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PERSPECTIVE

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The need for more inclusive deliberation on ethics and governance in agricultural and food biotechnology

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ABSTRACT

An inclusive and socially legitimate governance structure is absent to address concerns over new agricultural biotechnologies. Establishing an agricultural bioethics commission devoted to inclusive deliberation on ethics and governance in agricultural and food biotechnology is urgent. Highlighting the social and ethical dimensions of current agricultural bioengineering disputes in the food system, we discuss how a nationally recognized policy forum could improve decision-making and increase public understanding of the issues. We clarify ways the concepts that are used to categorize food and frame governance of food affect consumer choices, and how dissemination of information and the mode of dissemination can contribute to social inequities. We cite the record of medically-oriented bioethic commissions and the history of international bioethic commissions in support of our argument, and end by discussing what such a commission dedicated to agriculture and food issues could reasonably be expected to achieve.

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Contention around biotechnology use in agricultural crops and food animals has been a defining feature of early twenty-first century science and innovation. Yet by 2025, the agricultural and food sector is poised for even more dramatic transformations of food

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production and farming practice. Advanced technological innovations will transform food and fiber production, in addition to continued modification of plant and animal genomes through the recombinant DNA tools of the 1990s. Work is underway to create lab-based synthetic animal proteins well beyond meat and milk proteins, including elastin and collagen. Machine-learning and sensing technology for monitoring and delivery of nutrients or pesticides will optimize decision-making through Big Data and robotics. In combination, these advanced technologies improve data collection and will replace the human workforce. These innovations will combine with gene-editing tools that facilitate faster, targeted modification of genomes. CRISPR-Cas9 can itself be integrated into plant and animal genomes to enable gene drives that have the potential for chemical-free pest control, as well as non-heritable in-field management of gene-governed functions through engineered insect vectors. All of these transformations have social and ethical ramifications, running from uncertain environmental impacts to a complete makeover of farming practice and the termination of previous ownership regimes for genetic resources. In sum, our food systems are on the verge of another set of massive technological revolutions, and yet the role of ethics in informing innovation and implementation of agricultural technology is largely absent (Lyson 2004). This absence is striking both at the national level, where there is no commission comparable to those present for biomedicine, as well as the local level, where ethicists are largely absent from the academic departments and research stations at land grant institutions and other key sites for the technological developments we list above.

The Biden administration's 12 September 2022 Executive Order advancing biotechnology and biomanufacturing innovation for a sustainable bioeconomy highlights the need for greater investment in biotechnology, but also the importance of ensuring that uses of biotechnology are ethical and responsible, and that benefits are equitably shared (Biden 2022). While the Order signals important attention to biotechnology and agriculture, to date, the United States still has no inclusive and socially legitimate governance structure to address ethical concerns about emerging innovative agricultural technologies and their social and environmental implications. The absence of a commission is striking given the past experience with the first generation of gene technologies and the persistent need to address ethical and social implications of gene drives in insect populations, and monoculture agriculture-driven biodiversity loss.

The urgency of establishing a bioethics commission to address public health, biomedicine, and climate science has been recently highlighted by National Academy of Sciences President, Marcia McNutt and National Academy of Medicine President Victor J. Dzau (National Academies News Release 2022).

> For nearly half a century, federal commissions have advanced public dialogue and government policy on difficult ethical issues raised by emerging technologies, biomedical research, and health care. Since 2017, the U.S. has not had a bioethics commission to address such issues, or the increasingly complex questions raised by the COVID-19 pandemic, health inequities, genetic editing of living beings, artificial intelligence, and the accelerating health impacts of climate crisis. (Wolf et al. 2022)

We believe that the call to the Biden-Harris Administration to reinstate the U.S. Bioethics Commission signals that we should also be creating bioethics commissions for other areas as well – namely one focused on advanced technology for agriculture and food. This call

was echoed by a recent policy piece which also suggested that the need for a commission was urgent (Gould et al. 2022.). In their policy forum for *Science*, Gould et al. provide a compelling case for a technoscientific regulatory regime for crops developed using genetic engineering. But, in the final paragraph, they concede that there are significant social and ethical issues that cannot be captured in the technoscientific approach,

> We realize that there are important issues related to the use of GE crops and foods unrelated to health and environmental safety, such as cultural questions about what constitutes naturalness, ethical questions about intellectual property rights, and concerns about corporate control over plant genetics. In the past, power dynamics caused these societal concerns to become entangled with claims about health and environmental safety. Although a robust, trusted structure for assessing safety will not resolve culture- and market-based questions and debates, it should help to disentangle these issues. (Gould et al. 2022)

We situate our proposal as a response to (companion to?) theirs, supplying additional support and clarifying ways the concepts that are used to categorize food and frame governance of food affect consumer choices, and how dissemination of information and the mode of dissemination can contribute to social inequities.

Why do we need such a commission? We cite just a few of the current food system topics being debated, and in some cases litigated. In each case, we highlight the social and ethical dimensions of the issue and discuss how a nationally recognized policy forum could improve decision making and increase public understanding of the issues. We cite the record of medically-oriented bioethics commissions in support of our argument, and end by discussing what such a commission dedicated to agriculture and food issues could reasonably be expected to achieve. Why focus on ethics commissions rather than on the panoply of private sector business ethics solutions, or instances of ethical, legal, and social implications (ELSI) integration into STEM research, or other modes of ethics and agrotechnology governance? While ethics commissions are not a complete solution to the challenges of responsible innovation in agricultural technologies (Balmer et al. 2016), we argue that a national effort to develop high level conversations about technology and food systems is an important first step toward the development of embedded ethics in sites for technological development, with the ultimate goal of creating communities of practice that employ ethics to reflectively govern innovation (Smolka and Böschen 2023; Stahl 2022). Ethics commissions can provide an important site for discussion where new technologies, diverse value systems, and the conflicting economic and social interests can take place. The positionality of publicly accountable ethics commissions provides the opportunity to address the intertwined and conflicting values underlying potential policies and regulations. Regulatory and policy-making bodies focusing on specific initiatives or otherwise constrained may not be authorized to consider the breadth of the ethical issues in play (Wolf et al. 2022). When successful, robustly interdisciplinary ethics commission discussions reveal the underlying terrain of values on which policy can be informed and the possibility of public trust and consensus building may begin to be fostered.

Food labeling, governance and regulation of agricultural biotechnology

After years of rancor, the National Bioengineered Food Disclosure Law (NBFDL) has finally been implemented, with food manufacturers required to comply as of January

2022. Initially passed in 2016, the NBFDL requires food manufacturers to disclose to consumers whether their products are bioengineered or contain bioengineered ingredients. Both academics and non-governmental organizations (NGOs) have criticized this new disclosure standard as intentionally opaque and confusing for consumers (Jaffe and Kuzma 2021). The NBFDL labeling law inhibits rather than increases transparency around the use of biotechnology in food in several provisions, including the use of a new term 'bioengineered' in place of the more familiar term, genetically modified (GM) foods; exemptions granted from labeling for processed foods with trace percentages (<5%) of genetic material; and the allowance for disclosure through QR codes rather than through a clearly identifiable symbol that can be read directly on a package. Consumers who do not have access to cell phones or broadband internet will be unable to gain access to information about the use of biotechnology in food products provided in a QR code that would allow them to make choices over which food products they purchase and consume.

Implementation of the labeling standard follows another key piece of agricultural biotechnology legislation, the SECURE (Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient) rule, that was announced by the U.S. Department of Agriculture in the closing months of the Trump-Pence administration. It includes a package of initiatives intended to streamline and reduce the costs of moving new products developed using genetic engineering through the regulatory system (Kuzma and Greiger 2020). Critics claim the SECURE regulations would exempt many gene-edited products from oversight and essentially allow companies to self-regulate. Scientists, biotech developers, and NGOs contend that this laissez faire approach will amplify public risk perceptions and undermine public trust of the technology and of gene-edited food products (Montenegro 2020). Self-regulation may promise a swift and potentially cost-effective means of bringing genetically engineered products to market. This efficiency may prove irrelevant if consumers suspect labeling to be underregulated and the information shared with them to be at the discretion of producers (Cummings and Peters 2022). That an increasingly suspicious public is less likely to purchase these products points to the need for further evaluation. The impact consumer trust has in the market, the diverse social and economic values held by producers and consumers, presents challenges that an ethics commission focused on agrotechnology governance would be well-positioned to evaluate.

Challenges to governance and regulation of agricultural biotechnology

Two challenges to the SECURE rule were issued in July 2020. A group of mainstream environmental NGOs – including the Center for Science in the Public Interest and the World Wildlife Fund – called for the establishment of a registry of gene edited applications used in agriculture and food, ensuring an open, transparent, and accountable process. This group released a document outlining that a registry would be essential for ensuring the Responsible Governance of Gene Editing in Agriculture and the Environment (Gordon et al. 2021). Another coalition, led by the Center for Food Safety, has sued USDA over the SECURE rule regulations because they contend the USDA is allowing manufacturers to experiment, plant and sell gene edited plants without appropriate oversight related to the environmental or agronomic risks (Davies

2021). These new biotech regulations outlined in the SECURE rule were intended to be fully operational by October 2021, just as the first few food products produced through gene-editing, such as high oleic soybean cooking oil, were entering the market and several questions about the ethical and social implications of these products were as-yet unresolved (USDA 2021). For example, how might the biosynthetic milk proteins that Isha Datar, Ryan Pandya and Perumal Gandhi's (Pandya et al. 2016) company, Perfect Day's created be conceived of – as dairy products or something else? Does ice cream made from milk proteins produced by engineered filamentous fungi, *Trichoderma reesei* instead of dairy cows, qualify as a 'dairy product'? Is the inclusion of bovine DNA in *T. reesei* enough to make it a product that can be conceived of as being derived from mammalian milk?

Such questions are neither simple nor capable of being fully addressed by science. Whether they are to be labeled as milk and thus belong to the category of 'milk' or 'dairy product' affects how the products are evaluated by consumers. Labels facilitate the ability of consumers to make decisions by transparently informing them what is in the product so labeled. Labels inform consumers about *what* they will be ingesting and in doing so facilitates their assessment of which ethical, social, and religious values apply to their use of the product. However, a consumer's use of product information is itself determined by the diverse value-orientations of different groups. For instance, individuals might vary considerably in their judgment on whether vegans can eat them, or whether these products should be separated from meat products if one intends to maintain a kosher household. At the same time, lactose intolerant consumers might prefer a label utilizing traditional terminology to signal the presence of milk proteins. In such contexts, ethical considerations are less a matter of good vs. bad than of reconciling tensions among the types of information different populations consider meaningful in their value assessment processes.

In the meantime, debate over implementation of the NBFDL continues. In September 2022, a U.S. District Court in Northern California ruled that the USDA decision to allow genetically engineered food to be labeled in the NBFDL with a QR code alone was insufficient and therefore unlawful, and that USDA must add other disclosure options, such as a package label (Center for Food Safety 2022). The case against the use of QR codes alone was led by the Center for Food Safety on behalf of a coalition of NGOs and retailers and referenced a 2017 study commissioned by the USDA that showed that key technological challenges prevented consumers from obtaining information via electronic or digital disclosures (Deloitte 2017). As in the medical arena, a bioethics for food and agriculture will require greater collaboration from disciplines including law and philosophy, as well as the social and biological sciences.

Medical bioethics commissions

The contrasting approaches to governing and regulating gene editing in agriculture and food products (labeling vs a registry) among NGOs reflects the persistently contested climate of claims and counterclaims that has surrounded applications of genetic technology in food and agriculture since the 1990s. It is notable that, in contrast, biomedical technologies, which would presumably be more fraught ethically, have not experienced this degree of disagreement. A striking dissimilarity exists between debates over ethics

and governance in biomedical technologies and those over ethics and governance in agricultural and food technologies. While the former established bioethics commissions that fostered open public dialogue for consideration of the social and ethical issues involved, the latter did not. Both the development of biomedical commissions as well as the ways in which they facilitated discourse around controversial topics of interest to medical practitioners, patients, publics, and industries offers valuable lessons for how to approach debates over ethics and governance among agricultural researchers, the food industry, consumers, biotech industry, and farmers on how to foster more inclusive deliberation about the application of biotechnology in agriculture.

Starting in 1974, a series of presidential bioethics commissions (see Table 1) have conducted high level deliberations in which they heard testimony and developed consensus reports on all of the most difficult social and ethical issues in human biotechnology: research involving stem cells, cloning human embryos and the advent of synthetic biology. Although these efforts did not 'settle' complex issues nor resolve conflicting values and opinions, they did foster a public dialogue and developed a structure for understanding the issues. The existence of these commissions helped to build confidence in the processes for publicly examining biotechnology. The value of these commissions is not that they lead to a more tech-friendly dialogue. What is important is that the issue is weighty enough to society to have merited the creation of not one but several commissions that drew diverse stakeholders into discussions. The normative value of these bioethics commissions does not derive from the outcomes of the discussions, nor the commissions' rules, but instead by and through the identification of issues worthy of public discussion and oversight.

These bioethics commissions are one venue for social and ethical deliberation within the biomedical research establishment. Medical schools in the United States have bioethics departments for training students and conducting research on novel therapies, public health initiatives, and new technology. These multidisciplinary programs include faculty from philosophy, law, theology, and social sciences. The national commissions are able to draw upon this work in designing public consultations and in writing their reports, minimizing both scientific disputes and confusing recommendations.

Table 1. Presidential bioethics commissions 1974 to present.

Commission title:	Date created:	Administration:
National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research	1974–1978	Gerald Ford Jimmy Carter
Presidential Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research	1978–1983	Jimmy Carter Ronald Reagan
Biomedical Ethical Advisory Committee	1988–1990	George H. W. Bush
Advisory Committee on Human Radiation Experiments	1994–1995	Bill Clinton
The National Bioethics Advisory Commission created by President Clinton, The Presidential Commission for the Study of Bioethical Issues (reporting to the National Science and Technology Council)	1996–2001	
President's Council on Bioethics	2001–2009	George W. Bush
Presidential Commission for the Study of Bioethical Issues	November 2009	Barack Obama
None		Donald Trump
None		Joe Biden

Note: U.S. National Bioethics Advisory Commission / President's Council on Bioethics / Presidential Commission for the Study of Bioethical Issues (U.S. National Bioethics Advisory Commission, 1998).

Furthermore, this scholarship is supported by funding from the National Institutes of Health, as initiated by James Watson by a proposal that the effort to sequence the human genome should dedicate 5% of its budget to research on Ethical, Legal and Social Implications of human genomics (ELSI). The role of humanities departments in this endeavor was seen as necessary, not just as places scientists go to complete their required 'ethics training', but as spaces for conversations about the social, ethical, and legal implications of medical technology. Increased involvement of social scientists and humanities scholars, many of whom study how to overcome biases, improve institutional research ethics and culture, and advance science and technology in the service of public aims, are thereby an essential part of these bioethics commissions.

ELSI's focus on the *implications* of emerging science and technologies gave way to a broader, anticipatory approach to addressing social issues with technology development, known as ELSA (ethical legal and social *aspects*). While ELSI was critiqued for its limited influence on policy in the US, ELSA emerged in the EU context, was embedded in policy processes, and focused on ensuring innovations are not hampered by public resistance (Balmer et al. 2016; Zwart, Landeweerd, and van Rooij 2014). ELSA, and its recent iteration in Responsible Research and Innovation (RRI) framework, reflects the emphasis on early collaboration and co-creation between technology designers and those concerned with ethical and social aspects, but also on the necessity of innovations to address grand socio-economic challenges (von Schomberg and Hankins 2019; Zwart, Landeweerd, and van Rooij 2014). On rare occasions, these commissions have had direct policy influence.

Most notably, the original Belmont Commission led to the creation of Institutional Review Boards for federally funded research involving human subjects. However, we contend that more subtle impacts are just as significant in the long run. First, the commissions demonstrate that ethical review is taken seriously. This affects the attitudes of researchers and provides some degree of assurance to the public. Second, bioethics commissions serve as a forum in which the relevant science is translated into terminology accessible to the lay public. Third, commission reports function as scoping documents that delimit a range of issues that call for consensus or decisive determination, consigning others to matters on which the First Amendment calls for tolerance of differing viewpoints. Relatedly, commission reports provide legible summaries of the legal structure pertinent to these issues). Finally, bioethics commissions have produced agreement on the terminology in which both scientific and ethical claims are to be advanced or debated. In contrast, the acronym 'GMO' has continued to lack clarity and has frustrated rather than fostered debate for over more than three decades. These contributions from bioethics commissions carry over to the bioethics research community, where debates can continue, but with more logical consistency and agreement on what, in fact, is actually being debated (Young 2020). Ethics commissions provide a space for the rigorously interdisciplinary discussions within which a responsive and equitable processes of debate clarification can be pursued.

Nothing comparable serves the agriculture and food sector. Although food production and distribution have obvious ethical and social dimensions, no U.S. agricultural university has a department of agricultural or environmental bioethics. Most U.S. agricultural universities, including Land Grant Universities, have few philosophers, bioethicists, or legal scholars on their faculty. Since the closure of the USDA's Agricultural

Biotechnology Advisory Committee in 1996, there has been no national level forum for conducting deliberations on the social, ethical, and legal issues associated with gene technology. Recent social science research has highlighted structural and epistemological challenges involved in bringing together critical social scientists with agricultural and biotechnology developers (Sullivan 2023). Critical agri-food and STS scholars engage the RRI framework to suggest that agriculture technology designers and engineers should reflect on normative aspects and structural implications of innovations at the design stage to examine who will benefit from agricultural technologies, like digital farming technologies or gene editing (Bronson 2019; Gugganig et al. 2023). In robotics research, the development of AI personal care robots recently employed *embedded ethics* to facilitate discussion of values and sociological impacts throughout the project. Embedded ethics approaches integrate ethicists as domain research experts in research teams. This equips the team with the interdisciplinary skill set required to consider values at each stage of the research process, from conceptualizing hypotheses, collaboratively evaluating the choice of ethnographic methods and interviews used, to offering on-the-spot ethics skill workshops as needed and in response to problems (Tigard et al. 2023, 1–2). The recent use of embedded ethics approaches in robotics provides proof-of-concept research for how similar approaches might be used to deal with unexpected ethical aspects of research and technology as they arise in the course of development. How social and ethical considerations have been integrated within recent robotics technology using embedded ethics on the project-scale may also provide a model for interdisciplinary discussion of agricultural technologies in their development. These provide some suggestions for how a multi-level effort to develop a national forum for setting agendas, defining key issues and terms, and generating the institutional momentum to, in turn, inspire and support the implementation of reflective innovation practices in specific research contexts might be developed.

With the recent implementation of NBFDL and SECURE, and high-profile challenges to the implementation of the legislation from NGOs and retailers, a commission focused on public discussion of agriculture and agrifood biotechnology, including gene-editing, is urgently needed. Many details must be worked out about a commission's bylaws and remit, such as how to ensure inclusion of marginalized peoples and perspectives, including Black, Indigenous, and People of Color. It is important to craft a process that engenders trust and avoids the dominance of any one perspective. We recognize that critics and skeptics are often marginalized in academic settings – it is much easier to be a strong proponent of biotech than a mild critic. This is to say, the formation of an agricultural bioethics commission would itself require many ethical considerations. While the President's Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy issued this September 2022 acknowledged the need for discussion, an agricultural bioethics commission still has yet to be formed (Biden 2022). An agricultural bioethics commission could establish a collaborative agenda for humanities and social scientific research to identify and communicate food and agricultural biotech issues by following the many examples in biomedical research commissions. While commissions focusing on agricultural bioethics do not exist in the U.S., they have been successfully developed elsewhere. A recent example is the Bioteknologirådet, the Norwegian Biotechnology Advisory Board, which has recommended a forward-looking regulatory

framework for GMO use and gene editing in agriculture based on extensive public consultation (Bioteknologirådet 2018). Another example is the U.K.'s Nuffield Council on Bioethics, an independent forum funded by the Medical Research Council and the Wellcome Trust that has focused on animals, food, and the environment as key areas. Established in 1991, it is one of the longest running commissions. From 2019-2022, they published a series of reports on the social and ethical issues related to genome editing and farmed animal breeding, elicited public responses to proposed regulation changes, and facilitated public dialogs on genome editing in farm animals (Nuffield Council on Bioethics 2021). These followed an ethical review on genome editing across many fields of research published in 2016 (Nuffield Council on Bioethics 2016) and from 1998-2003 a series of consultations, inquiries, and reports on the ethical and social issues surrounding genetically modified crops (Nuffield Council on Bioethics 1999). These two models provide important justification for the establishment of a new presidential bioethics commission to address critical issues and promote inclusive engagement around biotechnology in food and agriculture, a recent recommendation made by co-chairs of the Bioethics Commission Working group of the National Academy of Science and National Academy of Medicine. A U.S. based agricultural bioethics commission would complement both national and international commissions as well as other governance approaches. Addressing critical agricultural and food biotechnological issues of both local and global importance within a larger multi-national network would enable countries to anticipate challenges, such as those posed by future synthetic technologies as well as known challenges to agricultural land use and climate crises and the growing use of artificial intelligence as a tool for producers and consumers.

The point that we are advancing is not that biotech needs 'substantive engagement' – a theme that most analysts of the biotech debate have interpreted in terms of reflecting the diversity of opinion among Americans. We are calling for ethics, an approach which begins with the possibility that majority or plurality opinions can be wrong, as they were with respect to American agriculture's widespread use of slave labor. More generally, our focus is not on biotech but on the food system, which is in the process of being altered by an unprecedented influx of venture capital supporting convergent applications of machine learning, big data, imaging and sensing tools, as well as continued development of chemical and bio-technologies. These changes are being discussed in a scholarly literature, but the function of a national level process such as the bioethics commissions would be to produce concise accounts that both review points of contestation, while also making explicit normative recommendations on points of consensus. Importantly, scientists actually read them.

Bioethics committees produced the Belmont Report, which led to a dramatic change in attitude toward the use of human subjects in scientific research, as well as influential findings on appropriate sourcing and use of stem cells. The committee that reviewed cloning technology arguably forestalled an extended political debate that could have ended in a legislative ban. We contend that discussing these issues in a high-level public forum has considerable impact. We acknowledge that bioethics-like commissions will be controversial in agriculture. Some farm organizations, corporations, scientists, and different publics are wary of ethical oversight. But this wariness is not (on its own) a reason to dismiss the prospect of such a commission.

It is important to note that while we focus here on the need for a US commission, there must also be global commissions that connect ethical discussions in North and South America, Europe, Africa, and East and South Asia. One prominent example is the Panel of Eminent Experts on Ethics and Food and Agriculture of the FAO which ran from 2000-2008, had the remit of promoting reflection on 'ethical issues arising out of food production and consumption as well as agricultural development' (Panel of Eminent Experts on Ethics and Food and Agriculture 2007). We recognize that many social and ethical considerations require a global approach. For instance, the erosion of crop genetic diversity in the Global North due to globalization and industrialization v. the preservation of crop diversity in the Global South through sustainable agricultural practices. The FAO Panel of Eminent Experts provides strong precedent for a much-needed international body or forum for discussion global agricultural issues, like crop genetic erosion that differentially affect regions of the world in ways that may, if not considered from a global perspective, exacerbate environmental crises and social justice disputes.

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