Genetically Engineered Animals, Drugs, and Neoliberalism: The Need for a New Biotechnology Regulatory Policy Framework

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Keywords
Coordinated Framework for Regulating Biotechnology (CFRB); Drugs; Food and Drug Administration (FDA); GE (genetically engineered) animals; Neoliberalism; Sociotechnical imaginary

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INTRODUCTION

Genetically engineered (GE) animals could be designed to suppress or even eradicate the population of their wild-type counterpart. Alternatively, they could be crafted to change traits in their wild-type population, which could affect other species that are in a symbiotic relationship of some sort with it. Given the potential of GE animals to significantly impact ecosystems, it is crucial that they are rigorously regulated. In other words, among other things, it is all too important that regulatory agencies conduct rigorous risk assessments that can be used for informed decision-making at the local, national, and global levels about the release of GE animals in the wild.

In the United States (US), certain genetically engineered (GE) animals (intended for release in the wild) will be regulated by the Food and Drug Administration (FDA) as new animal drugs (NADs). But that decision raises serious questions because those entities are living organisms and treating them as NADs for regulatory purposes may mean that relevant aspects of their existence may not be captured during the risk assessment conducted by the agency. This paper argues that the decision to regulate those animals as new animal drugs reflects the influence of neoliberalism on US biotechnology regulatory policy framework.

In part one, the FDA’s argument for categorizing GE animals as NADs is evaluated. Then, in part two, the statutory basis of the FDA’s claim to regulatory authority over GE animals is examined. The FDA’s protocol for reviewing new animal drugs is outlined and the agency’s efforts to meet its National Environmental Protection Act (NEPA) requirements are also discussed briefly. Then, in part three, the decision of the US to treat GE animals as new animal drugs is traced to a neoliberal sociotechnical imaginary shaping its biotechnology regulatory policy framework.

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1 The term ‘genetically engineered’ (GE) is used to denote organisms that have been manipulated in the laboratory by modern biotechnology methods such as recombinant DNA technology and gene editing.
PART ONE - THE REGULATORY BASIS OF CLASSIFICATION OF GE ANIMALS (MEANT FOR RELEASE IN THE WILD) AS NEW ANIMAL DRUGS (NADS)

GE animals: New animal drugs (NADs) or sentient beings?

The FDA has laid claim to regulatory authority over GE animals, including GE insects, as new animal drugs (NADs). The agency justifies its classification decision by making the following argument:

Premise 1: “Articles (except food) that are meant to “affect the structure or any function of the body of [hu]man or other animals” are drugs (FDA 2017c, p.7).

Premise 2: Intentionally altered genomic DNA\(^4\) is meant to affect the animal’s bodily structure or function (FDA 2017c, p.7).

Conclusion: Therefore, the intentionally altered genomic DNA qualifies as a drug.

While the FDA argues that it is the intentionally altered genomic DNA (within an animal) that is the drug and thus the article that it regulates, it has acknowledged that as “… a short hand …, we sometimes refer to regulation of the article (i.e., the altered genomic DNA) in such animals as regulation of the altered animal” (FDA 2017c, p.5).

But it seems that the agency might regard the animal with the intentional altered genomic DNA as the actual, rather than nominal, subject of its regulatory authority. For instance, the agency has claimed that its experience in “reviewing pending, but not yet approved, applications … (was) that the NADA

\(^2\) The FDA regulates food, drugs and cosmetics by virtue of the authority vested in it by Congress. The agency’s regulatory function is essentially protective in the sense that it is responsible for protecting public health. For instance, it has a duty to ascertain that foods (except those regulated by the U.S. Department of Agriculture) “are safe, wholesome, sanitary and properly labeled” (FDA 2017b). Among other things, it is also required to ensure “that human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective” (FDA 2017b).

\(^3\) This paper does not engage with the issue of the regulation of GE insects as NADs, but the arguments presented in it may have relevance for those cases. In October 2017, the FDA issued Guidance #236 that GE mosquitos meant to control the population of mosquitos would be regulated by the Environmental Protection Agency (EPA) as a pesticide. The FDA also stated that it would continue to regulate “mosquito related products” as a drug that are meant to “cure, mitigate, treat or prevent a disease (including [those intended] … to reduce the level, replication or transmissibility of a pathogen in mosquitos)” (FDA 2017a).

\(^4\) In January 2017, the FDA issued a revised Guidance #187. It is meant to apply to animals with intentionally altered genomic DNA developed by means of genome editing technologies, as well as techniques such as rDNA in genetic engineering. The former category of technologies included “the use of `nucleases’ or `genome editing technologies’ including engineered nuclease/nucleotide complexes such as zinc finger nucleases (ZFN), transcription activator-like effector nucleases (TALENs), and the clustered regulatory interspersed short palindromic repeats (CRISPR) associated systems. These nucleases are intended to introduce alterations at specific sites in the genome, rather than the more random changes associated with rDNA technology. The process of producing these targeted DNA sequence alterations is often referred to as ‘genome editing’” (FDA 2017c, p.4).
(i.e., the new animal drug application) requirements work very well as a means of regulating GE animals” (my italics) (FDA 2008). Also consider that the agency regulates drugs meant for humans, but it does not claim that it regulates the humans that use them. Nor does the FDA claim to regulate livestock even though it has regulatory authority over the antibiotics that are used for them. Thus, the FDA’s equivocation between the intentionally altered genomic DNA (which it construes as a drug) and the animals in which the ‘drug’ has been introduced suggests that it conceptualizes them as fundamentally different in kind from other animals. Whether that supposition is warranted is not obvious.

Aside from that issue, there are other problems with the FDA’s decision to treat GE animals as animal drugs. Two of them are discussed below.

The meaning of the term ‘drug’ problem

In 2008, when the FDA solicited comments about its intent to regulate GE animals as new animal drugs (NADs), the biotechnology industry offered positive feedback, but other constituencies expressed disapproval. Some argued that the category of new animal drugs was not intended to include “GE animals or rDNA constructs in GE animals” (FDA 2008). In response to that charge, the FDA invoked the FD&C Act, which defined ‘drug’ as “articles (other than food) intended to affect the structure or any function of the body of man or other animals” (FDA 2008). But in construing the intentionally altered genomic DNA as a drug, the agency seems to overlook the historical and current (standard) usage of the term ‘drug.’ Presumably, the term ‘drug’ (as used in the FD&C Act) was intended to denote an article was meant for “use in the diagnosis, cure, mitigation, treatment, or prevention of disease in the (hu)man or other animals (who suffer from an ailment or are at risk of an illness) (my italics)” by changing the structure or function of the body of the human or other animal. Even today, it is almost universally understood and accepted that the term ‘drug’ is employed to denote an article that is used on the organism that is unwell (or at risk of illness) to treat (or prevent illness in) it.

The agency is aware of the everyday usage of the term ‘drug,’ but it does not seem to believe that its use of the concept has to be consistent with it. The FDA’s 2017 Guidance #187 states that “the altered genomic DNA in an animal is a drug within the meaning of section 201(g) of the FD&C Act because such altered DNA is an article intended to affect the structure or function of the body of the animal, and, in some cases, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in the

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5 Aldrich has made the point that since GE animals cannot be separated from their “underlying genetic material” (2016, p.313) regulatory agencies should receive authorization to regulate the GE animal as that would clarify the regulatory process.

6 See section titled, “A. Adequacy and ...”

7 Ibid.

8 In common parlance, ‘drug’ also refers to chemicals that are designated illegal substances.
animal” (my italics) (FDA 2017c, p.7). In other words, the FDA construes an article (other than food) to be a drug if it is meant to have a structural or functional impact on the body of human or other animal species even if it is not “an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals” (FDA 2017c). Needless to say, the agency’s decision to use the term ‘drug’ for articles that have no drug-like function (i.e., they do not treat, cure, mitigate or prevent illness) raises the following question: Why is the regulatory agency engaging in such linguistic license?

While an answer to that question is outlined in Part Three, it is illuminating to examine the implications of the FDA’s linguistic license by considering the case of AquaBounty’s GE salmon. The introduction of an rDNA construct in the salmon results in the fish growing faster than its conventional counterpart, permitting salmon farming enterprises to bring the fish sooner to the market than they would otherwise, thus, presumably, increasing their profits (Meghani 2014). By conceptualizing as a ‘drug’ any intentionally altered genomic DNA and by claiming that the notion of ‘drug’ does not necessarily refer to articles that have a drug-like function, the FDA is able to exert regulatory authority over the GE fish.10

Of course, if the agency abided by the standard use of the term ‘drug,’ then it would be faced with the following challenging questions: What is the illness that the rDNA construct (that is introduced into the fish) meant to treat, mitigate or prevent in the fish? Is the species-typical rate of growth of the fish the ‘illness’ that the modification diagnoses, cures, mitigates, treats or prevent? Should the species-typical growth rate of any species be considered an illness that requires ‘treatment’ in the form of intentionally altered genomic DNA because a particular food industry wants to increase its profits? The latter is a normative matter and in a democracy such decisions should be based on public deliberations and not made by fiat by a regulatory agency at the behest of a particular constituency. But the agency is able to side-step those questions because it can claim that the GE salmon is a case in which the term ‘drug’ is

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9 Guidance documents are meant to provide the industries whose products the agency regulates with its current thinking about various issues. Some guidance documents describe the agency’s interpretation of policy, including the design, production, labeling, promotion, manufacturing, and testing of regulated articles. Guidance documents may also address the inspection and enforcement policies (FDA 2016b). Guidance documents are legally non-binding for the agency and the party to whose products they are applicable. (See Noah (1997) for a history of the changes in the legal status of guidance documents.)

10 At a 2010 FDA meeting about the AquaBounty GE salmon, the Regulatory Counsel to FDA Office of Chief Counsel, L. Epstein, provided an account of the process by which the agency arrived at the decision to construe the rDNA construct introduced in the fish as a drug:

Well, why is this construct (i.e., the rDNA construct introduced into the salmon) a drug? It doesn’t seem to make intuitive sense, but in fact, the definition of a drug in the Federal Food, Drug and Cosmetic Act includes -- it is sort of a long definition, so I won’t read the whole thing, but the relevant part is that it includes an ‘article intended to affect the structure or any function of the body of animals.’ And we have just learned that that is exactly what the rDNA construct in that animal is intended to do; it is intended to impart new traits. So, therefore, that rDNA construct meets the definition of a drug and is subject to FDA regulation under the drug laws and rules (FDA 2010, pp. 36-7).
used to refer to the rDNA construct introduced into the fish, but which is not meant to prevent or treat any illness.

But by detaching the term ‘drug’ from its standard meaning of a curative or preventive article, the agency, in effect, significantly expands the class of entities that qualify as ‘drug.’ For instance, given the FDA’s definition of ‘drug’ as an article that impacts the structure or function of an animal species, not only intentionally altered genomic DNA qualify as a ‘drug,’ but also a plethora of other articles. For instance, high heeled shoes that cause a change in the gait of the human wearer qualify as a ‘drug.’ Of course, the agency could avoid this problematic expansion of the term ‘drug’ by using it in the standard sense. But then it would have to deal with the GE salmon kind of case (discussed above). To side-step that, the agency could re-consider its use of the term ‘drug’ and assert that only when intentionally altered genomic DNA is introduced into an animal for the purposes of preventing or treating an illness, the use of the term ‘drug’ is justified. But that would mean the agency would, in effect, have to give up claim to regulatory authority over the alteration and the modified animal if the intentionally altered genomic DNA is not meant to treat or prevent an illness. That raises the question which agency should have regulatory authority over GE animals that are meant for release in the wild, but in which the intentionally altered genomic DNA does not prevent or treat any illness. It is arguable if no regulatory oversight is the solution either. Depending on the type of alteration to the animal and depending on the extent of uncertainty and level of knowledge regarding its ecological impact, the release of GE animals in the wild may pose significant risk to ecosystems (more on this below).

The ‘species and ecosystems’ problem

The FDA conceptualizes the category of ‘animal’ in terms of the common definition of animal, which is any organism in “the kingdom ‘animalia.’ Organisms within animalia include fish, shellfish, insects and other arthropods, and nematodes” (FDA 2008). Animals, including GE animals, are not reducible to or equivalent to a particular location on their genome. As a member of a species, any animal has a “specific way of being in the world” (Rose 2013, p.100). The particular ecosystem a species inhabit defines multiple dimensions of its existence, ranging from their foraging strategies to modes of sociality … (Rose 2013, p.100), including reproduction, teaching the young, nest building, and even mourning (van Dooren 2013; 2018, p. 4; Buchanan 2017; Rose 2011; Hatley 2017; Chrulew 2017). Thus, a species can be conceptualized as a way of life interwoven with other (unique) “ways of being” (i.e., species)

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11 Rose, an anthropologist and ethologist, borrowed this concept of species from the worldview of the Australian Aboriginal people in the Victoria River area of the Northern Territory of Australia. That worldview is a radically different one than the neoliberal one that conceptualizes non-human species and even many groups of humans as mere means.
within specific ecosystems. Depending on the nature and degree of their interaction, the species constituting a particular ecosystem define one another. The “interspecies association”\textsuperscript{12} may take the form of competition, predation, or some other form of symbiosis (such as mutualism, commensalism, or parasitism). The diversity and composition of the biological community of a particular ecosystem can vary significantly over time – both in the short and long timescales. Some of the changes may be caused by (non-human and human) organisms shaping their environment and thus their own evolution\textsuperscript{13} as well as environmental change (including changes caused by the activities of certain groups of humans), the development of new species, extinction of species, and the dispersal of species.

The larger point here is that the FDA’s decision to construe GE animals (that are meant for release in the wild) as ‘drug’ (which is a term that is generally used to denote inanimate chemicals that are meant to prevent, mitigate or treat illness) is inconsistent with the reality of their existence. They are sentient, relational beings.

Next, the statutory scope of the FDA’s regulatory authority over GE animals meant for release in the wild is considered. The larger aim is to try to make a determination about the quality of the FDA’s future regulation of GE animals (intended for release in the wild) as new animal drugs. But it is not publicly known which new GE animals are under development or being reviewed by the FDA.\textsuperscript{14} But given that a GE salmon (intended for use as food), a GE goat and a GE chicken (both designed to produce pharmaceuticals), and GE insects (intended to reduce their wild-type population) have been developed and approved for use in field trial, it is not unreasonable to suppose that other GE animals may be under development.

\section*{PART TWO- STATUTORY AUTHORITY AND GE ANIMALS MEANT FOR RELEASE IN THE WILD}

The FDA has laid claim to regulatory authority over certain GE animals and the EPA and the USDA over others. Thus, it is useful to investigate the statutory grounds of their claim to regulatory power.

\textit{The FDA's statutory authority}

While the FDA has declared its intent to regulate certain GE animals (including some of those that are meant for release in the wild), it is arguable if the agency has \textit{clear and direct} statutory

\textsuperscript{12} The notion of “interspecies association” is borrowed from Tsing’s work (2012, p.143).
\textsuperscript{13} See, for instance, Laland, Odling-Smee, and Feldman 2003.
\textsuperscript{14} Even the submission of an application for a new drug to the FDA is considered confidential business information.
wherewithal to do so. None of the statutes that govern the agency’s function give it authority over living animals.\textsuperscript{15} The FD&C Act is the primary source of the FDA’s regulatory authority. It places on the agency the obligation to ensure that human food product and animal feed are safe, sanitary and appropriately labelled. The FDA also has the responsibility to guarantee the safety and effectiveness of human pharmaceuticals,\textsuperscript{16} animal drugs and medical devices.\textsuperscript{17} As discussed above, GE animals are sentient, relational entities; they are not reducible to a specific genetic modification and nor are they ‘drugs’ (i.e., inanimate chemicals with a therapeutic or preventive function). To state the obvious, living GE animals are not human food products, animal feed, human pharmaceuticals, animal drugs or medical devices, so the basis of the FDA’s claim to regulatory authority over GE animals appears to be shaky. Thus, arguably, the agency may be vulnerable to justified legal challenges that are based on its lack of clear and direct statutory authority over GE animals.\textsuperscript{18} The question must be asked if awareness of that possibility might make the agency overly cautious in exercising its regulatory authority.

While that may seem like an unlikely possibility, it could account for the weaknesses in the review of a GE salmon conducted by the FDA’s Center of Veterinarian Medicine (CVM). In 2010, the FDA held a public meeting about the CVM’s risk assessment of the AquaBounty’s GE salmon, which grows faster than its conventional counterpart. The FDA also convened Veterinarian Medicine Advisory Committee (VMAC), an independent expert advisory committee, to review the risk evaluation of the GE fish conducted by the CVM. The VMAC was “… responsible for assessing whether CVM … [had] met its obligations under the regulatory framework that Congress [had] given [to the FDA]” (FDA 2010, p.12).

The VMAC criticized the CVM’s review of the AquAdvantage salmon. Among other things, some of the VMAC members rebuked the CVM reviewers for not asking Aqua Bounty Technologies to provide all of the data on the GE salmon (FDA 2010, p.179). The VMAC also noted that the CVM reviewers did not ask Aqua Bounty Technologies to re-run flawed studies (FDA 2010, p.224). Arguably,\textsuperscript{15} In part three, it is argued that the agency has asserted regulatory authority over GE animals because of the US biotechnology regulatory policy framework.\textsuperscript{16} It is unclear if the assessment of safety that the FDA conducts for standard animal drugs is akin to the safety evaluation it will perform for GE animals. Moreover, while there is a significant difference between the safety assessment it conducts for human pharmaceuticals and medications meant for animals (specifically, the former is a three step process that is more comprehensive than the latter, which has a two-step safety evaluation protocol), even the safety assessment that the FDA conducts for human pharmaceuticals has significant and troubling review ‘gaps.’ For instance, usually it evaluates the safety of every new drug in isolation rather than examine its safety if it is used in conjunction with other drugs for conditions that are likely to go hand in hand. Also, the agency recommends does not mandate the human clinical trials include multiple biologically diverse human populations; clinical trials tend to use adult males as research subjects (Rabin 2014).\textsuperscript{17} Cosmetics fall within the purview of the agency too.\textsuperscript{18} This analysis mirrors the argument constructed by Mandel and Marchant (2014) about the statutory warrant for the EPA’s attempt to regulate living microorganisms and the justified legal challenges to the agency’s regulatory authority (see below).
those omissions on the part of the CVM could be understood as attempts on the part of the agency to tread lightly as it attempted to assert its regulatory authority.

The FDA’s 2016 draft risk analysis of the GE *Aedes aegypti* mosquito seems to be marred by a similar lack of rigor. The less than thorough risk assessment of a GE mosquito could be understood in light of the fact that the agency is under a mandate to advance the biotechnology sector’s interests. But the case could be made that in part the agency may not have been rigorously asserting its regulatory power because of its awareness that its claim to regulatory authority is based on shaky grounds.

*The EPA’s statutory authority*

If there are questions about the FDA’s authority to regulate certain GE animals meant for release in the wild, then does the EPA have greater or better claim to regulatory authority over them? The statutes governing EPA are Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the FD&C Act, and the Toxic Substance Control Act (TSCA). FIFRA gives the agency authority over pesticides and related compounds, while the FD&C Act bestows the agency with additional power over pesticide chemical residue. The TSCA enables the EPA to lay claim over chemical substances. As argued above, GE animals (meant for release in the wild) are sentient beings, thus none of the three statutes overtly and directly give EPA regulatory authority over them.

But the agency has laid claim to regulatory authority over living synthetic biology organisms. While the 1976 TSCA does not indicate whether Congress intended for living microorganisms to be classified as “chemical substance,” the EPA has assumed that Congress did mean to include microorganisms in that category (Mandel and Marchant 2014). Since then the agency has used TSCA to claim regulatory authority over biotechnology products. But its claim to regulatory authority over living micro-organisms has been challenged on the grounds that such entities “do not generally have a ‘particular molecular identity’ pursuant to the definition of chemical substance” (Mandel and Marchant 2014). In response, the EPA has argued that “Congress defined the term ‘chemical substance’ broadly and non-inclusively, and furthermore … a cell could be described as a combination of chemicals occurring in whole or in part as a result of a chemical reaction or ‘occurring in nature’” (Mandel and Marchant 2014). Mandel and Marchant believe that “the EPA’s definition would prevail in a legal challenge under the *Chevron* doctrine, which requires reviewing courts to defer to an agency’s ‘reasonable’ interpretation of an ambiguous statutory provision” (Mandel and Marchant 2014). But because the EPA’s claim to regulatory authority is based on less than solid grounds, the agency is vulnerable to legal challenges that might result in rulings that are not in its favor. That possibility “may deter the EPA, at least at the margin, from regulating as aggressively as it otherwise might consider appropriate” (Mandel and Marchant 2014).
Given that the EPA now has regulatory authority over a GE mosquito that has been classified as a pesticide, Mandel and Marchant’s analysis deserves careful attention.

The USDA’s statutory authority

In contrast to the EPA and the FDA, the scope of the USDA’s regulatory authority is determined by the Animal Health Protection Act (AHPA), the Plant Protection Act (PPA), the Federal Meat Inspection Act (FMIA), and the Poultry Products Inspection Act (PPIA). The concerns of the AHPA are the animal pests and pathogens that pose a danger to livestock. The PPA protects agricultural plants and natural resources that are important for the purposes of agriculture (such as grazing land, flowing streams that provide water for agriculture, pollinators, etc.) from organisms that can be plant pests or pose noxious weed risks. The FMIA and the PPIA apply to meat and poultry food products. Thus, none of these statutes give the USDA regulatory authority over GE animals meant for release in the wild; the only exceptions would if the GE animals pose a threat to livestock or agricultural plants, in which case, the USDA would be justified in regulating them by invoking AHPA or PPA. In fact, the USDA is regulating a GE version of the Diamondback moth as a plant pesticide.

To sum up, it is arguable if the FDA, the EPA or the USDA has direct and clear regulatory authority over living GE animals meant for release in the wild (that are not livestock or agricultural pests). But given that (at least some kinds of) GE animals (meant for release in the wild) may be regulated by the FDA as new animal drugs, the agency’s risk assessment protocol for them is scrutinized next.

The new animal drug (NAD) application and NEPA requirements

Sponsors of GE animals are required by the FDA to file a new animal drug application (NADA) with its Center for Veterinary Medicine (CVM). The FDA has developed a seven step process for conducting the risk assessment of the intentionally altered genomic DNA and the GE animals in which the modification is made. It is as follows:

“Product definition (step 1): a broad statement characterizing the GE animal and the claim being made for the GE animal; Molecular characterization of the construct (step 2): a description of the rDNA construct or other genomic alteration and how they are produced; Molecular characterization of the GE animal lineage (step 3): a description of the method by which the

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19 As drugs require regulatory approval prior to market introduction, sponsors must fulfill the FDA’s premarket approval conditions and consider possible environmental significance (as required by NEPA) as part of their application to the FDA (OSTP 2017, p. 18) (more on this later). The exception would be if the sponsor claims a categorical exemption for investigational new drug.
rDNA construct or other genomic alteration was introduced into the animal and whether they are stably maintained over time; Phenotypic characterization of the GE animal (step 4): comprehensive data on the characteristics of the GE animal and its health; Durability plan (step 5): the sponsor’s plan to demonstrate that the alteration will remain the same over time, and continue to have the same effect; Environmental and food/feed safety (step 6): the assessment of any environmental impacts, and for GE animals of food species, an assessment of the safety of food derived from those GE animals is safe to eat for humans and/or animals; and Claim validation (step 7): a demonstration that the GE animal has the characteristics that the developer says it has” (OSTP 2017, p.19).

Within this risk assessment paradigm, during step six, the CVM would evaluate the environmental safety of the ‘drug,’ which the agency considers to be the intentionally altered genomic DNA and, at times, the GE animal. In other words, the agency would make the determination whether the modification made to the animal and the GE animals itself was safe for the environment.

Step six of the NAD application bleeds into FDA’s obligation to abide by NEPA, which calls on the agency to determine the environmental impact of any new animal ‘drug.’ When evaluating a new animal drug, the FDA has three options. It can give a ‘categorical exclusion’ designation to the new animal drug if it would not "individually or cumulatively have a significant effect on the human environment" (40 CFR 1508.4; EPA 2015). Alternatively, it can ask the sponsor of the new biotechnology to conduct an ‘Environment Assessment’ (EA) (or the agency can perform it). Or, the FDA can conduct a (relatively) comprehensive environmental assessment, i.e., Environmental Impact Statement (EIS).

The companies may consult with the FDA as they prepare the EA (more on this later). When a (draft) report is submitted to the agency, it posts it online and invites public comments that must be submitted by the agency specified deadline. The Federal Register announces that information. The public may post its comments, but it is at the FDA’s discretion to take the comments into consideration or not.

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20 In general, the FDA’s attempts to satisfy its NEPA obligations leave much to be desired. For instance, the agency’s guidance recommends that sponsors of new drugs evaluate their accumulation in the environment, but it does not require that they collect data about the possible complex interactions between the new drug and other drugs that have accumulated in the environment (see FDA (2000) and (2004)). Needless, to say, the significant accumulation of various kinds of medications in water ways from overuse in humans for medical purposes and in livestock for growth promotion is a substantial environmental issue, which the FDA does not address as it attempts to discharge its NEPA obligations.

21 In the case of a GE salmon and a GE mosquito, the agency chose to ask the sponsors of the GE animals to prepare an environmental assessment report. The GE mosquito has been developed by Oxitec, which is a subsidiary of Intrexon, which is also the largest shareholder of AquaBounty, the company that developed the GE fish (the author owes this point to C. Boëte).

22 In the case of the AquaBounty salmon, the company consulted with the agency over a period of more than ten years.
The agency has been steadfast in its refusal to engage with any ethical, religious, economic or other normative concern expressed by the public because it claims that its work is purely scientific\(^\text{23}\) (FDA, CVM 2008, ii-iii; also see Meghani and de Melo-Martin 2009). For instance, in response to public comments opposing GE animals, the agency stated that

The statutory and regulatory review and approval requirements for NADAs [i.e., new animal drug application] ensure that only drugs that are safe and effective are approved… The moral, ethical, and socioeconomic issues … do not fall within the scope of the guidance. It is FDA's intent, however, that the regulatory approach described in “the guidance will provide a predictable science-based framework that will ensure the safety and safe use of GE animals (FDA 2008, Section K).

That claim is not justified for two reasons. First, normative considerations influence all stages of risk evaluations. Specifically, ethical, political, or other normative considerations shape the four steps of risk assessment ranging from hazard identification to dose-response modeling to exposure assessment to risk characterization (NRC 2009; 1983; Meghani & Kuzma 2011; Meghani 2017). Risk assessors make normative decisions when they decide on the elements that they will classify as hazards that they investigate. Research methodology choices for exposure assessment may be shaped by non-scientific considerations. The choice of experiment design is likely to be constrained by cost constraints as well as community epistemic conventions (in other words, they design and conduct experiments that are likely to get uptake from their peers). Peer acceptance of methodology can be based on non-epistemic grounds (see Rabin 2014). Dose (or exposure) response evaluation entails conceptualizing the relationship between exposure and the incidence and severity of the adverse health effect (NRC 1994, p.5). Intensity and pattern of exposure, age, and elements of life style are all elements that impact the characterization of that relationship. So, in modeling the relationship between exposure and adverse health, risk assessors have to decide among competing modelling paradigm and scientifically plausible data (IOM 2001, p.28). But that may involve ethical or political choices (Meghani 2017). The larger point is that the risk assessment process cannot be denuded of normative considerations.

The other reason that the FDA’s blanket refusal to engage with the public’s normative concern is not warranted is that the agency’s original remit of protecting public health has moral and political significance (Meghani and de Melo-Martin 2009). Moreover, the (relatively recent) formal obligation of the FDA to advance commercial interests (more on this below) is itself a normative project (Meghani 2017).

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\(^{23}\) Presumably, it is acting under a Congressional mandate to conduct science-based risk evaluations.
Next, the requirements of the EA report are discussed below, followed by an analysis of the criteria for EIS.

Environmental Assessment (EA) (report)

The FDA gives sponsors of the new product considerable leeway as they conduct an environmental assessment and offers them its consultant services, with the larger end of ensuring that the environmental assessment will be acceptable to the agency reviewers. The agency suggests that applicants consider submitting “proposed protocols for environmental studies for technical review by agency staff. Applicants and petitioners also are encouraged to consult applicable FDA EA guidance documents, which provide additional advice on how to comply with FDA regulations” (FDA 2016a). The agency specifies the following:

“… the EA (environmental assessment) shall focus on relevant environmental issues relating to the use and disposal from use of FDA-regulated articles and shall be a concise, objective, and well-balanced document that allows the public to understand the agency’s decision. If potentially adverse environmental impacts are identified for an action or a group of related actions, the EA shall discuss any reasonable alternative course of action that offers less environmental risk or that is environmentally preferable to the proposed action. The use of a scientifically justified tiered testing approach, in which testing may be stopped when the results suggest that no significant impact will occur, is an acceptable approach” (FDA 2016a).

But whether those stipulations can ensure the quality of the EA is uncertain. Moreover, it is worth considering that as the FDA has chosen to construe GE animals as drugs (that have a curative or preventive function) or as ‘drugs’ (that have neither a preventive nor a therapeutic dimension) rather than as sentient, relational entities, its risk assessments may not adequately capture the various relevant aspects of their existence. For instance, it is not obvious the extent to which the risk assessments for GE animals meant for release in the wild will necessarily be informed by the work of (the relevant types of) ecologists; there is no clear statutory mandate about such consults.24

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24 It is also unclear if the risk assessment will necessarily draw on the knowledge of informal epistemic communities comprising of local laypersons who by virtue of their proximity to the designated area of release have firsthand, long term knowledge of that ecosystem.
Environmental Impact Statement (EIS)

NEPA requires that if the FDA believes that the new ‘product’ is likely to substantially impact the environment, then it must prepare an EIS, and consider its social and economic affects (FDA 2015, p.12). In other words, unlike the EA, the EIS is explicitly obligated to take into account the socio-economic impact on humans of the introduction of the new GE animal in the non-laboratory context. But as NEPA is a procedural statute, it does not give regulatory agencies the authority to reject an application for an activity that might cause damage to the environment or result in social or economic harm (FDA 2017c). Presumably, anticipating that the public might find it troubling that NEPA, in effect, is powerless, the FDA notes that it had been its experience that the “developers of new animal drugs will choose to mitigate potential environmental impacts so that FDA can come to a finding of no significant impact on the environment for an NADA approval. They prefer such mitigation to waiting for FDA to complete an environmental impact statement for a product whose approval will have a significant environmental impact” (FDA 2017c). This attempt to reassure the public is, at best, cold comfort.

But if the FDA prepares EIS rather than rely on EA, does it mean that GE animals under its regulatory authority will be rigorously evaluated by the agency? Depending on the kind of modification and given that the agency intends to evaluate the GE animals as drugs (rather than sentient, relational beings) and given that the FDA does not have clear and direct statutory authority to regulate living animals, the answer, at best, is uncertain. So the question must be asked why the agency is ‘choosing’ to regulate GE animals meant for release in the wild as NADs. In the next section, the argument is made that the FDA’s regulatory stance could be understood as at least partially the result of national biotechnology regulatory policies that are based on a neoliberal sociotechnical imaginary. To construct that case the key features of neoliberalism are delineated. Then, the influence of a neoliberal sociotechnical imaginary on US biotechnology regulatory policy framework is discussed.

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25 This question takes on particular importance in the case of animals with gene drives, based on CRISPR/Cas9. (CRISPR refers to Clustered Regularly Interspaced Short Palindromic Repeats and Cas9 is a nuclease that makes cuts in DNA next to CRISPR sequences.) Theoretically speaking, the release of a relatively few such animals could result in the trait affecting the entire wild-type population within a fairly short timespan in certain species (Burt 2003). Ideally, the use of the GE animals would have the intended effect on its wild-type counterpart only and be limited to the target area. But depending on the relationship of the target species to other species in an ecosystem or in the larger complex of inter-connected ecosystems, and depending on the introduced trait, there could be a cascade effect extending to multiple species whose ‘ways of life’ are entangled and which could compromise those other species. If the latter case is a serious possibility, then it is arguable if such GE animals (with gene drives) should be released in the wild without the consent of the global community.
Neoliberalism

The creators of neoliberalism identified themselves as political liberals, committed to individual liberty (Harvey 2005, p.20; Bonanno 1998). Given their liberal roots, they feared the (potentially tyrannical) power of the state, but unlike (historical) liberal political philosophers like John Stuart Mill, they believed the market to be the panacea to that evil (Harvey 2005, p.20). They held that because the state would be biased in favor of particular groups (such as trade unions or trade associations) it should not be permitted to regulate the economy (Harvey 2005, p.21). Rather impartial market forces should be allowed free reign because (like Adam Smith they believed that) the market would ensure that society would benefit even if individuals acted out of greed or self-interest (Harvey 2005, pp.20-1). Market forces would impartially determine the fair distribution of goods, services and wealth, without interference from the state (Harvey 2005; Bonanno 1998, p.227).

Neoliberals assert that the state should encourage and act in the interests of individuals who are enterprising, independent, self-sufficient, responsible, innovative risk takers. In fact, proponents of the ideology urge the state to allow individuals to fend for themselves instead of protecting them from risks. Neoliberalism conceptualizes persons as consumers who should be provided with information about risks from processes, services, and products and be given the opportunity to accept or walk away from them.\(^{26}\) In other words, neoliberalism proclaims supreme confident in the ability of the free market to weed out products whose risks consumers find unacceptable (Busch 2014).

But even as the neoliberal rhetoric valorizes self-reliance and competition for the individual, the ideology calls on the state to nurture and serve corporate and elite interests. It requires that the state protect corporations and the wealthiest class from liability by creating regulations that benefit them and protect them from losses.\(^{27}\) For instance, by establishing regulations that set safety standards for products that manufacturers consider acceptable, the state effectively reduces or limits corporate responsibility for harms and risks from their products. Similarly the neoliberal call for harmonization of standards across nations for GE foods serves corporate interests by facilitating trade and limiting manufacturers’ liability across national borders.

\(^{26}\) Neoliberalism supports disclosure of risks to consumers provided it does not impinge on the right of commercial endeavors to protect their proprietary interests or stifle innovation.

\(^{27}\) It is generally assumed that neoliberalism is averse to regulations, but that is not the case. It opposes regulations that do not serve the interests of corporations and the elite managerial and financial class (Harvey 2005).
A national neoliberal shift

The US ostensibly identifies itself as a liberal democracy committed to the moral equality of all persons. Thus, prima facie, its adoption of neoliberalism, an ideology that privileges and serves the interest of the corporate sector and the wealthy elite, is puzzling. The shift to neoliberalism is traceable to the 1970s when postwar Keynesian economics was judged as unable to address the problem of stagflation (Harvey 2005). In 1974, Austrian political philosopher Frederick von Hayek (who created the Mont Perelin society that was the birthing ground of neoliberalism) was awarded the economics Nobel prize, and in 1976, Milton Friedman (an American economist and key proponent of neoliberalism) received it; neoliberalism gained mainstream credibility. Harvey has argued that a powerful group of US industrialists and wealthy elite also played a crucial role in neoliberalism’s ascendency (2005, pp.21-2). Motivated by a desire to claw back the gains made by labor in the post WWII era that had undermined their profit margins, they used the stagflation of the 1970s to argue that the power of unions must be curbed and the economy deregulated (or to be more accurate, regulations eliminated that curbed the ability of corporations to make profits). In 1980, with President Reagan being voted into office, the large scale implementation of neoliberal policies, including de-regulation, in various sectors of the economy commenced (Harvey 2005, pp.24-5).

The neoliberalization of the sociotechnical imaginary (of the US biotechnology sector)

Ideologies represent particular aspirational political-economic worldviews; neoliberalism is an ideology. Sociotechnical imaginaries work in conjunction with the dominant ideologies of nations to configure their scientific and technologies policies about innovation and regulation. Sociotechnical imaginaries are not reducible to ideologies. Unlike ideologies, they are fluid, not “entrenched and immovable”; rather, they change as they reach into the future and are encoded in material technologies (Jasanoff 2015, p.29).

While socio-technological imaginaries extend beyond particular policy agendas, the policy frameworks they birth “… can be mined for insights into the framing of desirable futures…, as well as for specific verbal tropes and analogies that help identify the elements of the imaginary …” (Jasanoff 2015, p.27). Those imaginaries represent the dominant class’ fears regarding the future of the nation. They are also prescriptive in the sense that they are shaped by their understanding “of what is good or desirable in the social world … for instance, how science and technology can meet public needs and who even are the relevant publics” (Jasanoff and Kim 2009, p.123). Thus, a nation’s sociotechnical imaginaries can be

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28 The economics Nobel prize is unrelated to the other Noble prizes; the former was created by the Swedish banking elite (Harvey 2005, p.22).
29 For a careful and detailed account of the implementation of neoliberal policies, see Harvey 2005.
30 Neoliberalism takes on local hues and is affected by them.
used to decode its dominant class’ aspirations and worries. They can also be employed to analyze the
means that are used by them to present the technological developments as crucial to national interests
(Jasanoff and Kim 2009, p.121).

For more than three decades now, a neoliberal sociotechnical imaginary has dominated in the US, shaping its biotechnology regulatory policy framework. The ready adoption of a neoliberal sociotechnical imagines can be attributed to at least two factors. First, neoliberalism’s commitment to fostering industry interests appeals to the nation’s competitive spirit. That competitive streak has been used by transnational corporations to advance their agenda; they present their interests as aligned with and furthering those of the nations (like the US) in which they are embedded. Jasanoff writes, “Multinational corporations increasingly act upon imagined understandings of how the world is and ought to be, playing upon the perceived hopes and fears of their customers and clients (which include nations), and thereby propagating notions of technological progress and benefit that cut across geopolitical boundaries” (Jasanoff 2015). In other words, the US and other countries learn to associate their flourishing with that of transnational companies and since those commercial entities function in multiple nations and compete with other corporations (that are based in other countries), the state ‘sees’ those nations as competitors that it must best for its own survival and advancement. In the case of the US, neoliberalism appealed to the dominant class’ aspiration to compete against other nations and dominate them in the realm of biotechnology development and trade (more on this later). Second, the US has a “culture of support for technology and innovation” (Gaskell et al. 2005, p.84) that aligns just so with neoliberalism’s attitude of techno-optimism. Broadly speaking, techno-optimism is the belief that technological developments are the panacea to societal problems (Harvey 2005, p.68). This view also implies that the problems solved by technology are the only problems. For instance, in the case of techno-optimism about risk assessments, the assumption is that the only ‘real’ problems are the ones whose risks can be evaluated and managed. For all intents and purposes, problems that do not fit within the narrow parameters of scientific risk assessment, such as the inequitable distribution of power between groups, are marginalized, ‘disappeared,’ or re-conceptualized as technical-scientific problems.

Needless to say, in espousing the techno-optimist model of risk taking behavior, neoliberalism, in effect, ignores the breadth and complexity of the vulnerability that characterizes the existence of humans (Kittay 1999; Orcozo 2015) and non-humans. A limited number of controlled laboratory experiments cannot assess uncertainties and complex, complicated risks; it is false to claim otherwise (Jasanoff 2003).

In the next section, the key US biotechnology policy documents are analyzed. The larger aim is to

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31 The US is not the only nation that has succumbed to this appeal. Patel-Campillo (2014, pp.210-11) notes that this feature of neoliberalism appeals to all nations.

32 “Embedded” should not be read to mean “located for tax purposes.”
make explicit the historical connection between the influence of a neoliberal sociotechnical imaginary on US biotechnology policy and the decision of the FDA to construe and regulate GE animals as new animal drugs. It is argued that the agency’s decision primarily benefits the developers of those ‘biotechnology products.’ Being able to use an established policy framework to regulate this new class of living entities means that the US can take the global lead in the marketplace and establish international standards and policy frameworks that other nations might adopt.

Tracking the influence of a neoliberal sociotechnical imaginary on the US biotechnology policy framework

In February 1981, President Reagan signed Executive Order #12291, ordering an assessment of the economic impact of existing and new regulations (Reagan 1981). The neoliberal aim of the Order was to reduce or eliminate federal government regulations, permitting the private sector to govern itself; the larger goal was to remove regulatory obstacles to economic growth. In 1982, President Reagan made it clear that his administration would roll-back regulations that set limits on the activities of the commercial sector (Reagan 1982). He did not address the impact of that change on public health and safety (Meghani 2014).

In 1981, as part of his testimony before Congress, George Keyworth, Reagan’s science advisor and OSTP director stated, “[T]oday’s federal role in science and technology (including biotechnology) must be different from that which has prevailed since World War II…. [It must be] appropriate to a national mood which calls for increased vigor and acceptance of responsibility by individuals and organizations in the private sector and decreased involvement by the federal government in many of our affairs” (pp. 14-15).

Keyworth’s remarks revealed a neoliberal socio-technological imaginary at work. US biotechnology policy would serve corporate interests by rolling back the government’s directive and protective role in the economy and “motivating” individuals to look out for themselves by acting as enterprising risk-takers who were responsible for their destiny. (Neoliberalism conceptualizes the welfare state as damaging to individuals because it protects them from certain risks and harms and provides for their basic necessities.)

Next, the influence of a neoliberal sociotechnical imaginary on key biotechnology regulatory policy documents is identified and analyzed (see Table 1). It is because these documents were identified by the White House Office of Science and Technology Policy (OSTP) as key biotechnology regulatory policy documents (OSTP 2017), this analysis focuses on them. They gave the regulatory agencies their marching orders.
Table 1. Key biotechnology policy documents (in chronological order)

<table>
<thead>
<tr>
<th>Year of issue</th>
<th>Title of policy document</th>
<th>Issuing entity</th>
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<tbody>
<tr>
<td>1984</td>
<td>Proposal for a <em>Coordinated Framework for the Regulation of Biotechnology</em></td>
<td>White House Office of Science and Technology policy (OSTP)</td>
</tr>
<tr>
<td>1986</td>
<td><em>Coordinated Framework on the Regulation of Biotechnology</em></td>
<td>White House OSTP</td>
</tr>
<tr>
<td>1992</td>
<td><em>Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment</em></td>
<td>OSTP (in 57 FR February 27)</td>
</tr>
<tr>
<td>2016</td>
<td><em>National Strategy for Modernizing the Regulatory System for Biotechnology Products</em></td>
<td>Biotechnology Working Group (BWG) (of the Emerging Technologies Interagency Policy Coordination Committee, with representatives from the Executive Office of the President, the EPA, the FDA, and the USDA)</td>
</tr>
<tr>
<td>2017</td>
<td>(updated) <em>Coordinated Framework on the Regulation of Biotechnology</em></td>
<td>White House Office of Science and Technology policy (OSTP)</td>
</tr>
</tbody>
</table>

In 1984, an interagency working group under the White House Cabinet Council on Natural Resources and the Environment (OSTP 1986, p.3) wrote the precursor to the Coordinated Framework for Regulating Biotechnology. The working group claimed that its goal was “to achieve a balance between regulation adequate to ensure health and environmental safety while maintaining sufficient regulatory flexibility to avoid impeding the growth of an infant industry” (OSTP 1986, p.3). The group was also charged with the responsibility of ensuring that the regulatory protocol did not “stifle innovation and impair the competitiveness of U.S. industry” (OSTP 1984, p.50857). To that end, among other things, the group was asked to identify existing laws and regulations relevant to biotechnology, clarify regulatory protocol for new products, determine if new biotechnology products required new regulatory apparatus or whether current regulations would suffice.

Instead of formulating fresh legislation for regulating the new biotechnologies, the working group chose, for the most part, to use the existing statutes. It was motivated to do so because it “could provide more immediate regulatory protection and certainty for the industry than possible with the implementation of new legislation” (my italics) (OSTP 1986, p. 3).

On Dec. 31st 1984, the White House’s Office of Science and Technology Policy (OSTP) issued a proposal in the Federal Register for developing a Coordinated Framework for Regulating Biotechnology (pCFRB). The OSTP’s proposal claimed that while the US was a global biotechnology leader because of its scientific prowess and “vigorous entrepreneurial spirit and availability of venture capital,” its supremacy was likely to be challenged by international competition. The proposal echoed the warning offered by the Congressional Office of Technology Assessment, which contended that "[a]lthough the United States is currently the world leader in both basic science and commercial development of new biotechnology, continuation of the initial preeminence of American companies in the commercialization of new biotechnology is not assured" (OTA 1984, p.iii). The OSTP argued that given the potential of this new kind of technology to, first, foster the US economy, and second, address critical social needs, the US should nurture the biotechnology sector (OSTP 1984, p.50856). The proposal also articulated a commitment to reducing trade barriers and international harmonization of regulations even as it aimed to protect human health and the environment.

Analysis of pCFRB 1984

Needless to say, the 1984 proposal for a CFRB was shaped by a neoliberal sociotechnical imaginary. It revealed a state that aligned itself with the nascent biotechnology sector and made an explicit commitment to nurture it. It also reflected the fear of the ruling elite that the US would lose its edge on the global stage if it did not cultivate its biotechnology industry. To retain the competitive edge at
the international level of the US and the biotechnology sector, the working group deliberately chose to
use existing statutes to regulate the new products (OSTP 1986, p. 3). It should be noted that no claim was
made that the existing framework was particularly suited to the new kind of technology, rather
considerations of “immediate regulatory protection and certainty” for the biotechnology companies
prevailed (OSTP 1986, p. 3). This was not a science-based decision nor was it primarily motivated by
calls about public health or the environment, rather it served the interest of the biotechnology
industry, which the state (under the thrall of a neoliberal sociotechnical imaginary) believed to be in the
interest of the US on the global arena.

The Coordinated Framework on the Regulation of Biotechnology (CFRB) (1986)

In 1986, the White House Office of Science and Technology Policy (OSTP) issued the policy
document, Coordinated Framework on the Regulation of Biotechnology (CFRB). It was the nation’s first
defining regulatory document about GM food. The CFRB asserted that GM food should be treated the
same as their non-GM counterparts. The policy stance was justified on the grounds that it would allow the
US to globally lead and dominate the development of and trade in GM food (OSTP 1984; Levidow et al.
2007, p. 34). The policy document also attempted to justify its decision to not regulate GM food by
claiming that its position was scientific and rational. It asserted that the FDA would be acting irrationally
and unscientifically if it subjected GM food to scrutiny because they were produced by a different process
than their conventional counterparts: “[R]egulation by the FDA must be based on the rational and
scientific evaluation of products, and not on a priori assumptions about certain processes” (OSTP 1984, p.
50880).

Analysis of CFRB 1986

The CFRB made it relatively easy for biotechnology companies to bring their products to the
market because it did not subject them to a new regulatory regime and it asserted that GM foods did not
have to be identical to non-GM foods (Millstone et al. 1999, p. 525). The CFRB only required that they
be substantially equivalent in terms of their chemical composition to their non-GM counterparts (Levidow
et al. 2007, p. 34).

Ironically, the CFRB asserted a commitment to scientific neutrality even as it unquestioningly
adopted the larger goals of the Organization for Economic Cooperation and Development (OCED). The
OECD acknowledged that the environmental and agricultural risks from GE organisms were not well
known, but it claimed that they could be accurately assessed using knowledge of non-GM organisms
(OSTP 1986). The CFRB did not question the assertion of the OECD, a trade organization.
The CFRB also did not acknowledge the tension between its ostensive commitment to “rational and scientific evaluation of products” and fostering the business interests of biotechnology companies by allowing them to declare the studies and data about their products confidential business information, and thus foreclosing the possibility of independent, third parties scrutinizing their studies and data. So, in these three ways this key policy document served the biotechnology industry.

The (above mentioned) contradictions within this policy document, arguably, are the product of the state’s commitment to a neoliberal sociotechnical imaginary. For instance, presumably, it is because the US biotechnology industry was perceived by the state as advancing American interest on the global stage that it accepted the OECD’s assertion regarding the environmental and agricultural risks from GE organisms instead of requiring peer reviewed scientific evidence of public health and environmental safety.


In 1991, the President’s Council on Competitiveness/Biotechnology Working Group (CoC/BWG) re-affirmed the White House’s commitment to neoliberalism. It asserted that “[t]he proper role for the U.S. (federal) government is to (1) provide needed support to activities that are undersupported by the market when they generate social benefits that greatly exceed their private profitability, and (2) reduce artificial barriers to proper market functioning” (BWG/CoC 1991, p.5). The leader of that group, Vice-President Quayle, stated that the US should “avoid excessive restrictions that curtail the benefits of biotechnology to society” (BWG/CoC 1991: viii, 11; cited in Levidow et al. 2007, p.6).

*Analysis of RNBP*

The CoC/BWG’s position was starkly at odds with the political philosophy that motivates and shapes liberal democracies. The defining feature of liberal democracy is a commitment to treating all individuals as moral equals, including equal respect for their individual rights. It is not part of liberal political philosophy to serve as the handmaiden of the commercial sector and allow it a free hand to organize the nation’s social order.

The 1991 RNBP articulated the following commitments:

i. It displayed an attitude of techno-optimism, specifically, the conviction that biotechnology “can give us better and healthier food products, including meats, dairy products, fruits and vegetables, greatly reduce reliance on toxic pesticides, and improve pesticides, herbicides, and irrigation” (BWG/CoC 1991, pp. 1-2; see also p.3). This attitude of techno-optimism aligns precisely with neoliberalism’s stance
towards technologies that Harvey has described as verging on the fetishistic in its belief that “there is a technological fix for each and every problem” (Harvey 2005, p.68).

ii. The 1991 RNBP revealed considerable anxiety about possible challenges to American trade dominance in biotechnology: “Foreign governments have targeted biotechnology as of vital economic importance and are beginning to seriously challenge the American lead in particular areas” (BWG/CoC 1991, p.5). With the shift to neoliberalism, the federal government had pursued technology transfer policies that provided the newest scientific developments (funded by tax dollars) to the US biotechnology industry in the interest of “assisting” biotechnology corporations. The state had become vested in a neoliberal sociotechnical imaginary that asserted that the US should compete on the global stage with other nations and best and dominate them and the way to achieve that goal was by “supporting” the corporate sector. Thus, the report identified developing and “protecting” the rights of the biotechnology sector as a policy objective.

The goal of protecting the public good, especially public health, seems to have become a secondary concern. Instead, the NRBT expressed concern about existing and new regulations that would inhibit the development of the biotechnology industry by increasing costs, slowing innovation and undermining public confidence in biotechnology products. Existing regulations were to be used to “provide an adequate framework for regulation of biotechnology in those instances where private markets fail to provide adequate incentives to avoid unreasonable risks to health and the environment. In these instances, regulation also can help shield industry from avoidable incidents that could tarnish its image and impair its development” (my italics) (BWG/CoC 1991, p.11). Needless to say, this claim reveals a state deeply vested in the biotechnology sector. The state conceptualized itself as having a responsibility to protect the biotech industry even going so far as to prevent damage to its public image that could undermine its future.

Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment (EFOWSSA) (1992)

In February 1992, the OSTP issued an update to the 1986 CFRB. It specified that regulatory oversight for biotechnology products would be grounded on a scientific, risk based approach. Unlike the Proposal for the Coordinated Framework for Regulating Biotechnology (1984) which claimed that the existing regulatory framework should be used for GEOs because it would provide “immediate regulatory protection and certainty” for biotechnology companies (OSTP 1986, p. 3), the 1992 update to the CFRB cited a 1989 National Research Council's report (NRC 1989) to justify making no distinction between GMOs and non-GMOs. Among other things, the 1989 NRC report made the argument for its conclusion
by giving scientific reasons for it, such as the lack of molecular difference between the two kinds of
dentities (OSTP 1992, pp.6755-6).

Analysis of EFOWSSA

The OSTP acknowledged that its policy stance was influenced by a variety of sources, including
public comments, the 1991 Report on National Biotechnology Policy, and President’s Competitiveness
Council’s 1991 Fact Sheet on Critical Technologies. At least two of the Council’s recommendations reflected a neoliberal sociotechnical imaginary. They suggested that the state defer to private corporate actors and the market for regulatory purposes; in other words, they should be allowed to regulate themselves. The Council stated that “voluntary private standards and disclosure should be relied on where possible instead of inflexible (read: federal) regulation… (Moreover,) [h]ealth, safety and environmental regulations should … employ performance-based incentives that harness the creativity of market actors to design and continually innovate better ways of reducing excess risks. They should not specify technologies or designs that firms must employ” (OSTP 1992, p.6762).33 The Council’s stance reveals a neoliberal sociotechnical imaginary at work, which called on the state to permit the biotechnology sector to act as a self-governing authority, in effect, encouraging the state to abdicate its regulatory responsibilities. It recommended affording biotechnology companies the choice to create their own standards and make decisions about disclosures. The possibility that the profit motives of biotechnology companies might be at odds with the public’s interest was not acknowledged by the Council or the OSTP.


In May 1992, the OSTP issued this Guidance about GE plants. The Statement clarified that sponsors of food biotechnologies could voluntarily informally consult with the FDA about the safety and regulatory status of their product as they developed them.34

33 The Council also asserted that federal regulations that aimed to reduce health or safety risks ought to be “based upon scientific risk-assessment procedures and should address risks that are real and significant rather than hypothetical or remote” (OSTP 1992, p.6762). This recommendation divided risks into two types; risks that were legitimate because they were based on what it construed to be “real and significant” as opposed to risks that it considered to be lacking merit, i.e., risks that were “hypothetical or remote.” The Council’s attempt to distinguish between “real and significant risks” that are amenable to scientific risk assessment and “other” kinds of risks could be read as an attempt to discredit normative opposition to biotechnologies.

34 This was a new policy that was instituted in response to the sponsors of the FLAVR SAVR tomatoes seeking guidance from the FDA regarding their regulatory requirements for their food product (FR 57, May 29, p.22985).
Following this policy statement, the FDA issued the *Guidance to Industry for Foods Derived from New Plant Varieties* (1992). The agency's Guidance (1992) echoed the OSTP’s position about the change in the relationship between the FDA and industry. The agency’s reviewers were no longer to be at an arm’s length from the developers of new biotechnologies; rather they were mandated to give the latter “guidance about what evidence would be sufficient” to prove their products’ safety and effectiveness (Hilts 2003, p.228). Thus, an aim of the agency now became to help sponsors of new food products get approval so that they could bring them to the market. In keeping with its neoliberal philosophy, the agency re-conceptualized itself as a consultant to the industry, rather than as an entity whose primary mission is to protect public health (FDA 2012) and which was created by Congress to protect the public’s well-being from the profit motives of industry.

**National Strategy for Modernizing the Regulatory System for Biotechnology Products (NSMRSBP) (2016)**

Twenty three years after the OSTP issued the SOP, because of the advancement in the technologies and science of genetic engineering and genome editing, in 2015, the Emerging Technologies Interagency Policy Coordination Committee’s Biotechnology Working Group (under the auspices of the Executive Office of the President) asked the three key regulatory agencies responsible for biotechnology—the EPA, the FDA, and the USDA- to do the following (p.5):

1. Update the CFRB by clarifying the current roles and responsibilities (of regulatory entities)
2. Develop a long-term strategy to ensure that the regulatory system is equipped to efficiently assess the risks, if any, of the future products of biotechnology; and
3. Commission an expert committee to prepare a biotechnology product development horizon scanning report.

The NSMRSBP was formulated in response to the second objective. The 2017 update to the CFRB was developed to meet the first goal and a National Academies of Sciences, Engineering, and Medicine (NASEM) expert committee report was commissioned by the EPA, FDA, and USDA to address the third requirement.

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35 During the Reagan era, the FDA was identified as in ‘need’ of neoliberalization because it was “quite good at confronting businesses and reigning in their profit-seeking behavior if their interests conflicted with the public interest” (Markel 2005, p.2490). As a result the agency’s ability to serve as the public health watch dog was undermined, with its budget for food contamination prevention significantly cut, and its legal investigations cancelled (Hilts 2003, pp.215-6). The FDA employees were flooded with paperwork, compromising their ability to investigate companies that violated the agency’s regulations (Hilts 2003, p.215).
It was a forgone conclusion that a new regulatory framework would not be developed for GE animals (meant for release in the wild) or any other novel technology that might be identified by the 2016 NASEM expert committee charged with horizon scanning. The decision to hew to the existing regulatory framework regardless of the new forms of biotechnologies under development seems to hearken back to the choice made in 1984 by the White House Cabinet Council on Natural Resources and the Environment. The Working Group (as discussed above) chose to use the existing statutes for GEOs because it “could provide *more immediate regulatory protection and certainty for the industry* than possible with the implementation of new legislation (my italics)” (OSTP 1986, p. 3). It is worth considering that by using an existing regulatory framework for emerging technologies (even though they may pose significant risks given the high level of unknowns about them) means that the US will take the lead on the global stage with respect to establishing regulatory norms. The ambition of international biotechnology leadership is an integral feature of the neoliberal sociotechnical imaginary that holds sway over the nation.

*The (updated) Coordinated Framework on the Regulation of Biotechnology (2017)*

As mentioned above, the development of new technologies, such as CRISPR and gene drives (OSTP 2017, p.6), motivated the US to update the CFRB. When the 1986 CFRB was issued and updated in 1992, GE animals were not taken into consideration (OSTP 2017, p.6). To address that new challenge, among others, in 2017, an updated version of the CFRB was issued. The Obama White House OSTP made the decision that the 2017 updated CFRB would not create a new regulatory path specifically for GE animals rather it would serve to “clarify” the 1986 CFRB so that the public could more easily understand the regulatory protocol for GE animals and small and mid-sized biotechnology firms would not find regulations a burden (OSTP 2017, p.1).

*Analysis of CFRB 2017*

The White House OSTP’s concern about nurturing small and midsize biotechnology companies is worth noting. The OSTP no longer identified itself as concerned with the biotechnology sector as a whole, presumably, because some biotechnology companies are behemoths that have a substantial transnational
Another significant aspect of this new CFRB is that even before the NAS committee completed its biotechnology horizon scanning project, the decision was made by the OSTP that the updated CFRB would clarify the regulatory process for the public; the existing regulatory paradigm would not be changed or replaced by a new one that was tailored to the new biotechnologies under development (see, for instance, critique by Kuzma (2016) of that decision). As discussed earlier, the biotechnology sector stands to benefit if the existing regulatory schema is employed rather than a new one because it affords biotechnology companies “immediate regulatory protection and certainty” (OSTP 1986, p. 3). It also serves US interests by permitting it to be the first to have the standards and thus make it likely that other nations would follow its lead. This is the kind of alignment of interests between the corporate sector and the state that is idealized by neoliberal sociotechnical imaginaries.

To sum up, in this section, key biotechnology regulatory policies were analyzed and evaluated. The argument was made that they were influenced by a neoliberal sociotechnical imaginary. As the state believes that its interests are served by the biotechnology sector, it is committed to advancing the interest of this particular corporate sector. Thus, for instance, the decision of the FDA to lay claim to regulatory authority over certain GE animals and regulate them as new animal drugs rather than devise a new regulatory framework for this class of entities can be understood, at least partially, as the product of a neoliberal sociotechnical imaginary.

CONCLUSION

It is unclear whether under the current biotechnology regulatory policy framework GE animals meant for release in the wild will be effectively regulated. The FDA construes them as new animal drugs for regulatory purposes even though they are sentient relational beings and the agency does not have clear and direct statutory authority over living animals, which may cause it to tread too lightly as it conducts risk analyses, compromising their rigor. The larger point is that there is a need for a new regulatory framework for GE animals intended for release in the wild. The current biotechnology regulatory policy framework is significantly shaped by a neoliberal sociotechnical imaginary that privileges industry interests over other relevant normative concerns.

As a corrective measure to that state of affairs, there should be a series of national democratic dialogue and deliberation sessions about the sociotechnical imaginary that should guide the nation’s biotechnology regulatory policies. The iterative process of discussions and deliberations should be

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36 At least, from a public relations perspective, it would appear unseemly if the state presented its self as concerned with the profit margins of biotechnology corporations that spanned the globe and held virtual monopolies over the products that they sold.
inclusive, with representatives of all affected constituencies at the deliberation and decision-making
table.\textsuperscript{37} To be clear, this is not a call for simple democratic majoritarian decision-making. That would only
re-instantiate pre-existing inegalitarian power relations among groups and communities. Rather the notion
of democratic decision-making (about the values and concerns that should shape the nation’s
sociotechnical imaginary) invoked here is one that is committed to relationships of non-domination
between groups and communities (Schwartzman 2006), and it is premised on the recognition that the
analyses and critiques of the dominant worldview developed by marginalized groups and communities
should be used as a starting point for the discussion. (By virtue of their marginalized status, they may be
more likely to ‘see’ the flaws and weaknesses of the dominant standpoint that might not be readily visible
to those who occupy positions of power and privilege.\textsuperscript{38}) The self-conscious deliberative democratic
approach to formulating the nation’s sociotechnical imaginary stands in contrast to the way the current
neoliberal (biotechnology) sociotechnical imaginary came into existence. The latter was not the product
of democratic dialogue and decision-making; it was the product of executive fiat that re-conceptualized
the relationship between the state and private sector (see, for instance, the above analysis of the 1991

In closing, it must be acknowledged that the proposal for democratic deliberations and decision-
making requires two qualifiers. First, it is unclear whether such a democratic deliberative process is likely
to occur in the near future. According to the Pew Center (2017), the US lags behind most industrialized
democracies in voter turnout for national elections.\textsuperscript{39} Given that reality, the proposal for a deliberative
democratic model of decision-making\textsuperscript{40} should be read as the invocation of a regulative ideal. Second, it
must be conceded that the proposed measure is not comprehensive. But it is not meant to be. Rather, the
goal is to gesture at possible alternatives to the reality created by the dominant neoliberal ideology, thus,
enabling the public(s) to envision different and better possible futures with respect to questions about
biotechnology development, risks, and regulations.

\textsuperscript{37} This idea draws on Benhabib’s work (2004; 2016) that argues for a deliberative democracy that entails an
iterative, dialogical, inclusive approach.

\textsuperscript{38} See, for instance, Harding (2004) and Hartsock (1998) on standpoint epistemology.

\textsuperscript{39} According to the Pew Center article, the US Census Bureau has noted that voter turnout for the presidential
election in 1980 was 64%, in 1984 64.9%, in 1988 62.2%, in 1992 67.7, in 1996 58.4%, in 2000 59.5%, in 2004
63.8%, in 2008 63.6%, in 2012 61.8% and in 2016 61.4%. Thus, if voter turnout in presidential elections is
indicative of the population’s willing to participate in political decision-making, the picture is bleak.

\textsuperscript{40} Readers interested in the question of public engagement in democratic processes should see Carpini et al. 2004;
References


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