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## Novel Food Ingredients: Food Safety Law, Animal Testing, and Consumer Perspectives

Taimie Bryant

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# NOVEL FOOD INGREDIENTS: FOOD SAFETY LAW, ANIMAL TESTING, AND CONSUMER PERSPECTIVES

TAIMIE BRYANT\*

*In recent years, some major food companies have publicly stated that they will no longer test their product ingredients on animals. Yet despite the availability of more reliably predictive non-animal toxicity tests, some companies continue testing novel food ingredients on animals. This Article uses the lens of a particular innovative plant-based food company’s decision to test a novel food ingredient on animals as a means of considering more generally whether any food producer has rational legal reasons for testing on animals. The Article explores FDA requirements, consumer food safety litigation, and judicial evaluation of animal test data, all of which align with lack of necessity to use animal testing to protect consumer safety. The Article presents reasons to change to more reliable non-animal tests, describes results of recent research on consumer perspectives, and identifies several avenues for reducing animal testing while improving food safety.*

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## INTRODUCTION

Although protein alternatives to meat consumption have been in existence somewhere in the world since the year 965,<sup>1</sup> recognition of their importance has accelerated as people grow more conscious of negative animal welfare, environmental, and human health impacts of consuming animal-based foods.<sup>2</sup> Since the 1960s and '70s, Americans have had ready access to manufactured alternatives to meat,<sup>3</sup> but it was not until 2015 that near-perfect replicas of hamburgers began emerging on the scene. In 2015, Beyond Meat (Beyond) introduced the Beyond Burger,<sup>4</sup> followed closely by introduction of the Impossible Burger by Impossible Foods (Impossible) in 2016.<sup>5</sup> Both of these companies have developed burgers with the “mouth feel,” flavor, aroma, and “bleeding” properties of beef hamburgers.<sup>6</sup> They believe that the development

1. WILLIAM SHURTLEFF & AKIKO AOYAGI, HISTORY OF MEAT ALTERNATIVES (965 CE TO 2014): EXTENSIVELY ANNOTATED BIBLIOGRAPHY AND SOURCEBOOK 5 (2014).

2. *Plant-based Meat Market by Source (Soy, Wheat, Blends, Pea), Product (Burger Patties, Strips & Nuggets, Sausages, Meatballs), Type (Beef, Chicken, Pork, Fish), Distribution Channel, Storage and Region - Global Forecast to 2027*, MKTS. & MKTS. (July 2022), <https://www.marketsandmarkets.com/Market-Reports/plant-based-meat-market-44922705.html> [<https://perma.cc/4EVb-Q8D6>]; Emily Monaco, *How Meat Eaters, not Vegans, are Driving the Plant-Based Foods Boom, According to Industry Experts*, BUS. INSIDER (Sept. 21, 2020), <https://www.businessinsider.com/plant-based-meats-flexitarians-vegetarians-vegans-market-revolution-2020-9> [<https://perma.cc/DK59-FDRT>]; Fatma Boukid, *Plant-Based Meat Analogues: From Niche to Mainstream*, EUROPEAN FOOD RSCH. & TECH., Oct. 2021, at 298 <https://link.springer.com/article/10.1007/s00217-020-03630-9> [<https://perma.cc/U5R5-KE2X>].

3. SHURTLEFF & AOYAGI, *supra* note 1, at 8–9.

4. *The Beyond & the Beast: A Tale of Two Burgers*, BEYOND MEAT: BLOG (Dec. 21, 2016), <https://www.beyondmeat.com/en-US/whats-new/the-beyond-the-beast-a-tale-of-two-burgers> [<https://perma.cc/3238-LGRT>].

5. Impossible Foods Inc., *Impossible Foods*, [https://assets.ctfassets.net/hhv516v5f7sj/1sCviUjx24iZXOOJNmiFn/41d41396647482fd4a5d45fb60915b1f/CEL\\_IMP\\_CompanyOverview\\_English\\_210730.pdf](https://assets.ctfassets.net/hhv516v5f7sj/1sCviUjx24iZXOOJNmiFn/41d41396647482fd4a5d45fb60915b1f/CEL_IMP_CompanyOverview_English_210730.pdf) [<https://perma.cc/ZTM9-5GE2>] (last visited Nov. 15, 2022) (company overview).

6. *See Our Products*, BEYOND MEAT, <https://www.beyondmeat.com/en-CA/products/> [<https://perma.cc/6X8Y-XTRW>] (“Imagine a world where we’ve taken the animal off the table, while still delivering the meaty, plant-based, better-for-you meals you crave. That world is this one, and those meals are Beyond.”); *Our Mission*, BEYOND MEAT, <https://www.beyondmeat.com/en-US/mission/>

of plant-based meat alternatives can help arrest climate deterioration by reducing the significantly negative impact of meat consumption.<sup>7</sup> Both target meat-eaters unlikely to switch to plant-based meat alternatives unless those alternatives perfectly replicate the experience of eating meat.<sup>8</sup> These companies have generally succeeded in creating such substitutes; it is difficult to differentiate these plant-based burgers from beef-based burgers.<sup>9</sup>

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[<https://perma.cc/5NQY-7UKQ>] (“We combine expert innovation with simple, non-GMO ingredients to deliver the meaty experience you crave without the compromise.”); Impossible Foods Inc., *Impossible Foods Introduces Impossible Burger at Momofuku Nishi*, CISION PR NEWSWIRE (July 26, 2016), <https://www.prnewswire.com/news-releases/impossible-foods-introduces-impossible-burger-at-momofuku-nishi-300303881.html> [<https://perma.cc/W3RW-Q3JU>] (“The Impossible Burger looks, cooks, smells, sizzles, and tastes like conventional ground beef but is made entirely from plants. Among the breakthroughs that make the Impossible Burger unique is the discovery that a molecule called ‘heme’ is the magic ingredient that makes meat look, cook and taste gloriously meaty.”).

7. Tad Friend, *Can a Burger Help Solve Climate Change?*, NEW YORKER (Sept. 23, 2019), <https://www.newyorker.com/magazine/2019/09/30/can-a-burger-help-solve-climate-change> [<https://perma.cc/2F7W-LABH>] (“The use of animals in food production is by far the most destructive technology on earth. ‘We see our mission as the last chance to save the planet from environmental catastrophe’ . . . [Brown] understood that the facts [of climate change and the large role of meat consumption] didn’t compel people as strongly as their craving for meat, and that shame was counterproductive. So he’d use the power of the free market to disseminate a better, cheaper replacement. And, because sixty per cent of America’s beef gets ground up, he’d start with burgers.”) (quoting Pat Brown); David Gelles, *The “Hedonistic Altruism” of Plant-Based Meat*, N.Y. TIMES (Aug. 27, 2021), [www.nytimes.com/2021/08/27/business/ethan-brown-beyond-meat-corner-office.html](http://www.nytimes.com/2021/08/27/business/ethan-brown-beyond-meat-corner-office.html) [<https://perma.cc/7397-8UTP>] (“Ethan Brown contends there are several main benefits to consuming plant-based foods instead of animal meat. It leads to fewer greenhouse gas emissions, it consumes fewer natural resources and it is better for human health . . . ‘You can focus on one thing, which is to simply change the protein, and have a real impact on four global issues that fascinate me: the climate, natural resources, animal welfare and human health.’”) (quoting Ethan Brown).

8. Andrea Kramar & Catherine Clifford, *How Beyond Meat Became a \$550 Million Brand, Winning Over Meat-Eaters With a Vegan Burger That “Bleeds”*, CNBC (Jan. 22, 2019), [www.cnbc.com/2019/01/21/how-bill-gates-backed-vegan-beyond-meat-is-winning-over-meat-eaters.html](http://www.cnbc.com/2019/01/21/how-bill-gates-backed-vegan-beyond-meat-is-winning-over-meat-eaters.html) [<https://perma.cc/47SS-LL2M>] (“[W]e’re reaching mainstream consumers that are interested in healthier forms of meat’ . . . Brown says the company found that 93 percent of the consumers in conventional grocery stores that are buying a Beyond Meat product are also putting animal meat [in] their basket. ‘So they’re buying not only plant based meat, but they’re buying animal meat and that’s a really important breakthrough for us,’ Brown tells CNBC Make It.”) (quoting Patrick Brown); *Dr. Pat Brown, CEO, Impossible Foods*, CNBC (Oct. 29, 2019), <https://www.cnbc.com/dr-pat-brown-transcript/> [<https://perma.cc/6WLJ-MCHM>] (“In terms of who the actual consumers of our products are intended to be, it’s not vegetarians. We are entirely devoted to making delicious products for meat lovers. We are all about pleasing meat lovers. I’m vegetarian. I’ve been vegetarian for most of my life. I love vegetarians. But we’re not here to serve vegetarians.”).

9. Mariana Lamas, *How Scientists Make Plant-Based Foods Taste and Look More Like Meat*, CONVERSATION (May 5, 2021), <https://theconversation.com/how-scientists-make-plant-based-foods-taste-and-look-more-like-meat-156839> [<https://perma.cc/ZJ3D-B5VF>] (“Burger King Sweden created menu item where customers would have a 50-50 chance of getting a meat burger or a plant-based one. To find out, they had to scan the burger box in Burger King’s app. The results: 44 per cent guessed wrong—customers couldn’t tell the difference.”).

If it is true that these alternatives will drastically reduce consumption of beef, they would provide a significant benefit to human and nonhuman occupants of the earth because beef, the second most popular source of animal protein, has a considerably more damaging environmental footprint than other animal-based foods.<sup>10</sup> According to research reported in 2014, “[beef] causes about one-fifth of global greenhouse gas emissions, and is the key land user and source of water pollution by nutrient overabundance. It also competes with biodiversity, and promotes species extinctions.”<sup>11</sup> Of particular importance to those who care about animal welfare, both companies argue that these burgers will significantly reduce consumption of cows,<sup>12</sup> whose lives and deaths are filled with tremendous human-inflicted suffering.<sup>13</sup>

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10. Gidon Eshel, Alon Shepon, Tamar Makov & Ron Milo, *Land, Irrigation Water, Greenhouse Gas, and Reactive Nitrogen Burdens of Meat, Eggs, and Dairy Production in the United States*, 111 PROC. NAT’L ACAD. SCI. U.S. AM. 11996, 11996 (2014) <https://DOI.ORG/10.1073/PNAS/140218331> [<https://perma.cc/M7DX-W4GM>] (“Beef, the least efficient against all four metrics [extent of land use, amount of necessary irrigation water, extent of greenhouse gas emission, and reactive nitrogen burdens from animal waste] is the second most popular animal category in the mean US diet, accounting for 7% of all consumed calories. Interestingly, dairy, by far the most popular category, is not more efficient than pork, poultry, or eggs.”); See also Oliver Milman, *Meat Accounts for Nearly 60% of All Greenhouse Gases from Food Production, Study Finds*, THE GUARDIAN (Sept. 13, 2021), <https://www.theguardian.com/environment/2021/sep/13/meat-greenhouses-gases-food-production-study> [<https://perma.cc/Z22B-G8QK>] (“The global production of food is responsible for a third of all planet-heating gases emitted by human activity, with the use of animals for meat causing twice the pollution of producing plant-based foods, a major new study has found.”) (citing Xiaoming Xu, Prateek Sharma, Shijie Shu, Tzu-Shun Lin, Philippe Ciais, Francesco N. Tubiello, Pete Smith, Nelson Campbell & Atul K. Jain, *Global Greenhouse Gas Emissions from Animal-Based Foods Are Twice Those of Plant-Based Foods*, 2 NATURE FOOD 724 (2021) (finding that beef accounts for 25% of greenhouse gas emissions attributable to animal-based commodities) <https://www.nature.com/articles/s43016-021-00358-x> [<https://perma.cc/Z355-JTV8>])).

11. Eshel, Shepon, Makov & Milo, *supra* note 10, at 11996; see also Joseph Poore & Thomas Nemecek, *Reducing Food’s Environmental Impacts Through Producers and Consumers*, 360 SCIENCE 987 (2018) <https://www.science.org/doi/10.1126/science.aag0216> [<https://perma.cc/GM89-7T6W>] (including documentation of high impact of beef).

12. Patrick Greenfield, “Let’s Get Rid of Friggin’ Cows” Says Creator of Plant-Based “Bleeding Burger,” GUARDIAN (Jan. 8, 2021), <https://www.theguardian.com/environment/2021/jan/08/lets-get-rid-of-friggin-cows-why-one-food-ceo-says-its-game-over-for-meat-aoe> [<https://perma.cc/2HLL-KCBN>]; Brown also refers to cows as “technology.” Philippa Nuttall, *Pat Brown: “Farm Animals Are the Most Destructive Technology on Earth,”* NEW STATESMAN (Nov. 17, 2021), <https://www.newstatesman.com/the-environment-interview/2021/11/pat-brown-farm-animals-are-the-most-destructive-technology-on-earth> [<https://perma.cc/EH63-ASSV>].

13. Throughout their lives, cows and animals used in agriculture are subjected to practices that cause suffering. See, for example, research on common practices performed on cows in farms, such as dehorning. Kevin J. Stafford & David J. Mellor, *Addressing the Pain Associated with Disbudding and Dehorning in Cattle*, 135 APPLIED ANIMAL BEHAV. SCI. 226, 229 (2011) <https://www.sciencedirect.com/science/article/abs/pii/S0168159111003236?via%3Dihub>

Although both burgers are intended as hamburger replacements, they are not alike in all aspects. The Impossible Burger is based on soy protein, while the Beyond Burger is based primarily on pea protein.<sup>14</sup> This turns out to be significant because of the greater potential for allergic reactions from soy products than from pea products.<sup>15</sup> Another difference is that the Impossible Burger contains genetically modified material for flavor, aroma, and color enhancement.<sup>16</sup> Soy leghemoglobin (heme) can be derived from root nodules but not in amounts necessary to scale production of the Impossible Burger.<sup>17</sup>

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[<https://perma.cc/S2L2-QPP3>]; Matthew L. Stock, Sarah L. Baldridge, Dee Griffin, & Johann F. Coetzee, *Bovine Dehorning: Assessing Pain and Providing Analgesic Management*, 29 VETERINARY CLINICS OF N. AM.: FOOD ANIMAL PRAC. 103 (2012) <https://pubmed.ncbi.nlm.nih.gov/23438402/> [<https://perma.cc/W7PX-FJWY>]; Heather W. Neave, Rolnei R. Daros, João H. Costa, Marina A.G. von Keyserlingk & Daniel M. Weary, *Pain and Pessimism: Dairy Calves Exhibit Negative Judgement Bias Following Hot-Iron Disbudding*, 8 PLOS ONE, Dec. 2013, at 1, 4 <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0080556> [<https://perma.cc/K6EK-S86V>]; Daniela M. Meléndez, Sonia Marti, Derek B. Haley & Timothy D. Schwinghamer, *Effects of Conditioning, Source, and Rest on Indicators of Stress in Beef Cattle Transported by Road*, 16 PLOS ONE, Jan. 2021, at 1, 4 <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0244854> [<https://perma.cc/6RAP-2H8H>]. In 2019, the global organization World Animal Protection stated that “between Impossible and Beyond estimated sales at national QSRs, around 140,000 pigs and 110,000 cows—or a quarter million total—will exit the food system every year.” Ben Williamson, *Fast Food’s Love of Plant-Based Meat Saves a Quarter Million Animals Per Year*, WORLD ANIMAL PROT.: BLOGS (Dec. 11, 2019), <http://www.worldanimalprotection.us/blogs/fast-foods-love-plant-based-meat-saves-quarter-million-animals-year> [<https://perma.cc/49JC-ABYQ>].

14. See *Impossible Burger*, IMPOSSIBLE FOODS, <https://impossiblefoods.com/products/burger> [<https://perma.cc/7GZ7-WY9E>]; *Beyond Burger*, BEYOND MEAT, [www.beyondmeat.com/en-US/products/the-beyond-burger](http://www.beyondmeat.com/en-US/products/the-beyond-burger) [<https://perma.cc/LUZ3-NY6L>]. Ethan Brown has stated that Beyond also uses proteins from rice and mung bean in its burgers because “[o]ne goal of this innovation is to diversify protein sources.” Larissa Zimmeroff, *The Rise of the Pea: How an Unassuming Legume Emerged as a Frontrunner in the Race to Replace Meat and Dairy*, TIME (August 15, 2019) <https://time.com/5652178/pea-meat-dairy-alternative/> [<https://perma.cc/7VQJ-TYBK>] (quoting Ethan Brown).

15. *Food Allergies*, U.S. FOOD & DRUG ADMIN. (Jan. 31, 2022), <https://www.fda.gov/food/food-labeling-nutrition/food-allergies> [<https://perma.cc/6FPR-8QST>] (listing soybeans as one of the eight foods identified as “major food allergens” in the Food Allergen Labeling and Consumer Protection Act of 2004); see also Steve L. Taylor, Justin T. Marsh, Stef J. Koppelman, Jamie L. Kabourek & Philip E. Johnson, *A Perspective on Pea Allergy and Pea Allergens*, 116 TRENDS IN FOOD SCI. & TECH. 186, 186 (2021) (discussing pea allergies, but suggesting that peas are not likely to be as allergenic as soy) <https://www.sciencedirect.com/science/article/abs/pii/S0924224421004556?via%3Dihub> [<https://perma.cc/K45K-T6Q7>].

16. Amanda Capritto, *Impossible Burger 2.0: How Does It Taste, Is It Safe and Where Can You Get It?*, CNET (Nov. 8, 2019), <https://www.cnet.com/health/nutrition/impossible-burger-everything-you-need-to-know/> [<https://perma.cc/U5MC-EU4P>].

17. Big Brains Podcast, *A Scientist’s Beef with the Meat Industry, with Impossible Foods’ Pat Brown*, UCHICAGO NEWS (July 1, 2021), <https://news.uchicago.edu/big-brains-podcast-impossible->

Accordingly, Impossible engineered yeast cells to produce its genetically engineered heme (GE heme).<sup>18</sup> Beyond uses beet root as a coloring agent that produces “bleeding” characteristic of beef burgers, but Beyond incorporates beet root without use of a genetically modified organism (GMO) such as yeast.<sup>19</sup> While Beyond relies on beet root for color primarily, Impossible claims that its GE heme is important for meat-like flavor more than color enhancement.<sup>20</sup>

This second distinction leads to a third distinction between the two companies’ products: Impossible tested its GE heme on animals, even though it’s not required under FDA rules, while Beyond reports that it did not conduct animal testing.<sup>21</sup> Several organizations that purport to care about the protection of animals supported Impossible, despite the fact that it engaged in lethal animal

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foods-ceo-pat-brown-meat-industry-plant-based-vegetarian [<https://perma.cc/CS6N-GQYG>] (“It took us maybe the better part of a year, spending time out in Midwest soybean fields, digging off root nodules, and using an inverted street sweeper to strip them off the roots. But eventually [we] decided that for a whole variety of reasons, this was not going to be a scalable solution. And at that point we decided, okay, we’re going to express the heme protein in yeast, by engineering the yeast cells to produce the heme protein. The yeast cells, by the way, are completely able of making the heme molecule itself. Every cell has to be able to make heme pretty much, or else they have to be able to scavenge it on every cell on Earth, including yeast. But you need a specific kind of protein to hold that heme molecule, so that it protects it from oxidation. And then, when you cook, it unfolds and releases it, and sets off this explosion of chemistry. So, we engineered yeast to express heme protein, and now we have yeast cells that are world-class professional producers of heme protein.”) (quoting Pat Brown).

18. *Id.*

19. See *Frequently Asked Questions*, BEYOND MEAT, <https://www.beyondmeat.com/en-US/faqs> [<https://perma.cc/4CSK-VH3P>] (“We start with simple plant-based, non-GMO ingredients.”) *Beyond the Headlines: A Clarification Regarding Beyond Meat and Impossible Foods*, BEYOND MEAT (Aug. 15, 2017), <https://www.beyondmeat.com/en-US/whats-new/beyond-the-headlines-a-clarification-regarding-beyond-meat-and-impossiblefoods> [<https://perma.cc/GY8B-MZ65>] (“Beyond Meat does not use GMO ingredients. We believe it is entirely possible to recreate meat directly from plants without GMOs, and we would offer The Beyond Burger as evidence that we’re onto something.”); Capritto, *supra* note 16.

20. Capritto, *supra* note 16; Lydia Mulvany & Deena Shanker, “Blood” Keeps Fake Meat Off Retail Shelves, L.A. TIMES (Dec. 27, 2018), <https://www.pressreader.com/usa/los-angeles-times/20181227/281921659164714> [<https://perma.cc/9D5E-H2YY>].

21. Yes, *the Impossible Burger Is Vegan*, BETTER EATING INT’L. (May 15, 2019), <https://bettereating.org/updates/yes-the-impossible-burger-is-vegan/> [<https://perma.cc/B7TX-SXH4>] (“Some have argued that products made by companies like Impossible Foods . . . should not be consumed by vegans because the companies tested on animals.”); *Beyond the Headlines: A Clarification Regarding Beyond Meat and Impossible Foods*, *supra* note 19 (“Beyond Meat has never tested our products or ingredients on animals. Our scientists are focused on identifying existing plant-based ingredients that emulate the properties of meat. For example, to achieve the beefy red color of our Beyond Burger, they tested hundreds of vegetables and fruit extracts, before settling on a combination of beet powder and annatto.”).

tests.<sup>22</sup> This Article thoroughly discusses the lack of necessity to engage in such testing for any legal or marketing reasons and argues that such organizations should consider that when advocating for particular companies or products. Since development of bioengineered plant-based foods can be expected to continue, investors that consider themselves animal-protective should require developers to use non-animal tests to comply with FDA requirements.

What of consumers? Do they care about these differences of protein source, inclusion of GMOs, and animal testing? As of 2019, it was reported that more than fifty percent of consumers had never heard of pea protein.<sup>23</sup> Soy is a relatively cheaper ingredient, which consumers may like, but pea protein may be preferable to consumers as they become increasingly aware of its particular advantages, such as the lower allergenicity of pea protein, the prevalence of non-GMO crops, and potentially greater sustainability of pea farming as compared to soybean farming.<sup>24</sup> It is well-established that consumers are wary of GMOs in food.<sup>25</sup> At the least, the use of GMOs would not increase consumer

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22. The Good Food Institute's CEO, Bruce Friedrich has spoken out in support of Impossible Foods on a number of occasions, including a specific blog "*Impossible Foods? No Question!*" from 2018, where he states: "Humane foods took another step forward this week when the Food and Drug Administration issued a 'no questions' letter to Impossible Foods regarding the safety of the Impossible Burger's soy leghemoglobin (heme) . . ." Bruce Friedrich, *Impossible Foods? No Question!*, GOOD FOOD INST. (July 24, 2018), <https://gfi.org/blog/impossible-foods-no-question/> [<https://perma.cc/54LV-LB8K>]; see also *Yes, the Impossible Burger Is Vegan*, *supra* note 21 (praising Impossible Foods for creating a beef substitute that makes "veganism more normalized, convenient, and accessible to millions of people, including and especially those living in rural areas," arguing that animal testing should not change the "vegan" characterization of Impossible Burger, and stating erroneously that "[w]hile FDA policy doesn't specifically require animal testing, historical precedent is that the FDA will only grant approval if the applicant performs a feeding or digestibility study on rats or mice"). Open Philanthropy invested in Impossible Foods in order to advance the development of plant-based foods and based on the beliefs that the founder, Patrick Brown, is an outstanding scientist, that bioengineered products may be more transformative than other plant-based alternatives, and that the Impossible Burger's taste would be appealing. *Impossible Foods – R&D Investment*, OPEN PHILANTHROPY (Mar. 2017), <https://www.openphilanthropy.org/grants/impossible-foods-rd-investment/> [<https://perma.cc/S9KB-5MSY>].

23. Cathy Siegner, *More Than 50% of Consumers Have Never Heard of Pea Protein*, *Survey Finds*, FOOD DIVE (Oct. 17, 2019), <https://www.fooddive.com/news/more-than-50-of-consumers-have-never-heard-of-pea-protein-survey-finds/564143/> [<https://perma.cc/RUS8-D3BB>].

24. Fatou Ndiaye, Tri Vuong, Jairo Duarte, Rotimi E. Aluko & Chantal Matar., *Anti-Oxidant, Anti-Inflammatory and Immunomodulating Properties of an Enzymatic Protein Hydrolysate from Yellow Field Pea Seeds*, 51 EUR J. NUTRITION 29, 33–36 (2012) <https://pubmed.ncbi.nlm.nih.gov/21442413/> [<https://perma.cc/C8DB-2SEQ>]; Zimberoff, *supra* note 14.

25. Cary Funk, *About Half of U.S. Adults Are Wary of Health Effects of Genetically Modified Foods, but Many Also See Advantages*, PEW RSCH. CTR. (Mar. 18, 2020), [www.pewresearch.org/fact-tank/2020/03/18/about-half-of-u-s-adults-are-wary-of-health-effects-of-genetically-modified-foods-](http://www.pewresearch.org/fact-tank/2020/03/18/about-half-of-u-s-adults-are-wary-of-health-effects-of-genetically-modified-foods-)



receptivity to a product when an equivalent product does not contain GMO ingredients.

What about the third difference: animal testing of food ingredients? Some research suggests that people care about animal welfare<sup>26</sup> and that many prefer personal care items not tested on animals.<sup>27</sup> However, it has been unclear if consumers would treat food products differently from personal care products. Nevertheless, several major food companies, including Kellogg's, General Mills, and Coca-Cola, have made a point of letting consumers know that they would not test on animals unless explicitly required by governmental agencies,<sup>28</sup> presumably because they believe it would be a negative for consumers if they did. As will be discussed in Part I, FDA guidelines do not require animal testing of food ingredients. Accordingly, these companies' assurances can be understood as a commitment to avoid animal testing when conducting food ingredient safety assessments for which formal FDA approval is not required and to work with the FDA to use non-animal tests when formal FDA review is required.<sup>29</sup>

So, how is it that a new, remarkably innovative company like Impossible would test a new food ingredient, GE heme, on animals, when there are established food companies that have committed to not testing on animals? According to Impossible, "some large chains and several foreign countries

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but-many-also-see-advantages/ [https://perma.cc/7H88-A7F9]; Sydney E. Scott, Yoel Inbar, Christopher D. Wirz, Dominique Brossard & Paul Rozin, *An Overview of Attitudes Toward Genetically Engineered Food*, 38 ANN. REV. NUTRITION 459, 459 (2018), <https://www.annualreviews.org/doi/abs/10.1146/annurev-nutr-071715051223> [https://perma.cc/7BPL-4378] ("Laypeople tend to see genetically engineered food as dangerous and offering few benefits.").

26. Amber Itle & Susan Kerr, *Animal Welfare: A Complex Concept*, 5 WHATCOM AG MONTHLY, no. 6, 2016, at 1, 2 <https://extension.wsu.edu/wam/animal-welfare-a-complex-concept/> [https://perma.cc/2WBP-89AX].

27. Kerry Postlewhite, *Brands Can No Longer Ignore the 8.3 Million People Who Want End to Animal Testing*, REUTERS EVENTS (Oct. 14, 2018), <https://www.reutersevents.com/sustainability/brands-can-no-longer-ignore-83-million-people-who-want-end-animal-testing%20%5b> [https://perma.cc/G5C4-NUV9].

28. *Kellogg Company Animal Welfare Commitment*, KELLOGG, <https://crreport.kelloggcompany.com/ppm-animal-welfare-commitment> [https://perma.cc/J57J-ZRPD]; *Animal Welfare Policy*, GEN. MILLS, <https://www.generalmills.com/how-we-make-it/healthier-planet/sustainable-and-responsible-sourcing/animal-welfare> [https://perma.cc/E9S3-M3CY]; *Animal Health and Welfare Guiding Principles*, COCA-COLA CO. (June 30, 2020), <https://www.coca-colacompany.com/policies-and-practices/animal-health-and-welfare-guiding-principles> [https://perma.cc/HL7J-ELR3].

29. See *infra* Part I (describing FDA safety assessment requirements that do not require formal FDA approval and those that do).

would sell our product only when we received a ‘no questions’ letter<sup>30</sup> from the FDA, which required a rat-feeding study.”<sup>31</sup> Since thousands of substances in the food supply have not been assessed for safety,<sup>32</sup> it seems unlikely that grocery stores would require such a letter. The major food companies listed above and several others no longer conduct animal testing,<sup>33</sup> yet their products are readily available in grocery stores. It also seems unlikely that foreign countries would rely on the United States FDA for safety assessments. For instance, China and Europe have not yet opened their markets to Impossible’s GMO-containing products, despite the fact that the FDA does not regulate use of GMO ingredients other than requiring labeling.<sup>34</sup>

Even if particular grocery chains or foreign countries were to require an FDA “no questions” letter, the central problem with Impossible’s argument is that it conflates receipt of a “no questions” letter from the FDA with a

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30. A “no questions” letter means that the FDA has reviewed the safety assessment methodology and results and believes that the producer’s assessment meets FDA safety assessment requirements. *See infra* Part I.

31. *See PETA: The Unofficial Correction*, IMPOSSIBLE FOODS (July 30, 2018), [https://assets.ctfassets.net/hhv516v5f7sj/q95roYbzJAMea22kkiwQ2/7256a4ab2c24d0ea4a903991ba7150b1/PETA\\_The\\_Unofficial\\_Correction\\_FINAL.pdf](https://assets.ctfassets.net/hhv516v5f7sj/q95roYbzJAMea22kkiwQ2/7256a4ab2c24d0ea4a903991ba7150b1/PETA_The_Unofficial_Correction_FINAL.pdf) [<https://perma.cc/Y9NF-S67T>]; *See also* Mulvany & Shanker, *supra* note 20 (stating that the FDA treated Impossible’s GE heme as a color additive, leading to more stringent tests, but not reporting that animal tests are necessary).

32. *See, e.g.*, Maricel V. Maffini, Thomas G. Neltner & Sarah Vogel, *We Are What We Eat: Regulatory Gaps in the United States That Put Our Health at Risk*, 15 PLOS BIOLOGY, Dec. 2017, at 1, 5 <https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.2003578> [<https://perma.cc/W49J-N3RU>] (“Certainly, when it comes to managing the safety of chemicals in food, the FDA has been sluggish to modernize its science and is falling far short in effectively accounting for the safe use of thousands of chemicals in use today.”).

33. *See Victory! Global Food Industries Ditches Deadly Animal Tests—See the List*, PETA, <https://www.peta.org/features/victories-food-drink-companies-refuse-animal-tests/> [<https://perma.cc/PV6D-CYJJ>].

34. As of April 21, 2021, Impossible still lacked access to China and European countries because they ban GMO foods and food ingredients. Siddharth Cavale & Uday Sampath Kumar, *Analysis: Not Impossible, Just Unlikely: Wall Street’s Plant-Based Love Wilts*, REUTERS (Apr. 21, 2021), <https://www.reuters.com/business/faux-meat-growth-doubts-give-market-food-thought-impossible-2021-04-21/> [<https://perma.cc/E8QN-XZDN>] (“Impossible’s burgers and sausages are available at only 20,000 stores globally, versus Beyond’s 122,000 and it is still seeking regulatory approval in Europe and mainland China, where the genetically modified yeast it uses is banned.”). With regard to FDA’s lack of GMO regulations, see *New Plant Variety Regulatory Information*, U.S. FOOD & DRUG ADMIN. (Mar. 30, 2020) <https://www.fda.gov/food/food-new-plant-varieties/new-plant-variety-regulatory-information> [<https://perma.cc/W6CE-M3PL>] (“The FDA regulates human and animal food from plants, including plants produced through use of genetic engineering and genome editing, under the Federal, [sic] Food, Drug, and Cosmetic Act (FD&C Act) and holds them to the same standards as all foods produced, processed, stored, shipped or sold in the United States.”); Katharine Van Tassel, *Genetically Modified Plants Used for Food, Risk Assessment and Uncertainty Principles: Does the Transition From Ignorance to Indeterminacy Trigger the Need for Post-Market Surveillance?*, 15 B.U. J. SCI. & TECH. L. 220, 239 (2009).

requirement of animal testing. In fact, as will be shown in more detail in Part I, the FDA does not require animal testing of food ingredients—not even color additives, which require formal review.<sup>35</sup> Indeed, requiring animal testing at this point, when the science of product safety assessment has developed more reliable safety assessment tools, would negatively impact consumer safety and come at the cost of inflicting terrible and unnecessary animal suffering and death. Use of alternative, more reliable safety assessment tools is important for both human and animal welfare, and the FDA does not prevent a company from using those tools.

From a food marketing point of view, it makes little sense to test on animals, especially when other companies are making clear to consumers that they no longer test on animals. This is true unless the manufacturer is targeting meat-eaters, believes that those consumers do not care about animal testing, and safety assessments based on animals are the fastest and cheapest way to get FDA approval. As will be explored in Part III, such a belief about meat-eating consumers—or any consumers—would be misguided. Research conducted by the author and Professor Adam Feltz in late January 2022 reveals that consumers, including meat-eating consumers, clearly reject animal testing of food ingredients.<sup>36</sup>

The idea that animal testing does not reliably predict risk to humans and comes at too high a price for humans as well as animals is gaining traction. In September 2022, the U.S. Senate passed by unanimous consent the FDA Modernization Act 2.0 to end FDA's mandate to test experimental drugs on animals before clinical trials in humans.<sup>37</sup> In October 2021, when a similar bill was introduced in the Senate,<sup>38</sup> the justification was both the lack of reliability of animal testing and regard for animals used in those tests. According to one of the co-sponsors of both bills, Senator Cory Booker (D-New Jersey), “Thanks to modern scientific innovation, the use of animal toxicity testing for experimental drugs has become increasingly obsolete . . . . This legislation will eliminate unnecessary suffering for countless animals when scientifically

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35. 21 C.F.R. § 70.10 (2021). For petition requirements for color additives, see 21 C.F.R. § 71.1 (2021). Soy leghemoglobin is considered a color additive. Peter Cassell, *FDA In Brief: FDA Approval of Soy Leghemoglobin As a Color Additive Is Now Effective*, U.S. FOOD & DRUG ADMIN. (Dec. 17, 2019), <https://www.fda.gov/news-events/fda-brief/fda-brief-fda-approval-soy-leghemoglobin-color-additive-now-effective> [<https://perma.cc/HFJ8-38ZV>].

36. This research included three pre-tests to refine the design and to determine the correct sample size for the survey. See *infra* Part III.B.

37. FDA Modernization Act 2.0, S. 5002, 117<sup>th</sup> Cong. (2022).

38. FDA Modernization Act of 2021, S. 2952, 117<sup>th</sup> Cong. (2021). Another similar bill, sponsored by Rep. Vern Buchanan (R-Florida), was introduced in the House of Representatives in April 2021. FDA Modernization Act of 2021, H.R. 2565, 117<sup>th</sup> Cong. (2021).

reliable alternative testing methods are available.”<sup>39</sup> Similarly, the sponsor of both bills, Senator Rand Paul (R-Kentucky), said that “[t]he FDA Modernization Act would accelerate innovation and get safer, more effective drugs to market more quickly by cutting red tape that is not supported by current science. It would also prevent the needless suffering and death of animal test subjects—which is something I think both Republican[s] and Democrats can agree needs to end.”<sup>40</sup>

All things considered, it seems this would be a bad time for new and otherwise innovative food companies to use outdated animal testing for food ingredient safety assessments. This is particularly true since the FDA already has a “Predictive Toxicology Roadmap” for the development and evaluation of emerging toxicological methods for use in FDA regulatory review.<sup>41</sup>

This Article begins in Part I with the history and content of FDA rules regulating pre-market safety assessments of novel food ingredients. It is clear from the FDA’s own guidelines as published in its “Redbook 2000” (Redbook) that the testing protocols it provides as examples are not required tests. That these are but guidelines was confirmed by the Ninth Circuit in May of 2021 in the case of *Center for Food Safety v. U.S. FDA*, in which the plaintiff claimed that the FDA’s approval of Impossible’s GE heme was insufficient.<sup>42</sup> Part II considers whether there is any reason a reasonably risk-averse food producer should test new ingredients on animals to reduce liability exposure from consumer lawsuits alleging injury from a food ingredient. Included in Part II is consideration of how courts evaluate the reliability and applicability of animal test-based safety assessments. Because food product litigation concerning additives is sparse, this section considers judicial evaluation of such evidence in the analogous context of pharmaceutical product litigation. Judges are skeptical that animal test data can reliably predict human safety risk because of

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39. Press Release, Office of Senator Cory Booker, Booker, Paul Introduce Bipartisan FDA Modernization Act To End Animal Testing Mandates (Oct. 7, 2021), <https://www.booker.senate.gov/news/press/booker-paul-introduce-bipartisan-fda-modernization-act-to-end-animal-testing-mandates> [https://perma.cc/6P9A-A3QE].

40. *Id.* See also the press release issued by co-sponsor, John Kennedy (R-Louisiana), stating: “Testing new drugs on animals is often risky for both animals and people. The FDA Modernization Act would allow drug producers to improve safety by using more modern, humane and effective testing.” Press Release, Office of Senator Kennedy, Kennedy, Paul Introduce Bill To Improve Drug Safety and Reduce Animal Testing (Oct. 7, 2021), <https://www.kennedy.senate.gov/public/2021/10/kennedy-paul-introduce-bill-to-improve-drug-safety-and-reduce-animal-testing> [https://perma.cc/R3ZJ-Z2ZU].

41. *FDA’s Predictive Toxicology Roadmap*, U.S. FOOD & DRUG ADMIN. (Sept. 25, 2020), <https://www.fda.gov/science-research/about-science-research-fda/fdas-predictive-toxicology-roadmap> [https://perma.cc/M9WT-UFWX].

42. *Ctr. for Food Safety v. U.S. Food & Drug Admin.*, 854 F. App’x. 865 (9th Cir. 2021).

the difficulty of extrapolation from animal test subjects to humans, particularly when animals are subjected to massive doses to which humans would not be exposed. Part III reports the perspective of consumers, beginning with a brief consideration of the history of development of plant-based meat substitutes in the United States. Part III also describes results from the survey conducted by the author and Professor Adam Feltz in late January 2022, which was designed to reveal attitudes toward animal testing to assess safety and toxicity of food ingredients, beliefs about whether FDA rules do or should require animal testing, and perspectives about product labeling when manufacturers or ingredient suppliers have tested ingredients on animals.

The analysis presented in each of these Parts leads consistently in the direction of avoiding animal testing as unnecessary, inadequately protective of public safety, and as oppositional to consumer preferences for both food safety and protection of animal welfare. The Conclusion discusses a few implications of the information and perspectives provided in Parts I through III. These include the need for consumer safety organizations, investors, and animal protection organizations to seek the reduction of animal testing as a matter of improved consumer safety and reduced infliction of suffering on animals; the desirability of product safety assessment companies increasing capacity to conduct non-animal safety assessment tests; the need for the FDA to update its guidelines for product safety assessments; the wisdom and feasibility of the FDA requiring companies that want to use animal tests instead of non-animal tests to seek prior FDA approval in all cases; and provision of information to consumers about products whose ingredients have been tested on animals so that they can defend with their consumption dollars values of consumer safety and respect for the welfare of animals.

#### PART I. FOOD AND DRUG ADMINISTRATION RULES REGARDING NOVEL FOOD INGREDIENT TOXICITY TESTING

This Part examines the nature of food additive safety assessment required under federal law and whether animal testing is necessary. This is an important pair of questions. Animal testing has longevity as a chemical safety assessment method, but longevity does not necessarily confer reliability, especially as scientists continually develop new testing methods based on technological developments and new understandings of what to measure. There is ever-increasing evidence that animal methods of testing are not reliable for predicting toxicity in humans.<sup>43</sup> There is also increasing evidence that non-

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43. See, e.g., Donald Ingber, *Human Organs-on-Chips*, WYSS INST., <https://wyss.harvard.edu/technology/human-organs-on-chips> [https://perma.cc/KR8T-2C68]; Aysha

animal methods can be effective predictors of toxicity in humans, and there are several methods available now.<sup>44</sup> In light of significant and numerous developments in alternative testing methodology, consumer safety advocates should be supporting not just more safety assessments of substances with which consumers have contact; they should be supporting use of the most reliable assessment techniques available. If despite this evidence, the law requires

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Akhtar, *The Flaws and Human Harms of Animal Experimentation*, 24 CAMBRIDGE Q. OF HEALTHCARE ETHICS 407 (2015); Gail A. van Norman, *Limitations of Animal Studies for Predicting Toxicity in Clinical Trials: Is It Time To Rethink Our Current Approach?*, 4 JACC: BASIC TO TRANSLATIONAL SCI. 845 (2019); Kathy Archibald, Robert Coleman & Tamara Drake, *Replacing Animal Tests To Improve Safety for Humans*, in ANIMAL EXPERIMENTATION: WORKING TOWARDS A PARADIGM CHANGE 417 (Kathrin Herrmann & Kimberley Jayne eds., 2019). Systematic reviews that have been conducted generally reveal the unreliability and poor predictability of animal tests. See Pablo Perel, Ian Roberts, Emily Sena, Philipa Wheble, Catherine Briscoe, Peter Sandercock, Malcolm Macleod, Luciano E. Mignini, Pradeep Jayaram & Khalid S. Khan, *Comparison of Treatment Effects Between Animal Experiments and Clinical Trials: Systematic Review*, 334 BMJ, Jan. 2007 <https://www.bmj.com/content/334/7586/197> [<https://perma.cc/5J4H-2WZY>]; Fiona Godlee, *How Predictive and Productive Is Animal Research?*, 348 BMJ, Jun. 2014 <https://www.bmj.com/content/348/bmj.g3719> [<https://perma.cc/8F3F-9L7Y>]; Michael Benatar, *Lost in Translation: Treatment Trials in the SOD1 Mouse and in Human ALS*, 26 NEUROBIOLOGY OF DISEASE 1 (2006); Aysha Z. Akhtar, John J. Pippin & Chad B. Sandusky, *Animal Studies in Spinal Cord Injury: A Systematic Review of Methylprednisolone*, 37 ALTERNATIVES TO LABORATORY ANIMALS 43 (2009); Pandora Pound & Michael B. Bracken, *Is Animal Research Sufficiently Evidence Based To Be a Cornerstone of Biomedical Research?*, 348 BMJ, May 2014 <https://www.bmj.com/content/348/bmj.g3387> [<https://perma.cc/8TP4-RVD8>].

44. Ingber, *supra* note 43. Johns Hopkins University's Center for Alternatives to Animal Testing, <https://caat.jhsph.edu/> [<https://perma.cc/U6E4-C8PM>], contains an extensive list of alternatives as well as resources for more information and assistance with them. Researchers are involved with governmental agencies to reduce or eliminate animal testing. See, e.g., Holly Ober, *Finding Alternatives to Animal Testing*, UNIV. CAL. (Sept. 26, 2019), <https://www.universityofcalifornia.edu/news/finding-alternatives-animal-testing> [<https://perma.cc/JF6C-352A>]. PETA maintains a lengthy list of viable alternatives to animal testing. *Alternative Methods Validated for Regulatory Use*, PETA, <https://www.thepsci.eu/alternatives/> [<https://perma.cc/MBA7-Q6MM>]. The Animal-Free Safety Assessment Collaboration (AFSA) provides information regarding the use of animals in safety assessment, the drawbacks of such testing, and non-animal testing alternatives. *Why Animal-Free*, AFSA, [https://www.afsacollaboration.org/why-animal-free-faq/#alternatives\\_to\\_animal\\_testing](https://www.afsacollaboration.org/why-animal-free-faq/#alternatives_to_animal_testing) [<https://perma.cc/B4W9-Q9WJ>]. There is also scholarship on the subject. See, e.g., Rob B. M. de Vries, Marlies Leenaars, Joppe Tra, Robbertjan Huijbregtse, Erik Bongers, John A. Jansen, Bert Gordjin & Merel Ritskes-Hoitinga, *The Potential of Tissue Engineering for Developing Alternatives to Animal Experiments: A Systematic Review*, 9 J. TISSUE ENG'G & REGENERATIVE MED. 771 (2015); Jagdish Rai & Kuldeep Kaushik, *Reduction of Animal Sacrifice in Biomedical Science & Research Through Alternative Design of Animal Experiments*, 26 SAUDI PHARM. J. 896 (2018); Agnes L. Karmaus, Hedi Bialk, Suzanne Fitzpatrick & Mansi Krishan, *State of the Science on Alternatives to Animal Testing and Integration of Testing Strategies for Food Safety Assessments: Workshop Proceedings*, 110 REGUL. TOXICOLOGY & PHARMACOLOGY, Nov. 2019 <https://www.sciencedirect.com/science/article/pii/S027323001930279X?via%3Dihub> [<https://perma.cc/V39D-Zh2Z>].

animal testing to assess safety of food additives, then food safety will be compromised, and animals will be needlessly subjected to tremendous suffering.<sup>45</sup>

PETA is one of a few organizations that maintain lists of numerous tests, along with information about their lower reliability than non-animal testing methods.<sup>46</sup> For purposes of this Article, however, perhaps consideration of one test that is still commonly in use will suffice to convey the magnitude of suffering inflicted on animals. The “lethal dose 50” (LD50) is a type of “acute toxicity test,” described as follows by People for the Ethical Treatment of Animals:

To determine the danger of a single short-term exposure to a product or chemical, the substance is administered to animals (usually rodents) in extremely high doses via force-feeding, forced inhalation, and/or eye or skin contact. Animals in the highest-dose groups often endure severe abdominal pain, diarrhea, convulsions, seizures, paralysis, or bleeding from the nose, mouth, or genitals before they ultimately die or are killed . . . . In [the LD50] test, groups of animals are force-fed increasing amounts of a test substance or increasing amounts are applied to their skin until half of them die.<sup>47</sup>

Importantly, this test was not subjected to validation analysis until recently, and, in fact, it is a quite poor predictor (65% accuracy) when compared to human cell-line tests (75%–85% accuracy).<sup>48</sup> It is also important to note that

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45. There is little incentive for entities that test on animals to report their suffering. Such reporting is left to animal protection nonprofits. *See, e.g., Animal Testing Facts and Alternatives*, PETA, <https://www.peta.org/issues/animals-used-for-experimentation/animal-testing-101/> [<https://perma.cc/B6GX-P9PX>]; *Taking Suffering Out of Science*, HUMANE SOC’Y U.S., <https://www.humanesociety.org/all-our-fights/taking-suffering-out-science> [<https://perma.cc/87N2-FBJP>]; *Testing Chemicals on Animals*, ROYAL SOC’Y FOR PREVENTION CRUELTY TO ANIMALS, <https://www.rspca.org.uk/adviceandwelfare/laboratory/testingchemicals> [<https://perma.cc/3EL2-8UNG>]; There are various tests. *Animals Used for Experimentation Factsheets*, PETA, <https://www.peta.org/issues/animals-used-for-experimentation/animals-used-experimentation-factsheets/> [<https://perma.cc/J8LJ-QBRQ>].

46. *Toxic and Tragic Consequences of Product Testing on Animals*, PETA, <https://www.peta.org/issues/animals-used-for-experimentation/animals-used-experimentation-factsheets/product-testing-toxic-tragic/> [<https://perma.cc/873N-W4FX>].

47. *Id.*

48. *Id.* (“One international study that examined the results of rat and mouse LD50 tests for 50 chemicals found that these tests predicted toxicity in humans with only 65 percent accuracy—while a series of human cell-line tests was found to predict toxicity in humans with 75 to 80 percent accuracy.”) (citing B. Ekwall, *Overview of the Final MEIC Results: II. The In Vitro–In Vivo Evaluation, Including the Selection of a Practical Battery of Cell Tests for Prediction of Acute Lethal Blood Concentrations in Humans*, 13 TOXICOLOGY IN VITRO 665 (1999)).

there are less severe tests available, which Impossible used.<sup>49</sup> That said, the main driver of this section is the lack of necessity to inflict *any* suffering on animals. Whatever one might think about how much suffering is acceptable to inflict on animals, lack of necessity to do it at all makes *any* amount of suffering ethically problematic. Thus, the question of legal necessity takes on particular importance.

Considering the highly questionable safety benefits to humans and the infliction of suffering of animals, it is important to know what FDA regulations and the FDA require for assessing safety of food ingredients. To answer this question, it is necessary to consider the history through which the law developed in this area because it partially explains current FDA decision-making.

#### *A. History and Structure of Food and Drug Administration Requirements*

The law that governs this area was enacted in 1958 when the 1938 Food Drug and Cosmetic Act (FDCA) was amended to require premarket approval by the FDA for new food ingredients.<sup>50</sup> Its stated purpose was to charge FDA with preventing the use of unsafe food ingredients.<sup>51</sup> At that time, FDA estimated that only half of the chemicals currently used in food had been affirmatively found to be safe.<sup>52</sup> Current estimates are difficult to derive, but there is little doubt that the number of ingredients subjected to explicit FDA review is far less than the number of ingredients in commerce.<sup>53</sup> As explained

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49. Those tests included the following: Subacute Toxicity 14-Day test (48 animals) as a precursor to a 28-Day Repeated Dose Toxicity test (80 animals), and a 28-Day Investigative Study in Rats with 14-Day Estrous Cycle Pre-Screen (60 female animals and involving vaginal lavage). Rachel Z. Fraser, Mithila Shitut, Puja Agrawal, Odete Mendes & Sue Klapholz, *Safety Evaluation of Soy Leghemoglobin Protein Preparation Derived From Pichia pastoris, Intended for Use as a Flavor Catalyst in Plant-Based Meat*, 37 INT'L J. TOXICOLOGY 241, 244–60 (2018). Experimental observations included ophthalmologic evaluations, clinical observations, body weights, food consumption, clinical pathology including blood chemistry, hematology, coagulation, and urinalysis, gross necropsy, organ weights, and histopathology. *Id.*

50. Paul R. Hanlon, Joy Frestedt & Kelly Magurany, *GRAS from the Ground Up: Review of the Interim Pilot Program for GRAS Notification*, 105 FOOD & CHEM. TOXICOLOGY 140, 140 (2017); see also Carrie A. Scufari, *Substances Generally Recognized as Safe - Until They're Not: Challenges in Protecting the Food Supply in a Processed World*, 36 STAN. ENVTL. L. J. 219, 226–30 (2017), for a more in-depth history of the passage of the FFDCa and the 1958 amendment.

51. Scufari, *supra* note 50, at 228.

52. *Id.*

53. Scufari notes in her article, the “NRDC[Natural Resources Defense Council] estimates that there are as many as 1,000 chemicals that manufacturers have designated as GRAS [Generally Recognized As Safe], but whose safety FDA has not reviewed or approved.” *Id.* at 238 (citing Tom Neltner & Maricel Maffini, *Generally Recognized as Secret: Chemicals Added to Food in the United*



in more detail below, that is because of how time-consuming FDA premarket review of each substance would be, the way the law is written such that FDA has broad discretion in how it fulfills its duty, and how manufacturers comply with the law.

Under 21 U.S.C.A. § 321(s), a “food additive” is “any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing . . . packing, processing).”<sup>54</sup> That same subsection goes on to provide that substances generally recognized as safe (GRAS) under the circumstances of their intended uses, as determined by experts qualified to evaluate the safety of substances, would not be considered a food additive at all.<sup>55</sup> The FDA Commissioner has the authority to evaluate the safety of a substance and to take a number of different actions, such as determining it to be GRAS or regulating or prohibiting the use of the substance as a food additive.<sup>56</sup> However, FDA took

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*States*, 4 (2014), <https://www.nrdc.org/sites/default/files/safety-loophole-for-chemicals-in-food-report.pdf> [<https://perma.cc/BF6S-2BS7>]). The cited NRDC study goes on to say that:

All told, we were able to identify 275 chemicals from 56 companies that appear to be marketed for use in food based on undisclosed GRAS safety determinations. This is likely the tip of the iceberg—we previously published in an industry journal an estimate that there have been 1,000 such secret GRAS determinations.

Tom Neltner & Maricel Maffini, *Generally Recognized as Secret: Chemicals Added to Food in the United States*, 4 (2014), <https://www.nrdc.org/sites/default/files/safety-loophole-for-chemicals-in-food-report.pdf> [<https://perma.cc/BF6S-2BS7>] (citing Thomas G. Neltner, Neesha R. Kulkarni, Heather M. Alger, Maricel V. Maffini, Erin D. Bongard, Neal D. Fortin & Erik D. Olson, *Navigating the U.S. Food Additive Regulatory Program*, 10 *COMPREHENSIVE REVS. FOOD SCI. & FOOD SAFETY* 342, 342 (2011)). In fact, it is difficult to know how many untested chemical substances of all types exist in consumer products, with estimates ranging widely. *See, e.g., Debunking the Myths: Are There Really 84,000 Chemicals?*, *CHEMICALSAFETYFACTS* (Aug. 17, 2022), <https://www.chemicalsafetyfacts.org/health-and-safety/debunking-the-myths-are-there-really-84000-chemicals/> [<https://perma.cc/RN3P-6CG6>].

54. 21 U.S.C. § 321(s). There are enumerated exceptions, including: “(2) a pesticide chemical . . . (3) a color additive . . . [and] (6) an ingredient . . . intended for use in, a dietary supplement.” These exceptions are treated differently. Pesticides require target animal efficacy tests. Color additives require a higher standard of “convincing evidence,” 21 C.F.R. § 70.3(i) (2021), than GRAS determinations, and FDA review is required, 21 C.F.R. § 70.10 (2021). However, just like with GRAS approvals, animal testing is not required to satisfy the standard and FDA is willing to consider non-animal testing protocols. *See infra* note 99 and accompanying text.

55. 21 U.S.C. § 321(s); *See also* 21 C.F.R. § 170.30(a) (2021) (“General recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food.”).

56. “The Commissioner, on his own initiative or on the petition of any interested person, . . . may issue a notice in the Federal Register proposing to determine that a substance is not GRAS and is a food additive subject to section 409 of the [Federal Food, Drug, and Cosmetic] Act.” 21 C.F.R.

the position that food industry companies could evaluate whether a novel food ingredient is GRAS and provided an opportunity for a company to petition the FDA to review its GRAS determination. “By 1961, FDA had amended its regulations to include a list of food substances that are GRAS under certain conditions of use (the GRAS list),”<sup>57</sup> which is published in the Code of Federal Regulations.<sup>58</sup> During the 1960s, many manufacturers requested FDA’s opinion, perhaps because of a desire for publication of a substance on the GRAS list or for assurance that they had complied sufficiently to avoid subsequent compliance investigations.<sup>59</sup>

According to FDA, Congress initially believed that most substances in use at that time would not require formal review because of long enough use by the public to have confidence in their safety or because of “the nature of the substances, their conditions of use, and the information generally available to scientists.”<sup>60</sup> However, in 1969, due to continuing public concern about food safety, then-President Nixon ordered FDA to review all the food ingredients it had listed as GRAS.<sup>61</sup> FDA created the Select Committee on GRAS Substances (SCOGS), on which various scientists served to evaluate the scientific information available for GRAS-listed substances.<sup>62</sup>

Progress was slow. It took a decade for SCOGS to develop opinions on the safety of only 422 GRAS substances.<sup>63</sup> Of those 422, SCOGS recommended revocation of the GRAS status of thirty of them and identified five additional substances it considered worrisome at what it deemed to be current levels of consumption.<sup>64</sup> After all of that work, FDA allowed the GRAS status for seventeen of that group of thirty-five substances recommended for revocation

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§ 170.38(b)(1). After evaluation, the Commissioner may decide that a substance is GRAS, *id.* at § 170.38(b)(3), but if the Commissioner decides that it is not GRAS, the Commissioner has the authority to “promulgate a food additive regulation governing use of the additive,” either temporarily or permanently, or “require discontinuation of the use of the additive” or “adopt any combination of [those] three approaches for different uses or levels of use of the additive.” *Id.* at § 170.38(c)(1)–(4).

57. *FDA’s Approach to the GRAS Provision: A History of Processes*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/food/generally-recognized-safe-gras/fdas-approach-gras-provision-history-processes> [<https://perma.cc/6CW8-U35K>] (Jan. 4, 2018).

58. *Id.* The current list appears in 21 C.F.R. pts. 182, 184, 186.

59. *FDA’s Approach to the GRAS Provision: A History of Processes*, *supra* note 57.

60. *Id.*

61. *Id.*

62. *Id.*

63. GAO, FDA SHOULD STRENGTHEN ITS OVERSIGHT OF FOOD INGREDIENTS DETERMINED TO BE GENERALLY RECOGNIZED AS SAFE (GRAS) 20 (2010), <https://www.gao.gov/products/gao-10-246> [<https://perma.cc/G9PZ-ENUQ>].

64. *Id.* at 20–21.

or considered worrisome; FDA neither approved nor revoked the GRAS status of the other eighteen substances and provided no explanation for its silence.<sup>65</sup>

In 1972, while the SCOGS review was underway, FDA conducted rulemaking to create procedures to review the GRAS determinations of various substances.<sup>66</sup> FDA also established the GRAS affirmation petition process (GAP).<sup>67</sup> GAP did not require companies to petition FDA to affirm their GRAS determinations, but submitting a GAP petition may have been perceived as an opportunity to have substances publicly GRAS-listed and as an appropriate risk-limiting decision.<sup>68</sup> Ultimately, the FDA, through SCOGS, abandoned review of GRAS-listed substances, citing lack of funding.<sup>69</sup>

In 1974, FDA further clarified the distinction between GRAS substances and food additives, saying that a substance could be GRAS through a demonstration of a “general recognition of safety” by either scientific procedures or by experience grounded in the common usage in food for substances used in food before 1958.<sup>70</sup> Then, in 1997, FDA published a Proposed Rule outlining a voluntary GRAS notification process and interim policy to replace the “resource-intensive” GRAS affirmation petition process.<sup>71</sup> As part of an Interim Pilot Program, manufacturers could notify FDA of their GRAS determinations.<sup>72</sup> The safety assessment and basis for the GRAS notification would be the responsibility of the manufacturer.<sup>73</sup>

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65. *Id.* at 21.

66. U.S. FOOD & DRUG ADMIN., *supra* note 57.

67. *Id.*

68. Scufari, *supra* note 50, at 233–34. Scufari notes that “[h]istorically, however, FDA has seldom brought enforcement actions against manufacturers regarding their use of GRAS substances.” *Id.* at 234.

69. *Id.* at 235.

70. 21 C.F.R. § 170.30(a) (2021). The FDA regulations also clarify that:

General recognition of safety requires common knowledge throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food that there is reasonable certainty that the substance is not harmful under the conditions of its intended use . . . . General recognition of safety through scientific procedures shall be based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles, and may be corroborated by the application of unpublished scientific data, information, or methods.

*Id.* § 170.30(a)–(b).

71. U.S. FOOD & DRUG ADMIN., *supra* note 57.

72. *Id.*

73. *Id.*

Notifying FDA did not have the legal effect of placing safety assessment responsibility on the FDA. FDA could provide one of three possible responses:

1. No Questions: The FDA has no questions upon completing their review regarding the GRAS status of the substance under the intended conditions of use
2. Withdrawn: At the [manufacturer's] request, the FDA has ceased to evaluate the GRAS Notification
3. No Basis: The GRAS Notification does not provide a sufficient basis to determine the substance is GRAS under the intended conditions of use<sup>74</sup>

If the FDA responds with a “No Basis” letter or indicates in some way that they will likely do so, the manufacturer has the option to address issues raised by the FDA and resubmit its notification.<sup>75</sup> On the other hand, the manufacturer may withdraw its notification to the FDA and begin to sell food containing the substance without any kind of FDA approval,<sup>76</sup> as long as it has completed the GRAS assessment.<sup>77</sup> This provides something of a “best of both worlds” to manufacturers, and it is not surprising that over 600 notifications were filed during the Interim Pilot Program.<sup>78</sup> The Proposed Rule made notification more appealing, also, because it set a ninety-day review period and created a publicly accessible website repository of GRAS notices, which provides the disposition or outcome of each FDA review.<sup>79</sup>

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74. Hanlon, Frestedt & Magurany, *supra* note 50, at 141. As of Oct. 27, 2022, 1,068 GRAS Notifications appear on the FDA GRAS Notices website. *GRAS Notices*, U.S. FOOD & DRUG ADMIN., <https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices> [<https://perma.cc/7K5X-6ZMQ>]. Of those, the FDA provided a “No Questions” response in 77% (822). 17% (183) were withdrawn at the notifier’s request, 2% (17) received a “No Basis” response, and 4% (47) were still pending FDA resolution. *Id.* These numbers are helpful only in reflecting the percentage of the different types of FDA responses, but they are not helpful in understanding the extent of use of new substances. It is not possible to know how many times companies completed safety assessments to meet GRAS requirements without submitting petitions for review. *See* Scrufari, *supra* note 50, at 238–40, 264–65.

75. Scrufari, *supra* note 50, at 235–36.

76. *Id.* at 237.

77. *See* 21 C.F.R. § 170.30(a) (2021).

78. Hanlon, Frestedt & Magurany, *supra* note 50, at 142.

79. *Id.* at 141–42 (citing U.S. FOOD & DRUG ADMIN., *supra* note 74). “This website provides the substance name, GRAS Notification (GRN) number assigned by FDA, the FDA letter sent in response to the notice, name and address of the notifier (the person making the GRAS determination), substance conditions of use, and the basis of the determination (whether by scientific process or history of use prior to 1958).” Hanlon, Frestedt & Magurany, *supra* note 50, at 141 (citing U.S. FOOD & DRUG ADMIN., *supra* note 74).

The Proposed Rule was finalized in 2016.<sup>80</sup> With the final rule in place, manufacturers may rely on a GRAS status only if they have taken steps to assess the safety of a substance added to food, which requires scientific rigor.<sup>81</sup> In a piece of nonbinding guidance, FDA explained that “[f]or a substance to be GRAS [through scientific procedures], the scientific data and information about the use of a substance must be widely known and there must be a consensus among qualified experts that those data and information establish that the substance is safe under the conditions of its intended use.”<sup>82</sup> GRAS designations require the same scientific rigor as that “required to obtain approval” for a food additive (that is, a substance not exempt as GRAS),<sup>83</sup> but manufacturers need not share the actual data on which their claim is based.<sup>84</sup> Indeed, if a manufacturer, in compliance with the GRAS rules, determines on its own that the substance it proposes to use is safe, it can proceed to market without even notifying the FDA of the existence of the substance, the process they undertook to determine safety, or the specific outcomes of that process.<sup>85</sup> This is why it is very difficult to ascertain how many companies use animal tests.

Since the SCOGS review, the FDA has not initiated review of GRAS substances. Instead, “FDA reviews the safety of GRAS food items only when specific issues are raised regarding particular substances.”<sup>86</sup> There is no apparent attention to proactively developing lists of particularly reliable tests or spot-checking compliance with GRAS safety assessment requirements. Animal tests much less reliable than non-animal tests can be used without regard to their potential costs to consumer safety or infliction of suffering on animals for no or minimal benefit to humans.

Carrie Scrufari is among the critics of the GRAS process who have articulated that far from the lax regulations working to decrease stress on the industry and regulators alike, the program has created loopholes for

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80. Hanlon, Frestedt & Magurany, *supra* note 50, at 141 (citing Substances Generally Recognized as Safe, 81 Fed. Reg. 54960 (Aug. 17, 2016) (to be codified at 21 C.F.R. pts. 20, 25, 170, 184, 186, 570)).

81. *See supra* note 70 and accompanying text.

82. *How U.S. FDA's GRAS Notification Program Works*, U.S. FOOD AND DRUG ADMIN., <https://www.fda.gov/food/generally-recognized-safe-gras/how-us-fdas-gras-notification-program-works> [<https://perma.cc/5BVM-3NE8>] (Feb. 9, 2018).

83. Scrufari, *supra* note 50, at 234 (quoting 21 C.F.R. § 170.30(b)).

84. *See* GAO, *supra* note 63, at 12, 20, 25.

85. *See id.* at 8, 12, 25, 36.

86. Scrufari, *supra* note 50, at 235.

manufacturers that place a huge burden on regulators and the public.<sup>87</sup> She writes:

FDA hoped that, by minimizing the time required to review GRAS substances and by easing the burden on industry to submit information related to GRAS substances, industry would be motivated to comply with the less onerous requirements associated with the voluntary notification procedure. However, in reality, the GRAS voluntary notification scheme has incentivized industry to evade the costly and timely additive pre-market regulatory approval process by allowing food manufacturers to simply designate new substances as GRAS without any government oversight. Industry is not required to notify FDA of any new GRAS designations, nor is industry required to prove the safety of any of its proposed GRAS designations. In the event FDA disagrees with a manufacturer's proposed GRAS designation, the manufacturer simply withdraws the GRAS notice, requests that FDA cease its evaluation of the substance, and then continues using the substance in the food supply. . . . [T]he result has been the creation of a giant backdoor – a loophole of epic proportions . . . . Currently, the average estimated time to approve a food additive exceeds six years. The time and expense . . . incentivizes industry to designate new food substances as GRAS rather than as additives. . . . Moreover, many manufacturers “base their GRAS determinations on stale, conflict-ridden, and often unpublished, non-peer-reviewed science.”<sup>88</sup>

With these frustrations and concerns in mind, in 2017, the Center for Food Safety and others brought suit in the U.S. District Court for the Southern District of New York, claiming that FDA's interpretation of the law, allowing manufacturers to make safety assessments of products they want to sell, impermissibly “sub-delegates” to manufacturers FDA's responsibility to ensure

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87. *Id.* at 236–37; *see also* Neltner & Maffini, *supra* note 53, at 3 (stating the Natural Resources Defense Council's belief that a more accurate name for the “GRAS loophole” is “Generally Recognized as SECRET”).

88. Scrufari, *supra* note 50, at 236–37 (quoting Comment from the Ctr. for Sci. in the Pub. Int., Consumers Union, Env't Working Group & Nat. Res. Def. Council on Docket No. FDA-1997-N-0020 to Commissioner of Food and Drug Administration at 16 (Apr. 2015) [https://www.cspinet.org/sites/default/files/attachment/GRAS%20Comment%20FINAL\\_0.pdf](https://www.cspinet.org/sites/default/files/attachment/GRAS%20Comment%20FINAL_0.pdf) [<https://perma.cc/6MXM-E3U8>]).

the safety of food additives.<sup>89</sup> On September 30, 2021, the New York district court ruled in favor of FDA, finding that there was no impermissible sub-delegation.<sup>90</sup> However, an indication that the matter is not fully resolved is U.S. Representative Rosa DeLauro's introduction on June 4, 2021, of a bill that would change the law in the direction preferred by Center for Food Safety: the FDA would have to conduct a premarket review of the safety of ingredients, rather than relying on manufacturers to bear sole responsibility for assessing safety.<sup>91</sup>

While FDA abandoned its attempt to comprehensively assess GRAS-listed substances in the 1970s because of cost,<sup>92</sup> Congress's ultimate decision might turn on its view of how protected the public is under the current system, how much increased safety can be derived from FDA-led premarket reviews, and the level of funding to secure perhaps only small marginal gains in food safety. Congress should consider that the public would derive more benefit from requiring the most reliable predictive tests than from arguing about who orchestrates the testing—the FDA or manufacturers. If predictive reliability were the focus, the state of the science is such that much less animal testing would occur, with significant increases in consumer safety. The next section explores this idea that improved public safety can emerge from attention to the types of tests conducted, including their relative costs, reliability in predicting harm, and time needed to get those reliable data.

### *B. Is Animal Testing Required for GRAS Status?*

No matter who conducts the safety assessment, basic questions exist about how food ingredient safety evaluations should be conducted. Must evaluators have training in a variety of safety evaluation techniques? Does the law require specific kinds of tests? Should assessments include the use of nonhuman species to test probable effects in humans?

To review, federal law requires that GRAS determinations be based on the views of experts. In one of its guidance documents, the FDA states that for

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89. Jessica L.A. Marks, *Center for Food Safety Alleges FDA's GRAS Rule is Unlawful*, FINNEGAN: BLOGS (May 22, 2017), <https://www.finnegan.com/en/insights/blogs/ip-fda-blog/center-for-food-safety-alleges-fdas-gras-rule-is-unlawful.html> [<https://perma.cc/9KPV-GKF4>]. This litigation followed a similar suit brought in 2014 by the Center for Food Safety in the U.S. District Court for the District of Columbia, which was settled later that year through a consent decree. *Id.*; see also Scufari, *supra* note 50, at 238.

90. *Ctr. for Food Safety v. Becerra*, 565 F. Supp. 3d 519, 543 (S.D.N.Y. 2021).

91. Toxic Free Food Act, H.R. 3699, 117th Cong. (2021). A similar bill was introduced in the Senate by Senator Edward Markey on May 26, 2022. Ensuring Safe and Toxic-Free Foods Act, S. 4316, 117th Cong. (2022).

92. Scufari, *supra* note 50, at 235.

determinations based on scientific procedures, the relevant scientific data must be “widely known,” and there must be a “consensus among qualified experts” that the data “establish that the substance is safe under the conditions of its intended use.”<sup>93</sup>

Hanlon notes that “[a]lthough not specifically required by the Final Rule, a Notifier may convene a panel of appropriate experts who have expertise demonstrated by training and experience (a GRAS Expert Panel) to review the safety of the substance and to satisfy the requirement for this safety being ‘common knowledge throughout the scientific community.’”<sup>94</sup> FDA defines a GRAS panel as “a panel of qualified experts who are convened to evaluate whether the available scientific data, information, and methods establish that a substance is safe under the conditions of its intended use in human food or animal food.”<sup>95</sup> Further, the agency provides information about how to create a panel so as to avoid conflicts of interest and bias.<sup>96</sup>

If a manufacturer chooses to file a GRAS notification instead of simply fulfilling the requirement without notifying FDA, it must include information about the scientific procedures used to assess safety, which include the application of scientific data (including, as appropriate, data from “human, animal, analytical, or other scientific studies”), information, and methods, “whether published or unpublished,” as well as the application of scientific principles, “appropriate to establish the safety of a substance” under the conditions of its intended use.<sup>97</sup> This list, which appears in the Code of Federal Regulations, contains some non-animal testing methods. However, the Redbook, the FDA’s handbook of guidance for GRAS assessment, describes numerous animal study methods FDA says could satisfy testing requirements.<sup>98</sup>

Although many guidelines include animal testing protocols, the Redbook states in its Introduction:

FDA’s guidance for toxicity studies for food ingredients continue [sic] to emphasize that there is no substitute for sound scientific judgement. This guidance presents

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93. See *supra* notes 55, 70, 82 and accompanying text.

94. Hanlon, Frestedt & Magurany, *supra* note 50, at 141 (quoting 21 C.F.R. § 170.30(a)).

95. U.S. FOOD & DRUG ADMIN., BEST PRACTICES FOR CONVENING A GRAS PANEL: GUIDANCE FOR INDUSTRY 16 (Nov. 2017), <https://www.fda.gov/media/109006/download> [<https://perma.cc/8MKW-5E6M>].

96. *Id.* at 8.

97. 21 C.F.R. § 170.3(h) (2021).

98. See *Redbook 2000: IV.B.1. General Guidelines for Designing and Conducting Toxicity Studies*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/redbook-2000-ivb1-general-guidelines-designing-and-conducting-toxicity-studies> [<https://perma.cc/3UW5-Tx2v>] (Oct. 26, 2017).



recommendations—not hard and fast rules. If an investigator believes that he/she can provide the Agency with useful toxicological information by modifying a recommended study protocol, and is able to support the modification with sound scientific arguments, then the investigator should propose the modified protocol to the appropriate program division within [the Office of Food Safety]. As always, petitioners and notifiers should consult with the FDA prior to and during the design of study protocols for toxicity studies and/or before commencement of studies.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.<sup>99</sup>

Toxicologist Dr. Claire Kruger states that “it is critical to remember that [the] Redbook does not provide this guidance as a checklist. The reason for the flexibility in approach is that science evolves. Thinking evolves. Risk assessments should incorporate and embrace these new advances.”<sup>100</sup>

That Redbook guidelines are non-binding was also emphasized by the Ninth Circuit when deciding Center for Food Safety's lawsuit against FDA for allegedly improperly approving Impossible's GE heme ingredient despite Impossible's failure to fully follow one of the safety assessment guidelines.<sup>101</sup> In its May 3, 2021, decision, the Ninth Circuit emphasized that “CFS's contention that one study Impossible commissioned did not conform to the FDA's ‘Redbook’ is unavailing; the agency's recommendations regarding the design of toxicology studies are non-binding.”<sup>102</sup> Not only are the guidelines non-binding, many reliable alternative non-animal safety assessment measures

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99. *Redbook 2000: I Introduction*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/redbook-2000-i-introduction> [<https://perma.cc/VXS8-NPQY>] (Jan. 30, 2018).

100. Claire Kruger, *The Relevance of International Assessments to GRAS Determinations*, 79 REGUL. TOXICOLOGY & PHARMACOLOGY S119, S121 (2016).

101. *Ctr. for Food Safety v. U.S. Food & Drug Admin.*, 854 F. App'x. 865, 866 (9th Cir. 2021).

102. *Id.* Center for Food Safety argued that FDA should hold Impossible to a higher evidentiary standard of safety than it did because color additives require FDA approval. *Id.* For purposes of this Article, whether GE heme is a color additive is not an important issue because animal testing is not required to meet either the GRAS standard or the color additives standard. The Redbook guidelines apply to both, and the Ninth Circuit discussed the relevance of the Redbook as a source of guidelines only. *Id.*

are available.<sup>103</sup> Consumers are not protected by more animal testing, they are protected by better tests that more accurately predict negative human health effects than animal-based tests.

A significant challenge for manufacturers seeking to avoid animal testing stems from the fact that safety assessments must be tailored. Manufacturers cannot select just any non-animal-based test; it is necessary to consult with scientists because it is within the expertise of scientists to choose the most appropriate test for the type of substance and circumstances of intended use. This could turn out to be a complicated decision, turning on genuine desire for accuracy in safety testing, the market advantage anticipated from being able to claim that a product is free of animal testing, the cost of non-animal protocols compared to animal protocols, perceptions of FDA's willingness to promptly consider proposed testing plans, and the availability of experts trained in non-animal test methods.

Despite the fact that FDA rules allow for the use of non-animal tests, manufacturers might be likely to use animal test protocols as a matter of habit and misguided acceptance of FDA examples as requirements.<sup>104</sup> Since the FDA describes at least one sample animal-based test at each of the three "concern levels" and provides limited examples of non-animal alternative tests,<sup>105</sup> it seems unlikely that food producers would go out of their way to search for non-animal testing protocols, even though their use is allowed. A manufacturer that contracts with product safety assessment companies, rather than doing in-house assessment, would have to know to look for a company that has the willingness and capacity to conduct non-animal-based assessments. Thus, an important factor in the type of safety testing used is the extent of industry reliance on scientists and product testing companies that use animal testing as standard protocols for meeting their clients' FDA safety assessment needs. Scientists and companies set up to run testing in accordance with Redbook guidance can satisfy most customers without incurring costs of ramping up to conduct non-animal tests. If the number and type of testing services are limited, manufacturers will have fewer choices, even if more appropriate non-animal

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103. *See supra* note 44 and accompanying text.

104. The extent of non-animal and animal testing cannot be known exactly because manufacturers do not have to supply that information unless seeking some kind of approval from FDA. A full evaluation of the GRAS notices database would not fully reveal manufacturers' decisions because manufacturers satisfied with completion of GRAS requirements without notifying FDA would not be listed.

105. *Guidance for Industry: Summary Table of Recommended Toxicological Testing for Additives Used in Food*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-summary-table-recommended-toxicological-testing-additives-used-food> [<https://perma.cc/H3NG-A4RK>] (Sept. 20, 2018).

test methods are available. A large shift in the direction of non-animal testing could occur if product safety testing companies develop the capacity to perform various non-animal testing protocols. This could, in turn, be reasonably expected to improve public safety and reduce the suffering of animals.

It appears that manufacturers tend to use the same scientists to do assessments. Hanlon and co-researchers evaluated the first 600 GRAS notices submitted during the Interim (FDA Rule) Review period.<sup>106</sup> They found that a relatively small number of scientists were involved in a large number of GRAS evaluations,<sup>107</sup> “suggest[ing] a perceived value in having experts with extensive GRAS Expert Panel experience in addition to relevant scientific training on the Expert Panel.”<sup>108</sup> Yet, the small number of options may increase the difficulty for a manufacturer that wants to do animal-free, state-of-the-art safety testing to find scientists or a product safety testing company willing to do such testing at a price the manufacturer can justify paying.<sup>109</sup> Even so, it is to food manufacturers’ advantage to use state-of-the-art tests to produce safe food. Even if a manufacturer completes the testing without notifying FDA and engaging in prolonged FDA review, as allowed by law, the manufacturer is running the risk of a finding that the manufacturer has not met its burden under the law to determine that a substance is GRAS. Further, as food litigation expert Denis Stearns has written, the best defense for a food producer against

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106. Hanlon, Frestedt & Magurany, *supra* note 50, at 142 (“This article provides a detailed analysis of the first 600 GRAS Notifications submitted to FDA during the Interim Pilot Program, as well as the associated warning letters mentioning GRAS during the last 10 + years (i.e., since 2005).”).

107. Hanlon and co-investigators prepared a list of the most commonly used scientists in that group and the number of GRAS notifications in which they had been involved: Joseph Borzelleca (148), John Thomas (60), Michael Pariza (58), Robert Nicolosi (48), Madhusudan Soni (48), Richard Kraska (45), Robert McQuate (45), Walter Glinsmann (41), Stephen Taylor (33), Ian Munro (27), Stanley Tarka (25), W. Gary Flamm (24), Gary Williams (24), Robert Martin (18), William Waddell (18), Susan Cho (17), Eric Johnson (17), Robert Kapp (14), Roger Clemens (13), George Fahey (13), Claire Kruger (12), John Doull (11), Wallace Hayes (11), Douglas Archer (10), Robert Kleinman (10), and Glenn Sipes (10). *Id.* at 145.

From [the first] 400 GRAS Notifications, 26 individuals participated in 10 or more of the GRAS Expert Panels [], and eight of these individuals served on more than 10% of the GRAS Expert Panels. The most prolific GRAS Expert Panelist in the first 600 GRAS Notifications was Joseph Borzelleca, who served on 37%, or 148, of the first 400 GRAS Expert Panels. In addition, at least one individual from this list of prolific GRAS Expert Panelists served on 88%, or 352 of the first 400 GRAS Expert Panels, with many of the GRAS Expert Panels including multiple individuals from this list.

*Id.*

108. *Id.* at 147.

109. FDA regulations do not prohibit companies from doing in-house safety evaluations, but they do warn against bias and conflict-of-interest problems and the cost of in-house safety evaluations might be prohibitive.

consumer lawsuits “is to sell only safe food.”<sup>110</sup> Surely, the fact that companies like Kellogg’s, Coca-Cola, and General Mills reject animal testing indicates that it is possible and rational for food producers to use non-animal safety assessment methods.<sup>111</sup> It is also to their advantage if consumers would likely pay a premium for “cruelty-free” safety assessment, such that the costs and time spent on such testing are justifiable. In January of 2022, research was conducted on consumer attitudes toward the use of animal tests in safety assessments of food ingredients. That research, described in Part III, found that consumers strongly prefer avoidance of animal testing.

Even if there is considerable consumer preference for non-animal safety assessments, there is no denying that navigating FDA regulatory waters without simply following guideline animal test protocols could be daunting. This is where nonprofit organizations, such as People for the Ethical Treatment of Animals (PETA) and PETA Science Consortium International e.V. (PSCI), can become important agents for change through their scientists dedicated to developing paths forward for companies seeking to avoid animal testing.<sup>112</sup> PSCI provides comprehensive information on scientifically sound alternatives to animal testing.<sup>113</sup> Not only does PSCI organize workshops that are highly attended by regulatory, industry, and academic scientists, it also provides the following: maintenance of an extensive list of non-animal testing alternatives, scientific expertise in designing safety assessment protocols tailored to the specific use of a substance, assistance with securing consultations with the FDA

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110. Denis Stearns, *A Critical Appraisal of the Impact of Legal Action on the Creation of Incentives for Improvements in Food Safety in the United States*, in *FOOD SAFETY ECONOMICS: INCENTIVES FOR A SAFER FOOD SUPPLY* 359, 370 (Tanya Roberts ed., 2018).

111. *Kellogg Company Animal Welfare Commitment*, KELLOGG, <https://crreport.kelloggcompany.com/ppm-animal-welfare-commitment> [https://perma.cc/M855-54U7]; *Animal Welfare Policy*, GEN. MILLS, <https://www.generalmills.com/how-we-make-it/healthier-planet/sustainable-and-responsible-sourcing/animal-welfare> [https://perma.cc/K8TB-CN4A]; *Animal Health and Welfare Guiding Principles*, COCA-COLA CO. (June 30, 2020), <https://www.coca-colacompany.com/policies-and-practices/animal-health-and-welfare-guiding-principles> [https://perma.cc/C22R-ZUGT].

112. PETA U.S. and other PETA entities employ approximately 35 scientists. Virtual Interview with Kathy Guillermo, Senior Vice President, PETA Laboratory Investigations Department, and Jeff Brown, Science Advisor, PETA Regulatory Testing Department, (July 8, 2020). PETA is not the only nonprofit organization working to reduce corporate reliance on animal testing. Another example is the Animal-Free Safety Assessment Collaboration (AFSA), which brings together corporate leaders (including Proctor and Gamble and ExxonMobil) as well as non-profits (including Humane Society International and The Humane Society of the United States) to support innovative risk assessment methods that do not involve animal testing. *Home*, ANIMAL-FREE SAFETY ASSESSMENT COLLABORATION, <https://www.afsacollaboration.org/> [https://perma.cc/5PEL-SEDH].

113. *Alternative Methods Validated for Regulatory Use*, PETA SCI. CONSORTIUM INT’L, <https://www.thepsci.eu/alternatives/> [https://perma.cc/33ES-RAH7].

on the use of non-animal methods prior to conducting new testing for product approval, and assistance with subsequent FDA inquiries.<sup>114</sup> PETA scientists will assist companies at any stage of the regulatory process.<sup>115</sup> This is especially valuable at the pre-submission stage because the company can work out with the FDA the type of non-animal safety assessments the FDA will accept for the specific ingredient, based on information provided by PETA's scientists. The FDA actually invites consultation.<sup>116</sup>

Based on the information provided in this Part, there appear to be several levers for improving safety and reducing unnecessary suffering of animals. One is change at the FDA level. Another lies in food manufacturers and their suppliers insisting that product safety assessment companies ramp up to include non-animal testing protocols. A third can be found in the interactive relationship with the FDA through which manufacturers persevere in seeking FDA acceptance of those methods and increasing FDA receptivity to non-animal tests without significant delays in approving those tests. Without internal change at the FDA, it would be a haltingly slow process to use this method of seeking change in how they approach GRAS and formal reviews of food additives. For this to happen, there must be entities with scientific expertise to help companies and the FDA navigate a path to the use of the most reliable predictive tests in the specific contexts of those companies' food ingredients.

Change would occur most quickly if the first move were made by Congress or the FDA. This could be a comparatively modest move, such as including in its guidelines more examples of non-animal testing methods. Or it could take the form of bold change by the FDA, such as requiring explicit pre-approval for use of animal tests but only detailed written justification for non-animal tests used by the manufacturer. While some food manufacturers might be able to persuade the FDA that its proposed animal tests would be appropriate, the burden should still be on them to prove the reliability of predicting harm to consumers because they might well be using the least appropriate or up-to-date methods for food safety assessment. Moreover, this pre-approval requirement is consistent with the "3Rs" principle of humane research—refinement,

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114. PETA INT'L SCI. CONSORTIUM LTD., WORKFLOW FOR EVALUATING FOOD INGREDIENT SAFETY 1 (2019) <https://www.piscltd.org.uk/wp-content/uploads/2019/10/Food-Ingredient-Safety-Factsheet.pdf> [<https://perma.cc/C85E-GQEX>].

115. *Home*, PETA SCI. CONSORTIUM INT'L, <https://www.thepsci.eu/> [<https://perma.cc/4QPQ-L5E8>].

116. "FDA encourages individuals to thoroughly review its GRAS notification submission procedures prior to sending a notification to the agency. Additionally, a notifier may request a pre-submission meeting with FDA to discuss issues that may be relevant to the submission of the notifier's GRAS notice." U.S. FOOD & DRUG ADMIN., *supra* note 82.

reduction, and replacement of animal use in experiments.<sup>117</sup> The 3Rs has been a feature of the federal Animal Welfare Act since it was amended in 1985.<sup>118</sup> Accordingly, the FDA should require a showing that animal tests are necessary.

At the level of legislative influences leading to change, the FDA Modernization Act 2.0<sup>119</sup> could be significant. While specific to allowing pharmaceutical companies to bypass animal testing prior to human trials of pharmaceuticals, this Act would signal support for reduced reliance on animal testing.<sup>120</sup>

The FDA already allows non-animal tests in the novel food ingredient context, but this law could promote a useful cultural shift in the agency, which could enhance FDA's receptivity to non-animal testing for food safety testing.<sup>121</sup> In turn, FDA's approval of alternative test methods, its publication of acceptable non-animal protocols, and its willingness to promptly review non-animal-based tests without bias would boost manufacturer confidence in using non-animal alternatives. If their statements can be taken at face value, it appears that some members of the industry are ready for alternatives but are waiting for FDA to assure them that these tests will be acceptable.<sup>122</sup> That is why the

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117. Here, the issue is replacement with non-animal tests. The other Rs focus on refinement of experiments to require less distress imposed on animals and reduction in the number of animals used in an experiment. W.M.S. RUSSELL & R.L. BURCH, *THE PRINCIPLES OF HUMANE EXPERIMENTAL TECHNIQUE* ch. 4 (1959), <https://caat.jhsph.edu/principles/chap4d> [<https://perma.cc/4Y6T-U5SR>].

118. 7 U.S.C. § 2143(e).

119. S. 5002, 117<sup>th</sup> Cong. (2022).

120. *See supra* notes 39–40 and accompanying text.

121. Similarly, the Environmental Protection Agency's multi-faceted plan for reducing the use of vertebrate animals in chemical testing signals a change in thinking about testing on animals. *EPA New Approach Methods: Efforts to Reduce Use of Vertebrate Animals in Chemical Testing*, U.S. ENV'T PROT. AGENCY, <https://www.epa.gov/research/epa-new-approach-methods-efforts-reduce-use-vertebrate-animals-chemical-testing> [<https://perma.cc/B9EL-T7GG>]. It would be unfortunate if testing simply shifts to invertebrate animals because science is revealing that invertebrate animals suffer, and it is not clear that testing on invertebrates would be any more reliable than testing on vertebrate animals. All this signals is that an agency is considering alternatives to its business-as-usual model of animal testing.

122. *See, e.g.*, Comments from Biotech. Indus. Org., Calorie Control Council, Grocery Mfrs. Ass'n, and Unilever, FDA Docket No. FDA-2014-N-1497: Toxicological Principles for the Safety Assessment of Food Ingredients; Public Meeting on Updates and Safety and Risk Assessment Considerations (Request for Comments, Oct. 30, 2014), <https://www.regulations.gov/docket/FDA-2014-N-1497/comments>. In contrast, there are several companies that state that they are for alternatives to animal testing but recommend against including alternatives in FDA guidance before they are validated. *See, e.g.*, Comments from Am. Frozen Food Inst., Int'l Food Additives Council, Int'l Life Scis. Inst. N. Am., and even Grocery Mfrs. Ass'n, FDA Docket No. FDA-2014-N-1497, Toxicological Principles for the Safety Assessment of Food Ingredients; Public Meeting on Updates and Safety and Risk Assessment Considerations (Request for Comments, Oct. 30, 2014),

involvement of nonprofit animal protection organizations in identifying reliable non-animal testing methods and seeking FDA acknowledgement of their value can be so important.<sup>123</sup> The key to improved public health and safety and reduced animal suffering (another public value) is reliance on state-of-the-art safety assessments, which are often faster and less costly than animal tests.<sup>124</sup>

## PART II. CONSUMER FOOD PRODUCT SAFETY LITIGATION

Is there any other reason for a food manufacturer such as Impossible to do animal-based safety testing? What about avoidance of exposure to liability from consumer food safety lawsuits? The purpose of this Part is to explain why a reasonably risk-averse manufacturer would not pursue animal testing to reduce exposure to a consumer safety lawsuit, such as a consumer claiming injury from Impossible's novel food ingredient, GE heme. There are two reasons. First, such suits are rare and have low odds of success, primarily due to the difficulty of proving causation.<sup>125</sup> If as toxic tort litigator Lawrence G. Cetrulo states, "Toxic tort litigation involving injuries from hazardous chemical contaminants in food [against the food industry] is still in its infancy,"<sup>126</sup> the odds of such a suit regarding a substance not even identified as toxic would seem quite low. Second, animal test data would not reliably protect companies from liability because courts are skeptical about the validity and "fitness" of data derived from animal testing as a basis for evidence submitted by expert witnesses. Part II.A. explores the first reason, and Part II.B. is focused on the second.

### *A. Extent of Litigation and Liability Exposure*

A consumer who believes they have been harmed by a food manufacturer might start by considering federal laws that protect consumers from injurious food products. Indeed, there are several. However, while consumers can report complaints about food producers under such laws as the Food, Drug &

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<https://www.regulations.gov/docket/FDA-2014-N-1497/comments>. It is difficult, therefore, to parse out what such industry actors would actually support, but their at least outward support of non-animal alternatives could still be used as leverage in support of such tests.

123. *See supra* notes 43–44, 110.

124. Lucy Meigs, Lena Smirnova, Costanza Rovida, Marcel Leist & Thomas Hartung, *Animal Testing and Its Alternatives—The Most Important Omics Is Economics*, 35 ALTEX 275, 275 (2018) ("Only more recently has the economic view begun to have an impact: Many animal tests are simply too costly, take too long, and give misleading results.").

125. Denis Stearns, *On (C)redibility: Why Food in the United States May Never Be Safe*, 21 STAN. L. & POL'Y REV. 245, 249 n.12 (2010) (noting that the difficulty of tracing an illness back to the producer of the food reduces producer incentives to invest in improved safety).

126. 4 LAWRENCE G. CETRULO, *Toxins in Food and Associated Litigation*, in TOXIC TORTS LITIGATION GUIDE, 2021-2022, at § 39:45 (2021).

Cosmetic Act (FDCA),<sup>127</sup> the Food Safety Modernization Act (FSMA),<sup>128</sup> and the Nutrition Labeling and Education Act (NLEA),<sup>129</sup> they cannot directly enforce the provisions of those federal laws through private lawsuits.<sup>130</sup> The FDA holds that authority, though these laws also allow for coordinated state action.<sup>131</sup> Not only does the FDA hold enforcement power, but federal law preempts most state law food safety claims. Nevertheless, a few state law claims survive preemption<sup>132</sup> and, according to the Food and Drug Law Institute (FDLI), “litigants have employed a variety of approaches premised on state consumer protection statutes to indirectly bring the FDCA into play.”<sup>133</sup> None of the examples raised by the FDLI deal with toxicity or allergenicity of food substances. However, FSMA might seem most promising to consumers claiming injury because it concerns food safety. According to food lawyer Kim Bousquet,

As a result of these new [consumer safety protective] requirements [in the FSMA] and increased documentation demands, plaintiff’s attorneys will soon be able to look to a facility’s compliance program and easily determine whether the company complied with its own safety plan and with the FSMA’s stringent standards. They can then argue, based on the company’s well-documented efforts, that it failed to meet a state common law (or statutory) standard of care. Company

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127. Food, Drug & Cosmetic Act, 21 U.S.C. §§ 301–92.

128. Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified as amended in scattered sections of 21 U.S.C.).

129. Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (codified as amended in scattered sections of 21 U.S.C.).

130. The FSMA and the NLEA are amendments to the FDCA. There is no private right of action under the FDCA. MICHAEL T. ROBERTS, *FOOD LAW IN THE UNITED STATES* 304 (2016) (citing *Murphy v. Cuomo*, 913 F. Supp. 671, 679 (N.D.N.Y. 1996) (denying standing to plaintiff to bring an action based on the FDCA)).

131. Regarding the FDCA, the specific language can be found at 21 U.S.C. § 337(a) (“[A]ll such proceedings for the enforcement, or to restrain violations, of [the FD&C Act] shall be by and in the name of the United States.”). *See* *Murphy*, 913 F. Supp. at 679 (citing *Merrell Dow Pharmaceuticals v. Thompson*, 478 U.S. 804, 811 (1986) (denying standing to plaintiff to bring an action based on the FDCA)). Regarding the FSMA, which applies only to foods regulated by the FDA, the FDA has authority for enforcement. 21 U.S.C. § 350h(d) (“The Secretary may coordinate with the Secretary of Agriculture and, as appropriate, shall contract and coordinate with the agency or department designated by the Governor of each State to perform activities to ensure compliance with this section.”). Regarding the NLEA, specific language can be found requiring the Secretary of the FDA to be notified about states enforcing provisions of the NLEA. 21 U.S.C. § 337(b)(2).

132. ROBERTS, *supra* note 130, at 35–36 (describing generally federal preemption laws that nevertheless allow for consumer litigation in some cases).

133. Theodora McCormick, *Food and Supplement Class Action Suits That Rely on Alleged Regulatory Violations*, *FOOD & DRUG L. INST.*, Aug. 2021 at 12, 12.



compliance records, consequently, could be used to support viable claims for foodborne illness . . . .<sup>134</sup>

If sued on a state law consumer protection theory, a company's first defense would be that the state law had been preempted by federal laws consumers cannot use directly to file lawsuits.<sup>135</sup> Indeed, Cetrulo states that "in the limited number of food contaminant cases to date, defendants have relied on preemption defenses to defeat the plaintiff's failure to warn claims."<sup>136</sup> Nevertheless, in the case of claims for liability from harm allegedly caused by novel food ingredients or additives used by, say, a hypothetical client company producing meat analogues, it appears on first review that some state claims could survive preemption.<sup>137</sup> A particularly risk-averse company would be interested in considering whether and to what extent the company could be vulnerable to a consumer lawsuit based on state law and, secondarily, how best to defend itself if such a lawsuit went forward. State law varies, but types of claims that could be applicable in some states in some cases include negligence and strict liability torts, contracts, and commercial causes of action.<sup>138</sup> Cetrulo claims that plaintiffs rely most heavily on allegations of failure to warn,<sup>139</sup> but many of these would be pled in the alternative and with similar analysis.<sup>140</sup> The focus in the first section of this Part is how vulnerable a company is to the risk of successful state law claims.

## I. Tort Claims

A few different theories animate products liability cases, including manufacturing defects, design defects, and warning defects. In tort-based food

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134. Kim Bousquet, *Is the FSMA a Plaintiff's Lawyer's Dream and a Food Industry Nightmare?*, THOMPSON COBURN LLP (Dec. 21, 2016), <https://www.thompsoncoburn.com/insights/blogs/life-sciences-decoded/post/2016-12-21/is-fsma-a-plaintiff-s-lawyer-s-dream-and-the-food-industry-s-nightmare> [<https://perma.cc/A9YH-UR5Q>].

135. ROBERTS, *supra* note 130, at 35–36 (describing generally federal preemption laws that nevertheless allow for consumer litigation in some cases).

136. CETRULO, *supra* note 126, at § 39:46.

137. ROBERTS, *supra* note 130, at 35–36.

138. According to food law scholar Michael T. Roberts, "[C]onsumers made sick from eating unsafe food may recover damages from manufacturers or sellers of the unsafe food in actions brought under one or more theories of liability, including strict liability in tort, breach of implied warranty, and negligence." ROBERTS, *supra* note 130, at 197 (citing *Porrazzo v. Bumble Bee Foods, LLC*, 822 F. Supp. 2d 406 (S.D.N.Y. 2011)).

139. CETRULO, *supra*, note 126, at § 39:45.

140. See Katharine Van Tassel, *The Introduction of Biotech Foods to the Tort System: Creating a New Duty to Identify*, 72 U. CIN. L. REV. 1645, 1668–77 (2004) (concerning biotech foods but also providing an overview of state law causes of action). Van Tassel notes that "[c]urrent product liability law is actually an amalgamation of tort and contract theories." *Id.* at 1672 n.141. (describing overlap in torts causes of action in food product liability litigation).

liability cases, analysis of these causes can overlap when courts are actually conducting the analysis.<sup>141</sup> As an initial matter, courts “have historically used two tests: the foreign-natural test and the reasonable-consumer-expectations test.”<sup>142</sup> A minority of courts apply a test focused on whether the defect in the food was a foreign object (such as a piece of glass) or natural object (such as pieces of shell in a package of shelled nuts).<sup>143</sup> These courts assign no liability for defects that are natural to the food product regardless of the care producers exercised during product development and production.<sup>144</sup> Presumably, a customer would know to expect the possibility of shell fragments in a package of nuts but would not be expecting fragments of glass. Most courts have moved away from this categorical distinction—natural and foreign—in the direction of a more flexible “reasonable consumer” standard.<sup>145</sup> In the case of the nutshell fragments, this “reasonable consumer” standard would result in the same analysis and outcome as a “natural” versus “foreign” object test. The “reasonable consumer” standard avoids only the prior categorization of something as “foreign” or “natural.” This reasonable consumer standard is articulated in The Restatement (Third) of Torts: Products Liability section 7, through the example of a chicken bone in a chicken enchilada. “Although a one-inch chicken bone may in some sense be ‘natural’ to a chicken enchilada, depending on the context in which consumption takes place, the bone may still be unexpected by the reasonable consumer, who will not be able to avoid injury, thus rendering the product not reasonably safe.”<sup>146</sup>

In the case of a plant-based burger, a “reasonable consumer” might not expect an ingredient to have originated in a genetically modified organism or an ingredient derived from an animal product, for instance. This is where analysis would typically include consideration of labeling law, which is largely regulated at the federal level. However, as will be considered below as to

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141. *See id.* at 1680 n.163, 1683 (“The idiosyncratic plaintiff defense plays in the analysis for both design defects and failures to warn. . . . The injured consumer faces the same insurmountable hurdle in seeking to establish liability for the failure to warn as she faced with attempting to establish liability based on either a manufacturing [defect] or defective design.”).

142. ROBERTS, *supra* note 130, at 199.

143. *Id.* at 199–200 (citing *Mix v. Ingersoll Candy Co.*, 59 P.2d 144 (Cal. 1936) (holding that a reasonable consumer would anticipate the presence of chicken bone fragments in a prepared chicken potpie and that such a potpie would be fit for human consumption). *But see* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 7 cmt. b (AM. L. INST. 1998) (articulating when a chicken bone fragment might not be anticipated by a reasonable consumer).

144. ROBERTS, *supra* note 130, at 199.

145. ROBERTS, *supra* note 130, at 200.

146. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 7 cmt. b (AM. L. INST. 1998). *See also* Van Tassel, *supra* note 140, at 1674–77 (providing a more in-depth discussion of the general framework).

commercial “unfair or deceptive trade” claims, some state law-based labeling claims could survive federal preemption. Resolution of preemption claims requires fact-specific analysis, making prediction of outcome difficult in some cases.<sup>147</sup>

What about vulnerability under a negligence claim? For such a claim to succeed, the plaintiff bears the burden to establish that the defendant had a duty to exercise reasonable care and failed to do so, with resultant injury to the plaintiff.<sup>148</sup> In the case of a plant-based burger, the claim would be that the company was negligent in a way that resulted in consumer harm from consuming the company’s burger, such as Impossible’s burger containing GE heme. Recovery for injury from exposure to novel food ingredients is unlikely under the tort system for several reasons. First, it isn’t clear that consumers would know that there was a novel food ingredient; ingredient lists often contain long lists of unfamiliar ingredients.<sup>149</sup> A 2017 survey of more than 1,000 consumers found that most “feel confused at least some of the time about ingredients listed on food package labels,” and many are “concerned when they eat food products that contain ingredients that they don’t understand.”<sup>150</sup> Second, under negligence, a plaintiff must establish that a producer should have foreseen risk as well as prove causation,<sup>151</sup> both of which can be difficult. This is especially true for novel food ingredients, such as genetically modified ingredients, where risk assessment in human populations can lag behind production and distribution.<sup>152</sup> However, while the company might claim that compliance with FDA requirements should be the basis for the decision, a determined plaintiff could argue that the FDA standard is different, and at least one court has taken that position in the context of pharmaceutical companies’ safety assessments.<sup>153</sup> The knowledge available about a novel ingredient at the time of its FDA-required premarket safety assessment may be far less than

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147. See, e.g., *Wyeth v. Levine*, 555 U.S. 555 (2009). The Court found no preemption by the FDA in the context of a state failure to warn claim against a pharmaceutical manufacturer. *Id.* at 581. It was differentiated by the case *PLIVA, Inc. v. Mensing*, where the Court found preemption in a very similar case regarding generic drugs. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 609 (2011).

148. ROBERTS, *supra* note 130, at 203.

149. Label Insight, *Confusing Ingredients Cause Shoppers to Consider Switching Brands Even if it Means Paying More*, FOOD MFG. (June 28, 2017), <https://www.foodmanufacturing.com/labeling/news/13165312/study-confusing-ingredients-cause-shoppers-to-consider-switching-brands-even-if-it-means-paying-more> [<https://perma.cc/CM4E-WDYZ>].

150. *Id.*

151. ROBERTS, *supra* note 130, at 202.

152. See Van Tassel, *supra* note 34, at 247.

153. *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 513 (W.D. Pa. 2003) (stating that FDA’s premarket assessment “is based on a different standard than tort law-based scientific proof of causation”).

knowledge that accumulates as people actually purchase and consume a product.<sup>154</sup>

Significant obstacles for the consumer-plaintiff in establishing causation are defendants' potential ability to argue that a product became defective through the actions of others in the supply chain, that the harm might have been caused by other foods plaintiff consumed, or that a plaintiff's response is idiosyncratic or the result of plaintiff's mishandling of the product.<sup>155</sup> Accordingly, it may be quite difficult to show that but for consumption of a specific product or a specific ingredient in a product, the plaintiff would not have suffered harm.<sup>156</sup> Even if a plaintiff's reaction occurs soon after consuming the product, it can be difficult to prove causation.<sup>157</sup> If a plaintiff has an allergic or toxic response to a food that is ordinarily safe, their claim may be rejected as insufficient to establish liability because the plaintiff's response was idiosyncratic or unrelated to their consumption of the product.<sup>158</sup>

"Failure to warn" is a type of products liability claim that alleges that the manufacturer failed to alert the consumer of a foreseeable risk while using the product for its intended purpose. The Restatement (Third) of Torts imposes

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154. *See id.* at 542–43 (“This Court concludes that FDA does not—and the scientific community cannot—utilize postmarketing surveillance in assessing causation.”). Impossible began accumulating information early on because it had begun marketing its burger in restaurants, including fast food and chain restaurants, before it sought an FDA “no questions” letter. Impossible’s use of heme was reported in 2015. Yasmin Tayag, *The Meat Lover’s Guide to Heme, the Protein That Makes Everyone Crave Blood*, INVERSE (Sept. 4, 2015), <https://www.inverse.com/article/5948-the-meat-lover-s-guide-to-heme-the-protein-that-makes-everyone-crave-blood> [<https://perma.cc/TC72-54YH>]. Impossible launched the burger for the first time in 2016, first at a restaurant in New York City and then in west coast restaurants. Christina Troitino, *The Impossible Burger’s West Coast Debut and the Wild Frontier of Plant-Based Meat*, FORBES (Oct. 13, 2016), <https://www.forbes.com/sites/christinatroitino/2016/10/13/the-impossible-burgers-west-coast-debut-and-the-wild-frontier-of-plant-based-meat/?sh=fca4fd5cd8c1> [<https://perma.cc/7MKM-2K65>]. Impossible began conducting tests on animals in 2017 through a contract with Product Safety Labs. IMPOSSIBLE FOODS INC., GRAS NOTICE NO. 737, GRAS NOTIFICATION FOR SOY LEGHEMOGLOBIN PROTEIN PREPARATION DERIVED FROM *PICHTIA PASTORIS* 26, 28, 30, 31 (2017), <https://www.fda.gov/media/124351/download> [<https://perma.cc/BMD9-3HVQ>].

155. ROBERTS, *supra* note 130, at 205; *see also* Van Tassel, *supra* note 140, at 1680–81 (concerning idiosyncratic plaintiffs bearing responsibility for harm that occurs due to their ingestion of a substance that does not generally cause allergic reactions).

156. *See* Stearns, *supra* note 125.

157. ROBERTS, *supra* note 130, at 202–03.

158. *See* Stearns, *supra* note 110 (reporting that his firm had represented thousands of victims of foodborne illnesses but that only three went to trial and only one went to the jury because of the difficulty of proving causation); Van Tassel, *supra* note 140, at 1679. But specifically as to “failure to warn” cases, *see* CETRULO, *supra* note 126, § 39:46 (“[I]n the limited number of food contaminant cases to date, defendants have relied on preemption defenses to defeat the plaintiff’s failure to warn claims.”).

liability on defendants who, knowing of a danger, fail to provide reasonable warnings or instructions.<sup>159</sup> The elements of a failure to warn claim vary by jurisdiction but, when brought under a negligence theory, typically include the general tort requirements of duty, breach of duty, causation, and actual injury.<sup>160</sup> A consumer alleging injury from consuming a novel food ingredient they had no reason to expect in the food product might well argue that testing the ingredient would have uncovered the potential risk to consumers such that the “duty to warn” would have arisen. Certainly, food producers have a legal obligation to assess the safety of their novel ingredients, and failure to do so could lead to liability if causation were established. The issue is what type of testing would most reliably protect the company. There are various non-animal tests that can satisfy this requirement.<sup>161</sup>

Strict liability, on the other hand, requires showing only that the product was defective in some way and that the defect caused the harm to the plaintiff.<sup>162</sup> While this requires satisfaction of fewer elements, a difficult challenge remains: establishing a causal link between consumption of the specific substance and the harm to the consumer.<sup>163</sup>

Consider the case of *Watson v. Dillon Companies*,<sup>164</sup> in which a consumer brought claims against a microwave popcorn manufacturer alleging that his respiratory disorders were caused by flavoring ingredients in the defendant’s product.<sup>165</sup> Diacetyl, the specific chemical in the flavoring alleged to cause harm, was listed as GRAS for oral consumption, but exposure in this case was through inhalation.<sup>166</sup> The plaintiff brought product liability claims for negligence, strict liability, failure to warn, and a violation of the Colorado Consumer Protection Act (CCPA).<sup>167</sup> The *Watson* court found that because the popcorn manufacturer was aware of the health effects on workers from exposure to diacetyl in popcorn manufacturing plants, “[a] reasonable jury

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159. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (AM. L. INST. 1998) (“A product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings.”); *see also* W. PAGE KEETON, DAN B. DOBBS, ROBERT E. KEETON & DAVID G. OWEN, PROSSER & KEETON ON THE LAW OF TORTS § 99, at 697 (5th ed. 1984).

160. W. P. KEETON, DOBBS, R. KEETON & OWEN, *supra* note 159, at 164–65.

161. *See* Ingber, *supra* note 43.

162. ROBERTS, *supra* note 130, at 197–99.

163. *Id.* at 202.

164. 797 F. Supp. 2d 1138 (D. Colo. 2011).

165. *Id.* at 1147.

166. *Id.* at 1144 (“Although the U.S. Food and Drug Administration categorizes diacetyl as ‘GRAS,’ or ‘Generally Recognized as Safe,’ this label apparently concerns eating or consumption, and does not necessarily mean that the chemical is safe to inhale.”)(citing an expert witness’s report).

167. *Id.* at 1149.

could find that given the magnitude of the harm and the lack of information about the minimum exposure level capable of causing harm, the manufacturer acted recklessly in failing to investigate or warn consumers of the potential for harm.”<sup>168</sup>

In *Watson*, the court broke causation into two parts: first, the substance must be capable of causing the particular injury alleged, and second, the substance must have actually caused the plaintiff’s injury.<sup>169</sup> The court articulated four elements that may help in establishing specific causation: “(1) the toxic substance at issue has been demonstrated to cause in humans the disease or illness suffered by the plaintiff; (2) the individual has been exposed to a sufficient amount of the substance in question to elicit the health effect at issue; (3) the chronological relationship between exposure and effect is biologically plausible; and (4) the likelihood that the chemical caused the disease or illness is considered in the context of other known causes.”<sup>170</sup> Animal testing data could be relevant as to (3) and (4), but for reasons discussed in the next section, data derived from animal testing are not considered reliable by many courts. The *Watson* court did not find plaintiff’s expert’s evidence based on animal studies to be inadmissible, but the court relied heavily on the plentiful epidemiological data as a reason for admissibility of the expert’s opinion regarding causation.<sup>171</sup>

Consumer claims about unsafe food may also be brought under specific statutes of a given jurisdiction.<sup>172</sup> In the *Toxic Torts Litigation Guide*, Cetrulo points to California’s Safe Drinking Water and Toxic Enforcement Act of 1986, also known as Proposition 65 (Prop. 65), as a primary arena of litigation.<sup>173</sup> California’s Prop. 65 allows suits against manufacturers who fail to provide consumers warning of exposure to any chemical known to the state to cause

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168. *Id.* at 1162.

169. *Id.* at 1149.

170. *Id.* (citing *Henricksen v. ConocoPhillips Co.*, 605 F. Supp. 2d 1142, 1156 (E.D. Wash. 2009)).

171. *Id.* at 1154. (“Given the significant evidence of the toxicity of diacetyl and the epidemiological studies showing health effects from inhalation of butter flavoring ingredients containing diacetyl, I conclude that Dr. Egilman should be permitted to opine regarding general causation.”).

172. *See* *California v. Frito-Lay, Inc.*, 2008 WL 4108102 (Cal. Super. 2008) (verdict and settlement summary); *Sciortino v. Pepsico, Inc.*, 108 F. Supp. 3d 780 (N.D. Cal. 2015) (finding that Prop. 65 was not preempted and that consumer plaintiff could proceed on claim based on failure to warn of a known carcinogen in soft-drink products); *Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237 (3d Cir. 2008) (finding plaintiff was not preempted from bringing a claim for failure to warn of risks of consuming shellfish product, based on New Jersey Products Liability Act).

173. CETRULO, *supra* note 126, at § 39:47.

cancer or reproductive harm.<sup>174</sup> Failure to warn claims survive under Prop. 65, and are not preempted, because of the savings clause in the NLEA carving out an exception for warnings concerning food safety.<sup>175</sup> Accordingly, there is some minimal risk of exposure to liability if a new food ingredient falls within the scope of Prop. 65, but then the question, discussed in Part II.B. below, is whether data derived from animal testing would provide admissible evidence.

## II. Contract: Breach of Warranty

As an alternative theory to tort law, a consumer might want to make the contract claim of “breach of warranty” if the consumer is claiming injury from, say, ingestion of a plant-based burger in which an ingredient sourced from a genetically modified organism could not be anticipated without warning. An express warranty is one that is clearly communicated to the consumer, usually through writing, while an implied warranty of merchantability represents that the goods were of merchantable quality.<sup>176</sup> The exact requirements vary by jurisdiction, but in the food context, a manufacturer is typically required to provide food products fit for their intended use to a reasonable consumer.<sup>177</sup> Formulated this way, the analysis of these claims would overlap with tort analysis.<sup>178</sup> The courts often speak to whether a product was “wholesome” and

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174. CAL. HEALTH & SAFETY CODE § 25249.6 (West 2022).

175. The preemption provisions of the NLEA do not “apply to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food.” NLEA, Pub. L. No. 101-535, 104 Stat. 2364 (codified at 21 U.S.C. § 343-1). For a case that involved no preemption, see *Sciortino v. Pepsico, Inc.*, 108 F. Supp. 3d 780 (N.D. Cal. 2015). However, in some cases, failure to warn claims are found to be preempted, particularly when it comes to warnings on labels that are not required by the FDA. *See, e.g.,* *Cardinale v. Quorn Foods, Inc.*, 2011 WL 2418628 (Conn. Super. Ct. 2011) (holding that claims based on failure to warn of dangers in food product were preempted by FDA’s labeling requirements); *Mills v. Giant of Md., LLC*, 441 F. Supp. 2d 104 (D.D.C. 2006) (holding that FDCA preempted negligence and product liability claims based on failure to warn of harm to a lactose intolerant plaintiff from consuming dairy products). The FDCA contains three other preemption provisions on non-prescription drugs, 21 U.S.C. § 379r, medical devices, 21 U.S.C. § 360k, and cosmetics, 21 U.S.C. § 379s. In the case of both non-prescription drugs and cosmetics, the preemption expressly doesn’t affect actions under state products liability law. *E.g.*, 21 U.S.C. § 379r(e). All of the above-mentioned preemption provisions allow the Secretary of the FDA to create an exemption upon petition by the state. In the case of non-prescription drugs, the state requirement must “protect an important public interest that would otherwise be unprotected, including the health and safety of children.” 21 U.S.C. § 379r(b)(1)(A).

176. U.C.C. § 2-314 (AM. L. INST. & UNIF. L. COMM’N 1977).

177. *See Backus v. Gen. Mills, Inc.*, 122 F. Supp. 3d 909, 933 (N.D. Cal. 2015) (finding that plaintiff failed to state a breach of implied warranty claim where the amount of injurious ingredient at issue in baking mixes was not of the amount to “render[] them totally unfit for their intended use”).

178. *See generally* *Watson v. Dillon Cos.*, 797 F. Supp. 2d 1138 (D. Colo. 2011). *See also* *Van Tassel*, *supra* note 140, at 1672 n.141, 1685 n.180.

“fit for human consumption,” and apply either the foreign/natural object test or the reasonable consumer test as discussed above.<sup>179</sup>

Under breach of warranty analysis, a producer can be held liable for products that are “unmerchantable.”<sup>180</sup> A consumer would not have to establish negligence or fault on the part of the producer to recover damages under this theory, but merely that the producer sold the unmerchantable food and that the consumer’s illness was caused by the aspect of the food that made the product unfit.<sup>181</sup> Thus, this contract-based test of “unmerchantable” is nearly identical to that found for assessment of tort liability grounded in injury from which a “reasonable consumer” could not protect themselves.<sup>182</sup> In the hypothetical situation of claiming injury from ingestion of a plant-based burger with an ingredient produced from a genetically modified organism, a plaintiff would have to argue successfully that any reasonable consumer—not just the plaintiff—would not expect such an ingredient to exist in their plant-based product.

### III. Unfair or Deceptive Trade Practices

A claim for unfair trade practices may be argued under specific consumer protection laws of a jurisdiction. The legal requirements to bring such a claim and analysis of these claims vary by jurisdiction but typically turn on whether a manufacturer created a substantial danger to consumers and failed to adequately inform them.<sup>183</sup> Under federal law, “unfair or deceptive acts or practices in or affecting commerce[] are . . . unlawful.”<sup>184</sup> In addition, many states have individual consumer protection statutes, with requirements that vary by jurisdiction.<sup>185</sup> In general, these laws exist to protect consumers from unfair and unconscionable business practices that are likely to cause the consumer harm, which they cannot reasonably avoid, or when a representation or omission is likely to deceive or mislead a consumer in some meaningful way.<sup>186</sup> These claims, similar to the contract claims discussed above, are frequently

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179. ROBERTS, *supra* note 130, at 204–05.

180. U.C.C. § 2-314 (AM. L. INST. & UNIF. L. COMM’N 1977).

181. ROBERTS, *supra* note 130, at 204–05.

182. See Sean M. Flower, *Is Strict Product Liability in Tort Identical to Implied Warranty in Contract in the Context of Personal Injuries?*, 62 MO. L. REV. 381, 388–89 (1997).

183. Van Tassel, *supra* note 140, at 1685 (“There can be no negligence in the failure to warn about a risk in the absence of evidence that would justify a finding that a manufacturer or other seller knew or in the exercise of ordinary care should have known about the risk.”).

184. 15 U.S.C. § 45(a)(1).

185. ROBERTS, *supra* note 130, at 304.

186. *Id.* at 304–06.



brought in the alternative, and the analysis blends with torts, contracts, and failure to warn.<sup>187</sup>

Many of the cases regarding deceptive trade practices allege issues with the labeling of food products. These cases are frequently preempted by FDA regulations regarding labeling of food.<sup>188</sup> However, even when it comes to the highly, federally regulated field of labeling, some labeling claims have survived preemption. In one such case about the use of “natural” on a product’s label, the court held that the FDA had not established standards for use of “natural” and had not explicitly preempted states’ ability to define “natural” for sales of products in their jurisdictions.<sup>189</sup> There are other instances of surviving a manufacturer’s preemption labeling challenge, but all such cases show that there is considerable reliance on analysis of the specific factual circumstances of each situation.<sup>190</sup> A risk-averse company would analyze state laws that define “natural” or “organic” or “plant-based” to determine the company’s level of vulnerability and then label the product accordingly. If a non-GMO food product is labeled as “natural” in violation of a state law that defines “natural” in a specific way, there could be a challenge, but it is not a challenge that would most likely require animal testing to refute.

This Article has used Impossible’s use of GE heme as an example, so it is appropriate to consider GMO labeling requirements in somewhat more detail. Consumers have been wary of foods containing GMOs,<sup>191</sup> but the FDA has

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187. See generally *Watson v. Dillon Cos.*, 797 F. Supp. 2d 1138 (D. Colo. 2011).

188. See *Beasley v. Lucky Stores, Inc.*, 400 F. Supp. 3d 942 (N.D. Cal. 2019); *Beasley v. Conagra Brands, Inc.*, 374 F. Supp. 3d 869 (N.D. Cal. 2019); *Hawkins v. Kellogg Co.*, 224 F. Supp. 3d 1002 (S.D. Cal. 2016).

189. *Hilsley v. Gen. Mills, Inc.*, 376 F. Supp. 3d 1043, 1051 (S.D. Cal. 2019) (holding some claims regarding deceptive “natural” labels on fruit snacks were not preempted by FDA regulations).

190. See *Colella v. Atkins Nutritionals, Inc.*, 348 F. Supp. 3d 120 (E.D.N.Y. 2018) (holding NLEA preempted some, but not all, claims regarding deceptive low or no net carbs labels); *Garcia v. Kashi Co.*, 43 F. Supp. 3d 1359 (S.D. Fla. 2014); *Simpson v. Cal. Pizza Kitchen, Inc.*, 989 F. Supp. 2d 1015 (S.D. Cal. 2013).

191. Kevin T. Higgins, *What Do Consumers Think of GMOs?*, FOOD PROCESSING (June 7, 2018), <https://www.foodprocessing.com/product-development/gmos/article/11313385/what-do-consumers-think-of-gmos> [<https://perma.cc/55RZ-DHTE>] (finding that the overwhelming majority of consumers know about GMOs, that consumers have been less willing over time to purchase conventionally grown produce, and that they are increasingly relying on organic foods to reduce possible exposure to GMO foods); Cary Funk & Meg Hefferon, *Most Americans Accept Genetic Engineering of Animals That Benefits Human Health, but Many Oppose Other Uses*, PEW RECH. CTR. (Aug. 16, 2018), <https://www.pewresearch.org/science/2018/08/16/most-americans-accept-genetic-engineering-of-animals-that-benefits-human-health-but-many-oppose-other-uses/> [<https://perma.cc/ZY2Q-DLZX>] (finding that American respondents to survey were least likely to approve uses that provided little benefit, such as altering aquarium fish so that they would glow, and most likely to approve uses that benefit humans, such as altering mosquitoes’ reproductive capacity in order to limit spread of disease).

treated genetically engineered ingredients—even those that involve the insertion of genetic material from animals into plants—the same as ingredients produced by conventional plant hybridization techniques, and food producers have had no obligation to label products that include them.<sup>192</sup> While regulation of these ingredients may not change, new federal regulations regarding “bioengineered” food labeling (called the National Bioengineered Food Disclosure Standard) were published by the U.S. Department of Agriculture in 2018, and compliance became mandatory on January 1, 2022.<sup>193</sup> Prior to January 1, 2022, it was possible to argue that customers would be unlikely to bring causes of action based on an alleged injury from a GMO ingredient because they were unlikely to know of the existence of a GMO ingredient in a particular food product.<sup>194</sup> Consumer awareness of GMO ingredients may change in the aftermath of the new federal “bioengineered” labeling requirements, but critics of the law contend that there are hurdles to consumers learning about a GMO ingredient<sup>195</sup> and many loopholes that allow food producers to avoid labeling their products as containing GMO ingredients.<sup>196</sup> There might be an argument that state law should apply to products falling within such a loophole, but much would turn on how a court would evaluate the different bases of federal preemption of a state statute under the National Bioengineered Food Disclosure Standard.<sup>197</sup>

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192. See Van Tassel, *supra* note 34, at 223, 229–30, 237–42. Van Tassel notes that lack of consumer information means that consumers cannot make reasonable choices based on knowledge that the ingredients they are consuming are genetically modified. *Id.* at 238, 247.

193. National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 65814 (Dec. 21, 2018) (codified at 7 C.F.R. pt. 66).

194. Food producers could choose to label their products as “non-GMO,” but a producer that provided no labeling regarding GMO ingredients was not violating labeling laws, and nothing could be inferred from silence on the label. Van Tassel, *supra* note 140, at 1655, 1681–82.

195. See Keller and Heckman, LLP, *Legal Challenge to BE [Bioengineered] Food Disclosure Standard*, NAT. L. REV. (Jan. 4, 2022), <https://www.natlawreview.com/article/legal-challenge-to-be-food-disclosure-standard> [<https://perma.cc/JV7J-RLZQ>]. Among other complaints, several food producers and organizations fault the QR code option for disclosure of BE foods. *Id.* Not all customers have smartphones capable of reading the codes, and even those who do have smartphones may not take the additional time to scan the code. While the QR would not impede a determined consumer with a smartphone, consumers who would avoid GMO-containing foods if the information were more easily available may not gain information they consider valuable to some degree.

196. For example, the standard of “detectable” level of bioengineered food allows foods containing bioengineered ingredients to be present in food. *Id.*

197. The intent of the National Bioengineered Food Disclosure law is partially to avoid “a patchwork state-by-state system that could be confusing to consumers.” Press Release, U.S. Dep’t of Agric., Establishing the National Bioengineered Food Disclosure Standard (Dec. 20, 2018), <https://www.usda.gov/media/press-releases/2018/12/20/establishing-national-bioengineered-food-disclosure-standard>. [<https://perma.cc/G9RT-S8LY>]. See also this statement in the Federal Register:

As is the case in previous causes of action discussed in this section, consumers would face the challenge of showing that the cause of their alleged injury is attributable to the ingredient they allege injured them.<sup>198</sup> Most likely, they would have difficulty establishing specific causation or countering the producer's argument that they are partially at fault or that their injury is idiosyncratic rather than potentially common to all consumers.<sup>199</sup>

Taking all of this into account, it is reasonable to conclude that state law claims are not likely to cause problems for a food producer, and it appears that a food producer would have to be irrationally risk-averse to take strenuous steps to avoid a state law claim. In Part II.B., the focus is on how courts evaluate the admissibility of expert witness testimony based on animal test data. The purpose of this section is to assess whether it would make sense for a food producer to conduct animal tests to defend itself if sued under state laws not preempted by federal law.

### *B. Judicial Evaluation of Evidence Based on Animal Studies*

This section deals with judicial evaluation of evidence based on animal test data. As noted in the previous section, toxic tort litigator Lawrence Cetrulo says that food safety litigation is only in its infancy,<sup>200</sup> and food safety litigator Denis Stearns says that food safety cases are unlikely ever to go forward because of problems with causation.<sup>201</sup> Lucy Meigs et al. note, "The food industry is relevant with respect to animal testing only as to food additives and contaminants."<sup>202</sup> As discussed in the previous section, there are almost no such cases relevant to the subject of food additives. For that reason alone, a rational food manufacturer would not go to the expense of animal tests to reduce

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"This rule is intended to provide a mandatory uniform national standard for disclosure of information to consumers about the bioengineered status of foods." National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 65814, 65814 (Dec. 21, 2018) (codified at 7 C.F.R. 66). This suggests the intent to preempt state laws. However, the actual language regarding preemption in the National Bioengineered Food Disclosure statute is not completely clear: "State Food Labeling Standards.—Notwithstanding section 295 [of the Agricultural Marketing Act of 1946], 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 relating to the labeling or disclosure of whether a food is bioengineered or was developed or produced using bioengineering for *a food that is the subject of the national bioengineered food disclosure standard* under this section that is not identical to the mandatory disclosure requirement under that standard." National Bioengineered Food Disclosure Standard, Pub. L. No. 114-216, § 1, 130 Stat. 834, 837 (2016) (codified at 7 U.S.C. § 1639b(e)) (emphasis added).

198. See *supra* note 125 and accompanying text.

199. See *supra* notes 155–56 and accompanying text.

200. CETRULO, *supra* note 126, at § 39:44.

201. Stearns, *supra* note 110, at 370–71.

202. Meigs, Smirnova, Rovida, Leist & Hartung, *supra* note 124, at 302 (emphasis omitted).

negligible liability exposure risk. This is all the more true since more reliable, predictive non-animal tests exist<sup>203</sup> and since courts are not uniformly or predictably receptive to animal study-derived data to support safety assessment evidence. This section examines the basis for judicial skepticism about the predictive reliability of animal study data to assess the safety of substances to which consumers are exposed. Because of the lack of food additive cases, this section relies on consideration of judicial responses in the analogous context of pharmaceutical drug litigation.

Following enactment of Federal Rule of Evidence 702, the U.S. Supreme Court decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,<sup>204</sup> and then the subsequent amendment of Rule 702, the admissibility of a particular expert's testimony is not completely predictable because so many case-specific circumstances must be considered by courts. While *Daubert* itself dealt with live animal studies among other research methods, the Supreme Court's decision did not directly address the admissibility of expert testimony about data from such studies.<sup>205</sup> In addition to expert testimony based on data derived from live animal tests, petitioners submitted expert testimony based on data derived from chemical structural analysis and petitioners' reanalysis of respondent's epidemiological data.<sup>206</sup> These submissions were intended to support petitioners' claim that respondent's prescription anti-nausea drug, Bendectin, had caused petitioners' birth defects.<sup>207</sup> Both the district court and the court of appeals rejected the petitioners' evidence.<sup>208</sup> Discussing the importance of epidemiological evidence and the insufficiency of animal test-derived evidence, the district court stated:

The federal courts have held that epidemiological studies are the most reliable evidence of causation in this area [of Bendectin litigation]. Accordingly, expert opinion which is not based on epidemiological evidence is not admissible to establish causation because it lacks the sufficient foundation necessary under FRE 703 [general acceptance in the scientific

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203. See *supra* note 44 and accompanying text.

204. 509 U.S. 579 (1993).

205. See *id.*

206. *Id.* at 584; "Epidemiology is the study and analysis of the distribution (who, when, and where), patterns and determinants of health and disease conditions in defined populations." *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Litig.*, 509 F. Supp. 3d 116, 130 n.7 (D.N.J. 2020) (citing Michael D. Green, D. Michal Freedman, & Leon Gordis, *Reference Guide on Epidemiology*, in FEDERAL JUDICIAL CENTER & NATIONAL RESEARCH COUNCIL OF THE NATIONAL ACADEMIES, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 549, 551, 623 (Nat'l Acads. Press 3d ed. 2011)).

207. *Daubert v. Merrell Dow Pharms., Inc.*, 951 F.2d 1128, 1129 (9th Cir. 1991).

208. *Id.* at 1131.

community]. Therefore, expert testimony concluding that Bendectin causes limb reduction defects which is generally based upon *in vitro* studies, chemical structure analyses and animal studies is insufficient to take the issue to the jury. The plaintiffs' experts must be competent to testify that some epidemiological study or recalculation shows a statistically significant relationship between the ingestion of Bendectin and birth defects and that this study forms the basis of their opinion. In this case, the plaintiffs have failed to . . . provide some epidemiological evidence to support their claim that Bendectin is a teratogen.<sup>209</sup>

Having decided that petitioners lacked admissible evidence with which to make their case both as to scientifically acceptable methodology and the causal link to petitioners' own birth defects, the district court granted summary judgment to respondent, Merrell Dow Pharmaceuticals.<sup>210</sup> The Ninth Circuit Court of Appeals conducted a *de novo* review of whether the expert testimony advanced by the petitioners was based on reliable, accepted scientific methods.<sup>211</sup> The court ultimately agreed with the district court both as to scientific acceptability of the petitioners' evidence and as to petitioners' failure to establish a causal link between the ingestion of Bendectin and their birth defects.<sup>212</sup>

The Supreme Court did not agree with the lower courts regarding centrality of the scientific community's acceptance of the research method through which the proffered evidence had been derived.<sup>213</sup> The Court held that Federal Rule of Evidence 702, enacted after the case law on which the lower courts relied, included consideration of general scientific acceptance as only one aspect of a trial court's decision.<sup>214</sup> A trial court must also assess the scientific validity and reliability of evidence by considering such things as whether the method or theory used to derive the data offered into evidence had been tested, whether it had been subjected to peer review and had been published, whether the method has a high known or potential error rate, and the reliability of the method or theory as applied to the circumstances of the particular case before the court.<sup>215</sup> The case was remanded with directions to consider all of these aspects of the

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209. *Daubert v. Merrell Dow Pharms., Inc.*, 727 F. Supp. 570, 575 (S.D. Cal. 1989) (internal citations omitted) (citing *Brock v. Merrell Dow Pharms.*, 874 F.2d 307, 311–15 (5th Cir. 1989), *modified on reh'g* 884 F.2d 166 (5th Cir. 1989)).

210. *Id.* at 576.

211. *Daubert*, 951 F.2d at 1130.

212. *Id.* at 1131.

213. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993).

214. *Id.* at 594.

215. *Id.* at 592–94.

expert testimony petitioners offered.<sup>216</sup> On remand, the Ninth Circuit did not evaluate the scientific validity of animal test data, finding that petitioners' experts' data would not enable them to show that it was more likely than not that Bendectin had caused the birth defects from which petitioners suffered, as required by California tort law.<sup>217</sup>

Although the scientific reliability of animal research-derived data was not specifically addressed in the Supreme Court's analysis in *Daubert*, *Daubert* placed responsibility on courts to evaluate expert witness testimony and evidence, including animal research-derived data. Following its 1993 *Daubert* decision, the Supreme Court affirmed in a 1997 decision the importance of judicial evaluation of the scientific reliability and fitness of expert testimony in a specific factual context that involved animal testing.<sup>218</sup> When reviewing whether a court had abused its discretion in granting summary judgment based on refusing to admit evidence reliant on animal testing, the Supreme Court upheld the court's rejection of animal test-based evidence, holding that the court was entitled to deference and had not abused its discretion when it rejected animal studies involving infant mice that developed alveologenic adenomas after exposure to massive doses of PCBs administered directly into the lining of their stomachs.<sup>219</sup> The Court noted that plaintiff, Joiner, was an adult human whose type of cancer differed from that of the infant mice and whose exposure to PCBs was much less concentrated than was that of the mice.<sup>220</sup>

The post-*Daubert* case, *Watson v. Dillon Companies*, discussed above,<sup>221</sup> involved expert witness submissions based on both animal research data and epidemiological data.<sup>222</sup> There was considerable epidemiological evidence derived from the experience of microwave popcorn plant employees constantly exposed to diacetyl, and the court's decision relied heavily on that evidence.<sup>223</sup> However, both types of evidence were admitted into evidence, and the court does not state explicitly that animal test-derived evidence is less scientifically valid than epidemiological data, though it does acknowledge the limits of such evidence as applied to humans.<sup>224</sup>

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216. *Id.* at 598.

217. *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1320–21 (9th Cir. 1995).

218. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136 (1997).

219. *Id.* at 144–45.

220. *Id.* at 144.

221. *See supra* notes 164–71 and accompanying text.

222. *Watson v. Dillon Cos.*, 797 F. Supp. 2d 1138 (D. Colo. 2011).

223. *Id.* at 1154.

224. *Id.* at 1153–54.

*Watson v. Dillon Companies* is the only case that emerged in a search for food product litigation that involves animal test-derived data.<sup>225</sup> On the other hand, there are several such cases involving pharmaceuticals in which consumers claim injury. Perhaps one of the most extensively reasoned cases involving animal studies is that of *Soldo v. Sandoz Pharmaceuticals Corp.*, in which plaintiff relied on expert testimony regarding animal tests to allege harm from one of the defendant's prescription drugs.<sup>226</sup> The court began with a description of the requirements of *Daubert* and then drew attention to *General Electric Co. v. Joiner*, in which the Court did not disturb the lower court's decision that evidence derived from animal studies was inadmissible:

[A] two-step analysis is used to assess the admissibility of the proffered expert testimony on scientific issues under Rule 702. First, the expert testimony must be reliable, so that it must be "scientific," meaning grounded in the methods and procedures of science, and must constitute "knowledge," meaning something more than subjective belief or unsupported speculation.

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In addition, *Daubert* requires an appropriate "fit" with respect to the offered opinion and the facts of the case. The "fit" requirement stems from the instruction of Federal Rule of Evidence 702 that proffered expert testimony must "assist . . . the trier of fact." Under *Daubert*, scientific testimony does not assist the trier of fact unless the testimony has a *valid scientific connection* to the pertinent inquiry. For example, there is no fit where there is "simply too great an analytical gap between the data and the opinion offered," as when an expert offers animal studies showing one type of cancer in mice to establish causation of another type of cancer in humans.<sup>227</sup>

At numerous points, the court emphasizes the greater value of epidemiological research and diminishes the value of animal study data. For instance, the court includes multiple citations to support its view that epidemiology is "the primary generally accepted methodology for demonstrating a causal relation between a chemical compound and a set of

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225. This does not mean that such lawsuits have not been filed. Such lawsuits could have settled or withdrawn, for instance. It is to say only that food litigation that involves cases in which animal test-derived data might be submitted did not emerge in a search for such cases.

226. *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434 (W.D. Pa. 2003).

227. *Id.* at 526–27 (internal citations omitted) (first citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 590–91 (1993); and then citing *Gen. Elec. Co. v. Joiner*, 522 U.S. 136 (1997)).

symptoms or a disease.”<sup>228</sup> At another point, the court notes that “studies of laboratory animals are routinely excluded as irrelevant and unreliable when proffered as a basis for medical causation testimony.”<sup>229</sup> The court cites with approval *Wade-Greaux v. Whitehall Laboratories, Inc.*,<sup>230</sup> in which data derived from research on primates was disallowed, with the *Wade-Greaux* court “conclud[ing] that the theory of plaintiff’s expert witnesses that they can directly extrapolate from experimental animal studies without supportive positive human studies to opine as to causation in humans is one that has an extraordinarily high rate of error.”<sup>231</sup> Indeed, the *Soldo* court cites multiple cases in which evidence derived from animal study data was not admissible.<sup>232</sup>

As to the case at bar, the *Soldo* court writes, among other criticisms, that while “plaintiff’s experts recognize that human studies carry greater weight than animal studies, they provide no explanation for why they give more weight to an animal study showing alleged effects in the ‘dependent ear margins in dogs with long hanging ears’ than negative human studies or human studies demonstrating vasodilation, given that plaintiff is not a dog and does not have long hanging ears.”<sup>233</sup> In other words, the *Soldo* court first dealt with the matter of whether animal study research is scientifically sound and then dealt with the matter of its fitness for deciding the dispute before it, as required post-*Daubert*.

The *Soldo* court also dispenses with the argument that regulatory bodies might have approved marketing of a substance based on animal research data. The court agreed with the view that “the decisions made in the regulation of pharmaceutical companies do not necessarily reflect methodologies or conclusions considered acceptable in the scientific arena and are not necessarily based on the scientific method. . . . Such regulatory decisions are no better or worse than the scientific methodology and evidence on which they are based.”<sup>234</sup> Indeed, the court notes, “Plaintiff’s experts have themselves admitted that FDA decision-making is based on a different standard than tort law-based

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228. *Id.* at 532 (first quoting *Conde v. Velsicol Chem. Corp.*, 804 F. Supp. 972, 1025–26 (S.D. Ohio 1992), *aff’d*, 24 F.3d 809 (6th Cir. 1994); then citing *Allen v. Pennsylvania Eng’g Corp.*, 102 F.3d 194, 197 (5th Cir. 1996); then citing *Turpin v. Merrell Dow Pharms.*, 959 F.2d 1349, 1351–56, 1360 (6th Cir. 1992); and then citing *In re Breast Implant Litig.*, 11 F. Supp. 2d 1217, 1224 (D. Colo. 1998)).

229. *Soldo*, 244 F. Supp. 2d at 546.

230. *Wade-Greaux v. Whitehall Lab’ys, Inc.*, 874 F. Supp. 1441 (D.V.I. 1994), *aff’d without op.*, 46 F.3d 1120 (3d Cir. 1994).

231. *Soldo*, 244 F. Supp. 2d at 546–47 (citing *Wade-Greaux*, 874 F. Supp. at 1480).

232. *Id.* at 547.

233. *Id.* at 512.

234. *Id.* at 513 (citing a report submitted to the Court by Dr. David A. Savitz).



scientific proof of causation.”<sup>235</sup> This may be because of the greater availability of post-market epidemiological evidence than what is available during pre-market safety assessments.

Courts sometimes express multiple concerns about the use of animal studies. *Johnson v. Arkema* exemplifies how a court could reject the admissibility of evidence based on animal testing because of a failure to justify higher dosing in animals as compared to human exposure and, also, inappropriate extrapolation to humans.<sup>236</sup> Plaintiff alleged that his being diagnosed with severe restrictive lung disease and pulmonary fibrosis was the result of two exposures to a chemical used by his employer company, Arkema.<sup>237</sup> Plaintiff’s expert witness relied on two animal studies.<sup>238</sup> One involved exposing nine baboons to the chemical to which plaintiff had been exposed.<sup>239</sup> Although one of the baboons did develop lung impairment, the impairment arose after the baboon received a much higher exposure than the plaintiff had experienced.<sup>240</sup> The district court rejected the evidence, noting that plaintiff’s expert witness had not even attempted to address equivalency of the plaintiff’s exposure and that of the baboons.<sup>241</sup> That expert also acknowledged that “humans are ‘pretty unique.’”<sup>242</sup> For similar reasons the court rejected plaintiff’s submission of evidence from a study involving rats.<sup>243</sup> The court emphasized that animal studies have limited utility when addressing questions of toxicity, stating that studies of the effects of chemicals on animals must “be carefully qualified in order to have explanatory potential for human beings.”<sup>244</sup>

Full review of cases alleging harm from pharmaceutical products is well beyond the scope of this Article, which is focused on animal testing in the context of novel food ingredients. Nevertheless, even limited review of pharmaceutical cases reveals many cases in which the court rejects reliance on

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235. *Id.*

236. *Johnson v. Arkema*, 685 F.3d 452 (5th Cir. 2012).

237. *Id.* at 457–58.

238. *Id.* at 460.

239. *Id.* at 463.

240. *Id.*

241. *Id.*

242. *Id.*

243. *Id.* at 465–66.

244. *Id.* at 466 (quoting *Allen v. Pa. Eng’g Corp.*, 102 F.3d 194, 197 (5th Cir. 1996)).

animal study data.<sup>245</sup> Sometimes courts explicitly specify concerns about particular aspects of the study's methodology, such as choice of test species,<sup>246</sup>

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245. *See, e.g.*, *Siharath v. Sandoz Pharms. Corp.*, 131 F. Supp. 2d 1347, 1369 (N.D. Ga. 2001) (“Plaintiffs also contend that a number of studies conducted on pithed animals (Plaintiffs’ Exs. 18, 19, 20, 21 & 210) show that bromocriptine can cause severe vasoconstriction. Pithed animals have had their central nervous system obliterated. The pithed animal studies at issue include rats, mice, dogs, cats and rabbits. . . . Because causation must be based on scientific knowledge allowing for a reasonable degree of medical certainty rather than mere ‘leaps of faith,’ the Court must conclude that the animal studies do not assist Plaintiffs in satisfying the requirements of *Daubert.*”); *In re Zolof (Sertraline Hydrochloride) Prods. Liab. Litig.*, 26 F. Supp. 3d 466, 480 (E.D. Pa. 2014) (“Without evidence that the effects on the serotonin transporter are conserved across species, it is speculative to draw conclusions about human development from *in vitro* or even animal studies.”); *Blum v. Merrell Dow Pharms., Inc.* 705 A.2d 1314, 1323 (Pa. Super. Ct. 1997) (“Animal studies can also provide evidence suggestive of causation. However, animal studies without epidemiological studies cannot prove causation in humans because drugs do not have the same effect on humans as they do on animals; the doses given to animals in animal studies are very different from those given to humans.”); *Lust v. Merrell Dow Pharms, Inc.*, 89 F.3d 594, 596, 598 (9th Cir. 1996) (excluding expert opinion partly based on animal studies reporting fertility drug to be teratogenic in four species of animals); *Sorensen v. Shaklee Corp.*, 31 F.3d 638, 644, 648 (8th Cir. 1994) (rejecting plaintiff expert opinion based on animal studies showing sterilant caused teratogenic effects in mice, rats, rabbits, and monkeys).

246. *See, e.g.*, *Ellis v. Pneumo Abex Corp.*, 62 F. Supp. 3d 833, 841 (C.D. Ill. 2014) (questioning whether mice were appropriate species in a particular cancer study); *Bourne ex rel. Bourne v. E.I. DuPont de Nemours & Co.*, 189 F. Supp. 2d 482, 496 (S.D.W. Va. 2002) (proffered expert testimony excluded as neither reliable nor relevant due to extrapolation from high-dosage, single species *in vivo* testing and lengthy exposure *in vitro* testing where no epidemiological studies supported experts’ position, and the relied upon animal studies were far removed from child’s allegations); *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1338–40 (11th Cir. 2010) (“[The] study at most suggests a connection between the use of intra-articular pain pumps, bupivacaine, and chondrolysis in *rabbit* cartilage. This does not equate to a conclusion of direct causation (or a connection of any degree) between the use of such pain pumps and chondrolysis in humans. . . . [The expert] also could not explain the possible differences in dose-response relationship between humans and rabbits. . . . [Regarding] a study of cow and human cartilage . . . the authors could not state how their test results would transfer when conducted on a live human subject.”); *Turpin v. Merrell Dow Pharms., Inc.*, 959 F.2d 1349, 1359–60 (6th Cir. 1992) (“The record fails to make clear why the varying doses of Bendectin or doxylamine succinate given to the rats, rabbits and *in vitro* animal cells would permit a jury to conclude that Bendectin more probably than not causes limb defects in children born to mothers who ingested the drug at prescribed doses during pregnancy. . . . Several animal studies of cortisone, for example, found that it causes severe cleft palate birth defects in several animal species, but it does not cause this effect in humans.”); *Tyler ex rel Tyler v. Sterling Drug, Inc.*, 19 F. Supp. 2d 1239, 1244 (N.D. Okla. 1998) (excluding evidence based on animals because they were not necessarily reliable evidence of same reaction in humans); *Viterbo v. Dow Chem. Co.*, 826 F.2d 420, 424 (5th Cir. 1987) (excluding the evidence where there was only a single animal study of picloram and it showed a link to a disease completely different than plaintiff’s diseases); *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1410 (D. Or. 1996) (“Extrapolations of animal studies to human beings are generally not considered reliable in the absence of a scientific explanation of why such extrapolation is warranted.”); *E.I. DuPont De Nemours & Co. v. Castillo ex rel. Castillo*, 748 So. 2d 1108, 1120 (Fla. Dist. Ct. App. 2000) (rejecting plaintiffs’ expert’s testimony based solely on rat gavage studies, noting that “experts

choice of method of exposing animals to the substance,<sup>247</sup> and comparability of animal exposure to human exposure to the same substance.<sup>248</sup> As in the case of *Watson v. Dillon Companies*, courts value epidemiological data more than animal studies as scientific evidence to establish causation.<sup>249</sup>

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conceded . . . that the direct extrapolation method they used in their study was new and that they were unaware of any scientific study that has ever purported to determine a human teratogenic exposure level in this manner.”).

247. Some judicial decisions in which method of exposure is specifically addressed by the courts include the following: *Bourne ex rel. Bourne*, 189 F. Supp. 2d at 498–99 (holding that experts’ reliance on evidence based on administration of high doses of benomyl directly into the stomachs of rats was not justified because of lack of “fit” with the facts of the case as alleged and deciding that “the methodologies of [experts] in concluding that benomyl is a human teratogen [were] unsound”); *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 144 (finding that the District Court did not abuse its discretion in excluding expert testimony based on “studies involv[ing] infant mice that had developed cancer after being exposed to PCB’s [since] [t]he infant mice in the studies had had massive doses of PCB’s injected directly into their peritoneums or stomachs [and] Joiner was an adult human being whose alleged exposure to PCB’s was far less than the exposure in the animal studies”); *Nat’l Bank of Com. (of El Dorado, Ark.) v. Dow Chem. Co.*, 965 F. Supp. 1490, 1527 (E.D. Ark. 1996) (finding that the method of exposure in the animal studies does not fit with the method alleged by plaintiff).

248. For judicial decisions in which courts reject expert reliance on animal test data because of incomparability of exposure to a substance, either as a general matter or specific to the case, see for example, *Joiner v. Gen. Elec. Co.*, 864 F. Supp. 1310 (N.D. Ga. 1994) (excluding expert testimony based on animal studies in part because results from exposure to massive doses of undiluted PCBs could not be extrapolated to plaintiff whose exposure to PCBs was much less); *Bourne ex rel. Bourne*, 189 F. Supp. 2d at 498 (excluding experts’ reliance on rat gavage studies and the *in vitro* tests relied upon by experts, using injections of high-levels of benomyl, because of lack of fit with the facts of the case); *Gulf S. Insul. v. U.S. Consumer Prod.*, 701 F.2d 1137, 1146 (5th Cir. 1983) (rejecting evidence based on animal testing in part because rats in the study “were exposed regularly to much higher doses” than the average level of exposure in the experiment); *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 407 (S.D.N.Y. 2005) (rejecting plaintiffs’ proposed expert testimony in part because “the high doses often used in animal studies may not correspond to considerably lower concentrations of a drug or other substance to which humans are in reality exposed”); *In re Incretin-Based Therapies Prods. Liab. Litig.*, 524 F. Supp. 3d 1007, 1040 (S.D. Cal. 2021) (rejecting evidence based on animal test data because expert did not consider “whether the dose used in the animal studies upon which he relied, were similar to those administered to humans”); *Sorensen v. Shaklee Corp.*, 31 F.3d 638, 646 n.12 (8th Cir. 1994) (rejecting animal test data in this case because of problems with extrapolation to humans when the dose-response differential between animals and humans, is too great.); *Nat’l Bank of Com. v. Dow Chem. Co.*, 965 F. Supp. 1490, 1527 (E.D. Ark. 1996) (rejecting animal test data on the ground that the large doses used in animal tests ordinarily preclude extrapolation to humans), *aff’d*, 133 F.3d 1132 (8th Cir. 1998).

249. See, e.g., *In re Accutane Litig.*, 191 A.3d 560, 591 (N.J. 2018) (stating that “while animal studies may be helpful in ‘framing hypotheses,’ the [Federal Judicial Center’s] Reference Manual [on Scientific Evidence] intimates that such evidence is far less probative in the face of a ‘substantial body of epidemiologic evidence’ ”); *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823, 830 (D.C. Cir. 1988) (“These three types of studies then—chemical, *in vitro*, and *in vivo* . . . singly or in combination, are not capable of proving causation in human beings in the face of the overwhelming body of contradictory epidemiological evidence.”); *Brock v. Merrell Dow Pharms., Inc.*, 874 F.2d 307, 313

All of this is not to say that animal test-derived evidence will always be rejected as lacking scientific validity or fitness with the specific facts of the case. Indeed, the Federal Judicial Center's Reference Manual on Scientific Evidence states the following with specific regard to toxic metal testing: "In qualitative extrapolation, one can usually rely on the fact that a compound causing an effect in one mammalian species will cause it in another species."<sup>250</sup> Yet, the Manual goes on to say that care with dosing is necessary for extrapolation.<sup>251</sup>

As for in vitro tests, the Manual states the following:

There are short-term in vitro tests for just about every physiological response and every organ system, such as perfusion tests and DNA studies, [but] [r]elatively few of these tests have been validated by replication in many different laboratories or by comparison with outcomes in animal studies to determine if they are predictive of whole animal or human toxicity (footnote omitted). However, these tests, and their

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(5th Cir. 1989) (reviewing methodology of various animal studies offered as the basis of expert testimony and rejecting reliance on animal study data of "questionable applicability to humans" in the absence of conclusive epidemiologic evidence); *In re Abilify* (Aripiprazole) Prods. Liab. Litig., 299 F. Supp. 3d 1291, 1307, 1310 (N.D. Fla. 2018) (finding that an "epidemiological study identifying a statistically significant association between the use of a drug and a particular adverse effect, accompanied by a reliable expert opinion that the association is causal, is 'powerful' evidence of general causation" and noting that as to animal studies, "an expert must explain how and why the studies can be reliably extrapolated" to humans); *In re Incretin-Based Therapies* Prods. Liab. Litig., 524 F. Supp. 3d 1007, 1040 (S.D. Cal. 2021) ("[A]nimal studies are not generally admissible where contrary epidemiological evidence in humans exists.") (quoting *In re Silicone Gel Breast Implants* Prod. Liab. Litig., 318 F. Supp. 2d 879, 891 (C.D. Cal. 2004)); *Lee v. Richardson-Merrell, Inc.*, 772 F. Supp. 1027, 1030–33 (W.D. Tenn. 1991) (where extensive epidemiological data failed to establish a causal connection between human ingestion of Bendectin and birth defects, expert testimony reliant on animal testing and in vitro testing on isolated cells and tissue was not admissible.); *In re Agent Orange* Prod. Liab. Litig. 611 F. Supp. 1223, 1250 (E.D.N.Y. 1985) (rejecting plaintiffs' experts' opinions based on "studies on the effects of exposure to TCDD on animals and on workers after industrial accidents" because the experts did not include analysis of "epidemiological studies conducted on Vietnam Veterans . . . that address[ed] the actual population and amount of exposure involved in this lawsuit"); *Lynch v. Merrell-Nat'l Laboratories*, 830 F.2d 1190, 1194 (1st Cir. 1987) (rejecting in vivo and in vitro animal studies because they could not establish causation in human beings without any epidemiological data aligning with the animal-based data); *Raynor v. Merrell Pharms. Inc.*, 104 F.3d 1371, 1375–77 (D.C. Cir. 1997) (rejecting chemical structure analysis, in vivo animal studies, and in vitro studies in the context of contrary epidemiological evidence and lack of peer review).

250. Bernard D. Goldstein & Mary Sue Henifin, *Reference Guide on Toxicology*, in FEDERAL JUDICIAL CENTER & NATIONAL RESEARCH COUNCIL OF THE NATIONAL ACADEMIES, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 633, 646 (Nat'l Acads. Press 3d ed. 2011)).

251. *Id.* at 645.

validation, are becoming increasingly important.<sup>252</sup>

There are indeed many non-animal tests, which will surely displace animal-based testing because of their greater utility in protecting both human safety and animal welfare.<sup>253</sup> This section has shown that animal tests chosen for FDA approval purposes would not reliably pass judicial muster in post-marketing tort litigation. A rational food producer would use the most reliable tests available to produce the safest product, in order to meet FDA obligations and to protect against a consumer safety lawsuit. Such a producer would be looking at the science and not simply relying on either product safety assessment companies, whose incentives may not be fully aligned with the producer's objective, or the opinions of FDA reviewers that may not be familiar with the most current scientific methods available.

### PART III. CONSUMER PERSPECTIVES

Thus far, this Article has shown that there is no legal reason a rationally risk-averse food producer would test a new food ingredient on animals. Part III considers whether there might be a marketing advantage to testing on animals. Existing scholarship does not answer such questions as whether consumers would value a new product more if they assume that its new ingredient is so novel that it had to be tested on animals or whether consumers, not knowing its low predictive reliability, generally want assurance of safety testing on animals. Consumers appear to generally prefer personal care products that have not been

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252. *Id.* at 645–46. The criteria of reliability for an in vitro test include the following: (1) whether the test is predictive of in vivo outcomes related to the same cell or target organ system, (2) whether the test has come through a published protocol in which many laboratories used the same in vitro method on a series of unknown compounds prepared by a reputable organization (such as the National Institutes of Health (NIH) or the International Agency for Research on Cancer (IARC)) to determine if the test consistently and accurately measures toxicity, and (3) whether the test has been adopted by a U.S. or international regulatory body. These criteria of verification and cross-validation of methods are increasingly met such that reliance on whole animal testing is decreasing. Virtual Interview with Kathy Guillermo, Senior Vice President, PETA Laboratory Investigations Department, and Jeff Brown, Science Advisor, PETA Regulatory Testing Department (July 8, 2020). The U.S. Department of Health and Human Services' National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) maintains a list of testing methods "that are accepted by U.S. and international regulatory authorities as replacement, reduction, or refinement alternatives to required animal tests." *Alternative Methods Accepted by U.S. Agencies*, NAT'L TOXICOLOGY PROGRAM, <https://ntp.niehs.nih.gov/whatwestudy/niceatm/accept-methods/index.html> [<https://perma.cc/4DJ3-QVYE>].

253. *See supra* notes 43–44.

tested on animals,<sup>254</sup> but perhaps their views differ when the product is ingested as food.

Both Beyond and Impossible have paid particular attention to consumers, targeting those attached to meat and trying to replicate exactly the experience of eating meat. Perhaps some might think that meat-eaters would not care about ingredient testing on animals. However, meat-eaters might, in fact, care about whether animal testing, and non-meat-eaters who want to avoid animal testing may be the ones who provide the most market buoyancy for a plant-based product. For instance, Joseph Szala, managing director of a restaurant consultancy, stated with regard to plant-based menu items: “While vegan and vegetarian patrons will continue to order these kinds of items, they don’t hold much appeal outside of that.”<sup>255</sup> He was discussing this in the context of restaurants like Del Taco, TGI Friday, and Dunkin’ dropping altogether or reducing menu space for plant-based options as part of their menu-reduction strategies.<sup>256</sup>

Ultimately, consumers’ reasons for eating plant-based meat alternatives and their perspectives on animal-tested ingredients could be a very important factor in a food producer’s decision to use or to avoid animal testing. Accordingly, the history of adoption of meat substitutes, including reasons for use, accessibility, and preferences for types of protein sources and methods of production are all relevant to a consideration of plant-based food manufacturers’ decisions. Both Beyond and Impossible market their products throughout the world, complicating the picture of consumer perspectives. Part III.A. briefly considers first the history of meat substitutes, which reveals many reasons other than animal welfare for their adoption. Since it is not clear that animal welfare was a primary motivation to develop or consume meat alternatives, perhaps consumers would not avoid meat alternatives whose ingredients were tested on animals. To explore questions about consumer receptivity to animal testing to

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254. See Postlewhite, *supra* note 27; see also *Global Vegan Cosmetics Industry (2020 to 2027) – Market Trajectory & Analytics – ResearchAndMarkets.com*, BUS. WIRE (May 5, 2021), <https://www.businesswire.com/news/home/20210505005544/en/Global-Vegan-Cosmetics-Industry-2020-to-2027—Market-Trajectory-Analytics—ResearchAndMarkets.com> [<https://perma.cc/FMQ8-JHWT>] (“The global market for Vegan Cosmetics estimated at US \$15.1 Billion in the year 2020, is projected to reach a revised size of US \$21.4 Billion by 2027, growing at a CAGR of 5.1% over the analysis period 2020–2027.”).

255. Leslie Patton & Deena Shanker, *Beyond Meat Loses Some Early Restaurant Fans As Others Double Down*, BLOOMBERG (Feb. 3, 2022), <https://www.bloomberg.com/news/articles/2022-02-03/some-beyond-meat-early-adopters-move-on-as-others-double-down> [<https://perma.cc/Y4KY-ZL7F>].

256. *Id.* (noting a phenomenon of restaurants first adopting and later dropping plant-based food items and, quoting Szala, “Smaller menus mean quicker and more accurate ordering, preparing, delivering.”).

assess toxicity and allergenicity of novel food ingredients, the author and Professor Adam Feltz conducted a nationally representative survey of American consumers' views. Some of those survey results are discussed in Part III.B.

### *A. History of Meat Alternative Usage*

The use of processed plant foods explicitly identified as meat substitutes has a long history. That history reflects impacts due to the timing of identification and development of appropriate sources to replace the nutritional content of meat, changing technologies to produce alternatives to meat, and considerations of consumer receptivity to different types of meat alternatives.<sup>257</sup> Asia has a longer tradition of foods known now to be good sources of protein and as nutritionally adequate meat replacements. The first known written mention of such a food was in 965 CE in China, when the use of soybeans was facilitated by its easy production methods and encouraged as a frugality measure.<sup>258</sup> Called “mock lamb chops,” this substitution may have had more to do with the malleability of tofu to appear as different food products than to the deliberate search for a protein source; the term “protein” was first used in the scientific literature in 1838.<sup>259</sup> Soy is now accepted as a good but somewhat problematic protein source because of its potential to provoke an allergic response.<sup>260</sup> Processed in various ways and readily available in grocery stores in the United States, soy continues as a commonly used protein alternative to animal-based meat products. Indeed, it commands an increasing market share of protein-supplying foods.<sup>261</sup> MarketResearch.com reported in April 2021 that

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257. Jiang He, Natasha Marie Evans, Huaizhi Liu & Suqin Shao, *A Review of Research on Plant-Based Meat Alternatives: Driving Forces, History, Manufacturing, and Consumer Attitudes*, 19 COMPREHENSIVE REVS. FOOD SCI. & FOOD SAFETY 2639 (2020).

258. SHURTLEFF & AOYAGI, *supra* note 1, at 5.

259. Daniel E. Koshland, *Protein*, BRITANNICA, <https://www.britannica.com/science/protein> [<https://perma.cc/LP7R-ZD8A>].

260. *Food Allergies*, U.S. FOOD & DRUG ADMIN. (Jan. 31, 2022), <https://www.fda.gov/food/food-labeling-nutrition/food-allergies> [<https://perma.cc/82JC-VCW5>] (listing the 8 major food allergens recognized by the United States—milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, and soybean—which require allergen labeling, and noting that effective Jan. 1, 2023, sesame will be added to this list).

261. See Suzanne Hamlin, *Do You Speak Tofu or Miso Yet?*, N.Y. TIMES (Aug. 9, 1995), <https://www.nytimes.com/1995/08/09/style/do-you-speak-tofu-or-miso-yet.html> [<https://perma.cc/EAR3-RXCA>] (“At the turn of the century, there were two tofu suppliers in the United States. Today there are more than 200 tofu manufacturers . . . and tofu can be found in nearly every supermarket.”); Audrey Enjoi, *Move Over, Beyond Burgers, Tofu is Going Mainstream*, LIVEKINDLY (June 22, 2020), <https://www.livekindly.co/beyond-burgers-tofu-going-mainstream/> [<https://perma.cc/YVG4-Q9HY>] (“Sales of tofu have skyrocketed in the US amidst the coronavirus

“[i]n 2020, the global Tofu market size was US\$ 2244.29 million and it will reach US\$ 4629.25 million in 2027, growing at CAGR [Compound Annual Growth Rate] of 10.75% between 2021 and 2027.”<sup>262</sup>

Soy may be accelerating in popularity and variety, but it is certainly not the only plant-based meat substitute. Wheat gluten also has considerable longevity as a meat alternative. The first known reference to wheat gluten as a main ingredient in a meat alternative was in 1301 in China.<sup>263</sup> Like soy products, wheat gluten continues as an important ingredient in many plant-based meat alternatives, but like soy, some find it problematic because of physiological sensitivity. According to the Food Allergy Research & Education organization, soy and wheat rank among the top nine major food allergens responsible for most of the serious food allergy reactions in the US.<sup>264</sup>

Although soy-based and wheat gluten-based meat substitutes remain the most prevalent, the number and type of meat substitutes have grown steadily.<sup>265</sup> Nut-based meat alternatives have been available in the United States since the late 1800s, and a high protein fungus, *Fusarium venenatum*, was introduced to the market as “Quorn” in 1994.<sup>266</sup> Processed pea protein is perhaps the most recent addition to the menu.<sup>267</sup>

High market growth of all meat substitutes, not just soy and wheat-based alternatives, is predicted due to increasing demand for healthier protein sources

pandemic. . . . According to data from global market research firm Nielsen, tofu sales increased by 66.7 percent during the four-week period ending on March 28. This is compared to the same time period in 2019. Sales of tofu were up by 32.8 percent in May.”)

262. QYResearch Group, *Global Tofu Market Research Report 2021* (Description), MARKETRESEARCH (Apr. 2021) <https://www.marketresearch.com/QYResearch-Group-v3531/Global-Tofu-Research-14411396/> [<https://perma.cc/6P39-MQAJ>].

263. SHURTLEFF & AOYAGI, *supra* note 1, at 5.

264. *Food Allergy Essentials: Common Allergens*, FOOD ALLERGY RSCH. & EDUC., <https://www.foodallergy.org/living-food-allergies/food-allergy-essentials/common-allergens> [<https://perma.cc/B34D-TG76>].

265. Jeff Kart, *People Buying More Alternative Meat, Expected To Consume Less Real Meat Through 2025*, FORBES (July 17, 2020), <https://www.forbes.com/sites/jeffkart/2020/07/17/people-buying-more-alternative-meat-expected-to-consume-less-real-meat-through-2025/?sh=4cc280361a06> [<https://perma.cc/7TR8-62Z5>]; *see also* SHURTLEFF & AOYAGI, *supra* note 1, at 9.

266. Matt Connolly, *Timeline: A Short and Sweet History of Fake Meat*, MOTHER JONES (Dec. 2013), <https://www.motherjones.com/environment/2013/12/history-fake-meat/> [<https://perma.cc/34CT-5AGG>].

267. Commercial processing of peas to produce a concentrated protein for use in meat substitutes appears to have started in 2014 with its development by Puris Foods. Christopher Doering, *Once a Sidekick in Food, the Pea Finds Itself the Star of the Show*, FOODDIVE (Jan. 23, 2020), <https://www.fooddive.com/news/once-a-sidekick-in-food-the-pea-finds-itself-the-star-of-the-show/570224/> [<https://perma.cc/C8WV-V7Z4>].



than animal meat and increasing interest in plant-based diets.<sup>268</sup> Citing research reported in 2010, Jiang He et al. state that vegetarianism has increased due to religious beliefs, concern about animal rights, health benefits from consuming less meat, and personal preferences, such that the demand for plant-based meat alternatives has increased.<sup>269</sup> Predicted growth is also partially due to greater awareness of the climate impacts of methane gas from agricultural animals, notably cows.<sup>270</sup> It is also associated with predicted and real meat shortages due to supply chain problems during the Covid-19 pandemic.<sup>271</sup> In addition to environmental and economic concerns, other prominent, overlapping drivers of plant-based substitute consumption are increasing awareness of the human health problems associated with over-consumption of meat and increasing responsiveness to the significant harms to animals in the production of animal products.

In the United States, religious ideas were also a factor in the development of meat alternatives because of the impact of Dr. John Harvey Kellogg, a Seventh Day Adventist. Seventh Day Adventists are encouraged to avoid meat from animals identified as “unclean” in the Bible.<sup>272</sup> Dr. Kellogg was also influenced by his belief that “[an] increase of population would ultimately lead

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268. *Meat Substitutes Market Size, Share & COVID-19 Impact Analysis, By Source (Soy-based Ingredients, Wheat-Based Ingredients, Other Grain-based Ingredients, and Textured Vegetable Proteins), By Distribution Channel (Mass Merchandisers, Specialty Stores, Online Retail, Other Retail Channels, and Food Service), and Regional Forecasts: 2021-2029 (Summary)*, FORTUNE BUS. INSIGHTS (Aug. 2022), <https://www.fortunebusinessinsights.com/industry-reports/meat-substitutes-market-100239> [<https://perma.cc/6E63-4FE9>] [hereinafter *Meat Substitutes Market Size*].

269. He, Evans, Liu & Shao, *supra* note 257 (citing Leahy Eimear, Sen Lyons & Richard Tol, *An Estimate of the Number of Vegetarians in the World* (Econ. & Soc. Rsch. Inst., Working Paper No. 340, 2010)).

270. UN ENVIRONMENT PROGRAMME, GLOBAL METHANE ASSESSMENT: BENEFITS AND COSTS OF MITIGATING METHANE EMISSIONS 25 (2021) (“Emissions from livestock are the largest source of agricultural emissions with enteric fermentation the dominant process and cattle the dominant animal causing the emissions.”); *see also Meat Substitutes Market Size, supra* note 268.

271. *See, e.g.*, Alexandra Sternlicht, *Alternative Meat Sales Soar Amid Pandemic*, FORBES (May 4, 2020), <https://www.forbes.com/sites/alexandrasternlicht/2020/05/04/alternative-meat-sales-soar-amid-pandemic/?sh=d5e8261edfd7> [<https://perma.cc/EEU5-Q8P9>] (citing and describing Nielsen’s [consumer spending] report that meat alternative sales increased 255% in the last week of March 2020, outpacing the growth of meat sales, which increased 53% over the same period); Amelia Nierenberg, *Plant-Based “Meats” Catch On in the Pandemic*, N.Y. TIMES (May 22, 2020), <https://www.nytimes.com/2020/05/22/dining/plant-based-meats-coronavirus.html>; [<https://perma.cc/Q3AW-8NRC>]; Jacob Bunge & Heather Haddon, *Coronavirus Meat Shortages Have Plant-Based Food Makers’ Mouths Watering*, WALL ST. J. (May 13, 2020), <https://www.wsj.com/articles/coronavirus-meat-shortages-have-plant-based-food-makers-mouths-watering-11589371206> [<https://perma.cc/SET5-A49P>].

272. *Meat Laws*, SEVENTH-DAY ADVENTIST DIET, <https://www.seventhdayadventistdiet.com/meat-laws/> [<https://perma.cc/TR9A-FF9W>].

to an increase in the price of foodstuffs and particularly of meats, and possibly a scarcity of meats.”<sup>273</sup> Kellogg, a scientist, invented flaked cereals as a substitute for animal product-based breakfast foods and developed a number of meat substitutes derived from nuts.<sup>274</sup> He believed nuts to be “unquestionably the vegetable analogue of meat and other animal foods, not only containing all the food elements to be found in animal products, but in finer and more digestible form, more delicately flavored, and wholly free from deleterious elements which abound in meat.”<sup>275</sup> Vegetarianism, as promoted by Dr. Kellogg and the business he developed with his brother, was a matter of supporting health with “clean” foods in both religious and practical senses of that word.

For quite some time in the United States, there have been people who have chosen vegetarian and vegan diets because of regard for animals.<sup>276</sup> The term “ethical veganism” captures this perspective, which appears to have been heavily influenced initially by philosopher Peter Singer’s 1975 book, *Animal Liberation*.<sup>277</sup> His book describes the suffering of animals in western agribusinesses and encourages strong consciousness of individual responsibility to resist participation in animal cruelty through consumer choices.<sup>278</sup> While plant-based meat substitutes would appeal to such consumers generally, it is not clear that a burger reminiscent of bleeding meat would be a particular draw, and they are not the target consumer for either Beyond or Impossible.

Meat substitutes vary as to their health-conferring properties and extent of processing. As new technologies have emerged, variance among meat alternatives has increased. At one end of the processing spectrum is a product like Butler soy curls, which are made of one ingredient—organic non-GMO soybeans—and made with minimal processing to enable meat-like cooking

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273. SHURTLEFF & AOYAGI, *supra* note 1, at 6 (quoting JOHN. H. KELLOGG, THE NATURAL DIET OF MAN 334–36 (1923)).

274. *Id.*

275. *Id.* (quoting JOHN. H. KELLOGG, MODERN MEDICINE AND BACTERIOLOGICAL REVIEW 220–23 (1986)).

276. *See, e.g.*, KAREN IACOBBO & MICHAEL IACOBBO, VEGETARIAN AMERICA: A HISTORY 1 (2004) (“Vegetarian America has existed since at least the 1700s. Practiced by small pools of people during the eighteenth century, the meandering stream of vegetarianism would burst forth like Niagara Falls by the late twentieth century.”). Citing Benjamin Franklin as an example, Iacobbo and Iacobbo point to ethical concerns about the treatment of animals as a basis for avoiding consumption of products made from their bodies. *Id.* at 1–2.

277. *See generally* PETER SINGER, ANIMAL LIBERATION (1975).

278. *Id.* at 166–67 (describing vegetarianism as a boycott of cruelly produced animal products).

applications.<sup>279</sup> At the opposite end are the Beyond and Impossible burgers, which are highly processed and contain much higher amounts of sodium and saturated fats than desirable from a nutritional point of view.<sup>280</sup> Accordingly, they are not ideal replacements for meat products from the standpoint of human health and might appropriately be seen more as a fast-food equivalent than a staple in the diet.<sup>281</sup>

Driven by technological advancements necessary to produce these facsimiles of meat, these plant-based burgers may be responsive to consumer preference for meat-like attributes, particularly among those attached to the experience of eating meat, as Beyond and Impossible predict. Yet, consumers attached to meat itself might ultimately be more likely to eat animal flesh cultured from the cells of animal tissue (sometimes referred to as “clean meat”).<sup>282</sup> The results of research published by Christopher Bryant and others in 2019 comparing consumer attitudes to plant-based meat and clean meat suggest that meat attachment correlates more positively with clean meat and less positively with plant-based meats.<sup>283</sup> When reporting their results, Bryant et al. state the following:

In the USA, we find that meat-eaters are most likely to express interest in purchasing clean meat . . . . We also found that meat attachment predicted lower purchase likelihood of plant-based meat, but not of clean meat. This implies that plant-based and clean meat could cater to different markets in the US: whilst plant-based meats may be appealing to those low in meat attachment, clean meat may play a crucial role in

279. *How Are Soy Curls Made?*, BUTLER FOODS <https://www.butlerfoods.com/soycurlsmade.html#:~:text=Soy%20Curls%E2%84%A2%20are%20dried,chemicals%2C%20additives%2C%20or%20preservatives> [<https://perma.cc/T2MB-DWMC>]; see also Kelly Clarke, *The Soy Curl Was Born in Oregon*, PORTLAND MONTHLY (Aug. 17, 2017), <https://www.pdxmonthly.com/health-and-wellness/2017/08/the-soy-curl-was-born-in-oregon> [<https://perma.cc/CR6R-LUW3>] (“Butler Foods owner Dan Butler and his small crew have produced the all-natural curls for nearly 20 years—soaking, cooking, and stirring organic soybeans in spring water, then letting them slowly dry out.”).

280. Emily Gelsomin, *Impossible and Beyond: How Healthy are these Meatless Burgers?*, HARV. HEALTH PUBL’G: HARV. MED. SCH. (Jan. 24, 2022), <https://www.health.harvard.edu/blog/impossible-and-beyond-how-healthy-are-these-meatless-burgers-2019081517448> [<https://perma.cc/8FYX-HEHM>] (discussing high levels of sodium and saturated fat in both burgers and recommending black bean burgers as significantly healthier).

281. *Id.*

282. Christopher Bryant, Keri Szejda, Nishant Parekh, Varun Deshpande & Brian Tse, *A Survey of Consumer Perceptions of Plant-Based and Clean Meat in the USA, India, and China*, 3 FRONT. SUSTAIN. FOOD SYST., Feb. 2019, at 1, 2, 8 <https://doi.org/10.3389/fsufs.2019.00011> [<https://perma.cc/H28Q-TTXX>] (defining “clean meat” as meat “produced by culturing animal cells in a suitable medium”).

283. *Id.* at 8.

displacing demand for conventional meat amongst those who do not find plant-based meat appealing.<sup>284</sup>

Perhaps not surprisingly, vegetarians, vegans, and pescatarians have lower meat attachment and would be more apt to select plant-based meats than clean meat replacements for actual meat.<sup>285</sup> If those consumers also care about testing on animals,<sup>286</sup> their willingness to consume plant-based burgers might lead them to choose plant-based meat alternatives that do not involve animal testing. The next section examines that question: the extent of consumer acceptance or rejection of animal testing on food ingredients in plant-based foods.

### *B. Results of Research on Consumer Attitudes*

In late January of 2022, Professor Adam Feltz and I conducted a random, demographically representative survey designed to better understand if consumers think that animal testing of food ingredients is beneficial or necessary and the extent to which they believe such animal testing is required by the FDA.<sup>287</sup> We asked questions about such things as extent of meat consumption, preference for personal care products not tested on animals, knowledge about animal testing techniques, and whether animal testing of an ingredient in a favorite food product would negatively influence their decision to purchase it in the future. We chose “burgers” as the plant-based food because we predicted that most of the survey respondents would consume burgers of some type. In fact, more than 98% of respondents do consume burgers of some type. The survey required respondents to rate their willingness to consume burgers differing as to animal testing for purposes of allergenicity or toxicity assessments and whether it was the supplier or the manufacturer that engaged in the animal testing.<sup>288</sup> Here is a representative block of burger options provided to respondents:

Burger A is a plant-based burger. It has a new flavoring

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284. *Id.* (noting that their research replicates the finding of Matti Wilks & Clive J.C. Phillips, *Attitudes to in Vitro Meat: A Survey of Potential Consumers in the United States*, 12 PLOS ONE, Jan. 2017, at 1, 10–11 <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0171904> [<https://perma.cc/AU9A-L349>]).

285. *Id.* at 7.

286. This might be somewhat difficult to assess because survey data do not necessarily reveal whether consumers are more influenced by health and environmental concerns rather than by animal welfare concerns.

287. We used three pilot studies to determine the correct sample size and survey design. We doubled the sample size to 633 “clean” surveys. We are preparing an article describing the study in more detail and exploring its implications. In the meantime, information about the research methodology is available upon request from the author of this Article.

288. More detailed description of the methodology, specific questions, and results is forthcoming in a separate article.

ingredient that the Burger A Company toxicity-tested on animals. Burger A Company used painful methods. All of the animals used in the testing were killed at the end of the experiment.

Burger B is a plant-based burger. It has a new flavoring ingredient that the Burger B Company toxicity-tested on animals. Burger B Company used non-invasive, relatively pain-free methods. All of the animals used in the testing were placed in an animal sanctuary after the testing was complete.

Burger C is a plant-based burger. Its new flavoring ingredients were not tested on animals at all because Burger C Company used alternative methods of assessing safety.

All respondents rated their willingness to consume each burger by selecting among options running from “Would not consume at all” to “Extremely likely.” If a respondent “would not consume” any of the burgers, the respondent was asked why.

Respondents were asked in separate blocks of questions (similar to the block of options above) about burgers whose flavoring ingredients were tested for potential allergenicity and/or tested by suppliers instead of the manufacturer. In the end, each respondent made choices among three burger options in four different contexts: manufacturer testing for toxicity, manufacturer testing for allergenicity, supplier testing for toxicity, and supplier testing for allergenicity. At the start, respondents randomly did or did not receive information about animal testing techniques. Also, half the respondents received information that the FDA does not require animal testing, while answering the “burger” questions; half received that information after answering the burger questions and were asked to re-rate their burger ratings in light of that information.

In all of those iterations, respondents consistently rejected animal testing, including animal testing that involved only pain-free methods and placement of the test animals in sanctuaries. Respondents indicated the strongest preference for the burgers not tested on animals at all, followed at notable distance by burgers with ingredients tested painlessly on animals, and the least preference for burgers tested on animals using painful methods. The presence of any type of animal testing had a strongly negative effect on respondents’ ratings.<sup>289</sup>

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289. 46.15% of respondents indicated that they would not consume at all the burger whose ingredients were toxicity-tested using painful methods while 23.06% would not consume the burger tested with relatively pain-free methods. Only 11.15% indicated that they would not consume the burger that was not subject to an animal test. Among those who did not indicate that they would avoid the product altogether, the mean proclivities to consume for the burgers tested on animals for toxicity

Respondent willingness to consume burgers with ingredients tested with painful methods was not significantly less when respondents had been told that the FDA does not require animal testing, prior to their rating of the different burgers. The data suggest that respondents just generally did not like the idea of animal-tested ingredients.

Preference for plant-based burgers that were not tested on animals is consistent with 68.72% of respondents in this survey reporting that, whenever possible, they purchase personal care items that have not been tested on animals and with 57.91% of respondents indicating that if they learned that ingredients in a favorite product had been tested on animals, they would be less inclined to purchase that product. Moreover, respondents thought that products containing animal-tested ingredients should be labeled as such, whether the testing is done by the manufacturer (79.78%) or an ingredient supplier (80.57%).

It is important to note that this survey involved a random, demographically representative group of respondents consisting predominantly of consumers who regularly eat meat, as is true of the general population. Indeed, based on responses to the meat consumption questions included in the survey, only 2% of respondents were vegetarians or vegans. It would be a mistake to think that only vegan or vegetarian consumers care about animal tested consumer products. Nevertheless, because the study was focused on plant-based burgers, it is difficult to conclude without further research whether survey respondents objected to animal testing only as to plant-based burgers or in general. Further, important aspects of consumer decision making were held constant. If burgers varied as to cost, flavor, convenience, and inclusion of animal-tested ingredients, more information would emerge as to the relative value of each of those characteristics. It is not possible to predict with these data how important animal testing would be in comparison to these other consumer decisional criteria. More research would clarify this situation, but given the strength of these survey results, it is possible to say that consumers do care about animal testing even if we cannot say to what degree they would prioritize its avoidance in comparison to other criteria, such as cost, convenience, and flavor.

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using painful and non-painful methods were 2.67 and 2.99 respectively, while that for the burger not tested on animals was 3.71, where 1 is “extremely unlikely” and 5 is “extremely likely.” The responses with regards to the burgers tested for allergenicity using animal tests were similar: 44.41% would not consume at all the burger tested using painful methods and 25.13% would not consume the burger tested using pain-free methods, while only 12.98% would avoid the burger not tested on animals. Ratings among those who would not avoid the burgers altogether were 2.72, 3.08, and 3.72 respectively, for the burgers tested for allergenicity using painful methods, pain-free methods, and without animal testing altogether.

## CONCLUSION

This Article used Impossible's decision to test on animals as an organizing structure for considering reasons a manufacturer might test on animals. It is an important and timely issue as more bioengineered ingredients are being developed for inclusion in alternatives to animal-based products.<sup>290</sup> Impossible's decision is timely also in relation to recent lawsuits against the FDA, which validated the FDA's handling of GRAS assessments<sup>291</sup> and the fact that the Redbook guidelines are only guidelines.<sup>292</sup> Having considered federal regulation, food safety litigation, and judicial evaluations of data derived from animal testing, it is straightforward to conclude that there is no legal necessity or legal value to be gained from testing on animals. To the extent animal testing is used instead of more predictably reliable non-animal methods, both consumer safety and animal welfare suffer. Judicial concerns about extrapolation from animal study data to humans should be the concerns of all decision makers in this context, especially when test animals are exposed to massive doses of ingredients humans would not consume at similar levels.

It is not possible to know how much animal testing is actually occurring because manufacturers need not seek FDA review of their GRAS assessments.<sup>293</sup> Among the reasons a manufacturer might test on animals are ignorance that superior non-animal methods exist, unquestioning dependence on product safety assessment companies that maintain animal laboratories without being equipped to offer the most sophisticated and reliable safety testing methods, advantages of faster FDA processing if the manufacturer treats FDA sample animal tests as safe harbor rules, or use as a marketing strategy to claim that an ingredient is so unique and innovative that its safety requires animal testing.

The last reason devalues consumers' desire for reliable predictors of food ingredient safety and greatly misjudges consumer attitudes about animal welfare and animal testing. The fact that the "cruelty-free" personal care product market has remained quite strong should suggest to a manufacturer of any product that testing on animals might well risk a negative consumer response.<sup>294</sup> The survey described in Part III.B. reveals that even a large

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290. See, e.g., Aryn Baker, *The Next Hottest Alternative Milk Comes from Microbes*, TIME (July 22, 2022), <https://time.com/6199318/milk-alternatives-microbes-perfect-day/> [<https://perma.cc/865S-LLNP>]; Maija Palmer, *The Big Idea: Milking Microbes Instead of Cows*, SIFTED (June 18, 2021), <https://sifted.eu/articles/milking-microbes-imagindairy/#:~:text=Imagindairy%20uses%20a%20technique%20called,that%20make%20up%20cow's%20milk> [<https://perma.cc/6GMJ-Y5AU>].

291. E.g., *Ctr. for Food Safety v. Becerra*, 565 F. Supp. 3d 519, 543 (S.D.N.Y. 2021).

292. *Ctr. for Food Safety v. U.S. Food & Drug Admin.*, 854 F. App'x. 865 (9th Cir. 2021).

293. See *supra* Part I.A.

294. See *supra* note 254 and accompanying text.

majority of those who consume meat would choose a burger that does not involve animal-tested ingredients, just as a majority would choose personal care products that are not tested on animals. It is simply wrong to assume that meat consumers do not care about animals as a general matter. In the case of a plant-based burger, the manufacturer that tests on animals not only misses the opportunity to use the most reliable safety assessment methods, but it also misses the opportunity to truthfully claim a trifecta of animal protection: wildlife, cows, and laboratory animals. A plant-based food manufacturer that tests on animals is in the position of a film company that must say, “Only a few animals were harmed in the making of this film,” instead of, “No animals were harmed . . . .”

Chief among the changes necessary to better protect humans and animals is revision of FDA guidelines and procedures. If the state of the science supports major food manufacturers deciding not to test new ingredients on animals and legislators proposing that pharmaceutical companies have the option of bypassing animal testing before advancing to human clinical trials, the state of the science supports the FDA’s adoption of the presumption that non-animal safety assessments should be the basis of manufacturers’ GRAS assessments and their pursuit of “no questions” letters. Considering the “3Rs” principle embedded in the Animal Welfare Act<sup>295</sup> and the risks posed to consumers by use of less reliable safety assessments, manufacturers should have to seek advance permission to use animal testing, while non-animal safety assessments should not need prior FDA approval. FDA regulations already allow non-animal testing. This is a shift in priority of assessment methods already allowed by the FDA, a shift that would respect the public’s desire for both reliable safety assessment of food ingredients and protection of animals. There is ample justification to require food manufacturers relying on the least up-to-date safety assessment methodology to explain why animal testing is necessary for their novel food ingredient.

Increasing availability of reliable non-animal safety assessment tools can occur if the FDA puts in place the proposed presumption of non-animal safety assessment methods for novel food ingredients; surely, product safety assessment companies would ramp up to meet the demands of that new regulatory requirement. However, change may be generated more quickly by manufacturers’ insistence that such assessment tools be used for their novel food ingredients. If enough manufacturers take seriously consumer rejection of animal testing, manufacturers will more likely press for use of non-animal testing. At present, though, consumers do not yet realize that new food ingredients are tested on animals. 66.1% of survey respondents did not know

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295. *See* 7 U.S.C. § 2143(e).



that new food ingredients are ever tested on animals, and 57.6% stated that they were surprised by that information.<sup>296</sup>

Therein lies another critical issue—lack of consumer awareness. Manufacturers need not consider what consumers would reject if consumers do not have easy access to the knowledge necessary to defend their values. And consumers cannot knowledgeably speak with the dollars they spend if they cannot differentiate products in accordance with the values they hold. It is important that they know. Yet, certainly, food manufacturers that test on animals will not be inclined to advertise the fact. While some food manufacturers that do not test on animals do, in fact, let consumers know, others might not be inclined to label their products as “cruelty-free” until consumers are likely to know that food ingredients in their category of food could be tested on animals. In this case of plant-based food, consumers might mistakenly believe that all plant-based foods would be cruelty-free and consider it a competitor gimmick to label such a product as “cruelty-free.”

This is where food safety organizations and animal protection organizations can work toward increasing food manufacturers’ utilization of non-animal tests to increase consumer safety as well as animal protection. They can work for the replacement of animal tests with non-animal tests, and they can educate the public about products that contain animal-tested ingredients. If they do not, consumers will be unable to further their interests in consumer safety and avoidance of animal tested products. Despite the obvious value of informing the public of animal-tested food ingredients and supporting non-animal-tested alternatives, there is significant silence on this in the context of Impossible’s testing on animals. Several searches for statements by antivivisection and animal protection organizations came up empty; it appears that PETA has stood alone on this issue.

The Center for Food Safety’s argument in *Center for Food Safety v. U.S. FDA*<sup>297</sup> that the FDA should have required Impossible to do *more* animal testing<sup>298</sup> rather than *different* testing suggests that it is not aware of the lesser

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296. Half of the respondents were asked to respond to T/F questions regarding their knowledge of common animal test methods and whether the FDA requires animal testing. Of those who got the T/F questions and answered that they “did not know” if the FDA requires animal testing of novel food ingredients, 66.1% responded that they were surprised to learn that the FDA does not require such testing. See *supra* Part III.B. for more details about this survey.

297. 854 F. App’x. 865 (9th Cir. 2021).

298. Press Release, Center for Food Safety, Lawsuit Challenging FDA Approval of Novel Genetically Engineered Color Additive That Makes Impossible Burger “Bleed” Moves Forward (Jan. 29, 2021), <https://www.centerforfoodsafety.org/press-releases/6256/lawsuit-challenging-fda-approval-of-novel-genetically-engineered-color-additive-that-makes-impossible-burger-bleed-moves-forward> [<https://perma.cc/8R6T-Y3TD>].

reliability of animal testing as a predictor of human safety risk, despite the fact that consumer safety is core to their mission.<sup>299</sup> Similarly, the silence of antivivisection and nonprofit animal protection organizations other than PETA about Impossible's animal testing is mysterious, given their missions. It seems unlikely that this is attributable to lack of awareness. Moreover, access to the basic information, including the tests actually used, is not difficult when another organization has done the work of collecting the correspondence between the FDA and Impossible.<sup>300</sup> Even a brief look at the FDA's guidelines reveals that animal testing is not required. One would think that many antivivisection organizations would have spoken against this use of animals, just as one would think that animal-respecting investors would do the legal investigation sufficient to discover that testing novel food ingredients on animals is not required.

It is also reasonable to expect that nonprofit organizations specifically and deeply invested in reducing consumption of farmed animals would take a stand against unnecessarily inflicting severe suffering and death on laboratory animals, particularly when the marketplace is full of meat alternatives that do not include ingredients that have been tested on animals. Lack of necessity to inflict severe suffering on animals is the hallmark and baseline of every state anticruelty statute in the country.<sup>301</sup> Yet animal protection organizations did not support this principle in this case in which it was totally unnecessary to subject laboratory animals to terrible suffering and death by a company pursuing the production of "bleeding" hamburger equivalents.

It is difficult to know what is animating this, but perhaps this is an example of what legal scholar Gary Francione considers to be a damaging "single-issue"

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299. *About Center for Food Safety*, CTR. FOR FOOD SAFETY, <https://www.centerforfoodsafety.org/about-us> [<https://perma.cc/Q7ZG-9P7Y>] ("Through groundbreaking legal, scientific, and grassroots action, we protect and promote your right to safe food and the environment.").

300. In addition to PETA's work on this issue, Friends of the Earth has posted documents related to the FDA's approval of Impossible's GE heme, which it obtained through Freedom of Information Act requests. Email from Gary L. Yingling, Senior Couns., Morgan, Lewis & Bockius LLP, to Lauren Brookmire, Consumer Safety Officer, U.S. Food & Drug Admin., (May 29, 2015) [https://foe.org/wp-content/uploads/2017/08/072717\\_Impossible\\_Burger\\_FOIA\\_documents.pdf](https://foe.org/wp-content/uploads/2017/08/072717_Impossible_Burger_FOIA_documents.pdf) [<https://perma.cc/NBN2-4E33>].

301. "The legislatures of all 50 states and the District of Columbia have enacted anticruelty statutes that purport to protect animals against 'unnecessary suffering,' 'unjustified suffering,' or 'cruel mistreatment.'" Darian M. Ibrahim, *The Anticruelty Statute: A Study in Animal Welfare*, 1 J. ANIMAL L. & ETHICS 175, 179 (2006).

focus on some animals that inadvertently harms other animals along the way.<sup>302</sup> In this case, it is single-minded focus on the reduction of the suffering of farmed animals in such a way that other animals, even those directly harmed in the pursuit of that single issue, are deemed less important. There was no necessity for investors identifying themselves as animal-protective or animal protection organizations to throw laboratory animals under one of the many buses rolling toward a plant-based future. Indeed, protecting the least charismatic of animals when advocating for other animals is surely important for increasing respect for all animals. Before supporting or investing in the development of one product or another, it is important for organizations that identify with the value of protecting animals to consider whether animals were or will be harmed at some point in product development and to do the research to know whether actual necessity exists. It is important, also, that such entities seek to prevent the use of animal tests in the development of new products. The serious harms done to animals by subjecting them to testing are all the more unconscionable because use of such tests delays the application and further refinement of reliable non-animal tests that actually exist and confer greatest benefit to consumers.

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302. Gary L. Francione, *Single Issue Campaigns in Human & Nonhuman Contexts*, ANIMAL RIGHTS: THE ABOLITIONIST APPROACH: BLOG (Feb. 1, 2010), <https://www.abolitionistapproach.com/single-issue-campaigns-and-in-human-nonhuman-contexts/> [<https://perma.cc/M75G-GFQE>].