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Before We Make a Pig's Ear of It: How North Carolina Hog-Farming Nuisance Suits Provide Context for the Ethics of Gene Editing Livestock

Karen M. Meagher

Paul B. Thompson

BEFORE WE MAKE A PIG'S EAR OF IT: HOW NORTH CAROLINA HOG-FARMING NUISANCE SUITS PROVIDE CONTEXT FOR THE ETHICS OF GENE EDITING LIVESTOCK*

KAREN M. MEAGHER** & PAUL B. THOMPSON***

The development of accelerated gene-editing techniques, including clustered regularly interspaced short palindromic repeats (CRISPR), carries ethical, legal, and social implications for agriculture. There are some in the genomic sciences who dread continuation of—and others who hope to reset—fractious moral debates characteristic of social discourse during the advent of genetically engineered plants in the 1990s. First, we review the current ethical principles underlying regulation and governance of genetic technologies and research involving nonhuman animals. Second, we explore existing ethical tensions and social debates about hog farming, nuisance suits, and Right-to-Farm legislation in North Carolina, a U.S. context into which gene-edited pigs are likely to be introduced. The ethical issues of land use, environmental justice, global food security, and food ethics reach far beyond risk-based ethics frameworks that often lie behind standard research ethics and U.S. regulatory approaches. Third, we argue that gene editing in agriculture calls for a broader bioethics. We consider lessons learned and limitations of community engagement currently taking place around gene drives for reducing mosquito-borne illnesses. Bioethics can

** Assistant Professor, Biomedical Ethics Research Program, Department of Health Sciences Research, Mayo Clinic. The author wishes to disclose that her spouse was previously employed by the National Sustainable Agriculture Coalition. Support for the preparation of this Article was provided in part by the U.S. National Human Genome Research Institute (NHGRI) under (grant number NIH P50 HG004488) (G. Henderson, principal investigator) Center for Genomics and Society (CGS) 6/2013–5/2018.

*** W.K. Kellogg Chair, Agricultural, Food & Community Ethics; Professor, Department of Philosophy, Michigan State University.

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improve and develop new modes of engagement to bridge important policy gaps through novel forms of engagement among stakeholders, including those with genetic, farming, environmental, and local knowledge.

INTRODUCTION

> *There is no such thing as a new idea. It is impossible. We simply take a lot of old ideas and put them into a sort of mental kaleidoscope. We give them a turn and they make new and curious combinations. We keep on turning and making new combinations indefinitely; but they are the same old pieces of colored glass that have been in use through all the ages.*[1]

After decades of research examining the ethical, legal, and social dimensions of advances in genetic biotechnology, accelerated gene

1. 3 ALBERT BIGELOW PAINE, MARK TWAIN: A BIOGRAPHY 1343 (1912).

editing, such as clustered regularly interspaced short palindromic repeats ("CRISPR"), has arrived on the scene. Gene editing has prompted yet another kaleidoscopic turn in the genetic sciences, attendant social and ethical analyses, public and media attention, and science- and technology-policy governance. The issues raised seem paradoxically both new and old.

What about CRISPR is new? The advent of accelerated gene-editing technologies has vastly decreased the time and effort needed to achieve some forms of genetic modification.[2] This faster pace of gene editing has garnered much attention, as have improvements in precision,[3] editing efficiency,[4] and especially the increasing potential for human germline modification.[5]

Faster or more efficient gene editing is merely a difference in degree, not in kind, generating doubts about the need for novel or unique oversight.[6] Yet the applications of accelerated gene-editing technologies have diverse clinical, agricultural, and environmental uses,[7] including ease of simultaneously introducing multiple traits, also known as multiplexing.[8] These applications are scientifically and ethically similar to other emerging sciences and technologies, such as synthetic biology[9] and nanotechnology.[10] Such commonalities present

2. Jennifer A. Doudna & Emmanuelle Charpentier, *The New Frontier of Genome Engineering with CRISPR-Cas9*, 346 SCIENCE 1077, 1082–83 (2014) (highlighting the panoply of potential CRISPR-Cas9 uses in contrast to prior gene-editing technologies, which were comparatively more difficult to use, inefficient, and imprecise). Novel gene-editing tools, such as CRISPR, and other programmable nucleases, such as zinc finger nucleases ("ZFNs") and transcription activator-like effector nucleases ("TALENs"), exhibit greater efficiency and precision than their antecedents. *Id.* at 1078. For convenience, we refer to these new approaches under the inclusive phrase "accelerated gene-editing technologies."

3. *Id.*

4. Davide Seruggia & Lluis Montoliu, *The New CRISPR-Cas System: RNA-Guided Genome Engineering to Efficiently Produce Any Desired Genetic Alteration in Animals*, 23 TRANSGENIC RES. 707, 707 (2014).

5. H. Evitt et al., *Human Germline CRISPR-Cas Modification: Toward a Regulatory Framework*, AM. J. BIOETHICS, Dec. 2, 2015, at 25, 25.

6. *See* Evita V. Grant, *FDA Regulation of Clinical Applications of CRISPR-CAS Gene-Editing Technology*, 71 FOOD & DRUG L.J. 608, 626 (2016) ("Some have doubted whether the CRISPR-Cas technology is worthy of this ongoing [regulatory] attention and debate. Several gene-editing technologies . . . precede it, and are actively being used for the development of therapeutics.").

7. *E.g.*, Heidi Ledford, *CRISPR, the Disruptor*, 522 NATURE 20, 20 (2015).

8. *E.g.*, Xianglong Wang et al., *One-Step Generation of Triple Gene-Targeted Pigs Using CRISPR/Cas9 System*, 6 SCI. REP., no. 20620, Feb. 9, 2016, at 1, 2.

9. *See* Raheleh Heidari, David M. Shaw & Bernice S. Elger, *CRISPR and the Rebirth of Synthetic Biology*, 23 SCI. ENGINEERING ETHICS 351, 351 (2017) (indicating overlap of ethical and regulatory concerns arising due to CRISPR and those arising from synthetic biology).

challenges to the corresponding ethical, social, and policy analyses needed to respond to accelerated gene-editing technologies. At the outset of these major developments, multiple stakeholders wonder whether public attitudes will continue to reflect resistance to genetic engineering,[11] how scientists will and ought to interact with public perspectives,[12] and how to achieve appropriate division of labor in attending to emerging ethical issues.[13]

The emergence of accelerated gene-editing technologies has sparked a new round of discussion over the ethics of utilizing these tools in therapeutic situations, including germline modifications for clinical treatment and prevention.[14] Human gene editing has played a large part in both the calls for greater conversation between genetic scientists and bioethicists, and in the most explicit discouragement of further research, including proposals for a globally self-imposed scientific moratorium on germline genome modification in humans where not already required by existing regulations.[15] Our focus in this Article concerns uses of gene editing beyond these applications to human beings, looking specifically at editing in animals for agriculture.

10. Daniel Sarewitz, *CRISPR: Science Can't Solve It*, 522 NATURE 413, 414 (2015) (citing Dietram A. Scheufele et al., *Scientists Worry About Some Risks More than the Public*, 2 NATURE NANOTECHNOLOGY 732, 732 (2007)) (noting the challenges of emerging-technology risk-management strategies because scientists "cannot represent the cultural values, politics and interests of citizens—not least because their values may differ significantly from those of people in other walks of life").

11. *E.g.*, Alison L. Van Eenennaam & Amy E. Young, *Public Perception of Animal Biotechnology*, *in* ANIMAL BIOTECHNOLOGY 2, at 275, 275–77 (Heiner Niemann & Christine Wrenzycki eds., 2018).

12. *See* Asheley R. Landrum & William K. Hallman, *Engaging in Effective Science Communication: A Response to Blancke et al. on Deproblematizing GMOs*, 35 TRENDS BIOTECHNOLOGY 378, 378–79 (2017) (highlighting approaches scientists can take to improve their interaction with public perspectives).

13. *See* Henry T. Greely, *Of Science, CRISPR-Cas9, and Asilomar*, STAN. L. SCH. (Apr. 4, 2015), https://law.stanford.edu/2015/04/04/of-science-crispr-cas9-and-asilomar/ [https://perma.cc/W2YW-TSJG] ("I think the implications of non-human uses are more pressing than human uses, but it is fair to say I did not win that argument [at a bioethics workshop on gene editing].").

14. David Baltimore et al., *A Prudent Path Forward for Genomic Engineering and Germline Gene Modification*, 348 SCIENCE 36, 36–37 (2015).

15. *See* Eric S. Lander et al., *Adopt a Moratorium on Heritable Genome Editing*, 567 NATURE 165, 166 (2019) (describing how scientists and ethicists from seven countries call for a temporary moratorium on human germline editing and development of an international governance framework); *see also* Françoise Baylis & Lisa Ikemoto, *The Council of Europe and the Prohibition on Human Germline Genome Editing*, 18 EMBO REP. 2084, 2084 (2017) (discussing the competing scientific efficiency and deontological frameworks for evaluating the ethics of germline gene editing); Edward Lanphier et al., *Don't Edit the Human Germ Line*, 519 NATURE 410, 411 (2015).

In this Article we argue that traditional research-ethics frameworks often preclude the posing of questions relevant to the ethics of genetic biotechnology in agriculture, including but not limited to accelerated gene editing. This Article is organized into three parts. Part I delineates the tenets of research ethics undergirding the regulatory review of research involving genetic modification. Additionally, Part I explores the ethical questions of autonomy, risk, and safety that currently dominate moral and regulatory oversight of emerging genetic technologies. Importantly, consideration of the ethics of gene editing in animal agriculture merits examination of the contexts with the largest stake in such agriculture, as well as where such gene editing will have its greatest impact. One such place is North Carolina, which has the third largest pig production and inventory of pigs nationwide.[16] Part II presents an overview of ethical issues already at play in North Carolina hog farming, with particular attention paid to the pertinence of Right-to-Farm legislation and the moral claims often invoked in local nuisance suits. This part also discusses the relationship of these issues to biotechnology debates. We consider how traditional research ethics focusing on autonomy, risk, and safety often precludes the environmental-justice, land-use, and food-ethics questions that dominate nuisance suits and the discussion of whether the introduction of gene editing to animal agriculture could exacerbate existing tensions. Part III then proposes some ways of addressing ethical issues in gene editing with affected communities, gleaned from community engagement and field trials of genetically engineered *Aegesagypti* designed to mitigate the spread of mosquito-borne illnesses. In addition, this part explores the possibilities for broader bioethical approaches that support ethical discourse beyond the traditional foci.

I. RESEARCH ETHICS, REGULATION, AND GOVERNANCE OF GENE TECHNOLOGIES

This part provides an overview of the research-ethics model and its reliance on institutional review boards ("IRBs") and standardized regulatory procedures. Though the research-ethics model certainly does not exhaust the regulatory framework for biotechnology, it has a

16. *See* NAT'L AGRIC. STATISTICS SERVS., USDA, MEAT ANIMALS PRODUCTION, DISPOSITION, AND INCOME 2017 SUMMARY 15–17 (2018), https://downloads.usda.library.cornell.edu/usda-esmis/files/02870v85d/tb09j8383/jd473006x/MeatAnimPr-04-26-2018.pdf [https://perma.cc/RJ7X-PWUZ].

significant influence on the way in which the ethics of biotechnology is conceptualized. Currently, the United States system of ethical and legal oversight covers most, but not all, plant and animal research for agricultural purposes.[17] Due to this broad scope, such regulations and their moral underpinnings reveal the ethical issues currently given priority in gene-editing research, including its application to hogs and other animal agriculture.

In the United States, current ethical analysis of research involving human participants references a large body of regulatory guidelines governing the conduct of such research and conditions for drug approval. Among these regulations are those requiring external independent review and preapproval of proposed research involving human subjects.[18] Such review is performed by IRBs in the United States and research-ethics committees in many other countries.[19] One strength of an external-review process is its purported objectivity. Relatively small and insular scientific communities can apply disciplinary standards, emphasizing efficiency and robustness—along with other proposed merits such as transparency—as values undergirding the review process.[20] Notably, these merits form the basis for the scientific peer-review process and the awarding of public funds, despite continuing internal disagreement about how best to improve these processes.[21]

17. *See* Jennifer Kuzma, *Reboot the Debate on Genetic Engineering*, 531 NATURE 165, 166 (2016) (noting that several genetically engineered plants have not received USDA regulatory review since 2011); Jonas J. Monast, *Editing Nature: Reconceptualizing Biotechnology Governance*, 59 B.C. L. REV. 2377, 2398 (2018). More generally, agricultural research is regulated under a suite of laws for environmental and food safety, though many of these laws do not require preapproval. *See Laws and Regulations*, USDA, https://www.usda.gov/our-agency/about-usda/laws-and-regulations [https://perma.cc/9G53-B3XK].

18. NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH pt. B (1979) [hereinafter BELMONT REPORT], https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf [https://perma.cc/VW6R-5L25].

19. 42 U.S.C. § 289 (2012); WORLD HEALTH ORG., STANDARDS AND OPERATIONAL GUIDANCE FOR ETHICS REVIEW OF HEALTH-RELATED RESEARCH WITH HUMAN PARTICIPANTS 2–3 (2011), https://apps.who.int/iris/bitstream/handle/10665/44783/9789241502948_eng.pdf?sequence=1 [https://perma.cc/JW54-ERUM].

20. *See* David Gurwitz et al., *Grant Application Review: The Case of Transparency*, 12 PLOS BIOLOGY, no. e1002010, Dec. 2, 2014, at 1, 1, 3 (highlighting efficiency, robustness, and transparency as values emphasized in the review process).

21. *See* Jeffrey Mervis, *NIH's Peer Review Stands Up to Scrutiny*, 384 SCIENCE 384, 384 (2015) (noting debates about which measures of grantee success ought to matter, and the possibility of influence by journal editors' preconceptions due to the author's reputation).

A. Standard Research Ethics, Animal Ethics, and U.S. Institutional Oversight

Procedurally, standard research ethics entails review and preapproval by an independent oversight committee not well suited to address the ethical and social questions raised by accelerated gene-editing technology. The review associated with both human and animal subjects largely emphasizes regulatory compliance in practice, which is informed by underlying ethical principles for research, such as the Belmont Principles ("respect of persons, beneficence, and justice")[22] and the "three Rs" of animal research (replacement, reduction, refinement).[23] Distinction of the peer-review process for receipt of public funding (which continues to emphasize the importance of highly specialized expertise) and external review of legal, ethical, and social acceptability dates back to the 1950s in medical schools, although not much is known about the practice at the time.[24] As early as 1966, the Surgeon General established a scientific review process,[25] which was rendered more permanent by regulations in response to widely publicized research violations in the 1970s, including the Tuskegee Syphilis Study.[26] Substantively, standard research ethics tends to embrace a vision of emerging technologies as involving isolated applications, in which each proposed research project is discrete and capable of being analyzed within the silos of human medicine and animal science.[27] Such an

22. BELMONT REPORT, *supra* note 18, pt. B.

23. NAT'L RESEARCH COUNCIL OF THE NAT'L ACADS., GUIDE FOR THE CARE AND USE OF LABORATORY ANIMALS 4–5 (8th ed. 2011), https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf [https://perma.cc/8Q4J-E7YW]; Christian E. Newcomer, *The Evolution and Adoption of Standards Used by AAALAC*, 51 J. AM. ASS'N LABORATORY ANIMAL SCI. 293, 293–94 (2012) (discussing accreditation standards related to animal care for facilities housing animals for laboratory use).

24. *See* ROBERT J. LEVINE, ETHICS AND REGULATION OF CLINICAL RESEARCH 322–23 (2d ed. 1986) (describing the history and evolution of institutional review boards).

25. Surgeon General Directive no. 129 Revised Policy, Revised Procedure on Clinical Research and Investigation Involving Human Subjects (U.S. Pub. Health Serv. 1966), *reprinted in Surgeon General's Directives on Human Experimentation*, 22 AM. PSYCHOL. 350, 350–51 (1967).

26. Roger L. Bertholf, *Protecting Human Research Subjects*, 31 ANNALS CLINICAL & LABORATORY SCI. 119, 122–24 (describing how the Belmont Report, instigated by the fallout from the Tuskegee Syphilis Study, provided recommendations ultimately resulting in legislation regulating biomedical research on human subjects, specifically 45 C.F.R. §§ 46.101–.505 (2018) and 21 C.F.R. §§ 50.1–.3, 56.101–.124 (2018)).

27. *See* Paul B. Thompson, *Synthetic Biology Needs a Synthetic Bioethics*, 15 ETHICS POL'Y & ENV'T 1, 12 (2012) (arguing that novel applications of biotechnology should not be treated as isolated craft projects but rather as more versatile technological platforms that permit innovation across diverse domains).

approach can neglect cross-sector issues, such as those that connect human health, environmental hazards, and animal well-being.[28]

The use of institutional review for oversight of research activity has well-documented weaknesses. Although researchers are presumed to share norms for evaluating the merits of proposed research, the failure to assess or communicate what the research entails to those outside the research milieu sometimes occurs. For example, Dr. Kuzma documents how a career in risk analysis revealed her previous assumptions about the role of values in risk assessment and the causal role of novel technologies in providing solutions to social problems—–aspects of research evaluation that were less apparent to her during a career in natural science.[29] In response to this problem, U.S. regulations stipulate membership conditions of IRBs, such as requiring the inclusion of nonscientist members.[30] The review recusal process currently provides an attempted—albeit imperfect—check on conflicts that can also inappropriately derail a project's approval.[31]

Genetic engineering in animal research can serve many different purposes, such as agricultural research or basic research preceding clinical trials in humans. The Food Security Act of 1985 and the Health Research Extension Act of 1985 mandate animal research oversight, delineating review of research involving animals by an

28. *See* Paul B. Thompson & Monica List, *Ebola Needs One Bioethics*, 18 ETHICS POL'Y & ENV'T 96, 99–100 (2015) (contending that siloing in bioethics is inadequate to address cross-sector ethical issues raised by synthetic biology or global epidemics like Ebola).

29. *See* Jennifer Kuzma, *Trails and Trials in Biotechnology Policy*, *in* WOMEN IN SUSTAINABLE AGRICULTURE AND FOOD BIOTECHNOLOGY 85, 89 (Laura S. Privalle ed., 2017) ("[A]ssumptions and values color even the best of the risk analyses used for decision making.").

30. 21 C.F.R. § 56.107(c) (2018) (requiring that each IRB include "at least one member whose primary concerns are in nonscientific areas"); 45 C.F.R. § 46.107(c) (2018) (stating the same).

31. Robert Klitzman, *"Members of the Same Club": Challenges and Decisions Faced by US IRBs in Identifying and Managing Conflicts of Interest*, 6 PLOS ONE, no. e22796, July 29, 2011, at 1, 5. Klitzman reports data that demonstrate how

> IRBs usually seek to manage their own [conflicts of interest ("COIs")] through recusals, but face dilemmas of whether conflicted members can hear, join, and/or vote in deliberations, and how to decide. Chairs may tell members with potential COIs to recuse themselves, but definitions of such COIs (e.g., whether these include non-financial COIs) can be unclear. . . . IRBs may bar members from discussions, or leave these decisions to individual members, not all of whom may excuse themselves. IRBs may also suggest that members recuse themselves to avoid pressure from dissatisfied PIs.

Id. However, members can reject such nonbinding suggestions. *Id.*

Institutional Animal Care and Use Committee ("IACUC").[32] The ethical underpinnings of animal research ethics are often articulated as the three Rs, or the principles of replacement, reduction, and refinement.[33] Researchers debate the meaning of each principle's application to specific research proposals,[34] but the principles are grounded in the ultimate aim of decreasing the amount of pain and fear imposed on animals by human research practices.[35] The principle of replacement, as the name suggests, reflects the practice of using alternatives to research on sentient animals, including methods of complete replacement, such as computer modeling, and using organisms that are "nonsentient," or believed to be incapable of experiencing pain.[36] The principle of reduction requires minimizing the number of sentient animals used for studying a specified research question, although it is debated whether the principle demands the smallest number possible to support sound scientific inferences.[37] The principle of refinement reflects a commitment to employ practices and procedures that reduce the distress imposed on sentient animals during research.[38] Because these principles apply to any federally funded research in the United States involving animals, it is inevitable that social discourse around the gene editing of livestock will also overlap with the editing of animals in the course of research.[39] Some of these issues have already been addressed in the earlier adoption of

32. Food Security Act of 1985, Pub. L. No. 99-198, sec. 1752(a)–(b), § 2143, 99 Stat. 1354, 1645–46 (codified at 7 U.S.C. § 2143 (2012)); Health Research Extension Act of 1985, Pub. L. No. 99-158, sec. 2, § 289d, 99 Stat. 820, 875–76 (codified at 42 U.S.C. § 289d (2012)).

33. *See generally* WILLIAM M.S. RUSSELL & REX L. BURCH, THE PRINCIPLES OF HUMANE EXPERIMENTAL TECHNIQUE ch. 4 (1959), http://altweb.jhsph.edu/pubs/books/humane_exp/het-toc [https://perma.cc/9P9Y-72JU] (systematically addressing the question of how to treat animals during the course of experiments to establish general principles).

34. *See* Howard J. Curzer et al., *The Three Rs of Animal Research: What They Mean for the Institutional Animal Care and Use Committee and Why*, 22 SCI. & ENGINEERING ETHICS 549, 550–61 (2016) (contextualizing the three Rs in the debate over animal-experimentation ethics and positing that a fourth R, "refusal," should be included in the discussion).

35. *See, e.g.*, Jerrold Tannenbaum & B. Taylor Bennett, *Russell and Burch's 3Rs Then and Now: The Need for Clarity in Definition and Purpose*, 54 J. AM. ASS'N LABORATORY ANIMAL SCI. 120, 121–22 (2015) (documenting the concern for animal welfare that informs Russell and Burch's approach).

36. *Id.* at 126–28.

37. *Id.* at 128–29.

38. *Id.* at 129–30.

39. *See* Matthias Eggel & Rebecca L. Walker, *Replacement or Reduction of Gene-Edited Animals in Biomedical Research: A Comparative Ethics and Policy Analysis*, 97 N.C. L. REV. 1241, 1257–58 (2019) (arguing that use of genetically edited animals in research illuminates interpretive challenges for the three Rs).

gene editing,[40] and have influenced ethical assessment of current regulations as gene-editing research involving animals has accelerated.[41]

Research governance by local institutions also includes the work of biosafety committees. These committees govern gene editing on microorganisms not covered by IACUC review.[42] Unlike IRBs for human subjects and IACUCs for animal research, internal-review procedures for biosafety were established at U.S. research institutions in 1976, specifically in response to concerns about the safety of gene transfer that surfaced at the Asilomar Conference in 1974.[43] The meeting convened many of the world's leading experts in molecular biology and resulted in a report recommending three levels of containment for research attempting the genetic engineering of microorganisms and viruses on the grounds of maintaining laboratory safety for workers and preventing novel pathogens from escaping or developing outside the confines of research.[44] The establishment of biosafety committees at universities and laboratories undertaking such research was one component of the regulatory framework developed for oversight.[45] This framework at one time also included a central Research Advisory Committee ("RAC") at the National Institutes of Health ("NIH"), which reviewed proposed research on

40. *E.g.*, Melvin B. Dennis, *Welfare Issues of Genetically Modified Animals*, INST. LABORATORY ANIMAL RES. J. 100, 100—07 (providing an overview of animal welfare issues associated with transgenic animal production and arguments in favor of their use in research). Dennis notes that edits often intentionally disrupt animal physiology, generating conditions that are similar to pathogenic human genotypes or disease phenotypes. *Id.* at 101. To address attendant animal suffering, Dennis recommends treatment of conditions produced, restriction of gene expression to tissues of interest or to limited time periods, and establishment of end points for removing animals from studies. *Id.* at 107.

41. *See* Marcus Schultz-Bergen, *Is CRISPR an Ethical Game Changer?*, 31 J. AGRIC. & ENVTL. ETHICS 219, 219–38 (2018) (evaluating the current regulatory scope which is limited to transgenes, or genes introduced into one species from another).

42. *See* Elizabeth Heitman et al., *Gene Drives on the Horizon: Issues for Biosafety*, 21 J. ABSA INT'L 173, 175 (2016) (describing relevance and limits of institutional biosafety committees for gene-drive research).

43. *See* Nancy M. P. King, *RAC Oversight of Gene Transfer Research: A Model Worth Extending?*, 30 J.L. MED. ETHICS 381, 381 (2002) (tracing the origins of the Recombinant Advisory Committee and evaluating its merits as a mechanism for research oversight).

44. *See* Paul Berg et al., *Summary Statement of the Asilomar Conference on Recombinant DNA Molecules*, 72 PROC. NAT'L ACAD. SCIS. 1981, 1981–82 (1975) (overviewing events that prompted the Asilomar conference and major recommendations for containment and experimental design).

45. SHEILA JASANOFF, DESIGNS ON NATURE: SCIENCE AND DEMOCRACY IN THE UNITED STATES AND EUROPE 45–48 (2005) (providing an overview of events and concerns leading to Asilomar and the acknowledgment of the scientific community that a regulatory body like RAC was needed in addition to internal self-governance).

both safety and ethical grounds.[46] The committee was eliminated in 2018, and issues of biosafety containment will continue to be reviewed by local institutional biosafety committees.[47] Since their inception, biosafety committees have expanded their responsibilities beyond research involving ribosomal DNA ("rDNA") to include review of both research protocols and institutional policies and procedures for handling a variety of toxic substances, including biological and chemical hazards.[48]

B. U.S. Coordinated Framework for Federal Regulation of Biotechnology

These procedures for institutional review of research actually encompass a relatively small component of the regulatory framework for genetic engineering. In the United States, a suite of laws referred to as the Coordinated Framework for the Regulation of Biotechnology ("CFRB") regulates commercial and other nonresearch uses of products developed using genetic engineering.[49] The framework encompasses oversight by the Environmental Protection Agency ("EPA"), the Food and Drug Administration ("FDA"), and the U.S. Department of Agriculture ("USDA") under the general tenet that "product not process" ought to be the focus of regulations.[50] This focus is highly debated, as it is significantly different from regulatory foci in other contexts, especially the European Union.[51]

46. *Id.* at 47–48.

47. James M. Wilson, *The RAC Retires After a Job Well Done*, 29 HUM. GENE THERAPY CLINICAL DEV. 115, 115–16 (2018) (describing the end of the RAC's tenure and future plans for regulatory oversight).

48. *See* Raymond W. Hackney, Jr. et al., *Current Trends in Institutional Biosafety Committee Practices*, 17 APPLIED BIOSAFETY 11, 11–13 (2012) (reporting survey results of institutional biosafety committees and their purview).

49. Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).

50. Jennifer Kuzma et al., *Evaluating Oversight Systems for Emerging Technologies: A Case Study of Genetically Engineered Organisms*, 37 J.L. MED. ETHICS 546, 548 (2009) (providing an overview of genetic-editing oversight to anticipate governance of nanotechnology). *See generally* Alan McHughen & Stuart Smyth, *U.S. Regulatory System for Genetically Modified [Genetically Modified Organism (GMO), rDNA or Transgenic] Crop Cultivars*, 6 PLANT BIOTECHNOLOGY J. 2 (2008) (reviewing the history and procedures of each agency that has federal regulatory oversight of plant biotechnology).

51. *See* NAT'L RESEARCH COUNCIL, FIELD TESTING GENETICALLY MODIFIED ORGANISMS: FRAMEWORK FOR DECISIONS 14–15 (1989), https://www.nap.edu/catalog/1431/field-testing-genetically-modified-organisms-framework-for-decisions [https://perma.cc/ZDS2-3Q3A]; *see also* Monast, *supra* note 17, at 2411 (concluding that this debate "fails to address the broader range of societal interests and values inherent in the biotechnology debate"); Thorben Sprink et al., *Regulatory Hurdles for Genome Editing: Process- vs.*

To date, most regulatory review for agricultural products has concerned genetically engineered plants.[52] Each agency tends to view genetically engineered products in terms of the risks relevant to their agency mission and pertinent legislation, and it can be challenging to determine how each agency will apply the current framework to advances in targeted genetic engineering.[53] The USDA regulates genetically engineered products, via the Federal Plant Pest Act,[54] on the view that such products could, like weeds, become pests.[55] The EPA concerns itself with human and environmental risks when such products might be akin to pesticides if they have pest-resistant traits, as delineated in the Federal Insecticide, Fungicide, and Rodenticide Act.[56] As demonstrated by the approval of genetically engineered salmon, genetic engineering of animals for human consumption likely falls under FDA purview unless the regulations are revised in the future.[57] The FDA process addresses the potential for risks to the food and feed supply, and under the federal Food, Drug, and Cosmetic Act ("FDCA") tends to use a comparative risk approach, given counterpart products already on the market.[58] Industry consultation with FDA for these purposes results in a memo, not agency approval, and although consultation is voluntary, commentators note that the potential negative public response from a market participant's failure to consult the FDA has been sufficient to encourage consultation thus far.[59]

Product-Based Approaches in Different Regulatory Contexts, 35 PLANT CELL REP. 1493, 1501–02 (2016) (outlining regulatory approaches to gene editing in different contexts in order to evaluate reforms to the current system in the European Union).

52. *See, e.g.*, Jeffrey D. Wolt, Ken Wang & Bing Yang, *The Regulatory Status of Genome-Edited Crops*, 14 PLANT BIOTECHNOLOGY J. 510, 512–13 (2016) (examining approaches to regulating genetically edited plant products in different countries).

53. *See, e.g.*, Jennifer Kuzma & Adam Kokotovich, *Renegotiating GM Crop Regulation*, 12 EMBO REP. 883, 883–85 (2011) (emphasizing that it is unclear how targeted genetic modification through nucleases will be treated through the CFRB).

54. Agricultural Risk Protection Act of 2000, Pub. L. No. 106-224, 114 Stat. 358 (codified in scattered sections of 7 U.S.C.).

55. Jennifer Kuzma, *Regulating Gene-Edited Crops*, ISSUES SCI. TECH., Fall 2018, at 80, 83 (summarizing the USDA's transition to regulating genetically modified products under a "plant pest" rationale).

56. 7 U.S.C. §§ 136g–136y (2012).

57. *See Questions and Answers on FDA's Approval of Aqua Advantage Salmon*, FDA (Jan. 16, 2018), https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/BiotechnologyProductsatCVMAnimalsandAnimalFood/AnimalswithIntentionalGenomicAlterations/ucm473237.htm [https://perma.cc/KMG9-ZK5G].

58. *See, e.g.*, 21 U.S.C. § 350g (2012).

59. *See* McHughen & Smyth, *supra* note 50, at 4.

C. Common Critiques of U.S. Regulatory Gene-Editing Oversight

Our emphasis in this Article highlights governance of research rather than commercial products, such as drugs, plant varieties, or biologics. Yet it is worth noting the oversight of these commercial products because there are many critiques of U.S. regulatory oversight. Many who work in the genetic engineering of plant varieties have noted the arbitrary tendencies of current risk frameworks, given similar or worse risks that can be produced through conventional breeding.[60] For instance, some argue that the burdens of the regulatory process perversely give advantages to large corporations with the capital to persevere.[61] Recent perspectives gathered from U.S. subject-matter experts in plant gene editing revealed their view that accelerated gene-editing technologies raise concerns that the pace of the new technologies might present a serious challenge to regulatory mechanisms.[62] Some hope this will prompt revision of current governance schemes, often expressing a desire for less regulation than that applied to the first generation of technologies.[63] The National Academies of Sciences included an overview of different conceptions of risk in its report on the current U.S. regulatory system.[64]

Given the accelerated rate of product development likely to result from advances in gene-editing technologies, U.S. regulators are especially likely to be concerned with offsite effects within target species, effects on nontarget species, and consequences for

60. Fawzy Georges & Heather Ray, *Genome Editing of Crops: A Renewed Opportunity for Food Security*, 8 GM CROPS & FOOD 1, 7 (2017) (contending that "[i]f the standards applied to GM crops were applied with equal rigour to the results of classical plant breeding, few new cultivars would survive the process").

61. Ottoline Leyser, *Moving Beyond the GM Debate*, PLOS BIOLOGY, no. e1001887, June 10, 2014, at 1, 2 ("The GM-specific regulatory system currently in place creates huge financial barriers for GM crop introduction, which ironically is one of the main reasons why almost the only applications in the field today are driven by big business.").

62. *See* Jennifer Kuzma, Adam Kokotovich & Aliyah Kuzhabekova, *Attitudes Towards Governance of Gene Editing*, 18 ASIAN BIOTECHNOLOGY & DEV. REV. 69, 77–81 (2016) (reporting that nearly half of the experts surveyed were concerned about regulatory issues regarding gene-editing technology to a greater extent than they were about traditional biotechnology).

63. *Id.* at 88.

64. NAT'L ACAD. OF SCIS., PREPARING FOR FUTURE PRODUCTS OF BIOTECHNOLOGY 69 (noting that "[v]alues are always embedded in risk analysis by the choices and interpretations of the people conducting them and the selection of risk-assessment endpoints of concern, methods, and questions").

ecosystems.[65] While standard research ethics has focused on risks and autonomous decisionmaking, traditional risk analysis has been critiqued by a variety of commentators for its inattention to socioeconomic impacts[66] and limitations on producer or consumer choice and social equity.[67] Similarly, risk analysis can fail to examine the legitimacy of relationships between corporations and governments.[68] Meanwhile, regulatory systems also need to address a catalogue of public concerns, including the relationship of intellectual property and control over agricultural practices, the role of values and uncertainty in knowledge production, possible attitudes of hubris or objections to dominance over nature, and competing views of development.[69] Objections to gene editing on these grounds have little purchase in IRB, FDA, USDA, or EPA review of biotechnology. One way of understanding current regulations is to view such ethical questions as outside—or irrelevant to—the regulatory purview.

While the scope of regulatory authority for federal or state agencies, such as the FDA, USDA, and EPA, is derived from authorizing legislation, research institutions are necessarily more responsive to informal mechanisms, including reputational concerns. Scientific norms for research conduct—including the choice of topics for research—have always been responsive to public opinion about the character of individual scientists, the incentives of the organizations that support their work, and expectations about access

65. *See* PAUL B. THOMPSON, FROM FIELD TO FORK 201–07 (2015) (reviewing the precautionary principle, perverse risk outcomes in food safety regulation of sweeteners, and the challenges of regulating environmental risks).

66. *E.g.*, Klara Fischer et al., *Social Impacts of GM Crops in Agriculture: A Systematic Literature Review*, 7 SUSTAINABILITY 8598, 8604 (2015) (reviewing the literature and reflecting on a paucity of measurement of social impacts).

67. *See* Kathleen McAfee, *Beyond Techno-Science: Transgenic Maize in the Fight Over Mexico's Future*, GEOFORUM 148, 149 (2008) (describing the trinational Commission on Environmental Cooperation process for evaluating the social impact on importing transgenic maize through NAFTA, including a multistakeholder advisory panel and recognition of the cultural, symbolic, and spiritual meanings of maize in Mexican communities).

68. *See* Matthew Kearnes et al., *From Bio to Nano: Learning Lessons from the UK Agricultural Biotechnology Controversy*, 15 SCI. CULTURE 291, 300–01 (2006) (noting how risk assessment failed to capture consumer concerns about corporate control over food systems and reduction of choices, presenting early GM debates in the U.K. as a cautionary tale for developments in nanoscience).

69. *See* Amaranta Herrero et al., *Seeing GMOs from a Systems Perspective: The Need for Comparative Cartographies of Agri/Cultures for Sustainability Assessment*, 7 SUSTAINABILITY 11,321, 11,322 (2015) (reviewing the literature on these four topics).

to knowledge and other products of the research process.[70] In agricultural research, funding for universities and national research laboratories was explicitly linked to economic and social improvements in the profitability and quality of life for agricultural producers.[71] The history of agricultural innovations after the Industrial Revolution has been profoundly influenced by profit-driven research and technology development. The system of publicly funded research and education, on the one hand, and delivery of technology at a low- or no-cost basis to farmers and ranchers through state and federal extension services, on the other, was institutionalized as an ethic for agricultural science, dictating a wide-ranging concern for economic and social consequences of the resulting innovations.[72] Critics, however, have voiced concerns that this ethic has steadily eroded over the last several decades,[73] while sociologists have produced quantitative studies to document a shift in scientists' self-understanding of their responsibility to structure their research activity around norms of public access.[74]

Due to similar concentration on social understanding of risk, gene-editing debates about oversight and consequences of emerging biotechnology are tied up in debates about who shoulders the burden of proof—those who contend that a genetic intervention is safe or those who contend it is dangerous.[75] However, public discourse about the risks of a new agricultural biotechnology is also deeply connected to perceptions of the intent and trustworthiness of those who develop and promote their use.

70. *See generally* Paul A. David, *The Historical Origins of 'Open Science': An Essay on Patronage, Reputation and Common Agency Contracting in the Scientific Revolution*, 3 CAPITALISM & SOC'Y, July 2008, at 1, 20–33 (tracing the history of publicly funded open-science models of scientific patronage through the late-sixteenth and early-seventeenth centuries).

71. *See generally* CHARLES E. ROSENBERG, NO OTHER GODS: ON SCIENCE AND AMERICAN SOCIAL THOUGHT 187–99 (perm. ed., rev. 1997) (documenting the history of applied agricultural science in the United States during the late-nineteenth and early-twentieth centuries, including tensions felt by scientists).

72. *See* Frederick H. Buttel, *The Land-Grant System: A Sociological Perspective on Value Conflicts and Ethical Issues*, 2 AGRIC. & HUM. VALUES 78, 81–83 (1985).

73. *See* PAUL B. THOMPSON, THE SPIRIT OF THE SOIL: AGRICULTURE AND ENVIRONMENTAL ETHICS 47–51 (2d ed. 2017) (reviewing ethical criticisms of agricultural science).

74. *See* Jessica R. Goldberger, *Research Orientations and Sources of Influence: Agricultural Scientists in the U.S. Land-Grant System*, 66 RURAL SOC. 69, 87–90 (2001) (synthesizing data to explain influences on land-grant scientists in the 1990s, including productionist and environmental influences).

75. *See generally* CARL F. CRANOR, REGULATING TOXIC SUBSTANCES: A PHILOSOPHY OF SCIENCE AND THE LAW 71–77 (1993) (comparing the typical scientific burden of proof with the tort law burden of persuasion).

> A mutually reinforcing feedback loop begins to develop: lack of attention to key ethical issues is seen as evidence of poor moral character, and poor moral character is seen as evidence for risk. . . . This evidence does not derive from facts about GMOs or their fate in the environment or the human body, but from facts about the danger that we associate with people who fail to treat others with respect, or who displace serious moral issues with strategic or manipulative argumentation.[76]

In summary, while the regulations represented by the agencies in the CFRB and the various IRBs comprise a governance framework for oversight of biotechnology, publicly supported research in agriculture and food systems has traditionally held itself accountable to an ethic that encompasses a significantly broader set of concerns. Focused primarily on accountability to rural communities and agricultural producers, this ethic has not always responded effectively to the types of concerns associated with nuisance lawsuits and other concerns reviewed in Part II of this Article. Nevertheless, as our review demonstrates, the debates over genetic engineering in food and agriculture have been far more reflective of ethical interest in the reputation of science and scientists, and their accountability to democratic governance norms. These ethical issues contrast with standard research-ethics concerns that accompany specific risk-based issues that regulatory agencies and IRBs have been designed to address.

II. NORTH CAROLINA NUISANCE SUITS AND HOG FARMING

Moral discourse around food and animals has already influenced research and development in biotechnology. The influence of the animal-welfare movements is well underway in the gene editing of animals. Farthest along in the development of genetically engineered animals for human consumption are Recombinetics's "polled" cattle, which are cattle modified to not have horns.[77] Methods used to dehorn (or "disbud" young cattle) include hot iron, caustic paste, and

76. *See* THOMPSON, *supra* note 65, at 213–14.

77. *See* Tammy Lee, President & CEO, Recombinetics Inc., Speech at the Genome Writers Guild 2018 Conference: This Little Piggy Went to Market; This Hornless Cow Made Milk: Gaining Regulatory Approval for Precision-Bred Food Animals (July 20, 2018); *see also* Adam Shriver & Emilie McConnachie, *Genetically Modifying Livestock for Improved Welfare: A Path Forward*, 31 J. AGRIC. & ENVTL. ETHICS 161, 169–70 (2018) (challenging the assumption that the public will strongly resist the use of gene editing for animal welfare, and citing to preliminary data indicating approval for gene editing done for the purpose of animal welfare).

surgical methods.[78] Dehorning dairy cows in particular is a common practice because the trait of being polled, or without horns, is rarer amongst breeds best for dairy production.[79] The process of dehorning is sometimes unsafe or unpleasant for farmers, and it causes distress to the cows; for these reasons, gene editing the trait for hornlessness might be acceptable to dairy consumers on this animal-welfare basis.[80] In the United States, advocacy by the Humane Society and People for the Ethical Treatment of Animals ("PETA") has increased the number of traditional breeding programs to introduce the trait for hornlessness in the dairy industry, with mixed success.[81]

Any emerging genetic technology faces a landscape of complicated social, ethical, and legal issues, and nuisance lawsuits in North Carolina highlight the need for our social discourse to reflect this complexity. In this part, we review the moral issues related to nuisance claims that are rooted in (A) enjoyment of personal property and quality of life and (B) environmental justice. In addition, we explore how critics and defenders of agricultural biotechnology both situate the technologies in relation to (C) the moral imperative of addressing global food security and (D) broader "food ethics" claims.

A. Nuisance Suits, Enjoyment of One's Property, and Quality of Life

Recently in North Carolina, a series of hog-farming nuisance suits have highlighted ethical issues already at play in contemporary farming. The experience of two litigants, Elvis and Vonnie Williams, received press attention as a paradigmatic example of this type of nuisance suit.[82] The Williams live near a 4700-hog farm, which includes confinement buildings, lagoons, and spray fields.[83] Plaintiffs in such nuisance suits often have a variety of complaints, including

78. *See* G. Cozzi et al., *Dehorning of Cattle in the EU Member States: A Quantitative Survey of the Current Practices*, LIVESTOCK SCI., Sept. 2015, at 4, 7.

79. *See* Ann Bruce, *Genome Edited Animals: Learning from GM Crops?*, 26 TRANSGENIC RES. 385, 387 (2017). Bruce also notes the need for public communication, given the likely unawareness of dehorning practices outside agricultural communities. *Id.*

80. *See* Abbie Fentress Swanson, *Wanted: More Bulls with No Horns*, NPR: THE SALT (Aug. 3, 2015, 4:53 PM), https://www.npr.org/sections/thesalt/2015/08/03/429024245/wanted-more-bulls-with-no-horns [https://perma.cc/5RQR-TZQC].

81. *See id.*

82. Anne Blythe, *Jury Awards More than $25 Million to Duplin County Couple in Hog-Farm Case*, NEWS & OBSERVER (Raleigh June 29, 2018), https://www.newsobserver.com/news/local/article214096384.html [https://perma.cc/Y4TT-YLKB].

83. Complaint at 1–3, McGowan v. Murphy-Brown, LLC, No. 7:14-cv-00182-BR (E.D.N.C. Aug. 21, 2014), ECF No. 1.

polluted water, swarms of flies, health impacts such as respiratory problems and headaches, and miscellaneous detriments to their quality of life, like not being able to spend time outdoors.[84]

Legislation addressing the ramifications of farming for the nearby community has a long history in the United States. In North Carolina, the Williams' case was consolidated with other similar nuisance suits under *In re NC Swine Farm Nuisance Litigation*.[85] Such cases are adjudicated against the backdrop of Right-to-Farm legislation, which was passed by most states' legislatures in the late 1970s and early 1980s in order to prevent urban encroachment.[86] North Carolina's 1979 law was one of the first of its kind of legislation;[87] it was both influential and broad in its exemption of many preexisting agricultural activities from nuisance liability.[88]

Legally, the distinction between public and private nuisance is significant. The nuisance suits in question are often made on private, not public, grounds.[89] According to North Carolina law, private nuisance is "a non-trespassory invasion of another's interest in the private use and enjoyment of land."[90] In contrast, public nuisance is an infraction of the rights of the public at large, not the right of a private party.[91] Since 1979, the North Carolina legislature has continued to refine state nuisance laws. In 1992, nuisance laws were extended to forestry operations.[92] In 1995, the legislature required those considering a nuisance claim to go through pretrial mediation

84. *Id.* at 6–23.

85. No. 5:15-CV-13-BR (E.D.N.C. filed Jan. 9, 2015).

86. *See* Alexander A. Reinert, *The Right to Farm: Hog-Tied and Nuisance-Bound*, 73 N.Y.U. L. REV. 1694, 1695, 1707 (1998) ("States have enacted [Right-to-Farm laws] with the stated purpose of preventing the slow destruction of farmland as a result of expansion of urban areas into traditionally rural land." (citing Margaret Rosso Grossman & Thomas G. Fischer, *Protecting the Right to Farm: Statutory Limits on Nuisance Actions Against the Farmer*, 1983 WIS. L. REV. 95, 97–98)); *see also* Margaret Rosso Grossman & Thomas G. Fischer, *Protecting the Right to Farm: Statutory Limits on Nuisance Actions Against the Farmer*, 1983 WIS. L. REV. 95, 161–62 (reviewing justifications of Right-to-Farm legislation).

87. Grossman & Fischer, *supra* note 86, at 119.

88. *See* Cordon M. Smart, *The "Right to Commit Nuisance" in North Carolina: A Historical Analysis of the Right-to-Farm Act*, 94 N.C. L. REV. 2097, 2118 (2016).

89. Morgan v. High Penn Oil Co., 238 N.C. 185, 193, 77 S.E.2d 682, 689 (1953) ("The law of private nuisance rests on the concept embodied in the ancient legal maxim *[s]icuteretuoutalienum non laedas*, meaning, in essence, that every person should so use his own property as not to injure that of another.").

90. *Id.*

91. *See* NORTH CAROLINA LAW OF TORTS § 25.40 (3d ed. 2015).

92. *See* Act of July 8, 1992, ch. 892, sec. 1, § 106-700, 1991 N.C. Sess. Laws 441, 441–43 (codified at N.C. GEN. STAT. § 106-700 (2017)).

prior to pursuing litigation.[93] In 2013, the legislature expanded the circumstances under which both agriculture and forestry operations do not constitute a nuisance.[94] In 2018, the laws were again updated in the wake of the *In re NC Swine Farm Litigation* cases.[95] These legislative responses run parallel to the development of hog farm operations in the state.[96]

In North Carolina, the 1980s and 1990s marked a change to the industrial model of hog farming. Previously, hog production had often been a "secondary activity" for farms primarily dedicated to tobacco or cotton production, and pigs were reared and slaughtered on the same farm, known as a farrow-to-finish practice.[97] With industrialization and development of concentrated animal feeding operations ("CAFOs"), hogs became the primary focus of many farms, and the number of pigs increased from around 150 per farm to over 3000 per farm during these two decades.[98] Nationally, during this period, hog farming became much more specialized with split-phase operations. Each farm began to focus on one of three age-based periods.[99] Some operations concentrate on the first stages of sow fertilization, gestation, and farrowing.[100] Pigs are then transferred to a second farm, or nursery, that raises piglets to gain fifty to sixty pounds.[101] Finally, grow-out facilities slaughter pigs when they reach approximately 250 pounds.[102] These changes in pig operations were also accompanied by social and political reactions.

93. *See* Act of July 27, 1995, ch. 500, sec. 1, § 7A-38.3, 1995 N.C. Sess. Laws 1489, 1492–94 (codified as amended at N.C. GEN. STAT. § 7A-38.3 (2017)).

94. *See* Act of July 18, 2013, ch. 314, sec. 1, § 106-701(a1), 2013 N.C. Sess. Laws 858, 858 (codified as amended at N.C. GEN. STAT. § 106-701(a1) (2017)).

95. *See* Act of June 27, 2018, ch. 113, sec. 10.(a), § 106-701, 2018-3 N.C. Adv. Legis. Serv. 391, 397–98 (LexisNexis) (to be codified at N.C. GEN. STAT. § 106-701) (restricting the circumstances where a nuisance action may be filed against agricultural and forestry operations).

96. *See* Neil D. Hamilton, *Harvesting the Law: Personal Reflections on Thirty Years of Change in Agricultural Legislation*, 46 CREIGHTON L. REV. 563, 577–78 (2013) (arguing that Right-to-Farm laws have been extended beyond their original purpose of protecting farms, resulting in an imbalance of property rights tipped in the favor of farms).

97. Owen J. Furuseth, *Restructuring of Hog Farming in North Carolina: Explosion and Implosion*, 49 PROF. GEOGRAPHER 391, 393–94 (1997) (documenting that farrow-to-finish enterprises constituted eighty percent of hog production into the late 1970s).

98. *Id.* at 397–98 (describing the changes to U.S. hog-farming operations in the 1980s and 1990s).

99. *See* David Osterberg & David Wallinga, *Addressing Externalities from Swine Production to Reduce Public Health and Environmental Impacts*, 94 AM. J. PUB. HEALTH 1703, 1703 (2004) (describing industrialization of U.S. hog farming in the 1980s).

100. Furuseth, *supra* note 97, at 394.

101. *Id.*

102. *Id.*

The mid-to-late 1990s marked a period of pushback against the North Carolina hog industry in light of highly publicized incidents, including a Pulitzer-Prize-winning series of the *News & Observer* exposés and editorials.[103] Notably, the reporting included an ethical-legal appeal, highlighting conflicts of interest among state congressional representatives with a financial stake in the hog industry and the obstructive role of a statute of limitations on campaign finance violations that enabled further agribusiness influence in elections.[104] In 1995, the environmental toll of the state's hog industry also made national headlines after twenty-five million gallons of hog waste spilled from open-air storage ponds, or lagoons, into Onslow County's New River tributaries.[105] The environmental contamination due to waste-lagoon failures has also repeatedly followed in the wake of hurricanes, including, most recently, Hurricane Florence.[106] The environmental and public health consequences of water contamination likely constitute other legislative challenges: public rather than private nuisance, for example, or disagreements about the authority of the EPA to regulate

103. *See The 1996 Pulitzer Prize Winner in Public Service: The News & Observer (Raleigh, NC)*, PULITZER PRIZES (Jan. 19, 2019), http://www.pulitzer.org/winners/news-observer-raleigh-nc [https://perma.cc/TV96-SCGC (staff-uploaded archive)] (listing the nine pieces that won the 1996 Pulitzer Prize in Public Service).

104. *See Hog-Tied on Ethics: A News & Observer Editorial*, NEWS & OBSERVER (Raleigh), Feb. 23, 1995, *reprinted in The 1996 Pulitzer Prize Winner in Public Service: The News & Observer (Raleigh, NC)*, *supra* note 103.

105. *See Huge Spill of Hog Waste Fuels an Old Debate in North Carolina*, N.Y. TIMES, June 25, 1995, at 21.

106. *See* Katherine L. Martin, Ryan E. Emanuel & James M. Vose, *Terra Incognita: The Unknown Risks to Environmental Quality Posed by the Spatial Distribution and Abundance of Concentrated Animal Feeding Operations*, 642 SCI. TOTAL ENV'T 887, 892 (2018) ("Since 1990, 15 named tropical cyclones have made landfall in coastal North Carolina and an addition[al] 20 have affected the state without a direct hit. Some of these storms have resulted in flooding and breaching of swine waste lagoons, particularly in the Northeast Cape Fear watershed . . . , which has one of the highest concentrations of CAFOs in the country . . . and our data indicate many of these CAFOs are very near streams."); *see also* Eric Lach, *Lessons from Covering Hurricane Florence and the Pig-Waste Lagoons of North Carolina*, NEW YORKER (Sept. 26, 2018, 1:50 PM), https://www.newyorker.com/news/current/lessons-from-covering-hurricane-florence-and-the-pig-waste-lagoons-of-north-carolina [https://perma.cc/6767-6EM9] ("In recent years, news reporting on hurricanes has taken on a longitudinal aspect. The story isn't just one storm. 'The neighbors talked about how these things keep happening to them,' Bethea said, of the people who live near the lagoons. 'There was Hurricane Matthew, two years ago. In 1999, there was Floyd. Each time, lagoons breached. This is a thing that is happening several times in their lifetime. Meanwhile, Smithfield categorized it'—meaning Florence—'as a thousand-year event.'").

CAFOs in accordance with the Clean Water Act.[107] Importantly, while the law draws fine distinctions between public and private nuisance, public discourse does not. In North Carolina and beyond, media coverage often depicts the ethics of public and private ramifications of hog farming in the state as intertwined, unaddressed ramifications of hog-farming policy.[108]

The future of gene editing of hogs in North Carolina will be caught up in this social and ethical dynamic that long precedes such technological innovation. As industrialized agriculture developed, critiques of its practices developed as well and soon became widespread. The opposition supported the merits of other approaches, variously under the labels of alternative, local, organic, fair trade, slow food, and locally supported.[109] These alternatives respond to the negative consequences of industrialization in agriculture, including loss of biodiversity and the need to define and attain sustainable agriculture practices.[110]

Social resistance to genetically modified crops in Europe can provide a cautionary tale for the future of accelerated genetic-editing technologies in agriculture. In the 1990s, European survey methods effectively quantified public attitudes—including diversity of opinions across several countries—but often failed to qualitatively unpack the "black box" of why some members of the public find such

107. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-08-944, CONCENTRATED ANIMAL FEEDING OPERATIONS: EPA NEEDS MORE INFORMATION AND A CLEARLY DEFINED STRATEGY TO PROTECT AIR AND WATER QUALITY FROM POLLUTANTS OF CONCERN 48 (2008), https://www.gao.gov/assets/290/280229.pdf [https://perma.cc/2URJ-HB64] (describing how two federal court cases, *Waterkeeper Alliance Inc. v. EPA*, 399 F.3d 486 (2d Cir. 2005), and *Rapanos v. United States*, 547 U.S. 715 (2006), constrained the ability of the EPA to sustain oversight of CAFOs' impacts on water systems, depending on state laws).

108. *E.g.*, Jonathan Hahn, *A Sh** Storm in the Making*, SIERRA (Sept. 19, 2018), https://www.sierraclub.org/sierra/cafo-sh-storm-hurricane-florence-in-the-making [https://perma.cc/PD2A-TTZ5].

109. *See* Jeff Pratt, *Food Values: The Local and the Authentic*, 27 CRITIQUE ANTHROPOLOGY 285, 298–99 (2007) (describing various values at play in a variety of agricultural and food movements and their development in the United Kingdom and the United States); *see also* Gun Roos et al., *The Local in the Global—Creating Ethical Relations Between Producers and Consumers*, ANTHROPOLOGY FOOD (Mar. 2007), https://journals.openedition.org/aof/489?&id=489 [https://perma.cc/5ADY-2YX6] (describing the ethical norms of relationships that constitute goals of various agricultural movements).

110. *See generally* Leo Horrigan, Robert S. Lawrence & Polly Walker, *How Sustainable Agriculture Can Address the Environmental and Human Health Harms of Industrial Agriculture*, 110 ENVTL. HEALTH PERSP. 445, 448 (2002) ("Agriculture is dependent on biodiversity for its existence and, at the same time, is a threat to biodiversity in its implementation.").

modifications "not morally acceptable."[111] Their qualitative research explored such attitudes, including concerns that genetic modification takes place with indifference to socioeconomic agricultural contexts, where use of such technologies in the pursuit of twentieth-century agricultural goals can carry different consequences for farmers, consumers, and society.[112] In addition, the association between industrialized agriculture and genetic modification has led to heightened rhetoric, including historically and culturally powerful analogies.[113]

North Carolina nuisance suits illuminate one ethical backdrop into which the gene editing of hogs will be introduced. North Carolina nuisance law dates back to English common law and *William Aldred's Case* from 1611[114] and has developed particularly to the advantage of industrial farming in North Carolina.[115] While predominantly a legal notion, the rationale and political discourse justifying the right to farm shares a history with social and moral philosophy.[116] The invocation of rights, for example, is situated in political liberalism, and has a notable ethico-legal connotation that frames public and

111. J. Lassen, K.H. Madsen & P. Sandøe, *Ethics and Genetic Engineering – Lessons to Be Learned from GM Foods*, 24 BIOPROCESS & BIOSYSTEMS ENGINEERING 263, 264 (2002).

112. *Id.* at 268.

113. *See* Glenn Davis Stone, *The Anthropology of Genetically Modified Crops*, 39 ANN. REV. ANTHROPOLOGY 381, 385 (2010) ("Attempts to naturalize GM with assertions like 'people have been selecting plant genes for 5000 years' seem tantamount to claiming the textile mills of the early industrial revolution to be a simple continuation of the age-old act of making cloth." (quoting Robert Langreth & Matthew Herper, *The Planet Versus Monsanto*, FORBES (Dec. 31, 2009, 4:40 PM), http://www.forbes.com/forbes/2010/0118/americas-best-company-10-gmos-dupont-planet-versus-monsanto.html [https://perma.cc/286F-LB4J])).

114. (1611) 77 Eng. Rep. 816; 9 Co. Rep. 57 b.

115. *See* Smart, *supra* note 88, at 2102 (theorizing that North Carolina's current Right-to-Farm laws could favor industrial farmers and leave neighboring landowners without a legal remedy).

116. *See* Keith Burgess-Jackson, *The Ethics and Economics of Right-to-Farm Statutes*, 9 HARV. J.L. & PUB. POL'Y 481, 517–18 (1986) (arguing that Right-to-Farm laws that favor farmers are indefensible on grounds of allocative economic efficiency and their justification ought to be discussed on ethical grounds). Notably Burgess-Jackson's analysis assumes two parties have an economic (and moral) stake in disputes—farmers and neighbors—which is not the case in most nuisance suits in North Carolina. In the contemporary context, hog farmers or operators are often not the property owners named in litigation, but nevertheless have an economic and moral stake in the outcome. *See, e.g.*, Sarah Everhart, *Five Takeaways from the North Carolina Murphy-Brown Hog Farm Nuisance Case*, MD. RISK MGMT. EDUC. BLOG (May 22, 2018), http://agrisk.umd.edu/blog/five-takeaways-from-the-north-carolina-murphy-brown-hog-farm-nuisance-casee [https://perma.cc/MA6F-WDA7] ("Although the plaintiffs filed, and subsequently dismissed, a previous lawsuit against the owner of Kinlaw Farm, the case at issue was brought directly against the hog integrator.").

moral discourse regarding agricultural policy.[117] Nuisance laws, too, are sometimes grounded in appeals to broader notions of justice and fairness, appealing to the "rule of give and take, live and let live."[118] This principle dates back to 1862 English tort law. For example, *Bamford v. Turnley*[119] featured complaints about the smell coming from a neighbor's kiln.[120] Judge George Bramwell observed that the nuisance principle of live and let live "is as much for the advantage of one owner as of another,"[121] a rationale that would appeal to contractualists seeking the principles or maxims that others have reason to accept.[122] Nuisance cases can turn on what the plaintiff might reasonably expect regarding the use of his or her own land; for example, if my neighbors' house repairs create a temporary noise disturbance, my complaint for compensation holds no weight if I want to make any similar repairs in the future which might disturb them.[123]

The justification for Right-to-Farm laws is also about balancing the social contribution of farming with the rights of nearby residents; the stated purpose of the North Carolina law is to protect agricultural land from encroachment by nonagricultural land use.[124] Nuisance suits, therefore, exemplify laws reflecting a variety of underlying policy and ethical issues, including how to balance private and social values in land use, what constitutes acceptable behavior of neighbors, and what minimal moral standards ought to govern agriculture.

One question that remains to be answered is how accelerated gene-editing technologies may impact future nuisance suits in North Carolina. As with much of gene editing, advances in animal agriculture have been propelled by accelerated gene-editing

117. *See* Laura B. DeLind, *The State, Hog Hotels, and the "Right to Farm": A Curious Relationship*, 12 AGRIC. & HUM. VALUES 34, 37–38 (1995) ("The central issue was no longer whether hog hotels were a form of industrial agriculture and thus subject to the same environmental regulations and inspections as any other industry. Instead, the central issue became that of protecting the '*right to farm'*, both as a generic right and as a specific piece of legislation. Within this altered context, the debate was transformed.").

118. *See* ALLAN BEEVER, THE LAW OF PRIVATE NUISANCE 28 (2013) (noting prior interpretations reading Bramwell's comments as drawn from utilitarianism).

119. (1862) 122 Eng. Rep. 27 (Ex.) (Williams).

120. *Id.* at 29.

121. *Id.* at 33.

122. *See* Gregory C. Keating, *A Social Contract Conception of the Tort Law of Accidents*, *in* PHILOSOPHY AND THE LAW OF TORTS 22, 36–38 (Gerald J. Postema ed., 2001) (delineating social contract theory's support for the principle of give and take, live and let live, and noting that nuisance cases hinge on assumptions of only modest risk and that the potential for harm is reciprocal).

123. BEEVER, *supra* note 118, at 148.

124. *See* N.C. GEN. STAT. § 106-700 (2017).

technologies.[125] Some anticipate the use of gene editing for meat production, animal disease and stress resistance, and the efficient use of feed as the most likely paths forward for the agricultural-genetic modification of pigs.[126] For example, meat production might be increased through genetic modification by making pigs bigger or decreasing fat,[127] increasing muscle,[128] or improving sow milk quality to improve growth of suckling pigs.[129]

Further, gene knockout (inactivation) of *CD163* through accelerated gene editing carries the promise of creating resistance to porcine reproductive and respiratory syndrome virus ("PRRSV") in the hog industry.[130] Outbreaks of PRRSV first appeared in the United States in the 1980s.[131] PRRSV has several detrimental effects for pigs, including high rates of spontaneous abortion and stillbirth, and high

125. *See* Chris Proudfoot et al., *Genome Edited Sheep and Cattle*, 24 TRANSGENIC RES. 147, 148, 152 (2015) (noting previous achievements in gene editing of pigs and reporting on advances in editing of other species, including cattle and sheep).

126. Jeffrey J. Whyte & Randall S. Prather, *Genetic Modifications of Pigs for Medicine and Agriculture*, 78 MOLECULAR REPROD. & DEV. 879, 885 (2011).

127. *See, e.g.*, V.G. Pursel et al., *Expression and Performance in Transgenic Pigs*, 40 J. REPROD. & FERTILITY (SUPP.) 235, 242 (1990) ("Studies of pigs injected with exogenous pig GH indicate[d] that maximal growth rate is attained only if the diet contains adequate protein and, particularly, lysine . . . .").

128. *See* David Cyranoski, *Super-Muscly Pigs Created by Small Genetic Tweak*, 523 NATURE 13, 14 (2015) (describing TALEN-facilitated editing of the myostatin gene to create "double-muscled" pigs). *See generally* Ding-biao Long et al., *Effects of Active Immunization Against Myostatin on Carcass Quality and Expression of the Myostatin Gene in Pigs*, 80 ANIMAL SCI. J. 585 (2009) (describing ability to decrease myostatin gene expression and how this affects lean muscle percentage for pigs).

129. Whyte & Prather, *supra* note 126, at 885; *see also* Matthew B. Wheeler, Gregory T. Bleck & Sharon M. Donovan, *Transgenic Alteration of Sow Milk to Improve Piglet Growth and Health*, 58 REPROD. SUPPLEMENT 313, 313 (2001).

130. *See* Christine Burkard et al., *Precision Engineering for PRRSV Resistance in Pigs: Macrophages from Genome Edited Pigs Lacking CD163 SRCR5 Domain Are Fully Resistant to Both PRRSV Genotypes While Maintaining Biological Function*, PLOS PATHOGENS, no. 1006206, Feb. 23, 2017, at 1, 16 ("[I]t is possible to utilize a targeted genome editing approach to render livestock resistant to viral infection, whilst retaining biological function of the targeted gene."); Kevin D. Wells et al., *Replacement of Porcine CD163 Scavenger Receptor Cysteine-Rich Domain 5 with a CD163-Like Homolog Confers Resistance of Pigs to Genotype 1 but Not Genotype 2 Porcine Reproductive and Respiratory Syndrome Virus*, 91 J. VIROLOGY, no. 2, Jan. 3, 2017, at 1, 1 ("Genetic modification of the CD163 gene creates the opportunity to develop production animals that are resistant to PRRS . . . .").

131. Kousuke Hanada et al., *The Origin and Evolution of Porcine Reproductive and Respiratory Syndrome Viruses*, 22 MOLECULAR BIOLOGY & EVOLUTION 1024, 1030 (2005) (concluding that the PRRSV virus was transmitted from another species to swine in about 1980).

mortality rates.[132] Estimated cost to the pork industry has reached over $663 million per year.[133] A CRISPR solution to PRRSV could thereby be justified for both its instrumental value to farmers, by increasing their production and reducing costs, and also on animal welfare grounds, by providing a solution that offers greater effectiveness than PRRSV vaccination.[134]

In the context of North Carolina nuisance suits, the 2013 amendments to the Right-to-Farm law set the stage for a new interpretation of the "coming to the nuisance" affirmative defense. This defense was initially intended to address the encroachment of urban settings on rural land, allowing preexisting agricultural operations protection from newly developing residential complaints.[135] Right-to-Farm legislation has previously restricted the availability of this affirmative defense, especially in cases where a farming operation has undergone a "fundamental change."[136] However, the 2013 state legislation delineated further what does not constitute a fundamental change, including (1) a "change in ownership or size," (2) an "interruption of farming for a period of no more than three years," (3) "[p]articipation in a government-sponsored agricultural program," (4) "[e]mployment of new technology," and (5) a "change in the type of agricultural or forestry product produced."[137]

Under this law, a farming operation that uses genetically modified hogs could arguably employ this affirmative defense. In North Carolina, the grounds of a change in size, employment of a new technology, or a new type of product being made opens the possibility for new affirmative defenses if the pigs were genetically edited or the farm grew larger because of said edited trait. For example, the

132. *See* William T. Christianson & Han Soo Joo, *Porcine Reproductive and Respiratory Syndrome: A Review*, 2 SWINE HEALTH & PRODUCTION 10, 13 (1994) (describing signs and symptoms characteristic of the syndrome).

133. Derald J. Holtkamp et al., *Assessment of the Economic Impact of Porcine Reproductive and Respiratory Syndrome Virus on United States Pork Producers*, 21 J. SWINE HEALTH & PRODUCTION 72, 80 (2013).

134. *See* Yuchen Nan et al., *Improved Vaccine Against PRRSV: Current Progress and Future Perspective*, 8 FRONTIERS MICROBIOLOGY, no. 1635, Aug. 28, 2017, at 1, 17 ("Unfortunately, even with sustained efforts to understand PRRSV pathogenesis and vaccinology, an effective vaccine to prevent PRRSV has yet to be successfully developed.").

135. *See* Smart, *supra* note 88, at 2115–16 (citing Spur Indus., Inc. v. Del E. Webb Dev. Co., 494 P.2d 701, 708 (Ariz. 1972)) (summarizing the common law concept of coming to the nuisance and enactment of the 1979 Right to Farm Act in North Carolina).

136. *See* Act of July 18, 2013, ch. 314, sec. 1, § 106-701(a1), 2013 N.C. Sess. Laws 858, 858 (codified as amended at N.C. GEN. STAT. § 106-701(a1) (2017)).

137. *Id.*

enviropig was a genetic engineering experiment intended to reduce nutrient loading in the environment due to pig production. A genetic change allowed pigs to metabolize phosphates, leading to a reduction in the amount of land needed to safely spread manure from pig farms.[138] Although the project failed for social reasons,[139] it shows how a change brought about through gene editing can materially affect the considerations made in permitting and nuisance decisions.

When anticipating accelerated genetic technologies playing a role in nuisance suits, there are several possibilities to consider. One is an instance in which genetic editing achieves what agricultural biotechnology often sets out to do: increase farm productivity. For instance, a PRRSV genetically resistant herd of hogs could address precisely the problem the edit is meant to address, preventing herd loss early in the hog life cycle. In so doing, it also benefits the health of the sows and piglets, offering arguable animal welfare benefits. Yet the economic yields to the farm might create an opportunity for expansion and, for the sake of argument, the building of an additional waste lagoon in close proximity to the neighbor's property line, thereby prompting a nuisance suit. While hypothetical, this kind of case demonstrates how genetic editing in industrial agriculture might serve its intended goal and yet have negative consequences for the local community, entirely within the legal boundaries of the already existing Right-to-Farm laws.

New genetic-technology use in hog farming can have negative ramifications for neighbors of hog farms not by *deviation* from conventional agriculture practice in virtue of some unforeseen technological ramification; on the contrary, an improved vaccine could have the same outcome and likely fall under the same nuisance protections. That is, negative impact from gene technology is not unlike the negative impact from innovations that do not involve genetic editing. Yet, by acting in consonance with goals and processes of industrialized agriculture, there is a potential for the technology to sustain or exacerbate the harms characteristic of current large-scale hog production. Evaluation of novel gene-editing technologies in agriculture should take into account the social dynamics of contexts in which they are most likely to be implemented. Inevitably, such

138. C. W. Forsberg et al., *The Enviropig Physiology, Performance, and Contribution to Nutrient Management Advances in a Regulated Environment: The Leading Edge of Change in the Pork Industry*, 81 J. ANIMAL SCI. (E. SUPP. 2) E68, E71 (2003).

139. Robert Streiffer & Sara Gavrell Ortiz, *Animals in Research: Enviropigs*, *in* LIFE SCIENCE ETHICS 405, 411 (Gary L. Comstock ed., 2d ed. 2010).

evaluation will be difficult to disentangle from the moral objections to the preconditions of technological use.

B. Nuisance Suits and Environmental Justice

In *In re NC Swine Farm Nuisance Litigation*, the Williams' problems were similar to those reported by other North Carolina residents living in close proximity to large-scale hog operations.[140] A distinct set of arguments against industrial hog farming is based in environmental justice. The Williams's experience reflects the disparate impact of hog-farming operations on families throughout the state, with hog operations concentrated in areas with both high poverty rates and high percentages of nonwhite residents.[141] Considering the nuisance suits in North Carolina, we can ask how genetic engineering of animals for agricultural purposes will play out in the context of such dynamics, not only sustaining or exacerbating negative consequences of agriculture in the region but also the unequal distribution of these consequences.

Environmental justice can be conceptually unpacked in several ways. Some environmental justice advocates invoke the values of public health, articulating the problems that neighbors like the Williams face in terms of exposure and hazards and offering a relational definition of environmental injustice as a situation in which some populations benefit from practices that negatively impact the environment of others.[142] One study recently reported on the health disparities of North Carolina residents located near high-production hog farms; the findings reflect higher rates of all-cause mortality and

140. *See* Steve Wing & Susanne Wolf, *Intensive Livestock Operations, Health, and Quality of Life Among Eastern North Carolina Residents*, 108 ENVTL. HEALTH PERSP. 233, 236 tbl.4 (2000) (describing reports of North Carolina residents with respiratory, gastrointestinal, skin, and other ailments associated with proximity to livestock operations).

141. Steve Wing, Dana Cole & Gary Grant, *Environmental Injustice in North Carolina's Hog Industry*, 108 ENVTL. HEALTH PERSP. 225, 229 (2000) ("These facilities are located disproportionately in communities with higher levels of poverty, higher proportions of nonwhite persons, and higher dependence on wells for household water supply.").

142. Steve Wing, *Environmental Injustice Connects Local Food Environments with Global Food Production*, *in* LOCAL FOOD ENVIRONMENTS: FOOD ACCESS IN AMERICA 63, 64 (Kimberly B. Morland ed., 2015); *see also* Dana Cole, Lori Todd & Steve Wing, *Concentrated Swine Feeding Operations and Public Health: A Review of Occupational and Community Health Effects*, 108 ENVTL. HEALTH PERSP. 685, 695 (2000) ("Environmental injustice is not only a concern with regard to specific health effects, but also with regard to general community health, economic development, and disease surveillance.").

infant mortality.[143] Environmental justice has been defined by advocacy groups in terms of positive rights to clean air, land, water, and healthy ecosystems, combining social justice concerns that link (1) labor, public health, and safety; (2) ecological values; and (3) systemic views of disadvantage.[144] Further conceptual analysis emphasizes how environmentally just policymaking aims to include the voices of affected communities and to analyze policy consequences in terms of intergenerational justice and sustainability.[145] These last considerations are particularly pertinent to any germline modifications in animals made possible by accelerated gene-editing technologies, changes that could exhibit limited reversibility and population-wide livestock impacts that are far-reaching into future generations.[146]

Both the health and ecological elements of environmental justice loom large in the context of nuisance suits, and questions remain whether new biotechnologies can mitigate, sustain, or exacerbate existing disparities, directing attention to who shoulders the environmental and related health burdens of current and future agricultural practices. The environmental justice concern that urban North Carolina communities' food consumption displaces agricultural

143. *See* Julia Kravchenko et al., *Mortality and Health Outcomes in North Carolina Communities Located in Close Proximity to Hog Concentrated Animal Feeding Operations*, 79 N.C. MED. J. 276, 286 (2018) ("Southeastern North Carolina communities located in close proximity to hog CAFOs are characterized by poor indicators of health that are not solely due to the impact of converging demographic, socioeconomic, behavioral, and access-to-care factors, but are also due to the additional impact of multiple hog CAFOs located in this area. Although causality with specific exposures from hog CAFOs was not established, our findings suggest research is needed in environmental factors that may influence these outcomes.").

144. *See Principles of Environmental Justice*, ENERGY JUST. NETWORK (1991), http://www.ejnet.org/ej/principles.html [https://perma.cc/8X4Z-ZAN2] (delineating 17 principles of environmental justice); *see also* David Schlosberg & Lisette B. Collins, *From Environmental to Climate Justice: Climate Change and the Discourse of Environmental Justice*, 5 WIREs CLIMATE CHANGE 359, 368 (2014) ("What we see in the grassroots movement for climate justice are a variety of interrelated concerns—for the inequitable impact fossil fuel production has on a range of already vulnerable communities, for participation and procedural justice, for the basic functioning and provision of needs in vulnerable communities, including ecological communities.").

145. *See* Alistair Wardrope, *Intergenerational and Social Justice: There Is More to Environmental Justice than Accountability for Reasonableness*, AM. J. BIOETHICS, Mar. 2018, at 51, 51–53 (arguing for substantive intergenerational justice concepts as requisite complements to procedural justice approaches to environmental justice).

146. *See* Jennifer Kuzma, *Future Generations and Gene Drives: The Importance of Intergenerational Equity*, CTR. HUMANS & NATURE, https://www.humansandnature.org/future-generations-and-gene-drives [https://perma.cc/8H5R-RWJF] (concluding that intergenerational justice considerations imply obligations on the part of present generations, such as holding natural resources in trust for future generations).

costs onto rural communities ironically employs the same line of reasoning that motivated the development of Right-to-Farm legislation in the first place, reiterating the concern that urban areas can influence land use patterns to the detriment of rural residents.[147]

Moreover, there is also a disparate impact on farming economies in North Carolina. In the 1980s and 1990s, sociologists documented how farmers in low-income communities and black farmers, each independent of other sociodemographic variables, experienced greater loss of farms.[148] Farm loss was also higher in areas with greater hog-industry growth.[149] There were, of course, other factors associated with farm loss during this period, including national discriminatory lending practices[150] and increased population density in Eastern North Carolina—perhaps a reflection of unabated urban encroachment that inspired Right-to-Farm legislation only a decade earlier.[151] However, the impact on black farmers has been especially dramatic; from 1978 to 2012, the number of black-operated farms statewide declined from 7680 to 1637, a 79% decline.[152] In Duplin County, where the Williams live, the number of farms operated by black farmers decreased from 317 to 103 during this period.[153]

147. *See* Kaitlyn Kelly-Reif & Steve Wing, *Urban-Rural Exploitation: An Underappreciated Dimension of Environmental Injustice*, 47 J. RURAL STUD. 350, 354–55 (2016) (noting the need to increase urban residents' awareness of how their communities often do not feel the negative effects of resource use).

148. *See* Bob Edwards & Anthony E. Ladd, *Environmental Justice, Swine Production and Farm Loss in North Carolina*, 20 SOC. SPECTRUM 263, 263 (2000) (describing state patterns of farm loss during 1980s and 1990s, including "more pronounced [loss] in Black communities, regardless of income, and low-income communities, regardless of race").

149. *Id.* at 263–64.

150. Jess Gilbert, Gwen Sharp & M. Sindy Felin, *The Loss and Persistence of Black-Owned Farms and Farmland: A Review of the Research Literature and Its Implications*, 18 S. RURAL SOC. 1, 10–12 (2002) (highlighting, based on a literature review, that one of "[s]everal causes of black land and farm loss" was "continuing racial discrimination by lenders and government agencies"); Waymon R. Hinson & Edward Robinson, *"We Didn't Get Nothing:" The Plight of Black Farmers*, 12 J. AFR. AM. STUD. 283, 296–99 (2008) (describing delayed processing of lending applications and discriminatory lending practices).

151. *See* Edwards & Ladd, *supra* note 148, at 282–83 (noting "changing population density was a strong positive predictor" of farm loss but that "recent trends in urbanization . . . did not wash out or substantially diminish" the impact of the environmental justice variables used in their analysis).

152. *Compare* U.S. DEP'T OF COMMERCE, 1978 CENSUS OF AGRICULTURE: NORTH CAROLINA 199 tbl.41 (1978), *with* USDA, 2012 CENSUS OF AGRICULTURE: NORTH CAROLINA 48 tbl.60 (2012). The most recently available census data also show a small recent recovery, increasing by one hundred farms over a five-year period from 2007 to 2012. USDA, *supra*, at 48 tbl.60.

153. *Compare* U.S. DEP'T OF COMMERCE, *supra* note 152, at 199 tbl.41, *with* USDA, *supra* note 152, at 679 tbl.2.

As the second largest producer of hogs in the nation, North Carolina is an obvious location for interest in advances in genetic engineering of hogs.[154] One question facing accelerated genetic biotechnology use in pigs in North Carolina is how such technologies will be received by a populace steeped in not just an acrimonious social debate about the merits of genetic engineering but in an overlapping contentious debate about the role of hog farming in the state. While genetic scientists often want to decouple gene editing from industrialization in agriculture,[155] it is the dramatic scale-up of hog-farming operations that has generated ethical and social tension. This suggests that some of the first questions that will concern the public are how gene editing of hogs will manifest within the prevailing highly industrial production system, including effects on the few remaining smaller farming operations.[156] In addition, perception of hog-industry political influence is likely to set the stage for distrust of biotechnology commercial interests.[157] Such concerns are often dismissed as inadequately weighty in light of the moral imperative of producing enough food to feed the global population, to which we turn next.

C. *The Moral Imperative of Global Food Security*

Contemporary molecular genetics emerged long after the shift in how American farmers viewed crop heredity. In the early 1900s, the rise of industrialized agricultural practices reflected and instilled the values of crop uniformity and higher yields, leading to an end in seed saving and the trend toward purchasing seed.[158] Agriculture policy included USDA funds to support agricultural research, prompting

154. *See* NAT'L AGRIC. STATISTICS SERV., USDA, ACH12-4, 2012 CENSUS OF AGRICULTURE HIGHLIGHTS: HOG AND PIG FARMING 1–2 (2014).

155. Leyser, *supra* note 61, at 1 ("For as long as we imagine that GM itself is the cause of these problems, they are free to escalate unchecked.").

156. *See* BRAD WEISS, REAL PIGS: SHIFTING VALUES IN THE FIELD OF LOCAL PORK 59–60 (2016) (analyzing how industrialization has in part led to a combination of interest in small farms, local food, and better taste by driving the development of alternative pig production systems in the Piedmont area).

157. *See* Ken Fine & Erica Hellerstein, *Big Pork Has Given $272,000 to House Republicans Who Voted in Favor of Hog-Farm-Protection Bill*, INDY WEEK (Apr. 7, 2017), https://indyweek.com/news/archives/big-pork-given-272-000-house-republicans-voted-favor-hog-farm-protection-bill/ [https://perma.cc/8GPC-M4DJ].

158. *See* Catherine Phillips, *Cultivating Practices: Saving Seed as Green Citizenship*, 33 ENVIRONMENTS: J. INTERDISC. STUD., no. 3, 2005 at 37, 39 (defining "seed saving" as "the practice including the growing, collection, storage, reuse, and/or exchange of seeds" as well as the knowledge and networks needed to support seed saving practices); *see also* Keith Aoki, *Food Forethought: Intergenerational Equity and Global Food Supply—Past, Present, and Future*, 2011 WIS. L. REV. 399, 439.

development of the land-grant university system.[159] The marriage of farm policy and university research turned to modern science and technology as a source of innovation, and policies supported their integration into farming practices nationwide.[160] Over the twentieth century, farming in the United States underwent widespread change, including a drastic reduction from approximately 30% of the population living on a farm to approximately 2% by the advent of the twenty-first century.[161] In the wake of World War II, farms consolidated nationally, becoming fewer in number and larger in size.[162] By the 1960s, the promise of the Green Revolution held out the tantalizing possibility of remediating world starvation and malnutrition, as well as saving the planet from the threat of rising famine due to rapid population growth.[163]

Running in parallel, international efforts went toward rural agricultural development, such as the Rockefeller Foundation's investment in Mexico (in the 1940s) and India (in the 1950s).[164] An ethical and technological vision provided the backdrop of the Rockefeller Foundation's efforts, including the moral ethos of the head of the Social Science Division, Joseph Wiltis, who proposed the following formula: (population) / (resources) = (well-being).[165] The Industrial Revolution precipitated many new technological advances in food production, transportation, and distribution, beginning with

159. *See* McKinley Mayes, *Status of Agricultural Research Programs at 1890 Land-Grant Institutions and Tuskegee University*, *in* A CENTURY OF SERVICE: LAND GRANT COLLEGES AND UNIVERSITIES 1890–1990, at 53, 53–58 (Ralph D. Christy & Lionel Williamson eds., Routledge 2017) (1992) (providing the history of agricultural research funding through the land-grant system and its underlying philosophy).

160. *See* Frederick H. Buttel, *The Land-Grant System: A Sociological Perspective on Value Conflicts and Ethical Issues*, AGRIC. & HUM. VALUES, Spring 1985, at 78, 78–95 (documenting internal disagreements within the land-grant university system, including how ethical issues appear from the perspective of the author's work in rural sociology).

161. Linda Loboa & Katherine Meyer, *The Great Agricultural Transition: Crisis, Change, and Social Consequences of Twentieth Century US Farming*, 27 ANN. REV. SOC. 103, 108 tbl.1 (2001).

162. *Id.* at 107–09.

163. *See* Lowell S. Hardin, *Meetings that Changed the World: Bellagio 1969: The Green Revolution*, 455 NATURE 470, 470–71 (2008) (reflecting on the Bellagio conference in April of 1969, including its prompting by the overriding sense of global food crisis, and acknowledging that attendees "worried that a widespread Green Revolution could have unintended consequences, such as aggravating the inequalities between small farmers and large landowners" but ultimately "concluded that world food needs outweighed such potential difficulties").

164. *See* John H. Perkins, *The Rockefeller Foundation and the Green Revolution, 1941–1956*, AGRIC. & HUM. VALUES, Summer–Fall 1990, at 6, 7 (documenting the relative novelty of scientific study of agriculture during this period in these countries).

165. *Id.* at 13.

industrially produced mechanisms that were then motorized and the production of chemically produced fertilizers and pesticides.[166] These industrial techniques were spread globally through the Green Revolution, a 1960s effort launched jointly by the United States Agency for International Development and the Rockefeller Foundation.[167] In moral terms, the Green Revolution was largely depicted as a technological solution to the world's hunger.[168] The development of genetic engineering in agriculture in the 1990s invoked a continuation of this vision and hope for innovation, with the intent to feed a growing global population, echoing appeals to the moral imperative to address starvation and hunger.[169]

After years of declining rates, the World Health Organization ("WHO") currently estimates the number of people in the world affected by chronic food deprivation to be 821 million, a number that has been on the rise since 2014.[170] Domestically, fifteen million people are food insecure, lacking access to food due to insufficient economic or other resources.[171] Relatively, the prevalence of undernourishment is dramatically and unequally distributed in the Global South.[172] Contemporary genetic modification in agriculture is sometimes touted as a continuation of the Green Revolution, especially in its promise to help address problems of food scarcity and malnutrition.[173] And there is evidence that genetically modified crops have

166. *E.g.*, MARCEL MAZOYER & LAURENCE ROUDART, A HISTORY OF WORLD AGRICULTURE: FROM THE NEOLITHIC AGE TO THE CURRENT CRISIS 375–440 (James H. Membrez trans., 2006) (reviewing stages, changes in structure and function, difficulties, and policy failures).

167. *See* Perkins, *supra* note 164, at 11–13.

168. *See* THOMPSON, *supra* note 65, at 198 (noting the character and development of arguments supporting obligations of affluent nations to address the suffering of those in poverty).

169. *See* Norman Borlaug, *Ending World Hunger. The Promise of Biotechnology and the Threat of Antiscience Zealotry*, 124 PLANT PHYSIOLOGY 487, 487–89 (2000) ("Genetic modification of crops is not some kind of witchcraft; rather, it is the progressive harnessing of the forces of nature to the benefit of feeding the human race.").

170. FOOD & AGRIC. ORG. OF THE U.N., THE STATE OF FOOD SECURITY AND NUTRITION IN THE WORLD 3 fig.1 (2018), http://www.fao.org/3/I9553EN/i9553en.pdf [https://perma.cc/6ZT2-XMCR] (attributing the rise in recent years to a variety of highly context-dependent causal factors including ongoing violent conflict, adverse climate events, and lack of economic resources).

171. *Key Statistics & Graphics*, USDA, https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-us/key-statistics-graphics.aspx#foodsecure [https://perma.cc/G7BW-B74N].

172. *See* FOOD & AGRIC. ORG. OF THE U.N., *supra* note 170, at 6 tbl.2.

173. *E.g.*, Georges & Ray, *supra* note 60, at 1–12 (addressing the potential of genetically modified crops to address projected world population growth and climate change).

economically benefited farmers in resource-poor countries[174] and improved the food security of farming families.[175]

Globally, these issues are also situated in the economic and political debates about trade, global fairness of subsidies, and the lower price at which U.S. farmers are able to sell.[176] Moreover, they can be inextricably intertwined with local visions of development and the cultural meaning of crops, as exemplified by 1990s debates about importing transgenic maize into Mexico and its agricultural system employing landraces.[177] The continued debate over the possibility of transgenic contamination in Mexican maize is both social and technical, as a lack of methods for monitoring and detecting transgenes in landraces has been part of the discussion.[178]

How might accelerated gene editing in pigs meet an argument for advancing food security? One possibility is that CRISPR has been used to genetically edit a mouse *UCP1* gene for temperature regulation into pigs, enabling their ability to withstand colder temperatures.[179] The lower fat stores of such pigs has been publicly touted as a potential health benefit, saving farmers on energy, the cost of food, and promoting animal welfare as low-fat pigs suffer less from exposure to cold weather.[180] Elsewhere, *UCP3* gene editing for better temperature regulation suggested the possibility not only of

174. *See generally* Wilhelm Klümper & Matin Qaim, *A Meta-Analysis of the Impacts of Genetically Modified Crops*, 9 PLOS ONE, no. e111629, Nov. 3, 2014, at 1, 4.

175. *E.g.*, Martin Qaim & Shahzad Kouser, *Genetically Modified Crops and Food Security*, 8 PLOS ONE, no. e64879, June 5, 2013, at 1, 6 (finding that growth of Bt cotton reduced food insecurity by fifteen to twenty percent among cotton-producing households in India).

176. *See* Alejandro Nadal & Timothy A. Wise, *The Environmental Costs of Agricultural Trade Liberalization: Mexico–US Maize Trade Under NAFTA* 5–13 (Working Grp. on Dev. & Env't in the Ams., Working Paper No. DP04, 2004), http://ase.tufts.edu/gdae/pubs/rp/nadalwisecornbrasiliamar04.pdf [https://perma.cc/Q6TE-UNEJ] (considering the impacts of NAFTA). At the time of NAFTA, the United States was able to sell maize at roughly half the price of Mexican maize, and during the 1990s and early 2000s, genetically engineered corn was introduced in Mexico. *Id.* at 5.

177. *See* McAfee, *supra* note 67, 148–56 (2008).

178. *See generally* Sarah Z. Agapito-Tenfen & Fern Wickson, *Challenges for Transgene Detection in Landraces and Wild Relatives: Learning from 15 Years of Debate Over GM Maize in Mexico*, 27 BIODIVERSITY & CONSERVATION 539, 539–66 (2017) (conducting literature review on transgene detection in landraces in Mexican maize).

179. *See* Qiantao Zheng et al., *Reconstitution of* UCP1 *Using CRISPR/Cas9 in the White Adipose Tissue of Pigs Decreases Fat Deposition and Improves Thermogenic Capacity*, 144 PROC. NAT'L. ACAD. SCI. 9474, 9474–82 (2017) (reporting how *UCP1* expression could be modified to enhance the ability of piglets to resist cold stress).

180. *See* Rob Stein, *CRISPR Bacon: Chinese Scientists Create Genetically Modified Low-Fat Pigs*, NPR (Oct. 23, 2017), https://www.npr.org/sections/thesalt/2017/10/23/559060166/crispr-bacon-chinese-scientists-create-genetically-modified-low-fat-pigs [https://perma.cc/7UDL-64L7].

preventing herd loss but also of introducing larger hog-farming production in new locations, especially in colder climates previously inhospitable to such operations.[181] Such possibilities suggest a continuation of the Green Revolution vision, only now envisioning a future bringing increased sources of dietary protein to locations where such production was previously unthinkable. Moreover, envisioning such a future for hog production is not entirely fictional; gene editing in cattle with different climates in mind is farther along. For example, the company Recombinetics, Inc. views its genetically edited thermotolerant "SLICK" cattle as a way to increase beef and dairy production in warmer climates.[182]

Nuisance suits in the United States, especially in regions of high agricultural production like North Carolina, support a critical evaluation of land-use policies where genetically modified pigs suddenly make hog farming easier or more profitable. Presently, when such high-productivity hog farming takes place, the social problems at the core of nuisance suits are likely to follow if appropriate policies are not designed to respond. Hog production is hardly new to some of the areas where thermotolerant animals are under study, such as China, but it is worthwhile to consider increases in scale made possible by biotechnology.[183] Careful evaluation of existing protections in rural communities is a small step toward mitigating negative effects for neighbors and communities adjacent to hog farms.

181. *See* Oxford Univ. Press, *Scientists Discover How Some Pigs Cope in Cold Climates*, PHYS.ORG (May 31, 2017), https://phys.org/news/2017-05-scientists-pigs-cope-cold-climates.html [https://perma.cc/Q89D-VQB2].

182. *See* Holly Drankhan, *Gene-Editing Tool Could Improve Animal Welfare and Food Security*, PROGRESSIVE DAIRYMAN (Sept. 12, 2016), https://www.progressivedairy.com/topics/a-i-breeding/gene-editing-tool-could-improve-animal-welfare-and-food-security [https://perma.cc/SA7W-6DGG] (describing how the SLICK mutation results in traits that enable cattle to remain several degrees cooler, which leads to increased lactation, and how gene editing will accelerate current breeding programs with similar aims); *see also* Tad Sonstegard, Chief Sci. Officer, Recombinetics, Inc., Speech at the Genome Writers Guild 2018 Conference: A SLICK Way to Improve Animal Protein Production in the Tropics (July 20, 2018); Jason Bellini, *This Gene-Edited Calf Could Transform Brazil's Beef Industry*, WALL ST. J. (Oct. 1 2018), https://www.wsj.com/video/series/moving-upstream/this-gene-edited-calf-could-transform-brazil-beef-industry/D2D93B49-8251-405F-BC35-1E5C33FA08AF?mod=searchresults&page=1&pos=1 [https://perma.cc/ED5E-HF5S].

183. *See* David Chadwick et al., *Improving Manure, Nutrient Management Towards Sustainable Agriculture Intensification in China*, 209 AGRIC. ECOSYSTEMS & ENV'T 34, 36, fig.2 (2015) (noting the difference in herd size in China to qualify as a CAFO).

D. Food Ethics

Moral framing of food comprises an array of ethical issues that are sometimes grouped under the broad banner of "food ethics," or the ethical norms that encompass the role of food in caring for the self, family, and others in society, including animals.[184] There is a rift in food ethics between those who see it purely as a form of expressing ethical values through consumption choices and those who emphasize ethical deliberation in organization and performance of food production.[185] One commentator rightly notes that moral attitudes surrounding food are hardly new, tracing such attitudes through centuries of moral traditions.[186] The food ethics of accelerated gene editing in livestock includes religious attitudes toward animals, the cultural meaning of food and related activities, concerns about animal health and well-being, and public trust in scientists and the regulatory oversight process.[187]

Food ethics manifests differently from the perspective of consumers, environmentalists, or those dedicated to animal welfare. The development of local farmers markets is illustrative. National policy again played an influential role, as an increase in farmers markets followed the passage of the Farmer-to-Consumer Direct Marketing Act of 1976.[188] In some locations in the United States, consumers have indicated a willingness to pay more for local or organic products,[189] while another analysis of a Canadian market identifies spatial and social embeddedness as motivating farmers market attendance, connecting markets to advocacy movements for alternative forms of agricultural production.[190] Ethical analysis, too,

184. *See* Michael K. Goodman et al., *Ethical Foodscapes?: Premises, Promises, and Possibilities*, 42 ENV'T & PLAN. A 1782, 1784 (2010).

185. *See* Paul B. Thompson, *The Emergence of Food Ethics*, 1 FOOD ETHICS 61, 62–63 (2016) (mapping the disagreement about the meaning of the term).

186. *See* Hub Zwart, *A Short History of Food Ethics*, 12 J. AGRIC. & ENVTL. ETHICS 113, 113–26 (2000). The author also notes that food ethics is often considered a branch of applied or professional ethics. *See id.* at 114.

187. *See, e.g.*, Tetsuya Ishii, *Genome-Edited Livestock: Ethics and Social Acceptance*, ANIMAL FRONTIERS, Apr. 2017, at 24, 27–28, 28 fig.2a (providing an overview that includes solicited public attitudes toward livestock genetic editing in Japan).

188. The Farmer-to-Consumer Direct Marketing Act of 1976, Pub. L. No. 94-463, 90 Stat. 1982 (codified as amended at 7 U.S.C. §§ 3001–3006 (2012)); *see also* Allison Brown, *Counting Farmers Markets*, 91 GEOGRAPHICAL REV. 655, 657 (2001).

189. *See* Wuyang Hu et al., *Consumer Preferences for Local Production and Other Value-Added Label Claims for a Processed Food Product*, 39 EUR. REV. AGRIC. ECON. 489, 489–510 (2012) (using data from Kentucky and Ohio consumers).

190. *See* Robert B. Feagan & David Morris, *Consumer Quest for Embeddedness: A Case Study of the Brantford Farmers' Market*, 33 INT'L J. CONSUMER STUD. 235, 235–43 (2009).

has assessed social movements that aim to increase local production and consumption, exploring how such efforts invoke "place" as not merely a technical concept referencing geography but as a value-laden concept connected to political philosophies invoking community or civic responsibility and relating to community advocacy for expanded visions of local development.[191] Conducting ethnography among chefs, restaurant workers, farmers, and farmers market consumers in the Piedmont region of North Carolina, cultural anthropologist Brad Weiss notes the complex difficulty of realizing the values of place, as the local appeal of "heritage breeds" of pigs has both a genetic and social grounding.[192]

From the perspective of some farmers, genetic biotechnology can offer approaches that combine cutting-edge science with longstanding traditions of breeding, comprising a twenty-first-century extension of the agricultural value of husbandry. Yet an ethos tied to the land can also support the suspicion that gene editing too easily falls prey to biological reductionism.[193] Wildlife ecologist and environmental ethics writer Aldo Leopold sought a link between conservationism and farming in the value of husbandry.[194] He anticipated urban-rural conflicts similar to those present in North Carolina and noted how a lack of agricultural experience bore terrible environmental

191. *See* Laura B. DeLind & Jim Bingen, *Place and Civic Culture: Re-Thinking the Context for Local Agriculture*, 21 J. AGRIC. & ENVTL. ETHICS 127, 127–51 (2008) (exploring a qualitative concept of place, including "civic agriculture," or strategies for rural development).

192. *See* Interview by Emily Levitt with Brad Weiss, Professor of Anthropology, Coll. of William & Mary, https://culanth.org/articles/14-making-pigs-local-discerning-the-sensory [https://perma.cc/Y8L4-25JU] ("The relationship between the genetic characteristics of 'heritage breeds' of pigs (and other animals), and the wider socio-cultural dimensions of a breed's historicity (including their husbandry, migrations, ecological adaptations) is a really interesting question. I'm currently hoping to work with members of the American Livestock Breed Conservancy (ALBC), who are developing a 'Rare Breed Swine Initiative' designed to generate a model that can be used to expand the farming of rare breeds, as well as help to recover endangered breeds."). *See generally* Brad Weiss, *Making Pigs Local: Discerning the Sensory Character of Place*, 26 CULTURAL ANTHROPOLOGY 438, 438–61 (2011) (exploring the development of alternative pork-production practices in response to the industrial food complex).

193. *See* Kathleen McAfee, *Neoliberalism on the Molecular Scale. Economic and Genetic Reductionism in Biotechnology Battles*, 34 GEOFORUM 203, 213–14 (2003) (contending that transnational biotechnology arrangements are premised on the value of genetic components of crops only once these are removed and abstracted from the contexts in which they coevolved with human communities).

194. *See* ALDO LEOPOLD, A SAND COUNTY ALMANAC WITH OTHER ESSAYS ON CONSERVATION FROM ROUND RIVER 267–69 (3d prtg. 1966) (observing how husbandry is comprised of a sense of enjoyment that can only be found in managing land for agriculture or conservation).

consequences, claiming that "there are two spiritual dangers in not owning a farm. One is the danger of supposing that breakfast comes from the grocery, and the other that heat comes from the furnace."[195] In this pithy observation, Leopold highlights that unfamiliarity with farming and other forms of land management, such as forestry, can result in a disconnect from crucial aspects of daily life that depend on the land. In seeking to reconnect consumers to farming and the land, farmers markets can fill these knowledge gaps while also creating a sense of community.[196]

The rise of food ethics presents yet another discourse that overlaps with the social discussion of recent advances in gene editing and their agricultural applications. Genetic modification of animals for food production will follow in the wake of controversy that characterized the introduction of genetically modified plants.[197] Some commentators have expressed hope that the antagonism that has sometimes characterized these GMO debates in the 1990s will offer a cautionary tale, inspiring greater transparency for future development to garner public trust.[198] However, authors of the recent U.S. National Academies' report, *Genetically Engineered Crops: Experiences and Prospects*, note that existing social tension had already led many stakeholders (both for and against genetic technologies) to anticipate that the report would be biased before it had even been published.[199] There are also tempered views, noting likely continued public confusion concerning the science and "genuine resentment" of profit-driven licensing practices.[200]

195. *Id.* at 6.

196. *See, e.g.*, Abel Duarte Alonso, *To What Extent Do Farmers Educate Consumers, a Case Study from Alabama*, 11 J. AGRIC. & FOOD INFO. 307, 307–09 (2010) (noting that educational activities of Alabama farmers were varied and could extend beyond a sales pitch).

197. *See supra* text accompanying notes 65–66, 76.

198. *See* Caixia Gao, *The Future of CRISPR Technologies in Agriculture*, 19 NATURE REVIEWS MOLECULAR CELL BIOLOGY 275, 276 (2018) ("As scientists, we should not discount the challenge of providing transparency to CRISPR breeding methods, which would be crucial for gaining public trust and influencing regulatory policies that are evolving to govern the use of CRISPR technologies in agriculture. . . . With that comes a responsibility to continue to resolve both the scientific and public concerns regarding its usage.").

199. *See* Fred Gould et al., *Elevating the Conversation About GE Crops*, 35 NATURE BIOTECHNOLOGY 302, 302 (2017) ("Even before our committee's first meeting, letters were sent to the US National Academies highly critical of our study. Some saw no need for yet another study of what they consider a proven, safe technology, whereas others believed that our specific committee members would write a report biased in favor of GE crops and cropping system." (footnotes omitted)).

200. Georges & Ray, *supra* note 60, at 9.

Expectations of less controversy around gene editing of animals, however, seem primed for disappointment given the unfolding array of attitudes regarding the moral status of animals and meat consumption.[201] Concerns about the welfare of genetically engineered animals surfaced early and are a significant component of GMO debates in Europe.[202] Concerns about animal welfare inform food ethics questions regarding the morality of meat consumption, production, and livestock-farming policy.[203] Questions about the moral status of animals demonstrate a social shift in how agriculture can be evaluated, including from the animals' perspective.[204] Many of these ethical arguments do not play out in nuisance suits.[205] However, assumptions regarding the merits of livestock production and consumption form the basis of Right-to-Farm legislation. In particular, social movements for reducing meat consumption are likely to collide with the development of gene editing of animals.[206] In part, this moral connection results from some parallels between genetic editing of animals and meat consumption; at some level, both reflect an acceptance of the legitimacy of using animals to serve human purposes.[207] In addition, both agricultural use and genetic editing of animals raise questions about the morality of relationships between humans and animals. Independently, the justifications for eating meat[208] and using animals to support the advancement of

201. *See* Nick Fox & Katie Ward, *Health, Ethics and Environment: A Qualitative Study of Vegetarian Motivations*, 50 APPETITE 422, 422–29 (2008) (exploring motivations of vegetarians).

202. *See generally* PAUL B. THOMPSON, FOOD BIOTECHNOLOGY IN ETHICAL PERSPECTIVE 121–46 (2d ed. 2007) (providing an overview of the public's concerns about the use of gene editing in agriculture).

203. *See* THOMPSON, *supra* note 65, at 134 ("Food ethics could and should address . . . : (1) Is it ethically acceptable to eat animal flesh, or to raise and slaughter livestock for animal food product? (2) Are present-day methods for raising livestock ethically acceptable? (3) How should present-day livestock production systems be reformed or modified in order to improve animal welfare?").

204. *Id.* at 134–37.

205. *See* Blythe, *supra* note 82.

206. *E.g.*, Erik de Bakker & Hans Dagevos, *Reducing Meat Consumption in Today's Consumer Society: Questioning the Citizen-Consumer Gap*, 25 J. AGRIC. & ENVTL. ETHICS 877, 884–85 (exploring briefly cultural change and advocacy as routes of changing food choices).

207. *See* Phil Macnaghten, *Animals in Their Nature: A Case Study on Public Attitudes to Animals, Genetic Modification and 'Nature'*, 38 SOCIOLOGY 533, 533–51 (2004) (concluding that focus group responses are interpreted within changing dynamics of animal-human relations and practices and where ethical concern towards animals is a matter of social past, present, and imagined futures).

208. *See* Peter Singer, *Animal Liberation*, *in* ANIMAL RIGHTS: THE CHANGING DEBATE 7, 7–18 (Robert Garner ed., 1996) (arguing that our treatment of animals for

human knowledge[209] have each drawn criticism for reflecting an exclusively anthropocentric worldview. As a result, editing of animals for agriculture and editing them for research purposes to further human health are likely to be, yet again, complex overlapping issues involving a diversity of stakeholders.

III. TOWARD A BROADER BIOETHICS OF GENE EDITING IN ANIMALS

In this part we consider some possible next steps for ethics and gene editing in animals. We first examine recent community engagement efforts surrounding field trials of mosquitoes whose genes were edited to mitigate mosquito-borne illnesses. Such field trials offer lessons for engagement, as this research shares with future editing of livestock the merging of expertise in human health, ecology, and molecular biology with community perspectives. We then consider and support changes in bioethics that also open up room for broader normative analysis and engagement.

A. Lessons from Field Trials and Gene Editing for Mitigation of Mosquito-Borne Illnesses

Gene drives have been proposed as a possible way to intervene with vectors of infectious diseases in order to address mosquito-borne illnesses such as malaria,[210] dengue, chikungunya, yellow fever, and zika.[211] Gene-drive editing differs from other editing techniques because it pursues the additional goal of seeking higher rates of inheritance of specific genes across generations.[212] Gene drives are achieved by inserting the entire gene-editing apparatus as well as the desired edit.[213] This mechanism facilitates additional and repeated

human consumption and for research is based on attitudes that unreasonably elevate the moral status of humans).

209. *See* Elisabeth H. Ormandy & Catherine A. Schuppli, *Public Attitudes Toward Animal Research: A Review*, 4 ANIMALS 391, 395–96 (2014) (noting that vegetarian "world view[s]" are linked to negative attitudes toward animal research, as is an interest in environmental issues).

210. *See* John M. Marshall & Charles E. Taylor, *Malaria Control with Transgenic Mosquitoes*, 6 PLOS MED., no. 1000020, Feb. 10, 2009, at 164, 164–68 (describing advances in gene drives for mitigation of malaria).

211. *E.g.*, Appadurai Daniel Reegan et al., *Current Status of Genome Editing in Vector Mosquitoes: A Review*, 10 BIOSCIENCE TRENDS 424, 424–32 (2016) (critiquing the current status of genome-editing research on vector mosquitoes).

212. *See, e.g.*, Jackson Champer, Anna Buchman & Omar S. Akbari, *Cheating Evolution: Engineering Gene Drives to Manipulate the Fate of Wild Populations*, 17 NATURE REV. GENETICS 146, 146–47 (2016).

213. *Id.*

editing of other copies of the same gene inherited from another parent, enabling an entire generation of progeny to inherit the desired trait.[214] Such work follows on the heels of earlier efforts in gene editing of plants, including field trials.[215] Some have defended the use of gene drives for the purpose of reducing mosquito population size, or even driving some species of mosquitoes to extinction, on the grounds of the humanitarian gains given the large burden of disease imposed by pathogens like the Zika virus.[216]

Ethical and social analyses regarding gene drives tend to focus on risk to humans and the environment and often turn to community engagement in response to such risks. Community engagement is a contested term and practice, but generally refers to the process of "working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the wellbeing of those people."[217]

Research regulations regarding human subjects are often not applicable to most research involving genetic engineering for agricultural purposes. Field trials of gene-edited mosquitoes include a variety of designs, including caged trials in which gene-edited mosquitoes are released into a controlled or restricted setting, such as nets that hinder movement.[218] Contained field trials often use other barriers, such as rivers that limit the mosquitoes' geographic range, while open field trials involve no such restraints on movement.[219] All three designs seem to implicate some safety concern, given that each involves some risk of escape or exposure to local humans or ecosystems.[220] One working group recommended future gene-edited

214. *Id.*

215. *See, e.g.*, Kathryn S. Aultman et al., *Managing Risks of Arthropod Vector Research*, 288 SCIENCE 2321, 2321 (2000) (contending there is a need for researcher consensus about the risks of field trials and support from funders regarding experimental design in order to facilitate participation of affected communities).

216. *See* Zach Adelman, *When Extinction Is a Humanitarian Cause*, MIT TECH. REV. (Feb. 12, 2016), https://www.technologyreview.com/s/600793/when-extinction-is-a-humanitarian-cause/ [https://perma.cc/GU94-CRXD] (defending gene drives that pursue the goal of moving *Aedes aegypti* to extinction).

217. CLINICAL AND TRANSLATIONAL SCI. AWARDS CONSORTIUM & CMTY. ENGAGEMENT KEY FUNCTION COMM. TASK FORCE ON THE PRINCIPLES OF CMTY. ENGAGEMENT, NIH PUB. NO. 11-7782, PRINCIPLES OF COMMUNITY ENGAGEMENT (2011), at 7.

218. *See* Carolyn P. Neuhaus, *Community Engagement and Field Trials of Genetically Modified Insects and Animals*, 48 HASTINGS CTR. REP. 25, 26 (2018) (noting that what makes all field trials of mosquitoes morally relevant is the possibility of free movement of gene-edited animals despite variability in likelihood).

219. *Id.*

220. *Id.*

mosquito field trials proceed with contained field trials in which release occurs in a closed system, enabling improved ability to recapture genetically engineered organisms while studying them in environments that simulate real-world conditions.[221] Field trials of genetically edited mosquitoes have also been proposed as the significant stage at which nearby residents might be considered participants,[222] but this assertion is highly contentious in mosquito field trials, which often involve male mosquitoes that cannot bite humans.[223]

Community engagement is often seen as a way of addressing public concerns about gene-edited mosquito field trials. In its 2016 report, the U.S. National Academies supported public engagement, but also noted ongoing challenges such as whether the sites for field trials have the necessary capacity to support engagement, including the inadequacy of the EPA's platform for public engagement.[224] WHO emphasized the need for community engagement throughout the project timeline and the central importance of adequate funding for engagement.[225] Involvement of large affected communities has always presented a challenge to the individualized view of informed consent and respect for participant autonomy.[226] Obtaining individual

221. *See* Mark Benedict et al., *Guidance for Contained Field Trials of Vector Mosquitoes Engineered to Contain a Gene Drive System: Recommendations of a Scientific Working Group*, 8 VECTOR-BORNE & ZOONOTIC DISEASES 127, 128 (2008) (describing guidance for risk mitigation in field trials).

222. *See* Pamela A. Kolopack & James V. Lavery, *Informed Consent in Field Trials of Gene-Drive Mosquitoes*, 1 GATES OPEN RES. 1, 3–4 (2017) (considering both the application of human subject research regulations during caged field trials and environmental release trials).

223. *Id.* at 3, 5 (reporting the disagreement about human subjects regulation in relation to disagreement about the role of informed consent); *see also* Andrew McRae et al., *Who Is the Research Subject in Cluster Randomization Trials in Health Research?*, 12 TRIALS 1, 7 (2011) (contradicting the Council of International Organizations of Medical Science's definition of research, which emphasizes intentional manipulation of an individual's social or physical environment, claiming that "[a]n unduly broad interpretation of environmental manipulation is, however, untenable").

224. *See* NAT'L ACADS. OF SCIS., ENG'G, & MED., GENE DRIVES ON THE HORIZON ADVANCING SCIENCE, NAVIGATING UNCERTAINTY, AND ALIGNING RESEARCH WITH PUBLIC VALUES 7–8 (2016) (calling for public engagement in several governance recommendations, including possible frameworks for engagement, and anticipating challenges).

225. *See* WORLD HEALTH ORG., GUIDANCE FRAMEWORK FOR TESTING OF GENETICALLY MODIFIED MOSQUITOES, at xxiv, 69–89 (2014) (describing engagement at the community, project, and third-party levels and the need for funding to build interdisciplinary teams and local capacity).

226. *See* Jeffrey Kahn, *Informed Consent in the Context of Communities*, 135 J. NUTRITION 918, 919 (2005) ("Part of the problem is that we talk about community consent, but we know that it does not make sense as a concept. A community cannot

consent from everyone in the vicinity can present both conceptual and logistical challenges.[227] Nevertheless, the epidemiological end points that are the ultimate goal of these trials present an ongoing challenge regarding interpretation of relevant regulations.[228]

In addition to engaging local communities, such efforts will need to bridge disciplinary divides from molecular genetics to population health. In areas of West Africa where malaria has been especially recalcitrant, evidence supports the use of many interventions tied into an integrated vector-management strategy. There will also be questions of how genetic modification will translate to combine with other elements of this population health approach.[229] For example, it remains uncertain how such interventions will be viewed or accepted by population-health professionals more familiar with evidence in favor of other modes of prevention, including improving access to clean water, screens, insecticide spraying, and vaccination.[230]

Genetic field-trial research projects take place at the intersection of emerging technology ethics and global-health ethics. Situating genetic technologies as part of larger ethical issues in global health includes attending community engagement that addresses relationships between researchers and local communities.[231] Field trials also take place against the backdrop of colonialism and ongoing power differentials that pervade relationships between researchers

consent, because there is no entity that is the community. . . . In the end, what we are really after is partnership.").

227. *Id.*

228. Kolopack & Lavery, *supra* note 222, at 4 (embracing the view that genetically edited mosquito field trials become human-subjects research "(1) when blood and other forms of clinical data are collected from them, as will likely be the case in some studies involving epidemiological endpoints, such as the incidence of new infections with dengue and malaria; (2) when they participate in social science and/or behavioral research involving the completion of surveys and questionnaires; or (3) when their home or property is accessed and the location recorded as a spatial variable for the release or collection of mosquitoes because the precise location of the household is important for entomological reasons and these data constitute identifiable private information at the household level").

229. *See* Scott A. Ritchie & Brian J. Johnson, *Advances in Vector Control Science: Rear-and-Release Strategies Show Promise . . . but Don't Forget the Basics*, 215 J. INFECTIOUS DISEASES 103, 106 (2017) (contending that advances in genetic technology are not yet ready for widespread roll-out and that available methods for vector control should be supported and improved in the short term).

230. *Id.*

231. *See* Paulina O. Tindana et al., *Grand Challenges in Global Health: Community Engagement in Research in Developing Countries*, 4 PLOS MED., no. e273, Sept. 11, 2007, at 1451, 1452 (identify multiple goals for community engagement in global-health research, including addressing the risk of exposing poor and otherwise marginalized communities to an unfair burden of research risks).

from affluent countries and communities in moderate- or low-income contexts. Two areas that have received attention as this research progresses include the ethical conduct of field trials, especially site selection, and community acceptance of gene-edited mosquito release.[232]

First, some progress has been made in the ethics of site selection. One study noted that host-country political support of such research played an important role in their project's location; their team viewed enacted legislation as indicative that some public deliberation on the acceptability of such research had already taken place, and existing national ethical guidance as reflective of greater local oversight.[233] Another study offered criteria for identifying and evaluating candidate sites for open-field trials, emphasizing similar ethical and regulatory conditions including the simultaneous scientific and ethical significance of differences between the residents of the study site and the human populations where a larger-scale targeted release effort might occur.[234] Experiences also reflect how the ethics of site selection is deeply tied to anticipated forms of community engagement,[235] requiring ethical frameworks that link community health concerns with environmental values.[236]

Second, community engagement is one important area of developing ethical guidance for accelerated gene-editing biotechnology. In 2011, field trials in the Cayman Islands and Malaysia by U.K. biotechnology firm Oxitec were critiqued for coming by surprise to some residents, in part because there was

232. *See* Marshall & Taylor, *supra* note 210, at 167 (noting that "there is a clear need for much more analysis of the human research participant issues posed by these new methods").

233. James V. Lavery, Laura C. Harrington & Thomas W. Scott, *Perspective: Ethical, Social, and Cultural Considerations for Site Selection for Research with Genetically Modified Mosquitoes*, 79 AM. J. TROPICAL MED. & HYGIENE 312, 313 (2008).

234. *See* David M. Brown et al., *Criteria for Identifying and Evaluating Candidate Sites for Open-Field Trials of Genetically Engineered Mosquitoes*, 14 VECTOR-BORNE ZOONOTIC DISEASES 291, 293 (2014) (encouraging those engaged in field trials to consider specific criteria for identifying candidate sites, such as no widespread opposition, the presence of a local researcher, and availability of the target species at the site).

235. *See* Lavery et al., *supra* note 233, at 317 (considering ethical, social, and cultural considerations for site selection, such as "adequate infrastructure for case studies and on-going community engagement and collaboration").

236. *See* NAT'L ACADS. OF SCIS., ENG'G, & MED., *supra* note 224, at 5–6 (outlining values relevant to potential environmental effects and "human welfare"); *see also* David B. Resnik, *Ethical Issues in Field Trials of Genetically Modified Disease-Resistant Mosquitoes*, 14 DEVELOPING WORLD BIOETHICS 37, 45–46 (2014) (noting risks to the ecosystem if gene drives reduce or eliminate a species that plays an important role in the food chain).

miscommunication in Malaysia, and members of the public were confused by another project's delayed plans for future release.[237] Reporting on community engagement in northern Australia in 2011, Kolopack and her colleagues describe ethics of community engagement for field trials of a technology involving *Wolbachia*, a bacterially infected mosquito.[238] Their approach involved formative social-science research, including in-depth interviews, focus groups, and written surveys.[239] Among the findings was the tendency for respondents to frame the biotechnology in light of past efforts at biological pest control, especially the release of cane toads in the 1930s, revealing the importance of ecological assumptions and acknowledgement of uncertainty, as well as the unpredictability of social responses to such interventions.[240]

The challenges of public or community engagement are conceptual, logistical, empirical, and normative. It is, however, questionable whether the consent-based orientation reflected in the literature discussed above provides an adequate basis for understanding the ethics of community engagement. More broadly, we suggest that an IRB-focused conception of research ethics may be constraining the way in which the ethics of gene drives are being approached. For example, key concepts employed in engagement reveal the importance of definitions, such as who constitutes the community or public, and what constitutes meaningful engagement as opposed to tokenism.[241] Addressing logistics, Kolopack and her

237. *See Letting the Bugs Out of the Bag*, 470 NATURE 139, 139 (2011) (describing local surprise and confusion in the wake of a field release); *see also* T.S. Saraswathy Subramaniam et al., *Genetically Modified Mosquito: The Malaysian Public Engagement Experience*, 7 BIOTECHNOLOGY J. 1323, 1326 (2012) (describing the release of male mosquitoes of the OX513A (My1) strain, which, after mating, results in inviable offspring, and offering suggestions for future engagement efforts).

238. *See* Pamela A. Kolopack et al., *What Makes Community Engagement Effective?: Lessons from the* Eliminate Dengue *Program in Queensland Australia*, 9 PLOS NEGLECTED TROPICAL DISEASES, no. e3713, Apr. 13, 2015, at 1, 2 (articulating the findings that translating ethical intentions into effective community engagement is "more socially complex" than community engagement literature sometimes acknowledges).

239. *See generally* Darlene McNaughton, *The Importance of Long-Term Social Research in Enabling Participation and Developing Engagement Strategies for New Dengue Control Technologies*, 6 PLOS NEGLECTED TROPICAL DISEASES, no. 1785, Aug. 28, 2012, at 1 (describing the extensive engagement project which was undertaken during two years prior to release).

240. *See* Richard Shine & Benjamin L. Phillips, *Unwelcome and Unpredictable: The Sorry Saga of Cane Toads in Australia*, *in* AUSTRAL ARK: THE STATE OF WILDLIFE IN AUSTRALIA AND NEW ZEALAND 83, 83–104 (Adam Stow et al. eds., 2015) (reviewing longstanding social controversy in response to release of the cane toad).

241. *See* Lara El Zahabi-Bekdash & James V. Lavery, *Achieving Precaution Through Effective Community Engagement in Research with Genetically Modified Mosquitoes*, 18

colleagues also emphasize the infrastructure, funding, and support needed to make community engagement possible, acknowledging that even well-funded and supported efforts can struggle to adequately access and report on the views of stakeholders who do not have positive views of a research project.[242]

Discourse about best practices in community engagement for field trials[243] reflects wider discourse about community engagement in public health practice[244] and health research[245] writ large. For example, engagement in health promotion can serve utilitarian or systems-based goals of improving desired outcomes, whereas social-justice rationales for engagement emphasize empowerment.[246] Empirically, the larger global-health research community is seeking better metrics to evaluate community engagement.[247] The search for evaluative metrics concerns what community engagement attempts to accomplish, what constitutes success, and how to measure these values.[248] While community engagement is sometimes thought of as a collective parallel to informed consent, there are many reasons not to conflate engagement with consent, one being that gaining social permission and legitimacy are not the only goals of engagement practices.

ASIA PAC. J. MOLECULAR BIOLOGY & BIOTECHNOLOGY 247, 248 (2010) (supporting early community engagement that helps inform technological development and avoid “tokenism”).

242. *See* Kolopack et al., *supra* note 238, at 15–19.

243. *See generally* Bipin Adhikari et al., *Community Engagement and Population Coverage in Mass Anti-Malarial Administrations: A Systematic Literature Review*, 15 MALARIA J. 523 (2016) (systemically reviewing the literature on community engagement).

244. *See generally* Alison O’Mara-Eves et al., *The Effectiveness of Community Engagement in Public Health Interventions for Disadvantaged Groups: A Meta-Analysis*, 15 BIOMEDICAL CENT. PUB. HEALTH 129 (2015) (systematically reviewing the effectiveness of public health interventions that engage the community).

245. *See generally* JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS, GOOD PARTICIPATORY PRACTICE: GUIDELINES FOR BIOMEDICAL HIV PREVENTION TRIALS (2d ed. 2011), https://www.avac.org/sites/default/files/resource-files/Good%20Participatory%20Practice%20guidelines_June_2011.pdf [https://perma.cc/K956-KPZ6] (providing an example of effective engagement in biomedical HIV prevention trials).

246. *See* Ginny Brunton et al., *Narratives of Community Engagement: A Systematic Review-Derived Conceptual Framework for Public Health Interventions*, 17 BIOMEDICAL CENT. PUB. HEALTH 1, 12 (2017) (noting the variety of definitions of community engagement and explicating perspectives behind some of the more significant definitions and what they mean in practice).

247. *See* Kathleen M. MacQueen et al., *Evaluating Community Engagement in Global Health Research: The Need for Metrics*, 16 BIOMEDICAL CENT. 1, 5–8 (2015) (emphasizing what different models of community engagement mean in practice so that different approaches might be identified as more suited to specified contexts).

248. *Id.*

In field trials, securing community acceptance or endorsement of the project is sometimes articulated as a necessary goal or central element of an engagement process.[249] The resources and commitment required to undertake community engagement that accompanies a field trial help explain this rationale, and the pressure felt by those undertaking the project to achieve such outcomes. However, this framing of community consent can problematically envisage the possibility of a community rejecting a project altogether as a failure of the community engagement—rather than one of many possible outcomes. Community engagement, however, guards against the potential to depict success or goals solely in terms of researchers' desired outcomes. Rather, by having researchers and community members engage, they may reach shared understandings about what endorsement means and what are desired ways of achieving it, by viewing engagement in ongoing relational terms.[250]

The views of researchers, too, can be relevant to the future improvement of community engagement design, and scientists' experiences of genetic engineering's attempted integration into society are worthy of study in their own right. One survey revealed gaps in communication within the scientific community working on vector-borne diseases, and how respondent researchers valued more public engagement, especially desiring more creative or novel methods of engagement.[251] To move beyond the current constraints of research-ethics discourse, it is not only necessary for gene-editing researchers to engage differently, but for bioethics as a practice to change as well.

B. Changes in Bioethics

The current focus of ethics in gene-drive research is shaped by a standard research-ethics approach, reflecting the dominance of regulatory frameworks, such as when community members become human subjects within the research. There are other ways, however, to set an agenda to articulate the kinds of ethical questions that might be pursued as gene editing in mosquito-borne illnesses continues. These questions include, but go beyond, standard research-ethics

249. *See* Benedict et al., *supra* note 221, at 162–63.
250. *Id.*
251. *See generally* Christophe Boëte et al., *Engaging Scientists: An Online Survey Exploring the Experience of Innovative Biotechnological Approaches to Controlling Vector-Borne Diseases*, 8 PARASITES & VECTORS, no. 414, Aug. 10, 2015, at 1 (discussing survey respondents' views supporting new, more creative methods to educate and involve the science community and the public in the deliberative process).

questions and risk management, encompassing questions regarding: (1) scientists' fiduciary responsibilities to stakeholders, (2) social science research that can democratize technology by infusing public perspectives into science and technology policy, (3) the normative dimensions and power dynamics implicit in scientific epistemology, and (4) procedural-ethics questions about processes that fairly pursue these other substantive topics.[252] Building this broader agenda in gene-editing field trials is similar to the crosscutting and multifaceted effort needed for ethics and gene editing more generally.

The ethical, social, and legal questions raised by accelerated gene-editing biotechnology consistently transcend the traditional domains of environmental, animal, and research-ethics risks that informed current governance schemes. Community interests around genetically edited hogs will likely reflect an array of social questions, with many touching on genetic biotechnology, but often not limited to an assessment of the technology independent of the specific contexts in which it will be adopted.

As argued in Parts I and II, the ethical issues reviewed confound the delineations characteristic of U.S. regulatory purview, and the divisions that characterize research ethics, medical ethics, environmental ethics and related behavioral- and social-sciences fields of study. The restriction is partly a reflection of the view that the governance of technological risk, especially safety to humans, is the primary ethico-legal function of research oversight. In 1998, the limits of biotechnology regulatory oversight were openly admitted by one European advisory body member, who confessed that

> the responsibility of advisory committees, such as ACRE, is to develop scientific procedures for assessing risks, consider risk assessments and advise whether the GMOs [genetically modified organisms] are at least as safe as the parents from which they are derived. Social, ethical and other issues arising from this technology should be debated elsewhere by those with the appropriate competence.[253]

If there are to be broader societal discussions around accelerated gene-editing biotechnology, scientists will need to be involved, just as they have been in community engagement for field trials of

252. Paul B. Thompson, *The Roles of Ethics in Gene Drive Research and Governance*, 5 J. RESP. INNOVATION (SUPP. 1) S159, S167–65 (2018).

253. Susan Carr & Les Levidow, *Exploring the Links Between Science, Risk, Uncertainty, and Ethics in Regulatory Controversies About Genetically Modified Crops*, 12 J. AGRIC. ENVTL. ETHICS 29, 30 (2000) (internal citation omitted).

genetically edited mosquitoes. Such conversations could include or involve inquiries by bioethicists and social scientists, and here, too, there is room for improvement.

The search for more inclusive or nontraditional forms of bioethical analysis is not new. In contrast to Van Renssalear Potter's vision of bioethics as uniting environmental, ethical, and biological science perspectives, it was the Georgetown model of bioethics that came to dominate, emphasizing dilemmas and case-based clinical ethics as encountered largely in hospital health-care settings.[254] Resnik notes that siloing of expertise in bioethics has its parallel in policymaking, especially when human health and environmental protection are at odds.[255] Scientists who hesitate to lump their technological advances in with broader debates might be more willing to engage around open policy issues on matters where joint public and expert perspectives could converge fruitfully, albeit not without tension.[256] From an ethical perspective, an ideal topic for North Carolina would be broad public engagement with Right-to-Farm legislation; however, bioethicists should exercise caution in choosing a policy question that is not truly open, which can undermine community trust. In the current Republican-dominated legislature, there may be minimal political will for revising the statute.[257]

The bioethical frameworks needed to grapple with policy issues intersecting with environmental, agricultural, and public health must combine divergent perspectives. Many applications of gene editing in animals will pose challenges to the containment of the modified organism, and, as such, raise questions of environmental risk that concern the spread and unintended effects of modified organisms'

254. *See generally* Warren T. Reich, *The Word "Bioethics": The Struggle Over Its Earliest Meanings*, 5 KENNEDY INST. ETHICS J. 19, 19–34 (1995) (evaluating the Hellegers/Georgetown or Madison versus Washington distinctions in the understanding of bioethics).

255. *See* David B. Resnik, *Human Health and the Environment: In Harmony or in Conflict?*, 17 HEALTH CARE ANALYSIS 261, 262 (2009) (noting the lack of political and theoretical resources for mediating and resolving human health and environmental value conflict).

256. *See* PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, BIOETHICS FOR EVERY GENERATION: DELIBERATION AND EDUCATION IN HEALTH, SCIENCE, AND TECHNOLOGY 33–36 (2016), https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/PCSBI_Bioethics-Deliberation_0.pdf [https://perma.cc/WXS8-QZQ9] (describing a deliberative democracy model of engagement around open policy questions that are "not purely theoretical; rather, the topics in question should have practical implications—deliberations should involve questions about how we can move forward and what should be done").

257. *See* Fine & Hellerstein, *supra* note 157.

interactions with the animal and plant life of affected ecosystems.[258] The primary experience base for such questions resides outside the context of medical research institutions.[259]

In addition, critique of contemporary bioethics can also include an individualized focus to the detriment of social theory. Neglect of social issues on the bioethics agenda is intertwined with tensions in its embrace of multiple disciplinary modes of analysis, as reflected in both past and present struggles to incorporate insights from the social sciences.[260] In the same vein, one study notes that embracing political liberalism (including its attendant individualism) was a way at the advent of bioethics to signal that bioethics was a "friendly force" within the sociopolitical and economic context of the United States health system.[261] As Jonson reflects on the course of bioethics:

> [W]e have to begin to reflect on the series of questions and answers that will take us in the direction of a social ethics of bioethics. We must retrace the steps of bioethics back to their beginnings and take note of the turns on the paths that have made that demidiscipline into an ethics of personal autonomy rather than an ethic of social responsibility. We must ask why that turn was taken and whether a different turn could have been taken or, perhaps, find deeper understanding of the implications of that turn.[262]

258. *See* Ledford, *supra* note 7, at 23–24 (discussing ecological concerns about forthcoming edits in livestock and gene drives).

259. *See* Thompson & List, *supra* note 28, at 99 ("'[B]ioethics' is largely associated with studies housed in medical schools or medically oriented research institutes. It is pursued by individuals with training in philosophy, sociology, anthropology, politics, and economics, as well as disciplines of medical science. Scholars whose work emphasizes the moral standing, use, and preservation of non-humans and of eco-systems similarly combine work from philosophy and the social sciences with insights from ecology, climatology, forestry, and other environmental sciences. They are housed either in their traditional disciplinary homes or in environmental studies and sustainability programs. . . . Seldom do practitioners from these fields find occasion for professional cross-talk.").

260. *See, e.g.*, Alexander A. Kon, *The Role of Empirical Research in Bioethics*, AM. J. BIOETHICS, June–July 2009, at 59, 59–60 (exploring how an interdisciplinary approach can best serve patients and families in healthcare); *see also* Marcel Mertzet et al., *Research Across the Disciplines: A Road Map for Quality in Empirical Ethics Research*, 15 BIOMEDICAL CENT. MED. ETHICS 1, 1 (2014). *See generally* Rachel Davies, Jonathan Ives & Michael Dunn, *A Systematic Review of Empirical Bioethics Methodologies*, 16 BIOMEDICAL CENT. MED. ETHICS, no. 15, Mar. 7, 2015, at 1 (reporting on empirical bioethics using data "about stakeholder values, attitudes, beliefs and experiences to inform normative ethical theorising").

261. Daniel Callahan, *Why America Accepted Bioethics*, 23 HASTINGS CENT. REP. (SPECIAL SUPP.) S8, S8–S9 (1993).

262. Albert R. Jonsen, *Social Responsibilities of Bioethics*, 78 J. URB. HEALTH 21, 24 (2001).

Although not new, there are also signs of a shift underway. A recent issue of the *American Journal of Bioethics* explores a revival of Potterian bioethics, in which public health ethics is offered as one domain that bridges "between individual-focused biomedical ethics and a weak anthropometric-focused environmental ethic."[263] Commentaries emphasized other possibilities for theoretical ethical frameworks that wed human health and environmental ethics, including human-rights approaches[264] and, for environmental-health professionals, virtue ethics.[265] Other commentaries emphasized examples of practices that might already constitute such bridges; for example, McLaughlin and colleagues delineate how cancer registries appreciate both environmental contamination and human-health hazards by tracking cancer incidence in order to identify potential conditions or environmental exposures.[266]

Within bioethics, many acknowledge the current gaps in regulatory oversight, including the U.S. CFRB, but also an absence of global consensus within the scientific community. For example, Caplan and colleagues also appear to call for a broader bioethics and research-ethics agenda that speaks to the wide array of ethical issues characteristic of accelerated genetic modification.[267] Concrete proposals for broader engagement have also been put forward, such as the evaluation of gene-editing technology's consistency with sustainability or human-health goals.[268] Several commentators have supported risk assessment that considers potential benefits as well, especially in light of what would occur if genetically modified methods or products were not employed.[269] Despite their stated

263. Lisa M. Lee, *A Bridge Back to the Future: Public Health Ethics*, *Bioethics, and Environmental Ethics*, AM. J. BIOETHICS, Sept. 2017, at 5, 9.

264. *See* George J. Annas, *(Public) Health and Human Rights: Of Bridges and Matrixes*, AM. J. BIOETHICS, Sept. 2017, at 13, 13 (noting traditions linking public health to human rights).

265. *See* Matthew O'Madigan Gribble, *Environmental Health Virtue Ethics*, AM. J. BIOETHICS, Sept. 2017, at 33, 34 (noting that environmental health professions look toward communal traits as normative ideals).

266. *See* Robert Hugh McLaughlin et al., *Cancer Registries as a Resource for Linking Bioethics and Environmental Ethics*, AM. J. BIOETHICS, Sept. 2017, at 17, 18 (depicting the registry as a resource for the common good).

267. *See* Art L. Caplan et al., *No Time to Waste—The Ethical Challenges Created by CRISPR*, 16 EMBO REPS. 1421, 1426 (2015).

268. *See* Yann Devos et al., *Towards a More Open Debate About Values in Decision-Making on Agricultural Biotechnology*, 23 TRANSGENIC RES. 933, 939 (2014).

269. *Accord* Whyte & Prather, *supra* note 126, at 885 ("It is agreed that the risks must be addressed, but the assessment should constitute a *true* risk-benefit analysis . . . that considers the risk, if any, against the potential benefits and the cost to the consumer, the producer, the environment and to the animals themselves if the technology is *not* used.");

concern with objectivity and risk, such proposals also invoke the moral imperative of addressing food security as justification for reducing participatory regulation of genetic engineering in agriculture.

In contrast, Rivera-Ferre and colleagues call for engagement with an even broader variety of affected stakeholders, embracing a policy design process that reflects principles such as flexibility, participation, and diversity.[270] Elsewhere, proposed "in-context trajectory evaluation" does not try to replicate the rigid control of laboratory setting, instead inviting social analysis of farmers' behaviors, especially with new technologies or practices, and embracing longer time frames for study that acknowledge ecological complexity.[271] Not surprisingly, given overlapping issues in synthetic biology, there are also proposals for modifying policy advisory practices. For example, the United States National Nanotechnology Initiative employed governance coordinating committees which provide an alternative to cost-benefit analysis.[272] These bodies meet iteratively during technological development and implementation to seek both subject-matter expertise and stakeholder engagement.[273]

Importantly, while community engagement facilitates addressing key applications of gene editing in medical research and therapeutic contexts, it is challenging to adapt local and discrete engagement

see also James D. Murray & Elizabeth A. Maga, *Is There a Risk from Not Using GE Animals?*, TRANSGENIC RES. 357, 358–59 (contending that risk assessment should take into account the cost to human society when a gene-editing technology is not used); Joyce Tait & Guy Barker, *Global Food Security and the Governance of Modern Biotechnologies*, 12 EMBO REP. 763, 766 (2011) (arguing that precautionary-based regulatory oversight has been politically motivated, not risk-based, in Europe).

270. *See* Marta G. Rivera-Ferre et al., *Rethinking Study and Management of Agricultural Systems for Policy Design*, 5 SUSTAINABILITY 3858, 3865–68 (2013) (recommending agricultural management practices that address stakeholders' demands, meet needs, and further the preservation of agricultural ecosystems and the delineating of eco-social fundamental principles).

271. *See* Vicenzo Pavone et al., *From Risk Assessment to In-Context Trajectory Evaluation—GMOs and Their Social Implications*, 23 ENVTL. SCI. EUR., no. 1, 2011, at 3, 4–5 (2011) (arguing that this alternative process acknowledges how values are embedded in a given technology's trajectory and calling for risk assessment and risk management procedures to incorporate those who can identify such implicit values, rendering them available for public deliberation).

272. *See* Wendell Wallach, Marc Saner & Gary Marchant, *Beyond Cost-Benefit Analysis in the Governance of Synthetic Biology*, 48 HASTINGS CTR. REP. (SUPP. 1) S70, S74 (2018) (presenting such an alternative governance model as a "high-level issues manager" who is independent of regulatory oversight, and instead serves the function of coordinating and harmonizing oversight, and convening all interested stakeholders for a role in the process).

273. *Id.*

practices to address the wide-ranging complexity of food and agricultural questions raised by gene editing. Public engagement around emerging technology can be intended to serve such a purpose, but community engagement that is directly attached to a research project rarely supports such broader inquiry. Engagement across policy, scientific, and lay power differentials requires training and experience. Polarization in genetic biotechnology debates can also depict scientists and policymakers as purveyors of expertise, contrasting with a public citizenry often characterized as "only capable of taking sentimental, emotional, and intellectually vacuous positions."[274] Importantly, it is possible for an ethics agenda accompanying genetic modification to encourage this view, rather than seeking to better understand the reasoning behind the reasoning of members of the public; the attachment of bioethicists and policy researchers to studying public attitudes reinforces the idea that other experts are needed to render their views intelligible for expert decisionmaking.[275] To move forward with a vision for improved ethical engagement around accelerated gene-editing biotechnologies, all expert stakeholders therefore have room for improvement.

Procedurally, the iterative, participatory, and inclusive nature of public-engagement practices contrasts with the compliance model, in which the logistical need for approval and disapproval drives dichotomous terms, oversimplifying the nature of most value disagreements and tradeoffs.[276] Substantively, such ethical questions prompt development of a clear public record of what efforts were made to elicit different views and debate possible policy options, as opposed to an oversight gateway that delivers a "yes" or "no" verdict on a project.[277] Some of the most engaged participatory research models are negotiation and revision of project plans in collaboration with community participants, from the inception of the project to dissemination of research results.[278] However, without sufficient

274. Brian Wynne, *Creating Public Alienation: Expert Cultures of Risk and Ethics on GMOs*, 10 SCI. CULTURE 445, 445 (2001).

275. *Id.* at 458–60 (contending the division of scientific and ethics reports can "suggest[] that public concerns are only moral, not intellectual").

276. *See* BERNARD E. ROLLIN, SCIENCE AND ETHICS 247–74 (2006) (exploring the influence of values in scientific practice, including in genetic engineering).

277. *Id.*

278. *See* Nina Wallerstein & Bonnie Duran, *The Theoretical, Historical, and Practice Roots of CBPR*, *in* COMMUNITY-BASED PARTICIPATORY RESEARCH FOR HEALTH: FROM PROCESS TO OUTCOMES 25, 25–46 (Meredith Minkler & Nina Wallerstein eds., 2d ed. 2008) (articulating the history of CBPR, including both utilization-focused and emancipatory approaches, and describing practical skills and techniques).

resources to develop expertise and dedicate professional time, few scientists will be able to develop and sustain the relationships likely to foster community trust; barriers are especially considerable for early-career faculty whose promotional structures rarely recognize such activities.[279] Funders of gene-editing research will need to provide the necessary incentives to forging new paths in genetic editing, agriculture, and public attitudes.[280]

CONCLUSION

One of the cases that was consolidated into *In re NC Swine Farm Nuisance Litigation—McKiver v. Murphy-Brown LLC*[281]—resulted in a ruling in favor of the plaintiffs in April 2018. Each plaintiff was reportedly awarded $75,000 in compensatory damages and $5 million in punitive damages, for a total of $50.75 million.[282] Following the decision, the judge applied the North Carolina law that places a cap on such nuisance suits,[283] reducing the damages to $325,000 for each plaintiff and a total of $3.25 million.[284] The jurors in the case were reportedly not informed about the state law capping punitive damages.[285] As a result of this and other recent nuisance rulings, the state legislature passed the North Carolina Farm Act of 2018 in June of 2018, overriding the Governor's veto.[286] The revisions included diminution of the ability to proceed with a nuisance complaint in instances of negligent or improper operation of an agricultural operation and a requirement that any recovery of punitive damages be contingent on state or federal criminal conviction or civil enforcement action against the agricultural operation.[287]

279. Andrew J. Hoffman et al., *Academic Engagement in Public and Political Discourse: Proceedings from the Michigan Meeting Working Paper* 24 (Ross Sch. of Bus., Univ. of Mich., Working Paper No. 1367, 2017).

280. Such funding is in keeping with the NASEM community-engagement guidelines for gene-drive research. *See supra* text accompanying note 224.

281. No. 7:14-CV-180-BR (E.D.N.C. filed Aug. 21, 2014).

282. Jury Verdict at 1–3, *McKiver*, No. 7:14-CV-180-BR, ECF no. 267.

283. N.C. GEN. STAT. § 1D-25(b) (2017).

284. Order at 1–3, *McKiver*, No. 7:14-CV-180-BR, ECF no. 277.

285. *See* Everhart, *supra* note 116.

286. Act of June 27, 2018, ch. 113, 2018-3 N.C. Adv. Legis. Serv. 391 (LexisNexis) (to be codified in scattered sections of N.C. GEN. STAT. § 106).

287. Specifically, these revisions provide that

> [a] plaintiff may not recover punitive damages for a private nuisance action where the alleged nuisance emanated from an agricultural or forestry operation that has not been subject to a criminal conviction or a civil enforcement action taken by a State or federal environmental regulatory agency pursuant to a notice of violation

Taking lessons from field trials and genetically modified mosquitoes, developing an ethics of site selection, and fostering community engagement would be prescient ways to identify and engage ethical issues around genetic research in pigs for agricultural purposes. Developing community-research partnerships that far precede introduction could also depart from the standard research-ethics model, charting new terrain in anticipatory biotechnology development.[288] The resource-poor setting and long history of social conflict over hog farming in North Carolina suggest that greater collaborative efforts could alert biotechnology researchers to local views regarding where genetically edited hogs will have the greatest impact. Such activities would seek new ways to include local voices in the design and implementation of new gene-edited agricultural technology.

Often, the terms of engagement about genetic engineering and agriculture can reflect deep polarization and dichotomous terms, such as viewing productivity and large-scale operations as mutually exclusive with practices that encourage biodiversity and respect for agricultural labor as meaningful work.[289] Yet some proponents of the next generation of genetic modification in agriculture hold out hope that better stakeholder engagement and novel project designs could help create a different set of dynamics.[290] These could constitute

> for the conduct alleged to be the source of the nuisance within the three years prior to the first act on which the nuisance action is based.

Id. sec. 10.(b), § 106-702, 2018-3 N.C. Adv. Legis. Serv. at 398–99 (to be codified at N.C. GEN. STAT. § 106-702).

288. *See* Thompson, *supra* note 252, at S171 (describing how such an approach "blends empirical study of public attitudes toward emerging technology within a framework that is intended to aid researchers, sponsors of research (including public, nonprofit and for-profit organizations) and the various offices of government in the joint project of bringing forth technical changes that enjoy broad public support and that meet compelling needs").

289. *See* Curtis E. Beus & Riley E. Dunlap, *Conventional Versus Alternative Agriculture: The Paradigmatic Roots of the Debate*, 55 RURAL SOC. 590, 591 (1994) (acknowledging that most individuals involved in agriculture-policy discourse do not fit neatly into the two depicted paradigms—conventional and alternative—but contending that public debate can lead to invocation of such polarized terms); *cf.* Thomas A. Lyson, *Advanced Agricultural Biotechnologies and Sustainable Agriculture*, 20 TRENDS BIOTECHNOLOGY 193, 193–96 (2002) (describing the distinct scientific and social-science foundations of biotechnology and sustainable approaches to agriculture).

290. *See generally* David E. Ervin, Leland L. Glenna & Raymond Adelard Jussaume Jr., *Are Biotechnology and Sustainable Agriculture Compatible?*, 25 RENEWABLE AGRIC. FOOD SYSTEMS 143 (2010) (noting the need for broader structural change in institutions that govern biotechnology research and development, including novel approaches to intellectual property, processes that seek inclusion of all relevant stakeholders, and the need for public support for innovation of public goods where there are likely market failures).

structural changes that enable the biotechnological pursuit of sustainability goals, responding to the diverse perspectives of farmers, consumers, agricultural researchers, conservation groups, and governmental actors.[291] In contrast, there are those who think conflating genetic editing with industrialized agriculture only gets in the way of policy change that would support greater sustainability.[292] We have argued that North Carolina nuisance suits demonstrate how gene editing in agriculture will inevitably be drawn into existing local debates about agriculture policies and practices. The genomic research community's desire to turn the page in gene-editing debates will require attending to ethical issues that are often well beyond those addressed by standard research ethics.

Many nuisance complaints are linked to whether specific farmers, or agricultural institutions generally, have created a context in which farmers fail to live up to obligations of husbandry, or what Hamilton calls a "duty of stewardship."[293] There are open ethical, social, and legal questions regarding whether forestalling the detriments to the quality of life, health, or property value of neighbors to hog farms are entailed by such obligations. And there are crucial assumptions that drive the desire to bring social discourse into discussions about industrial agriculture, or to seek a social conversation that separates out the merits of gene editing.[294] Given the current role of technology clauses in Right-to-Farm legislation in North Carolina, such a separation is neither possible nor desirable if gene-edited hog farming is to offer the North Carolina community the benefits promised, and not bring with these a perpetuation or exacerbation of hog-farming social costs.

291. *Id.* at 145.

292. *See also* Leyser, *supra* note 61, at 2–3.

293. *See* Neil D. Hamilton, *Feeding Our Future: Six Philosophical Issues Shaping Agricultural Law*, 72 NEB. L. REV. 210, 225–40 (1993) (anticipating litigation regarding Right-to-Farm laws in the 1990s, but noting other likely legal avenues for implementing a duty of stewardship).

294. *Cf.* Leyser, *supra* note 61, at 3 ("For issues this big, there will of course be differences of opinion about how to move forward, what to prioritise, and how to decide. These are important areas for debate. GM, as a technique, is not.").