.F.R. §§ 65.300, 65.135(a)(1)-(7) & 7 C.F.R. § 60.105 (fish and shellfish); Packed Honey- Country of Origin Labeling, U.S. DEP'T OF AGRIC., https://www.ams.usda.gov/rules-regulations/cool/honey.

³⁶²Geoffrey S. Becker, Country-of-Origin Labeling for Foods, CRS REPORT FOR CONGRESS (May 13, 2008),

 $https://www.everycrsreport.com/files/20080513_97-508_ca1b2a2ba3ebc452809732b2f4f0bb55216658ao.pdf.$

USDA regulations, issued in 2009, allowed for "comingling" of these countries, with the label simply naming all the countries, as in "product of U.S., Mexico, and Canada." ³⁶³

Canada and Mexico subsequently brought a World Trade Organization (WTO) legal challenge to the USDA rules for COOL, arguing that they discriminated against their meat products, reducing the value and number of cattle and hogs shipped to the U.S. market, violating WTO trade commitments.³⁶⁴ In 2011 the WTO ruled in their favor, holding that the U.S. labeling was not specific enough.³⁶⁵ So USDA tried again with another set of regulations, in 2013.³⁶⁶ These were more precise, listing each country specific to each step, and prohibiting comingling (e.g., "Born in Mexico, Raised in Mexico, Slaughter in the U.S.").³⁶⁷ Canada and Mexico maintained their WTO challenge and it was again successful, finding that it treated imported livestock less favorably than domestic livestock, with the U.S. appeal denied in 2015.³⁶⁸ The WTO found the rule had a discriminatory effect towards Canadian and Mexican livestock, and authorized approximately \$1 billion in retaliatory tariffs.³⁶⁹ Rather than pay those tariffs, the U.S. instead amended COOL to repeal it as applied to beef and pork products.³⁷⁰

³⁶³ 2013 Labeling Provisions for Meat Muscle Cuts, U.S. DEP'T OF AGRIC., https://www.ams.usda.gov/rules-regulations/cool/2013-labeling-provisions.

³⁶⁴ Joel L. Greene, Country-of-Origin Labeling for Foods and the WTO Trade Dispute on Meat Labeling, Congressional Research Service (Dec. 8,2015), https://sgp.fas.org/crs/misc/RS22955.pdf.

³⁶⁵ Id.

³⁶⁶ Id.

³⁶⁷ 2013 Labeling Provisions for Meat Muscle Cuts, supra note 363.

³⁶⁸ Greene, supra note 364.

³⁶⁹ Id.; Kelsey Gee & Paul Vieria, WTO Says Canada, Mexico Can Slap \$1 Billion in Tariffs on U.S. Over Meat Labels, WALL STREET J. (Dec. 7, 2015), https://www.wsj.com/articles/wto-says-canada-mexico-can-slap-1-billion-in-tariffs-on-u-s-over-meat-labels-1449508424.

³⁷⁰ USDA Ends COOL Enforcement With President's Signature on Omnibus Bill, FOOD SAFETY NEWS (Dec. 21, 2015), https://www.foodsafetynews.com/2015/12/usda-ends-cool-enforcement-with-presidents-signature-on-omnibus-bill/; final rule repealing beef and pork from COOL, 7 C.F.R. 60, 65

https://www.ams.usda.gov/sites/default/files/media/COOL%20final%20rule%20federal%20register%20version.pdf; FAQs on the repeal, FAQs-Country of Origin Lableing (Beef and Pork Recipe), U.S. DEP'T OF AGRIC.,

https://www.ams.usda.gov/sites/default/files/media/FAQs%2o-%2oCOOL%2oBeef%2oPork%2oRepeal.pdf.

With the loss of COOL, legislators have introduced several state and federal bills that would require any product that has "product of USA" to come from a U.S. ranch.³⁷¹ Without COOL, cattle farmers struggle while the consolidated meatpacking industry enjoys record profits.³⁷² Currently this label can be just from meat processed domestically even if it was born and raised in another country. So this would shift from identifying other countries to just identifying U.S. origin. The American Beef Labeling Act of 2021 would require that "Product of USA" means the beef was "born, raised and harvested" in the USA.³⁷³ Other U.S. ranch organizations have also petitioned FSIS to set a "product of USA" beef label standard.³⁷⁴ Additionally, the 2021 incoming Biden administration has said that USDA will be similarly working to create federal rules for "product of USA" for beef.³⁷⁵

In closing, a fair critique of COOL is asking how useful it really is for consumers. At best it is an indirect manner of providing information: for the information to be useful, the shopper must know something else about the location in order to apply the information in context.

Instead of indirect, a more direct label for whatever the concern—e.g., for climate concerns, food miles; for environmental, animal welfare, or worker production concerns—a certification

³⁷¹ Tom Lutey, In Congress, 'Made in the USA' Beef Labeling is Back on the Menu, BILLINGS GAZETTE (Auf. 10, 2021), https://billingsgazette.com/news/state-and-regional/govt-and-politics/in-congress-made-in-the-usa-beef-labeling-is-back-on-the-menu/article_5fe76780-f162-5f1e-be8e-c57ccb3691b6.html.

³⁷² Darvin Bentlage, Corporate Meat Lobby Claims They're the Scapegoat When They're Really the Problem, MISSOURI INDEPENDENT (Oct. 8, 2021), https://missouriindependent.com/2021/10/08/corporate-meat-lobby-claims-theyre-the-scapegoat-when-theyre-really-the-problem-opinion/.

³⁷³ Billings Gazette: In Congress "Made in the USA' Beef Labeling is Back on the Menu, U.S. SENATOR FOR MONTATA JON TESTER (Aug. 10, 2021), https://www.tester.senate.gov/?p=news&id=8530.

³⁷⁴ Dan Flynn, It Won't be COOL, but Cattlemen Say it Will Improve Beef Labeling, FOOD SAFETY NEWS (June 17, 2021), https://www.foodsafetynews.com/2021/06/it-wont-be-cool-but-cattlemen-say-it-will-improve-beef-labeling/.

³⁷⁵ Executive Order, Promoting Competition in the American Economy, July 14, 2021, available at

https://www.federalregister.gov/documents/2021/07/14/2021-15069/promoting-competition-in-the-american-economy ("to ensure consumers have accurate, transparent labels that enable them to choose products made in the United States, consider initiating a rulemaking to define the conditions under which the labeling of meat products can bear voluntary statements indicating that the product is of United States origin, such as "Product of USA"); see also FTC Issues Rule to Deter Rampant Made in USA Fraud, FED. TRADE COMMISSION (July 1, 2021), https://www.ftc.gov/news-events/press-releases/2021/07/ftc-issues-rule-deter-rampant-made-usa-fraud.

specific to the issue would undoubtedly be preferred. On the other hand, geographic disclosures are precedent for other location disclosure, a step towards local food, or watershed-based food systems, ideas that regenerative agriculture proponents have championed. And as the COOL meat labeling fight shows, it can help small farmers and ranchers compete against multinational corporations and damaging industrial agriculture, a goal many food, environmental, and animal welfare advocates would favor.

Genetically Engineered Food Labeling

A third example of 21st century food labeling issues is genetically engineered (GE) food labeling. As a matter of labeling law, GE labeling exemplifies many of the issues discussed above: what we determine warrants a label (the food production process versus the product), why we label (broader environ/health/ethics/corporate control), who labels (market, state, or federal government), and how we label (what on-package text we use and on-package text versus new electronic methods).

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But there is important broader context: with regard to our food system and agriculture writ large, GE labeling is really just a proxy war of two different, diametrically opposed philosophies about what the food system is and should be. The current dominant economic systems and intertwined technological systems are at odds with the ecological cycles of nature, irreparably harming the planet. Humanity is outstripping land, air, and water resources in every way measurable: water depletion, species extinction, deforestation, desertification, and of course including the existential threat of the climate crisis. This is known as the technological dilemma:

"developed" countries are dependent on the current unsustainable technological approach, but it is threatening the planet's very viability.

This is not new. During the dawn of the environmental movement more than fifty years ago leaders urged reforming technologies to be more in sync with natural cycles; it was based on this view that attorneys and advocates succeeded in passing laws like the Endangered Species Act, the National Environmental Policy Act, and other foundational environmental laws. Scientists developed more holistic approaches to their disciplines. These were positive steps towards a more holistic approach. Of course, neither were these ideas new then, but instead build on the wisdom of native pre-industrial cultures.

Others face the same conclusion—that current technology is incompatible with nature, the ever-intensifying conflict between natural laws, globalization, and mass consumption—but their solution is very different. Rather than change technological systems to better comport with the needs of living things, corporations and governments changed life so that it fits technology. Ignoring natural constraints, living systems are remade, engineered at the genetic and molecular level to further the needs of the technological paradigm. Thus, genetic engineering can be seen as a tool by which we can alter life at the genetic level to better fit industrial production systems and become a technological commodity. Cloning is the tool by which we can emulate the factory model of identical production for life forms. Rather than redesigning industrial agriculture to fit the animal's natural behavior, we are redesigning animals themselves to fit industrial agriculture. Because patent control spurs production, we must now patent genes and cells from plants, animals, and humans. Nanotechnology is a means by which we can control and manipulate matter at the atomic and molecular level to enhance industrial processes. Synthetic biology permits us to combine several of these tools to create and design entirely new life forms to perform industrial tasks.

And so it is unsurprising that GE crops are a pillar of the current dominant industrial agricultural paradigm. Commercially they are overwhelmingly engineered with patented

resistance to pesticides (including the subsets of herbicides and insecticides), facilitating the heavy reliance on synthetic pesticides that monocultures require and ever-intensifying and industrialized production model. Further GE crop systems prop up not only the *monoculture* crop side of that paradigm, but also the industrial *animal* agriculture side of the model: the vast majority of GE crops (GE corn and soy) go not to feed people but as cheap subsidized livestock feed, allowing confined animal feeding operations to be viable and dominant.

And while GE food animals themselves are still mostly in research and development, past is prologue and we have thirty years of agricultural biotechnology in GE crops to learn from: overwhelmingly GE crops are used to sell more and more toxic pesticides, and contrary to the hype, in the reality they do not increase yields, feed the world, or help combat climate change. Instead their harms to the environment and agriculture are now well documented. As such, future GE food animals will similarly be used to further support rather than reform the industrial animal factory model in which billions of animals suffer and die every year, one of the greatest moral failings of our time.

But fostering a shift in consciousness requires recognizing and addressing the underlying philosophy that drives and controls technological innovation. That is why labeling and the public's right to know where their food comes from is so important, in raising awareness about the decisions we must make as a society in an effort to shift the social contract. Human technologies should function within an integral relationship with earth technologies, not in a despotic manner and society must move from the technological age to the ecological age. This requires treating ourselves and the natural world as part of an interconnected web. Without question, this is an idealized vision, but still considerably less naïve than the world vision that claims we can sustain our current industrial food system.

WHY LABEL GE FOOD

Next, a short summary of the twenty-five year fight for GE food labeling: Since their commercial introduction in the 1990s, the U.S. did not historically require the labeling of GE foods. This makes it an outlier: 64 countries around the world required GE food be labeled, including all of the European Union, Japan, China, Russia, New Zealand, and Australia.³⁷⁶ Many have GE specific regulations and laws. The U.S. did not pass any such laws and instead determined by guidance that genetically engineered organisms would be regulated under existing laws.³⁷⁷ Then, in 1992, the FDA made a policy decision that the process of genetic engineering was not "material" for purposes of labeling and as such no labeling would be required.³⁷⁸ For the same reason, the new GE food ingredients would not be classified as food additives, requiring premarket approval and review and instead would be classified as "generally recognized as safe" or GRAS, meaning they could be added to food without FDA review and approval. A legal challenge to both decisions was unsuccessful.³⁷⁹

As GE crops came to predominate in U.S. commodity crops, and consumers became aware that while few whole foods are genetically engineered, a substantial majority of processed foods are now produced with genetic engineering, polls showed repeatedly that over 90% of Americans favored mandatory labeling of GE foods.³⁸⁰ People wanted to know for numerous good reasons: health, personal, economic, environmental, religious, and cultural.³⁸¹ And believed it was misleading not to label GE foods: the public recognized that having thousands of

 $^{{}^{376}\,}See,\,e.g.,\,Genetically\,Engineered\,Food\,Labeling\,Laws,\,CTR.\,FOR\,FOOD\,SAFETY,\,https://www.centerforfoodsafety.org/ge-map/.$

³⁷⁷ Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. 23,302 (1986).

³⁷⁸ FDA, Statement of Policy: Foods Derived From New Plant Varieties (57 Fed. Reg. 22984 (May 29, 1992)).

³⁷⁹ Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166 (D. D.C. 2000).

³⁸⁰ See, e.g., U.S. Polls on GE Food Labeling, , CTR. FOR FOOD SAFETY, https://www.centerforfoodsafety.org/issues/976/ge-food-labeling.

³⁸¹ See generally Kimbrell & Paulsen, The Constitutionality of State-Mandated Labeling for Genetically Engineered Foods: A Definitive Defense, 39 Vt. L. Rev. 341 (2014).

processed foods produced with genetic engineering, yet unlabeled, is deceptive, or at best confusing, to consumers.³⁸²

Further, Americans became increasingly aware of the risks and negative impacts of genetically engineered crops, correctly seeing through several decades of myths that were carefully constructed by agrochemical companies to promote their products. For example on the human health side, the public realized that the FDA does not actually test the food safety of engineered foods or "approve" them; 383 rather, it has confidential meetings with industry in which it merely reviews the industry's own testing—and even that is voluntary. 384 Further, independent scientists are prohibited from conducting safety and risk-assessments of GE materials used in food products due to industry restrictions on research of those materials. 385 Americans became aware that no long-term or epidemiological studies in the United States have examined the safety of human consumption of genetically engineered foods, and that without labeling, there is no accountability or traceability to link such foods to proliferating public health problems. 386 These facts rightly give consumers pause; disclosure through labeling allows them to make their own choices about whether to buy and consume GE foods.

On the environmental side, risks do not come from the unknown, but from the known:

GE crops are a key pillar of inherently unsustainable industrial agriculture and cause significant
adverse environmental impacts. GE crops are essentially a pesticide-promoting technology:

 $^{^{382}}$ Willian K. Hallman et al., Public Perceptions of Labeling Geneticaly Modified Foods (Nov. 1, 2013),

http://humeco.rutgers.edu/documents_pdf/news/gmlabelingperceptions.pdf.

³⁸³ William Freese & David Schubert, Safety Testing and Regulation of Genetically

Engineered Foods, 21 BIOTECH. & GENETIC ENG'G REVS. 299, 303-04 (2004), http://goo.gl/B9wSIa.

³⁸⁴ Consultation Programs on Food from New Plant Varieties, U.S. FOOD & DRUG ADMIN. (Mar. 30, 2020),

https://www.fda.gov/food/food-new-plant-varieties/consultation-programs-food-new-plant-varieties.

³⁸⁵ Emily Waltz, Under Wraps, 27 NATURE BIOTECH 880, 880–82 (2009); Andrew Pollack, Crop Scientists Say Biotechnology Seed Companies Are Thwarting Research, N.Y. TIMES (Feb. 19, 2009), http://goo.gl/Nz7tWu.

³⁸⁶ Philip J. Landrigan, M.D. & Charles Benbrook, Ph.D., GMOs, Herbicides, and Public Health, New England J. of Medicine (2015), http://www.nejm.org/doi/full/10.1056/NEJMp1505660#t=article.

They are overwhelmingly engineered to be resistant to pesticides or produce pesticides,³⁸⁷ and consequently have dramatically increased overall pesticide output into the environment.³⁸⁸ Monsanto's GE "Roundup Ready" crops, which are resistant to glyphosate, have made glyphosate the most used pesticide in history, with roughly 280 million pounds applied annually in U.S. agriculture since 2012.³⁸⁹ Newer GE crop varieties have increased the use of older pesticides on our food, such as dicamba and 2,4-D, by facilitating late-season, over-the-top application.³⁹⁰ Reliance on these pesticide-promoting GE crop systems has caused a number of harms, including widespread pollution of our waterways and ecosystems, injury to beneficial insects such as pollinators,³⁹¹ and harm to soil health.³⁹² Glyphosate is also a leading culprit in herbicidal drift injury to sensitive crops, and also injures wild plants that many other organisms depend upon for food and/or habitat.³⁹³ Glyphosate-containing Roundup formulations are extremely toxic to tadpoles and frogs, and likely have contributed to the worldwide decline in

³⁸⁷ Charles M. Benbrook, Impacts of Geneticaly Engineered Crops on Pesticide Use in the U.S.- the First Sixteen Years, 24 ENV'T SCIS. EUR. 1 (2012), https://enveurope.springeropen.com/track/pdf/10.1186/2190-4715-24-24.pdf

³⁸⁸ Ramon J. Seidler, Pesticide Use on Genetically Engineered Crops (Sept. 2014),

http://static.ewg.org/agmag/pdfs/pesticide_use_on_genetically_engineered_crops.pdf.

³⁸⁹ Pesticide National Synthesis Project–Pesticide Use Maps: Glyphosate, U.S.

GEOLOGICAL SURVEY (2012), http://goo.gl/hSFYLo; Charles M. Benbrook, Impacts of genetically engineered crops on pesticide use in the U.S. – the first sixteen years, 24 Envt. Sci. Eur. 1, 3 (2012), http://goo.gl/RaFkeM; Ramon J. Seidler, Pesticide Use on Genetically Engineered Crops (Sept. 2014), http://static.ewg.org/agmag/pdfs/pesticide_use_on_genetically_engineered_crops.pdf. 390 David Mortensen et al., Navigating a critical juncture for sustainable weed

management, 62 BIOSCIENCE 75–84 (2012), http://goo.gl/RxZVM2; Brandon Keim, New generation of GM crops put agriculture in a 'crisis situation,' WIRED (Sept. 25, 2014), http://goo.gl/ejbTLF.

³⁹¹ Richard Coniff, Tracking the causes of sharp decline of the monarch butterfly, YALE ENVIRONMENT 360 (Apr. 1, 2013),

http://goo.gl/EBCU33; J.M. Pleasants & K.S. Oberhauser, Milkweed loss in agricultural fields because of herbicide use: effect on the monarch butterfly population, 6 INSECT CONSERVATION & DIVERSITY, 135–44 (2013),

http://home.cc.umanitoba.ca/~frist/PLNT4600/biodiversity/icad196.pdf.

³⁹² Feng-Chih Chang et al., Occurrence and Fate of the Herbicide Glyphosate and its Degradate Aminomethylphosphonic Acid in the Atmosphere, 30 ENVTL. TOXICOLOGY & CHEMISTRY 548, 548–50 (2011), http://goo.gl/bZZTve;

Richard H. Coupe et al., Fate and Transport of Glyphosate and Aminomethylphosphonic Acid in Surface Waters of Agricultural Basins, 68 PEST. MGMT. SCI. 16, 16–17 (2012), http://goo.gl/WSvHO2.

³⁹³ 2005 Pesticide Drift Enforcement Survey Report, ASSOC. OF AM. PESTICIDE CONTROL OFFICIALS https://www.centerforfoodsafety.org/files/aapco-2005_29712.pdf.

frog populations.³⁹⁴ The well-established environmental impacts of GE crops (and their attendant pesticides) are widespread and dire. Many people reasonably want labeling to align their food purchasing choices with their environmental values.

On the agricultural side, transgenic contamination³⁹⁵ of traditional crops from engineered crops³⁹⁶ has caused U.S. farmers literally billions of dollars in market losses.³⁹⁷ And the widespread adoption of crops engineered for pesticide resistance has proliferated an epidemic of resistant "superweeds" now covering more than 120 million acres of U.S. farmland.³⁹⁸ And in 2015, the World Health Organization's International Agency for Research on Cancer concluded that glyphosate is probably carcinogenic to humans, based in part on epidemiology studies showing increased risk of non-Hodgkin lymphoma among farmers who used glyphosate formulations.³⁹⁹ Many consumers do not want to support unsustainable agricultural practices that harm American farmers and instead want to make choices that align with their support of family farmers, not agrochemical companies. Proper labeling provides them this choice.

Juxtaposed against these facts, the U.S. public discovered that the pesticide industry's hype about genetically engineered crops is false: Despite billions of dollars in research and

 $^{^{394}}$ Rick A. Relyea, The Lethal Impact of Roundup on Aquatic and Terrestrial Amphibians, 15 ECOLOGICAL ADAPTIONS 1118, 1120–23 (2005), http://goo.gl/ZjYiHG.

 $^{^{395}}$ Michelle Marvier & Rene C. Van Acker, Can Crop Transgenes Be Kept on a Leash?, 3 Frontiers Ecology & Env't 99, 10001 (2005), http://goo.gl/m2K6rS.

³⁹⁶ Genetically Engineerd Crops: Agencies are Proposing Changes to Improve Oversight, but Could Take Additional Steps to Enhance Coordination and Monitoring, Gov't Accountability Office (Nov. 2008), https://www.gao.gov/assets/gao-09-60.pdf.

³⁹⁷ Jef Feeley & Margaret Cronin Fisk, Syngenta to pay \$1.4 billion to settle Viptera claims, FARM FUTURES (Sept. 26, 2017), https://www.farmprogress.com/business/syngenta-pay-14-billion-settle-viptera-claims; Tom Polansek, China rejections of GMO U.S. corn cost up to \$2.9 billion, Reuters (Apr. 16, 2014), http://goo.gl/5Nc6Ub; Andrew Harris, Bayer Agrees to Pay \$750 Million to End Lawsuits Over Gene- Modified Rice, Bloomberg (July 2, 2011), http://goo.gl/ymerOa; K.L. Hewlett, The Economic Impacts of GM Contamination Incidents on the Organic Sector (June 2008), http://goo.gl/jf2F5E.

³⁹⁸ J. Pucci, The war against weeds evolves in 2018, CROPLIFE (March 20, 2018), https://www.croplife.com/crop-inputs/the-war-against-weeds-evolves-in-2018/.

³⁹⁹IARC Monographs Volume 112: evaluation of five organophosphate insecticides and herbicides, WORLD HEALTH ORGANIZATION (March 20, 2015), http://goo.gl/KRhWNX.

nearly three decades of commercialization, no GE crops are commercially produced to increase yields, reduce world hunger, or mitigate global warming.⁴⁰⁰ Rather, the commercial reality is that agrochemical companies have largely succeeded in engineering these crops to be resistant to the companies' own products—pesticides—in order to reap huge profits. Moreover genetic engineering is very different than conventional breeding.⁴⁰¹ It is an imprecise technology that causes random and, in some cases, large-scale mutations in crop genomes,⁴⁰² and has a higher potential for generating unintended and potentially adverse human health effects than conventional breeding methods.⁴⁰³ Scientific studies have shown that mixing plant, animal, bacterial, and viral genes through genetic engineering, in combinations that cannot occur in nature,⁴⁰⁴ can and has caused unintended consequences: for instance, by making foods allergenic⁴⁰⁵ or by introducing novel toxins.⁴⁰⁶ Manipulating genes via genetic engineering and inserting them into organisms is an imprecise process; the results are not always predictable or controllable.⁴⁰⁷ Nor is there any consensus that such foods have been proven safe. Numerous

⁴⁰⁰ DOUG GURIAN-SHERMAN, UNION OF CONCERNED SCIENTISTS, FAILURE TO YIELD: EVALUATING THE PERFORMANCE OF GENETICALLY ENGINEERED CROPS, 1–5 (2009), https://www.ucsusa.org/resources/failure-yield-evaluating-performance-genetically-engineered-crops; Jack A. Heinemann, Reply to comment on sustainability and innovation in staple crop production in the US Midwest, 12 INT'L J. OF AG. SUSTAINABILITY, 387-390 (2014), http://goo.gl/GruWvv.

⁴⁰¹ Allison Snow, Genetic Engineering: Unnatural Selection, 424 NATURE 619 (2003), http://goo.gl/Fn6hs3.

⁴⁰² Allison K. Wilson et al., Transformation-induced mutations in transgenic plants: Analysis and biosafety implications, 23 BIOTECH. & GENETIC ENG'G REV. 209–34 (2006), http://goo.gl/JtDyk8.

 $^{^{403}}$ Inst. of Med. & Nat'l Research Counsel of the Nat'l Acads, Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects 64, 65 n. 3 (2004), http://goo.gl/g9AuE1.

 $^{^{404}}$ Stanley N. Cohen et al., Construction of Biologically Functional Bacterial Plasmids in Vitro, 70 PROC. NAT'L ACAD. SCI. 3240-44 (1973), https://www.pnas.org/content/pnas/70/11/3240.full.pdf.

⁴⁰⁵ J.A. Nordlee et al., Identification of a Brazil-nut allergen in transgenic soybeans, 334(11) NEW ENGLAND J. MED. 688-92 (1996).

⁴⁰⁶ T. Inose & K. Murata, Enhanced accumulation of toxic compound in yeast cells having high glycolytic activity: a case study on the safety of genetically engineered yeast, 30 INT'L JOURNAL OF FOOD SCIENCE AND TECHNOLOGY 141, 141–46 (1995).

⁴⁰⁷ A.K. Wilson et al., Transformation-induced mutations in transgenic plants: analysis and biosafety implications, 23 BIOTECHNOLOGY AND GENETIC ENGINEERING REVIEWS 209–34 (2006); See also F. Jupe et al., The complex architecture ad epigenomic impact of plant T-DNA insertions, 15(1): e1007819PLoS Genetics (2019).

scientific, health, and legislative bodies have concluded that GE foods have not been proven safe, that mandatory safety assessments are needed, and that they support labeling.⁴⁰⁸

A SHORT HISTORY OF GE FOOD LABELING LAWS

In the absence of mandatory government disclosure, private certification for absence (Non-GMO) labeling proliferated in the marketplace. And the organic label of course denoted, among other things, a prohibition on the use of genetically engineered ingredients. But market-based absence labeling could not provide the public's right to know for the rest of the food supply by requiring manufacturers using genetically engineered ingredients to provide that information, leaving consumers in the dark.

For these reasons, into the federal breach, state-required labeling efforts proliferated, in the venerable "states as laboratories" tradition of American federalism. Over 30 states introduced labeling bills over the course of 2013-2015.⁴⁰⁹ Connecticut and Maine passed labeling laws in 2013,⁴¹⁰ albeit with clauses tying their effective dates to similar laws in other states, and in May 2014, Vermont became the first state to pass a stand-alone labeling law.⁴¹¹ And despite spending over \$100 million dollars,⁴¹² crushing election spending records, opponents of labeling

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⁴⁰⁸ Angelika Hilbeck et al., No scientific consensus on GMO safety, 27:4 ENVTL. SCI.

EUROPE (2015), http://goo.gl/k2f4R6; Sheldon Krimsky, An Illusory Consensus behind GMO Health Assessment, Sci., Tech., and Human Values (August 7, 2015).

⁴⁰⁹ GE Food Labeling: States Take Action, CTR. FOR FOOD SAFETY (June 10, 2014), https://www.centerforfoodsafety.org/fact-sheets/3067/ge-food-labeling-states-take-action.

⁴¹⁰ Maine Legislature Passes Center for Food Safety Supported GE Labeling Law, CTR. FOR FOOD SAFETY (June 12, 2013), https://www.centerforfoodsafety.org/issues/976/ge-food-labeling/press-releases/2297/maine-legislature-passes-center-for-foodsafety-supported-ge-labeling-law; More States Support GMO Labeling Bills, CTR. FOR FOOD SAFETY (May 22, 2013), https://www.centerforfoodsafety.org/issues/976/ge-food-labeling/press-releases/2240/more-states-support-gmo-labeling-bills.

⁴¹¹ Victory for Food Movement in Vermont on GE Food Labeling, CTR. FOR FOOD SAFETY (May 8, 2014),

⁴¹² Anit-Labeling Campaign Tries to Buy Oregon Election with Record Setting \$19 Million in Misleading Advertising, CTR. FOR FOOD SAFETY (Oct. 29, 2014), https://www.centerforfoodsafety.org/issues/976/ge-food-labeling/press-releases/3577/anti-labeling-campaign-tries-to-buy-oregon-election-with-record-setting-19-million-in-misleading-advertising.

also barely beat back three state ballot initiatives, in California (2012),⁴¹³ Washington (2013),⁴¹⁴ and Oregon (2014)⁴¹⁵ by increasingly narrow 51%-49% margins.⁴¹⁶

The food industry challenged Vermont's law, but after a year of litigation the U.S. District Court for the District of Vermont rejected their arguments, upholding the law.⁴¹⁷ Namely, the court held that state labeling was not preempted by federal law, that it did not impermissibly interfere with interstate commerce, and that food manufacturers did not have a First Amendment right to refuse the state mandated disclosures about whether their food was genetically engineered.⁴¹⁸ The court found the reasons Vermont gave for the mandated disclosure labeling—those described above, promoting public health and environment protection, and preventing consumer confusion and deception—were substantial state interests to support labeling requirements.⁴¹⁹

The food industry appealed, but at the same time realized the writing on the wall: mandatory labeling was not a matter of if, but when. As such they sought a new venue that was more friendly to their views, lobbying Congress to pass legislation preempting the state labeling laws. And in 2016, Congress passed the U.S.'s first mandatory GE disclosure law.⁴²⁰

⁴¹³ California Proposition 37, Mandatory Labeling of Genetically Engineered Food, BALLOTPEDIA (2012),

https://ballotpedia.org/California_Proposition_37,_Mandatory_Labeling_of_Genetically_Engineered_Food_Initiative.

⁴¹⁴ Washington Mandatory Labeling of Geneticaly Engineerd Food Measure Initiative 522, BALLOTPEDIA (2013),

https://ballotpedia.org/Washington_Mandatory_Labeling_of_Genetically_Engineered_Food_Measure,_Initiative_522_%282013 %29.

⁴¹⁵ Oregon Mandatory Labeling of GMOs Intiative, Measure 92, BALLOTPEDIA (2014),

https://ballotpedia.org/Oregon_Mandatory_Labeling_of_GMOs_Initiative,_Measure_92_%282014%29.

 $^{^{\}mbox{\tiny 416}}$ Oregon lost by only 837 votes, the closest election in Oregon history.

⁴¹⁷ Grocery Mfrs. Ass'n v. Sorrell, 102 F. Supp. 3d 583 (Dt. Vermont 2015).

⁴¹⁸ Id. at 604-10, 613-17, 621-36.

 $^{^{419}}$ Id. at 631–36. See also Kimbrell & Paulsen, supra note 381.

⁴²⁰ 7 U.S.C. § 1639 et. seq.

THE FEDERAL DISCLOSURE ACT AND CURRENT LITIGATION

While the 2016 Act was the culmination of a twenty-four year struggle for the public's right to know, it was also very much a compromise, and different in several important ways from the state labeling laws and ballot initiatives championed by the food movement. Several of those differences were only revealed after USDA—not FDA, which is the more obvious candidate for such labeling oversight—finalized its implementing regulations, in December 2018.⁴²¹ Unfortunately, in its final decision the agency fell far short of fulfilling the promise of meaningful labeling of GE foods. In fact, in many ways the result is in the direct or *de facto* concealment of these foods and avoidance of their labeling.

Consequently, a coalition of nonprofits and grocers⁴²² challenged the federal labeling standard in 2020, with litigation currently ongoing.⁴²³ The claims in the case double as highlighting key controversial issues of the law. First is the issue of *how* the disclosure is provided under the final rule: electronic or digital forms of labeling, also known as "QR code" or "smartphone" labeling. Congress included this potential form of disclosure in the new law, but, recognizing its untested nature, made USDA undertake a study of its potential efficacy to eventually use it alone as a means of labeling.⁴²⁴ The study showed undeniably what opponents told the agency: (a) it was not realistic to have customers in a grocery store use their phone to scan barcodes for dozens of products, and (b) this form of disclosure would discriminate against major portions of the population—the poor, elderly, rural, and minorities—with lower percentages of smartphone ownership, digital expertise, or ability to afford data, or who live in

⁴²¹ See National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 65,814-28 (Dec. 21, 2018).

⁴²² The Plaintiffs are Natural Grocers, Citizens for GMO Labeling, Label GMOs, Rural Vermont, Good Earth Natural Foods, Puget Consumers Co-Op, and Center for Food Safety.

⁴²³ Natural Grocers et. al. v. Perdue, No.20-cv-05151-JD (N.D. Cal.).

^{424 7} U.S.C. § 1639b(c)(1).

areas in which grocery stores do not have internet bandwidth.⁴²⁵ But USDA nonetheless greenlit QR codes without other forms of labeling on products, which the plaintiffs allege is unlawful.⁴²⁶

Second is the issue of what *terminology* is permitted. For 25 years, all aspects of the public dialog around GE foods—scientific, policy, market, legislative, consumer—have used either "genetically engineered" (GE) or "genetically modified" (GMO) to refer to genetically engineered foods. Those are terms that all federal agencies (including USDA during the rulemaking) used. They are what the public knows, understands, and expects, and what is currently used in the marketplace by producers. They are what other countries and U.S. trade partners use internationally. And, while Congress used the new term "bioengineered" in the Act, at the same time, it also instructed USDA to include "any similar term" in its new standard.⁴²⁷ Despite that instruction and the overwhelming support from stakeholders to allow continued use of the far more well-known "GE"/"GMO" terms, in its final rule USDA instead excluded "GE" and "GMO," prohibiting the terms from use in the on-package text or symbol labeling, and only allowing use of the term "bioengineered"—a decision that the plaintiffs allege is unlawful, will fail to fulfill the Act's fundamental purpose of informing consumers, and is antithetical to the Act's purpose because it will confuse and mislead consumers.⁴²⁸

Third is the issue of what foods are covered (or not covered) under the *scope*. The vast majority of GE foods are not whole foods but rather highly processed foods with GE ingredients like sodas and oils, which by some estimates account for over 70% of all GE foods. The Act provided broad scope to USDA to cover all GE foods, 429 and the legislative history shows that

⁴²⁵ A Third-Party Evaluation of Challenges Impacting Access to Bioengineered Food Disclosure (July 2017),

https://www.ams.usda.gov/sites/default/files/media/USDADeloitteStudyofElectronicorDigitalDisclosure 20170801.pdf.

⁴²⁶ See 7 C.F.R. § 66.106 (electronic or digital disclosures).

^{427 7} U.S.C. § 1639(1).

⁴²⁸ 7 C.F.R. § 66.102(a)(1)-(2) (listing only "bioengineered foods," "bioengineered food," or "contains a bioengineered ingredient" as permissible disclosure options); id. § 66.102 ("A text disclosure must bear the text as described in this section.").

⁴²⁹ 7 U.S.C. § 1639b(a)(1) (directing USDA to establish a disclosure standard for "any bioengineered food and any food that may be bioengineered."); see also 7 U.S.C. § 1639(1)(A) (defining "bioengineering" as a food "that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (rDNA) techniques.").

USDA and Congress made assurances that the majority of GE foods—those highly refined GE foods—would be covered. Yet in the final rulemaking, USDA decided to exclude highly refined GE foods, unlawfully creating a new extra-statutory limitation according to the plaintiffs and again undermining the very purpose of the law.⁴³⁰

Fourth is the right of *improving* on the limited and flawed disclosure the rules provide, particularly important given all the problems explained above. Manufacturers and retailers have a fundamental First Amendment right to provide truthful commercial information to consumers, and consumers have a right to receive it. In this context, manufacturers and retailers have the right to label foods as produced through genetic engineering or as genetically engineered. Yet the final rule attempts to restrict that right in multiple ways, providing only limited and restricted voluntary labeling beyond its narrow scope.⁴³¹ Those speech-chilling restrictions violate the statute's text and purposes as well as the First Amendment's guarantees.

GE ANIMAL FOODS SPECIFICALLY AND THE DISCLOSURE ACT

The new federal standard also has a major scope problem with regard to meat from genetic engineering: namely, most of it is not covered and does not appear that it will be in the future.

First, the Disclosure Act excludes animals that consume GE feed from the scope of the disclosure standard. The Act "prohibit[s] a food derived from an animal to be considered a bioengineered food solely because the animal consumed feed produced from, containing, or

⁴³⁰ See 7 C.F.R. § 66.1 (defining "bioengineered food," as, in relevant part, "a food that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (rDNA) techniques," but "provided that such a food does not contain modified genetic material if the genetic material is not detectable pursuant to § 66.9."); see also 83 Fed. Reg. at 65,835 ("[F]oods with undetectable modified genetic material are not bioengineered foods").

⁴³¹ See 7 C.F.R. § 66.102 ("A text disclosure must bear the text as described in this section."); id. § 66.102(a)(1)-(2) (listing only "bioengineered foods," "bioengineered food," or "contains a bioengineered ingredient" as acceptable terms); 7 U.S.C. 1639b(b)(1); 7 C.F.R. § 66.116(b) (limiting voluntary disclosures of highly refined foods to "derived from bioengineering"); 83 Fed. Reg. at 65,827 ("The 'may be bioengineered' disclosure cannot be used."); 7 U.S.C. 1639b(b)(2)(A); 7 C.F.R. § 66.5(d) (prohibiting even voluntary disclosures of any meat or dairy from livestock fed genetically engineered feed).

consisting of a bioengineered substance."⁴³² As a result, only meat from animals that are themselves genetically engineered may bear the disclosure. But as discussed above, the commercial reality at this time is GE food made from GE crops, not GE farm animals. More prevalent however currently is the meat of factory farm animals that are overwhelmingly fed GE grains—that meat is *not* required to be labeled. The standard also appears to prohibit grocers from improving on this lack of clarity. As with other GE foods, consumers care about the lack of sustainability in the process itself, including the feed propping up the factory farm confinement system; these foods should also be labeled.

Second, even those animals that are *themselves* genetically engineered must fall within new standard's narrow scope to be covered. The Act states that the disclosure standard must apply to all "foods" subject to the labeling requirements under the FFDCA; the Federal Meat Inspection Act FMIA; the Poultry Products Inspection Act PPIA; or the EPIA.⁴³³ But for those foods not covered under the FFDCA, the Act sets strict limitations. Specifically, the Disclosure Standard may only apply to foods subject to the labeling requirements of the FMIA or PPIA *if* the most predominant ingredient of the food would independently be subject to the labeling requirements under the FFDCA; or if the most predominant ingredient of the food is broth, stock, water, or a similar solution and the second-most predominant ingredient of the food would independently be subject to the labeling requirements under the FFDCA.⁴³⁴

Consequently, as explained above in Section I, this FFDCA-FMIA/PPIA distinction, while mirroring the general FDA-FSIS breakdown (although particularly nonsensical here, since *USDA* itself, not FDA, is the regulating agency) actually could significantly restrict what future GE meat products covered by the disclosure standard. FDA regulates seafood (except catfish) under the FFDCA, as well as "exotic" meats. And the only current GE food animal, a genetically

 $^{^{432}}$ 7 U.S.C. \S 1639b(b)(2)(A); 7 C.F.R. \S 66.5(d).

⁴³³ 7 U.S.C. § 1639a.

⁴³⁴ See 7 U.S.C. § 1639a(c)(2).

engineered salmon, which a federal court held unlawful in 2020,⁴³⁵ is covered and is listed on USDA's List of Bioengineered Foods.⁴³⁶

But beef, pork, chicken, and lamb are labeled under FMIA/PPIA and FSIS.⁴³⁷ This means these meats need not bear a GE disclosure (unless they are included in a larger processed food in which the most predominant ingredient of the food is covered by the FFDCA or the second-most predominant ingredient is covered after broth, stock, water, or a similar solution.) Again they appear outside the scope of what USDA is covering in the new disclosure standard. This too appears to be misleading and confusing to consumers, who would just as logically believe that a GE animal meat should be disclosed as bioengineered as a GE plant substance, *if not more*, and for similar reasons. And while FSIS might approve a particular label for future GE factory farm meats, it seems unlikely they would set specific standards rather than individual label approvals, although action from FSIS could ameliorate any future confusion. Either way, the juxtaposition again also vividly illustrates why one agency should be in charge of all food labeling and regulation.

CONCLUSIONS AND THEMES

First, once again, process matters. The battle for integrity in GE labeling mirrors that of organic: this is another process-based label, an important precedent for other future labels to address externalized impacts of food production.

Second, the disclosure "how" matters. Terminology matters. Plainly the industry (and an obliging agency) believes the past decades have created a negative connotation for the terms GE/GMO and seek to shed that baggage despite how confusing and misleading that will be for consumers. And the disclosure act is the first time in any federal law that mandatory

⁴³⁵ Institute for Fisheries Resources v. FDA, 2020 WL 6495656 (N.D. Cal. 2020).

 $^{{}^{436} \}text{List of Bioengineered Foods, U.S. DEP'T OF AGRIC., https://www.ams.usda.gov/rules-regulations/be/bioengineered-foods-list.} \\$

government disclosure information has been permitted to be placed not in clear text on the package, but instead through an electronic disclosure. As such, this is the first battle of a future war over the package and represents the camel's nose under the tent. What's next, calories, ingredients, nutrition, allergies? Manufacturers would love to use the whole package for geewhiz advertising and put all the required boring information behind a QR code scan.

Finally, the history of GE crops and the fight for the public's right to know portends what the specter of GE animal agriculture will almost certainly mirror, a process that has already begun: use of the technology to further entrench industrial factory farm paradigms to the benefit of a handful of integrated agricultural corporations; the externalization of those costs on the animals and the environment; and a knife fight for any meaningful disclosure or labeling of those changes to our food for the public.

The Rise and Weaponization of Commercial Speech

The last example is not about a new food label, but about a 21st century change in the law affecting all labeling. In circumstances where governments do require new types of labels on foods, corporations are fighting back, weaponizing First Amendment "commercial speech" protections in order to stop governments from forcing the disclosure of impacts or risks.

First, while the First Amendment's language is broad—"Congress shall make no law ... abridging the freedom of speech..."—not all speech is protected under the Constitution.⁴³⁸ In fact, traditionally only certain narrow categories of speech were held by the Courts to warrant protection—religious speech, political speech, ideological speech⁴³⁹—categories that made perfect sense given the importance of protecting the right to speak freely about them in a democracy. Other speech could be regulated easily, and still other speech was totally

⁴³⁸ U.S. Const., 1st Amd.

 $^{{\}it 439}\ Congressional\ Research\ Service, The\ First\ Amendment:\ Categories\ of\ Speech\ (Jan.\ 16,\ 2019),\ \underline{https://sgp.fas.org/crs/misc/IF11072.pdf}.$

unprotected. For protected types of speech, Courts placed a high burden on governments—in order to regulate that speech, the restriction must pass muster in judicial review, known as strict scrutiny. "Strict" scrutiny requires that a law is (1) narrowly tailored and (2) that it serves a compelling government interest,⁴⁴⁰ and laws receiving strict scrutiny review very rarely survive. In contrast, "rational" basis review upholds government action so long as the government can show a rational basis for its action and laws receiving review under it are almost always upheld.⁴⁴¹

Commercial speech—like food product labeling—was not of the same as protected caliber; this was speech simply about a commercial transaction or economic interest, an exchange of goods in the marketplace. And for 200 years it received only rational basis review. A 1976 Supreme Court decision, *Virginia State Board of Pharmacy v. Virginia Citizen Consumer Council*, changed that for the first time and provided some protection to commercial speech.⁴⁴² Prior to then, commercial speech was outside the First Amendment's scope of protection.⁴⁴³ But importantly, the rationale the Court gave to protect commercial speech was that the speech was most constitutionally valuable not for the *speaker*, but for the *listeners*' rights (e.g. the consumer) to have the information provided to them. That is, the extension of First Amendment protection to commercial speech is "justified principally by the value to consumers of the information that such speech provides."

⁴⁴⁰ Brown v. Entm't Merchs. Ass'n, 131 S. Ct. 2729, 2738 (2011).

⁴⁴¹ Raphael Holoszyc-Pimentel, Reconciling Rational-Basis Review: When Does Rational Basis Bite?, 90 NYU L. REV. 2070, 2074-75 (2015).

⁴⁴² 425 U.S. 748, 761–62, 770 (1976); Ohralik v. Ohio State Bar Ass'n, 436 U.S. 447, 455 (1978) ("Expression concerning purely commercial transactions has come within the ambit of the [First] Amendment's protection only recently").

 $^{^{443}}$ Valentine v. Chrestensen, 316 U.S. 52, 54 (1942), overruled by, Va. State Bd. of Pharm., 425 U.S. 748, 758-61, 770 (following the progression of First Amendment jurisprudence to eventually provide explicit protections for commercial speech).

⁴⁴⁴ Zauderer, 471 U.S. at 651 (citing Va. State Bd. Pharm., 425 U.S. at 762).

In the decades since, commercial speech protections have occupied a middle tier, known as "intermediate scrutiny." This protection is not as strong as strict scrutiny,⁴⁴⁵ but still requires a government requiring a product disclosure to pass multiple hurdles if challenged. Imagine a state passed a law requiring disclosure of meat products that came from animals raised in factory farm confinement conditions, or a warning disclosure if seafood came from an overfished depleted fishery, or prohibited seafood from being labeled as natural if it came from of unsustainable, damaging netpen aquaculture that prohibited the fish's natural behaviors. In a court challenge, assuming the commercial speech concerned lawful activity and was not misleading, the government would need to show that the law or regulation (1) directly advances a (2) substantial government interest(s),⁴⁴⁶ and the law/regulation is (3) not "more extensive than is necessary to serve that interest," in order to pass muster.⁴⁴⁷ Cognizable government interests include preventing potential consumer confusion or deception, promoting public health, and environmental protection, among others.⁴⁴⁸

That said, there is an important difference between government-required commercial speech *restrictions* and government-required commercial speech *disclosures*.⁴⁴⁹ Restrictions proceed along the above analysis, known as the *Central Hudson* analysis.⁴⁵⁰ Courts have differed in how they have characterized required disclosures, sometimes treating them as a subcategory

⁴⁴⁵ See Florida Bar v. Went For It, Inc., 515 U.S. 618, 623 (1995) ("We have always been careful to distinguish commercial speech from speech at the First Amendment's core").

⁴⁴⁶ Cent. Hudson, 447 U.S. at 566.

⁴⁴⁷ Id.

⁴⁴⁸ Kimbrell & Paulsen, supra note 381 at 396-402 (explaining cognizable government interests and surveying cases).

⁴⁴⁹ Kimbrell & Paulsen, supra note 381 at 389–93 (detailing the difference between Central Hudson review for label restrictions and Zauderer review for label mandated disclosures).

⁴⁵⁰ Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 561, 566 (1980).

of *Central Hudson*, ⁴⁵¹ or an "exception to the general rule of *Central Hudson*," ⁴⁵² and other times as a separate test known as the *Zauderer* test. ⁴⁵³ Either way, *Zauderer* review is easier to satisfy. Under that test, so long as the disclosure required is (1) purely factual and (2) uncontroversial information, all the government must show is that the disclosure requirement is rationally related to a legitimate government interest. ⁴⁵⁴ This is akin to traditional rational basis review, although the scope and rigor of its application is currently an open question. But it makes sense that it would be an easier threshold, understanding that the whole purpose of any protection is for the "listener" (e.g. public), not the speaker, and required disclosures provide more, not less, information. In the inverse, a food corporation's "constitutionally protected interest in *not* providing any particular factual information in his advertising is minimal." ⁴⁵⁵

Grocery Manufacturers v. Sorrell, the food industry's challenge to Vermont's GE food labeling law discussed supra nicely illustrates the difference in strength between Zauderer and Central Hudson review. Most of that law was required disclosures, about whether a food was produced with genetic engineering. And those provisions withstood the industry's First Amendment attack under Zauderer-level review. An Namely, the court held that Zauderer—not

⁴⁵¹ American Meat Institute v. USDA, 760 F.3d 18, 25-26 (D.C. Cir. 2014) (en banc) (comparing Central Hudson and Zauderer review); id. at 27 ("to the extent that the pre-conditions to application of Zauderer warrant inferences that the mandate will "directly advance" the government's interest and show a "reasonable fit" between means **327 *27 and ends, one could think of Zauderer largely as "an application of Central Hudson, where several of Central Hudson's elements have already been established."); but cf. id. at 28 (Rodgers, J., concurring in part) ("Viewing Zauderer as simply an application of Central Hudson to special circumstances, as AMI has suggested to the en banc court, see AMI Supp. Br. 8–11, finds support in neither Supreme Court precedent nor the precedent of this court or our sister circuits. Although the en banc court stops short of endorsing this reformulation, stating only that "one could think of Zauderer largely as an application of Central Hudson," blurring the lines between the standards portends unnecessary confusion absent further instruction from the Supreme Court.") (citation omitted).

 $^{^{452}\,\}text{CTIA} - \text{The Wireless Ass'n v. City of Berkeley, California, } 928\,\,\text{F.3d 832, } 843\,\,\text{(9th Cir.), cert. denied.} \\ \text{140 S. Ct. 658 (2019).}$

⁴⁵³ Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio, 471 U.S. 626 (1985).

⁴⁵⁴ Zauderer, 471 U.S. at 651.

⁴⁵⁵ Zauderer, 471 U.S. at 651 (emphasis in original); Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 113–14 (2d Cir. 2001) (internal citations and quotation marks omitted); ("[T]he individual liberty interests guarded by the First Amendment, which may be impaired when personal or political speech is mandated by the state, are not ordinarily implicated by compelled commercial disclosure." (internal citations omitted)).

⁴⁵⁶ Grocery Mfrs. Ass'n, 102 F. Supp. 3d at 626-36.

Central Hudson—applied to the mandatory disclosures and that they passed muster because they were factual, noncontroversial statements reasonably related to several legitimate government interests. 457 But another part of the state law prohibited manufacturers from labeling their GE foods as "natural." Here, the Court reviewed the prohibition on speech under Central Hudson and struck it down, finding that while use of the label could be potentially misleading, Vermont had not sufficiently established that the restriction "directly and materially advances" the state's interest or that it was "no more extensive than necessary to serve that interest," in large part because the state had itself failed to define what was "natural," or to explain why state consumer protection statutes were inadequate to police misuse of the term. 458

First, even under the existing "intermediate" scrutiny, food corporations have flexed their First Amendment muscles in challenges to government required labeling, with mixed results. For example, In *Am. Meat Inst. v. U.S. Dept. of Agric.*, 459 the American Meat Institute brought action against the USDA for their country-of-origin labeling (COOL) requirement, arguing such requirement unconstitutionally compels commercial speech disclosures. But the D.C. Circuit *en banc* rejected their arguments and held that USDA's myriad interests in making country-of-origin information available to consumers was sufficient to justify the required disclosure under *Zauderer* review. However, while *AMI* and the aforementioned *Grocery Manufacturers* cases failed, in *Am. Beverage Ass'n v. City & Cty. of S.F.*, 460 beverage manufactures sued San Francisco alleging the city's required health warning on advertisements for various sugar-sweetened drinks unconstitutionally compels commercial speech. The Ninth Circuit sitting *en banc* agreed with the plaintiffs, holding the health warning to be "unduly burdensome" and "not justified" and therefore "offen[sive] to the Plaintiff's First Amendment

⁴⁵⁷ Id.

⁴⁵⁸ Id. at 640–41 ("Because Act 120's "natural" restriction is bereft of definitional content, it will either sweep too widely or too narrowly in penalizing commercial activities that employ an advertising term that is "susceptible to more than one interpretation."). ⁴⁵⁹ 760 F.3d 18 (D.D.C. 2014).

^{460 916} F.3d 749 (9th Cir. 2019).

rights."⁴⁶¹ And in *National Association of Wheat Growers v. Becerra*,⁴⁶² agricultural trade associations successfully challenged California's Prop 65 cancer warning labels on the pesticide glyphosate as violating their First Amendment rights. The court determined that lower level *Zauderer* scrutiny did not apply because the Prop 65 warning was not "purely factual and uncontroversial."⁴⁶³ The court went on to conclude the disclosure requirement did not survive *Central Hudson* review because California could not show how it directly advanced the asserted state interest, nor that it was not more extensive than necessary.⁴⁶⁴

But <u>second</u>, this area of the law is very much in further flux, with the Supreme Court blurring the lines more and more between commercial speech and those higher forms of traditionally protected speech that are reviewed under strict scrutiny. Increasingly, commercial speech challenges consider whether speech restrictions are "content" or "viewpoint" based, which are types of strict scrutiny analysis normally undertaken in the other traditional categories, never commercial speech.⁴⁶⁵ For example, in *Reed v. Town of Gilbert*, the issue was a town's ordinance that restricted the size and location of directional signs, a quasi- form of commercial speech regulation.⁴⁶⁶ Yet when challenged by a local church, the Supreme Court overturned the regulation based on being impermissible "content" regulation – laws that target speech based on its content—and which are presumptively unconstitutional and must pass strict scrutiny (justified only if the government proves they are narrowly tailed to serve compelling

⁴⁶¹ Id. at 757.

^{462 468} F.Supp.3d 1247 (E.D. Cal. 2020).

⁴⁶³ Id. at 1259. Instead the Court held the disclosure itself to be misleading. Id. at 1260.

⁴⁶⁴ Id. at 1264-65.

⁴⁶⁵ These arguments were previously rejected. See, e.g., NEMA, 272 F.3d at 116 (observing that "[i]nnumerable federal and state regulatory programs require the disclosure of product and other commercial information" and that subjecting each to "searching scrutiny" is "neither wise nor constitutionally required"); Pharm. Care Mgmt. Ass'n v. Rowe, 429 F.3d 294, 316 (1st Cir.2005) (noting that "[t]he idea that … thousands of routine [disclosure] regulations require an extensive First Amendment analysis is mistaken").

⁴⁶⁶ 576 U.S. 155 (2015)

state interests).⁴⁶⁷ Justice Breyer concurred in the judgment but wrote separately to express his "great concern" over the spread of "content-based" regulation standards, including to commercial speech cases, and listing scores of regulations that could be construed as involving "content" discrimination, from securities disclosures to signs at petting zoos.⁴⁶⁸

Reed followed on the heels of a 2011 Supreme Court decision, Sorrell v. IMS Health
Inc.,469 in which a Vermont law restricted the way in which pharmaceutical companies could use
pharmacy records and data, which the Supreme Court majority subjected to strict scrutiny
review and struck down as impermissible content and viewpoint based restrictions.470 It rejected
Vermont's arguments that this was commercial speech and thus higher form of scrutiny were
inapposite.471 Justice Breyer (joined by Justice Ginsburg and Kagan) dissented, arguing that
simple commercial speech review applied and "the far stricter, specially 'heightened' First
Amendment standards that the majority would apply to this instance of commercial regulation
are out of place here."472 He emphasized that the Court had "never found" this type of First
Amendment prohibition, nor had the Court "ever" applied "content-based" and "speaker-based"
strict scrutiny review to commercial speech restrictions.473 And he warned of many other normal
types of commercial regulation that similarly could be considered "content" or "speaker" based,
when it only applied to one class of entities.474

⁴⁶⁷ Id. at 164, 171 ("Because the Town's Sign Code imposes content-based restrictions on speech, those provisions can stand only if they survive strict scrutiny, "'which requires the Government to prove that the restriction furthers a compelling interest and is narrowly tailored to achieve that interest.")

⁴⁶⁸ Id. at 177-78 (Breyer, J., concurring).

⁴⁶⁹ 564 U.S. 552 (2011).

⁴⁷⁰ Id. at 565-66.

⁴⁷¹ Id. at 567, 572 ("Under a commercial speech inquiry, it is the State's burden to justify its content-based law as consistent with the First Amendment."). The Court's majority went on to apply Central Hudson and conclude the law also failed intermediate scrutiny review, but only after applying the content and viewpoint based frame first. Id. at 572-73.

⁴⁷² Id. at 583 (Breyer, J., dissenting).

⁴⁷³ Id.at 588 (emphases in original).

⁴⁷⁴ Id.

Finally, the issue arose again in 2018 in *National Institute of Family and Life Advocates v. Becerra*, ⁴⁷⁵ a First Amendment challenge by crisis pregnancy centers to a California notice requirement about family planning services. The Court held that *Zauderer* review did not apply because the notice topic, abortion, was not uncontroversial; ⁴⁷⁶ yet while recognizing that *Zauderer* applied (a form of commercial speech review), the Court at the same time held that the notice requirement was content-based speech regulation, which was presumptively invalid and subject to strict scrutiny. ⁴⁷⁷ Justice Breyer dissented, joined by 3 other justices, again explaining the risk to health and safety disclaimers long considered permissible or purely factual and uncontroversial disclosures about commercial products that may now be similarly subject this heightened scrutiny. ⁴⁷⁸ He warned that the majority's new test "invites courts around the Nation to apply an unpredictable First Amendment to ordinary social and economic regulation, striking down disclosure laws that judges may disfavor, while upholding others, all without grounding their decisions in reasoned principle." ⁴⁷⁹

One might think the above Supreme Court examples far-afield from food labels, and perhaps closer to religious speech given the plaintiffs in *Reed* (a church) and *Becerra* (pro-life pregnancy crisis center). But notably, in the San Francisco beverage case discussed above, *Am. Beverage Ass'n v. City & Cty. of S.F*, while the majority of the court applied *Zauderer* review to the soda obesity disclosure ordinance (and still affirmed the preliminary injunction against it based on the rationale it was unduly burdensome in its size on the label), Judge Ikuta concurred

⁴⁷⁵ 138 S.Ct. 2361 (2018).

⁴⁷⁶ Id. at 2372 ("The Zauderer standard does not apply here. ...Most obviously, the licensed notice is not limited to "purely factual and uncontroversial information about the terms under which ... services will be available. Instead, it requires these clinics to disclose information about state-sponsored services—including abortion, anything but an "uncontroversial" topic.").

⁴⁷⁷ Id. at 2371 ("The licensed notice is a content-based regulation of speech ... Here, for example, licensed clinics must provide a government-drafted script about the availability of state-sponsored services, as well as contact information for how to obtain them.").

⁴⁷⁸ Id. at 2380-81 (listing required commercial disclosures); id. (explaining that the majority's disclaimers seem more likely to invite litigation than to provide needed limitation and clarification.").

⁴⁷⁹ Id. at 2381.

separately to explain her view that the aforementioned *Becerra* case provided an entirely "new framework for analyzing First Amendment challenges to government-compelled speech," and that a government regulation that compels a disclosure like San Francisco's soda ordinance is a "content-based regulation of speech, which subject to heightened scrutiny under the First Amendment unless the *Zauderer* exception applies."⁴⁸⁰

In conclusion, overall the new 6-3 conservative supermajority appears likely to be moving commercial speech towards full protected status, which would require more strict scrutiny level review (on which the government regulation almost always fails). These shifting legal sands seem certainly of a piece with broader jurisprudential rightward drift, continuing to elevate corporate rights in numerous realms, such as *Citizens United*, which held that financial donations from corporations (also considered a type of "speech") must be held to the same standards as people.⁴⁸¹ And in this food labeling context, what this will mean is that, even when Congress, federal agencies, or state governments find the political will to require progressive, 21st century food labeling requirements on corporations, including for example animal welfare or environmental disclosures, it will be more and more difficult for those legal requirements to survive commercial speech challenges by the food industry.

Conclusion

How we eat is one of the most direct animal welfare and environmental decisions we make every day, and food labels—what we label, how we label, and what we omit from labels or allow to be misrepresented on labels—are major legal drivers of that decision. Deceptive labels mislead consumers, but also facilitate one of the greatest moral failings of our time, billions of animals in unspeakable, inhumane conditions. Deceptive labels also damage the prospects of those farmers

⁴⁸⁰ Am. Beverage Ass'n v. City & Cty. of S.F, 916 F.3d at 758 (Ikuta, J., concurring).

⁴⁸¹ See generally James Wright, A Step Too Far: Recent Trends in Corporate Personhood and the Overexpansion of Corporate Rights, 49 J. MARSHALL L. REV. 889 (2016).

trying to establish a better food future and practice humane husbandry. Consumers should know their food sources and buy consciously; they should see labels as drivers of change. History teaches that what is the public's "right to know" changes over time and can continue to grow and improve, in a slow arc towards enlightenment. Because shifting the social consciousness is how we can build a better food future and a more robust animal law.