FDA AS FOOD SYSTEM STEWARD

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The Food and Drug Administration ("FDA") is one of the primary regulators of the U.S. food system, yet it all but ignores the food system's vast environmental footprint. Although the agency is not technically an environmental agency, it could and should view redressing the food system's significant environmental footprint as part of its health and safety mission. In this Article, we review FDA's history of National Environmental Policy Act ("NEPA") compliance. This history affirms our hypothesis that FDA does not view its own work as environmental. The review, along with assessment of some of FDA's core food programs, reveals that FDA's failure to act as an environmental agency follows from three conceptual mistakes. First, it focuses its safety mission around product safety, discounting safety related to production and disposal. Second, it approaches risk assessment on a product-by-product basis, missing the cumulative and synergistic effects of production, consumption, and disposal. Finally, it orients its work solely toward promoting individual health, disregarding population-level health. We argue that FDA should be a proactive environmental steward of the food system. We describe how it might use NEPA to begin such a transformation, and we identify a variety of areas where its existing substantive authority leaves room for incorporation of environmental goals. Throughout the Article, we return frequently to plastic packaging. The environmental threats of plastic packaging have become increasingly clear and FDA's power to regulate plastics as "food contact substances" provides an important opportunity to mitigate those harms. We also assess opportunities for change in FDA's authority over food additives, animal drugs, and food labeling. We conclude by observing that many environmental problems require widespread collaboration to solve. Given the well-recognized, pressing need for action on a variety of environmental fronts, every federal agency has a role to play. This analysis of how FDA might embrace a role as a robust steward of the food system offers a roadmap for other non-environmental agencies to participate meaningfully in these endeavors.

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Introduction

Why isn't the Food and Drug Administration ("FDA") an environmental agency? Its mandate is to protect the public health by ensuring a safe supply of food and drugs.[1] But our food supply is far from safe. Including production, processing, distribution, and disposal, the food system is responsible for over 15% of the United States' greenhouse gas ("GHG") emissions.[2] Food production is extremely resource intensive.[3] Agriculture is the leading source of surface water contamination.[4] Millions of Americans are exposed every year to toxic agricultural chemicals in the air they breathe and the water they drink.[5] Some

1. *See What We Do*, FDA (Sept. 18, 2021), https://perma.cc/8Y68-QZ6M.

2. Claudia Hitaj et al., *Greenhouse Gas Emissions in the United States Food System: Current and Healthy Diet Scenarios*, 53 Env't Sci. & Tech. 5493, 5497 (2019) (estimating total emissions for 2017). Other estimates are higher. Patrick Canning et al., Econ. Rsch. Serv., U.S. Dep't of Agric., ERR-273, Resource Requirements of Food Demand in the United States, at iii (May 2020), https://perma.cc/US2E-8H2M (estimating 18.1% in 2007); Sonja J. Vermeulen et al., *Climate Change and Food Systems*, 37 Ann. Rev. Env't & Res. 195, 198 (2012) (offering a range of global estimates from 19% to 29%).

3. *See generally* Canning et al., *supra* note 2 (surveying food production demands on land use, freshwater resources, GHG emissions, and fossil fuel withdrawals).

4. *See generally* Paul D. Capel et al., U.S. Geological Survey, Agriculture—A River Runs Through It—The Connections Between Agriculture and Water Quality (2018), https://perma.cc/84KG-APMK (cataloguing agriculture's various water quality impacts).

5. *See, e.g.*, Hannah M.M. Connor, *The Industrialization of Animal Agriculture: Connecting a Model with Its Impacts on the Environment*, *in* Food, Agriculture, and Environmental Law 65, 82–84 (Mary Jane Angelo et al. eds., 2013) (describing some of agriculture's air quality impacts).

environmental impacts of the system are regulated.[6] But many others—including water discharge and air pollution emissions from most farms—remain almost entirely unregulated. FDA can help fill this gap. It should be an environmental agency.

Federal law separates responsibility over direct consumer safety concerns related to food ingestion from responsibility for systemic safety concerns related to environmental effects of production, processing, transportation, and disposal.[7] Formally, FDA has jurisdiction over only the former. But we argue that there is room within its existing mission to embrace at least some elements of the latter. Although the agency's power to engage in proactive environmental protection is limited, it has discretion pursuant to the Federal Food Drug and Cosmetic Act ("FDCA")[8] to take environmental considerations into account in many areas of its decision-making. Even where it cannot engage in affirmative environmental regulation, it can exercise that discretion to ensure that its approach to ingestion-related safety does not exacerbate environmental impacts.

We begin, as FDA should, with the National Environmental Policy Act ("NEPA").[9] NEPA requires FDA to identify the environmental effects of its regulatory actions. NEPA applies to "major federal actions significantly affecting the human environment" and requires agencies to prepare statements assessing the environmental consequences of and alternatives to their actions prior to implementation.[10] FDA has vastly underutilized this opportunity for environmental reflection. It considers many of its regulatory activities to be excluded from NEPA requirements, and even when NEPA does apply the agency typically takes minimal compliance steps. This Article reviews FDA's NEPA compliance activity to develop a better picture of FDA's view of its own environmental responsibilities. This review suggests that FDA does not take that responsibility seriously. To be sure, NEPA is a limited tool, and there is a significant body of literature lamenting its costs and criticizing its effectiveness at improving the environmental quality of decision-making.[11] In this context,

6. For instance, the Clean Water Act directs the Environmental Protection Agency ("EPA") to regulate water discharge from large animal feedlots. 33 U.S.C. §§ 1311(a), 1362(12), 1362(14). EPA also regulates phosphate emissions from fertilizer manufacturing facilities, 40 C.F.R. §§ 63.601–632 (2020), and licenses manufacture and sale of pesticides, 7 U.S.C. § 136a.

7. *See generally* Emily Broad Leib & Margot J. Pollans, *The New Food Safety*, 107 CALIF. L. REV. 1173 (2019) (calling for a systemic definition of food safety that incorporates cradle-to-grave food-related risks).

8. 21 U.S.C. §§ 301–399f.

9. Pub. L. No. 91-190, 83 Stat. 852 (1970) (codified as amended in scattered sections of 42 U.S.C.).

10. 42 U.S.C. § 4332(2)(C); *What Is the National Environmental Policy Act?*, EPA, https://perma.cc/2B2N-PXZZ.

11. *See, e.g.*, Joseph L. Sax, *The (Unhappy) Truth About NEPA*, 26 OKLA. L. REV. 239, 239 (1973) (criticizing NEPA as ineffectual); Dinah Bear, *Some Modest Suggestions for Improving*

however, where the environmental footprint of an agency's regulatory activity is vast, the agency's environmental mandate is limited, and the regulated industry is, to a large extent, exempt from other environmental law, NEPA represents one of the few tools in a limited arsenal and thus is worth taking seriously.

This Article argues that FDA's narrow view of its mandate reflects three conceptual mistakes. First, in most contexts, the agency defines safety narrowly to include only product safety and ignore process safety.[12] Second, the agency examines safety primarily via an ingredient-by-ingredient approach and therefore often misses the cumulative effects of food and food packaging production, consumption, and disposal. Third, the agency defines safety only at the individual level and, in most cases, fails to consider population level health and safety. We return to these three themes throughout the Article as motivating explanations for FDA's current regulatory behavior and as guideposts for potential reform.

Ultimately, we argue, even if FDA will never be the Environmental Protection Agency ("EPA") of food,[13] it has the power to be an integral player in environmental protection. Environmental concerns are inextricable from ingestion-related public health goals,[14] and FDA has a variety of regulatory tools at its disposal to address them. Although we do not argue that FDA should take on the primary responsibility of regulating the full scope of food system environmental effects, it should seek to minimize the extent to which its own regulatory actions may exacerbate those effects. More robust use of NEPA may allow the agency to identify opportunities for incorporating environmental concerns into its daily decision-making.

Implementation of the National Environmental Policy Act, 43 NAT. RES. J. 931, 935 (2003) (arguing that NEPA is not sufficiently incorporated into agency decision-making processes); Bradley C. Karkkainen, *Whither NEPA?*, 12 N.Y.U. ENV'T L.J. 333, 338 (2004) (criticizing NEPA's approach to information gathering). *See generally* Daniel R. Mandelker, *Thoughts on NEPA at 40*, 39 ENV'T L. REP. 10640 (2009).

12. *See* Broad Leib & Pollans, *supra* note 7, at 1193–99 (offering a historical hypothesis for FDA's narrow focus on food-borne illness and situating the process/product distinction in an analysis of FDA's understanding of food safety); Douglas A. Kysar, *Preferences for Processes: The Process/Product Distinction and the Regulation of Consumer Choice*, 118 HARV. L. REV. 525, 560 (2004) (discussing FDA's emphasis on product over process in the context of regulation of genetically modified foods).

13. FDA's narrow focus simplifies its task, relieving it of the challenge of balancing sometimes competing regulatory goals. Eric Biber, *Too Many Things to Do: How to Deal with the Dysfunctions of Multiple-Goal Agencies*, 33 HARV. ENVTL. L. REV. 1, 2–6 (2009) (introducing the challenges faced by multiple-goal agencies). And there are many reasons to think that FDA would be ill-suited as an environmental regulator. It has neither the infrastructure nor the expertise to ramp up comprehensive environmental regulation of food production. For additional discussion of the limits to the agency's potential as an environmental regulator, see *infra* Part I.B.

14. *See* Broad Leib & Pollans, *supra* note 7, at 1215–20, 1224–30 (elaborating on the nature of these interconnections).

FDA should also take the limited opportunities available through existing statutory authority to engage in affirmative environmental regulation, particularly where such actions are consistent with its other regulatory goals. We identify two strategies. First, FDA has the authority to ensure that its approach to regulating ingestion-related food safety does not exacerbate environmental impacts of food production. In some narrow instances, it may even directly regulate those environmental impacts. The Article focuses on FDA's authority over food packaging, animal drugs, and food additives.

Second, through its mandate to prevent food fraud, FDA controls consumer access to information. The agency has power over mandatory disclosures, including the nutrition facts panel, food standards of identity (e.g., requirements for what products can be considered milk, yogurt, or bread), and voluntary label claims. Within each of these information contexts, FDA influences food choices and can steer consumers toward more environmentally friendly dietary patterns.

Part I of this Article explores FDA's mandate, considering the scope of the agency's authority to regulate on environmental grounds. It also briefly makes the case that FDA should engage in at least some environmental regulation. FDA is not, and cannot easily become, the primary environmental regulator of food production. The challenge of incorporating environmental ethics into FDA decision-making sheds light on the broader problem of holistic decision-making in modern multipurpose federal agencies. Adding environmental concerns to FDA's already significant regulatory burden risks piling on, distracting from the agency's primary goals, and setting unrealistic expectations for agency activity. Despite these concerns, however, FDA should play a role in environmental regulation of food production, and that role is permissible within its existing statutory mandate.

Part II reviews FDA's NEPA compliance history. We show, through analysis of NEPA compliance documents, that FDA does the bare minimum necessary to meet its statutory obligations. This history of NEPA avoidance confirms the hypothesis that FDA does not view its work as environmental. The agency's NEPA compliance documents also illustrate two of the three conceptual mistakes described above—the focus on product over process and the overemphasis on individual ingredients.

Part III imagines FDA as an environmental agency. Part III begins with a brief analysis of the challenges of this path and suggests NEPA as a jumping off point for identifying environmental concerns across FDA decision-making. NEPA analyses can also provide the agency the information that it needs to begin to take some of the other steps identified in this Article. We then explore the areas for substantive action within FDA's food safety and food fraud mandates. Here we engage with the third conceptual mistake—the emphasis on individual-level as opposed to population-level health and safety.

We conclude with the argument that FDA is not unique. Many non-environmental agencies have regulatory portfolios with significant environmental consequences. NEPA recognizes this concern and creates a procedural mechanism in response.[15] In limited contexts, such as climate change, the Executive Office of the President has, at times, also acknowledged this and ordered agencies to take substantive steps to address their environmental footprints.[16] But formal substantive incorporation of environmental goals across the federal government remains out of reach. We offer this roadmap for FDA in part as a model that might be applied to other federal agencies.

I. The FDA and the Environment

Food, like any other consumption industry, has an environmental footprint. What is unique about food is that it is not subject to a comprehensive environmental regulatory scheme. This is not to say that the industry is entirely unregulated, but the regulatory scheme is haphazard, arbitrarily addressing some externalities but not others. Numerous environmental impacts of agriculture remain entirely or almost entirely unregulated, including non-point source water pollution, agricultural air emissions, energy use, and destruction of biodiversity.[17] Other food industry issues are subject to piecemeal state and local regulations. For instance, in some states and localities, organic waste (which is primarily food waste) is banned from traditional solid waste streams and must be donated or composted.[18] Many states and localities also mandate recycling and limit single use plastic food packaging, particularly grocery bags.[19]

15. *See infra* Part II (describing the limits of this mechanism to achieve the desired goal of incorporating environmental concerns into everyday agency decision-making).

16. Exec. Order No. 13,693, 3 C.F.R. 281 (2016) (ordering all federal agencies to reduce their greenhouse gas emissions and improve energy and water use practices), *revoked by* Exec. Order No. 13,834, 3 C.F.R. 814 (2018); Exec. Order No. 13,990, 86 Fed. Reg. 7037 (Jan. 20, 2021) (directing agencies to review any actions taken during the Trump Administration that conflict with the objective of combatting climate change).

17. *See generally* J.B. Ruhl, *Farms, Their Environmental Harms, and Environmental Law*, 27 Ecology L.Q. 263, 266 (2000); Margot J. Pollans, *Drinking Water Protection and Agricultural Exceptionalism*, 77 Ohio St. L.J. 1195 (2016); Mary Jane Angelo et al., Food, Agriculture, and Environmental Law (2013).

18. *See, e.g.*, 310 Mass. Code Regs. 19.017 (2014) (banning "commercial organic material" from solid waste disposal facilities as of October 1, 2014); *see also* David Abel, *The State's Ban on Food Waste Lacks Teeth, Critics Say*, Bos. Globe (Feb. 26, 2019), https://perma.cc/NLM8-39TC (asserting that insufficient inspections and issuance of fines has led even stricter state food waste management programs to be ineffective).

19. *See, e.g.*, N.Y. Env't Conservation Law § 27-2803 (McKinney 2021) (banning distribution of "plastic carryout bags").

FDA is one of two primary food regulatory agencies, along with the U.S. Department of Agriculture ("USDA").[20] This Part argues that although FDA does not have an express environmental mandate, the agency should, and may, use existing regulatory authority to take more aggressive action to reduce the food system's environmental externalities. We begin with a brief overview of the agency's environmental authority and then make the case that it should use that authority.

A. FDA's Environmental Regulatory Authority

FDA has considerable discretion to make regulatory decisions designed to reduce environmental consequences. We identify here some overarching provisions of the FDCA and the FDA Food Safety Modernization Act ("FSMA")[21] that allow, or even invite, FDA to take on a role as an environmental agency. In Part III, below, we delve more deeply into particularly relevant FDA regulatory programs.

The FDCA contains no express mention of environmental issues. Instead, the statute establishes various sets of criteria for FDA approval that orbit around the broad goal of food "safety."[22] Many of these sets of criteria are vague—allowing the agency wide discretion to determine, for instance, under what circumstances a food additive "may be safely used."[23] The statute defines safe use by reference to several ingestion-related factors such as "the cumulative effect of such additive in the diet of man or animals."[24] But the statute also invites consideration of "other relevant factors."[25] Courts have confirmed, in the animal drug context, that environmental considerations may properly fit within "other relevant factors" for purposes of FDA's safety regulation.[26] Although the

20. Of course, there are many other agencies with regulatory authority over various aspects of the food system, including, among others, the Federal Trade Commission ("FTC") (authority over food advertising), EPA (authority over pesticides), the Department of Labor (authority over workplace safety in food production), and the Department of Commerce (authority over international food trade). For a detailed discussion of division of labor over food safety, see RENEE JOHNSON, CONG. RSCH. SERV., THE FEDERAL FOOD SAFETY SYSTEM: A PRIMER (2016).

21. Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified in scattered sections of the U.S. Code).

22. The agency's own mission statement repeats this trend, announcing that the agency "is responsible for protecting the public health by ensuring the safety . . . of our nation's food supply." *What We Do*, *supra* note 1; *accord* Broad Leib & Pollans, *supra* note 7, at Part I (arguing that FDA narrowly defines safety).

23. 21 U.S.C. § 348(c)(1)(A).

24. *Id.* § 348(c)(5)(B).

25. *Id.* § 348(c)(5).

26. *See, e.g.*, Inst. for Fisheries Res. v. FDA, 499 F. Supp. 3d 657, 663–64 (N.D. Cal. 2020) (rejecting FDA's argument that the FDCA precludes consideration of environmental factors and holding that the "other relevant factors" language "[a]t a minimum . . . means that a

language is likely not so broad as to allow FDA to ban additives for purely environmental reasons, it certainly does not foreclose environmental considerations where they are relevant to human and animal safety.[27] Indeed, where an FDA decision generates environmental risks, ignoring that factor might be construed as arbitrary and capricious. Parts III.B and III.C take a deeper dive into some specific FDCA provisions that provide FDA discretion and, in some cases, obligation, in this regard.

Unlike the FDCA, FSMA expressly requires FDA to take environmental considerations into account. The statute directs the agency to develop rules to ensure the safety of raw produce and requires the agency to "take into consideration, consistent with ensuring enforceable public health protection, conservation and environmental practice standards and policies established by Federal natural resource conservation, wildlife conservation, and environmental agencies."[28] In other words, the statute mandates that FSMA regulations should not conflict with or undermine the goals of conservation and environmental practices undertaken pursuant to federal programs.[29]

This mandate to avoid conflict with the conservation programs and policies of other agencies overlays FSMA's regulatory directives, which are themselves extremely broadly worded and leave FDA with great flexibility as to how to implement them. The statute directs FDA to:

> [E]stablish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities for which the Secretary has determined that such

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threat to the health of *any* human or animal would be properly within the scope of the Secretary's evaluation").

27. *See id.* at 662–64. In that case, the court rejected as "wrong" FDA's argument that it did not need to engage in environmental review under the FDCA when it took action to allow the operation of facilities that farm genetically engineered salmon. *Id.* More particularly, in considering the action-forcing purpose of NEPA, to inform agency decisions, the court held that "FDA's narrow view of its authority [to engage in environmental review under the FDCA] becomes even less defensible" because "NEPA is largely designed to ensure that agencies take environmental concerns into account when deciding whether to take a particular action" and if "FDA were precluded from acting on the concerns that NEPA requires it to consider, the purpose of the statute would be largely undermined." *Id.* at 663–64. The court ultimately held that FDA "was required to consider—and had the authority to act upon—concerns regarding the effect of AquAdvantage salmon on normal salmon," which were the only environmental effects at issue in the case. *Id.* at 664–65.

28. 21 U.S.C. § 350h(a)(3)(D).

29. *But see* Margot J. Pollans, *Regulating Farming: Balancing Food Safety and Environmental Protection in a Cooperative Governance Regime*, 50 Wake Forest L. Rev. 399, 420–27 (2015) (arguing that FSMA rules may do exactly that).

> standards minimize the risk of serious adverse health consequences or death.[30]

Given this instruction, FDA can consider particular categories of activity—biological soil amendments such as animal manure; worker hygiene; packaging; temperature control; animals in the growing area; and water—but the agency is not required to establish any particular on-farm safety practices.[31] Nor does the statute require elimination of all pathogen risk, leaving open the possibility that some levels of reasonable risk may be appropriate under circumstances in which further reduction of pathogen risk would generate significant environmental risk.[32] Despite the reach and flexibility FDA has through FSMA, however, the agency is limited in its ability to regulate environmental externalities beyond the fence-line of the farm. For instance, it has no authority to regulate what is potentially one of the most significant sources of microbial contamination of produce: concentrated animal feeding operations ("CAFOs").[33]

Neither the FDCA nor FSMA nor any of the other statutes granting FDA power provide blanket environmental authority, but these statutes offer the agency significant discretion. Next we argue that the agency should use it.

B. FDA as an Environmental Regulator

FDA is not an obvious regulator for environmental problems. Its regulatory purview is primarily over *products*—i.e., consumer safety related to use and ingestion of food and drugs—rather than over *process*—i.e., the circumstances and methods of production, distribution, and disposal of food and drugs. To

30. 21 U.S.C. § 350h(a)(1)(A).

31. *Id.* § 350h(a)(3)(B).

32. *Id.* § 350h(c)(1)(A) (requiring implementation only of "reasonably necessary" standards designed to prevent against "reasonably foreseeable" risk). Indeed, the only way to eliminate all risk from raw agricultural commodities would be to ban raw agricultural commodities.

33. The statute directs FDA to set standards for "the safe production and harvesting" of raw agricultural commodities. *Id.* § 350h(a)(1)(A). Although arguably regulating neighboring CAFOs would be a strategy for achieving the safe production and harvesting of agricultural commodities, the structure of the produce safety section, the legislative history of the statute, and the background regulatory context in which meat production and processing are regulated by an entirely different agency under and entirely different set of laws, would all suggest that FDA does not have such authority. *See id.* § 2251 (clarifying that nothing in FSMA is meant to upset the allocation of authority between the USDA and FDA); *id.* § 350h(a)(3)(B) (directing FDA to address concerns related to "animals *in the growing area*" (emphasis added)). See also the Leafy Greens STEC Action Plan (STEC refers to Shiga toxin–producing *E. coli*), in which FDA is working with public and private partners to prevent food-borne illness associated with leafy greens by taking action to set standards for agricultural water conditions for particular crops and antimicrobial water treatments for preharvest water, but FDA does not have the capacity to regulate the arguable root-sources of contamination—CAFO water contaminants themselves. *Leafy Green STEC Action Plan – Accomplishments*, FDA (Apr. 6, 2021), https://perma.cc/7AJX-M26L.

the extent that the agency has historically focused on process, it has done so where process affects product safety. For instance, it regulates the sanitary conditions in which food is produced.[34] FSMA continued this trend, directing FDA to regulate on-farm produce growing, harvesting, and packing practices in order to reduce microbial contamination.[35] FDA's staff expertise and institutional resources are thus oriented toward ingestion and use-related safety.[36] Nevertheless, we argue that FDA should take on an environmental regulatory role to the extent that its decisions in other realms have significant environmental consequences. It should ensure that its regulatory activities promote rather than detract from environmental progress in the food system.

We identify three pragmatic reasons why FDA should become a quasi-environmental agency. The first is efficiency and clarity. Many FDA decisions have consequences for what food is produced, how food is produced and processed, and how it is disposed. The environmental footprint of the food system is well-documented, and, as FDA decisions shape particular aspects of that system, those decisions have environmental implications.[37] FSMA provides a clear illustration: the statute directs FDA to establish minimum standards for growing, harvesting, and packing raw produce. These rules influence farm management choices, including practices such as water use and wildlife management, and thus affect agriculture's environmental footprint.[38] Similarly, FDA has authority to approve or exclude food additives, thereby influencing which food additives are produced.[39] Removing particular food additives from production accordingly affects the material footprint of the food system.[40]

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34. *See* 21 U.S.C. § 342(a)(4) (defining "adulterated food" to include food that "has been prepared, packed, or held under insanitary conditions").

35. FDA Food Safety Modernization Act, Pub. L. No. 111-353, § 105(a)(1)(A), 124 Stat. 3885, 3899–90 (2011) (codified at 21 U.S.C. § 350h(a)(1)(A)) (directing FDA to establish minimum standards for the "safe production and harvesting of . . . raw agricultural commodities").

36. *See also* FDA, STAFF MANUAL GUIDE 1110.1, at 1 (1997), https://perma.cc/HAU5-SZ2L (stating that FDA's mission is to: "(a) Promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner; (b) With respect to such products, protect the public health by ensuring that: foods are safe, wholesome, sanitary, and properly labeled; human and veterinary drugs are safe and effective . . . ."); *cf.* Todd Aagard, *Environmental Law Beyond the Canon*, 89 IND. L.J. 1239, 1272–73 (2014) (observing that "embedded environmental laws," i.e., environmental laws that are integrated with non-environmental regulatory mandates can be challenging to implement because agencies other than EPA lack EPA's vast expertise in environmental protection).

37. *See supra* note 17 and accompanying text.

38. Pollans, *supra* note 29 (exploring the environmental effects of FSMA rulemaking).

39. 21 U.S.C. §§ 342(a)(2)(C), 348.

40. *See infra* Part III.A.3 (exploring this possibility in more detail).

Environmental agencies, including EPA and others like the Fish and Wildlife Service, might be preferable regulators.[41] These agencies have the expertise and the internal political will to engage in robust environmental protection.[42] But if they stepped into the fray unilaterally, the risk of counterproductive, or even directly contradictory, regulation would remain. For instance, in FDA's early efforts to address on-farm risks to produce safety, the agency made a variety of decisions that were at cross-purposes with longstanding USDA conservation programs.[43] Given FDA's extensive role and influence in the food system, folding environmental considerations into its existing work could increase efficiency and consistency between environmental and food safety regulation. At the very least, this folding-in might help reduce the extent to which FDA directives themselves exacerbate environmental harms and thereby reduce the need for environmental agencies to step in to redress those additional harms.

Second, because there are significant gaps in the existing authority of environmental agencies, identifying pathways through the existing statutory authority of non-environmental agencies is essential to achieving progress. Environmental agencies might in theory directly regulate food producers to ensure that they rein in environmental externalities in the process of complying with FDA's food safety directives. In practice, environmental agencies are constrained by the scope of their own regulatory authority.[44] Federal environmental agencies do not currently have the authority either to ensure that FDA does not undermine their efforts at environmental protection or to engage in more direct regulation of the environmental externalities of the food system. Further, the immediate prospects for statutory change are quite limited.

Finally, environmental protection, like anti-racism and poverty-alleviation, is a public interest goal that likely cannot be achieved if it is solely the purview of a particular issue-specific agency.[45] Instead, it can be achieved only if it is

41. This argument follows from what Yoon-Ho Alex Lee calls the "core mission" model of agency regulation. Yoon-Ho Alex Lee, *Beyond Agency Core Mission*, 68 ADMIN. L. REV. 551, 554–55 (2016) (identifying a "pervasive sense that each regulatory agency's agenda should be guided by a narrowly defined core mission" and arguing that there are "good reasons to move beyond conceptualizing regulatory agencies in terms of core missions").

42. Of course, the scope of this politically ebbs and flows.

43. *See* Pollans, *supra* note 29, at 420–27 (describing tension between early drafts of the Produce Safety Rule and the Conservation Stewardship Program).

44. *See supra* note 17 (citing sources documenting the "agricultural exceptionalism" of environmental law).

45. For examples of calls to incorporate anti-racist ideology across the federal government, see Exec. Order No. 13,985, 86 Fed. Reg. 7009, 7009 (Jan. 20, 2021) (announcing that "[o]ur Nation deserves an ambitious whole-of-government equity agenda that matches the scale of the opportunities and challenges that we face" and ordering that "[b]ecause advancing equity requires a systematic approach to embedding fairness in decision-making processes, executive departments and agencies must recognize and work to redress inequities in their policies

embedded across the regulatory agenda by every agency whose decisions have significant environmental implications. As further discussed in Part II, NEPA reflects this concern on a systemic basis. Through NEPA, Congress recognized that all kinds of decisions have environmental implications, and the statute requires that all federal agencies consider those implications. In this sense, NEPA is a tool meant to "embed" environmental law across the federal government.[46] NEPA "essentially provides institutional support for the implementation of embedded environmental laws."[47] We argue in Parts II and III that NEPA provides a procedural mechanism for FDA to begin to transform into an environmental agency, pushing the agency to take advantage of its existing, and underutilized, substantive power to take environmental goals into account.

Internalizing environmental decision-making at FDA itself is essential to managing the food system's environmental footprint. Such an approach recognizes that while FDA does not have environmental expertise, it does have expertise about various aspects of the food system and may therefore be well-positioned to mitigate environmental harms in this space.[48]

Interagency coordination and oversight can help FDA to make decisions that generate fewer negative environmental externalities (or more positive environmental externalities) but is also quite constrained under existing law. EPA is required to review and comment on certain NEPA compliance efforts of other agencies, but EPA conducts review only of environmental impact statements ("EISs").[49] If EPA finds an EIS to be inadequate, it files a statement to that effect with the Council on Environmental Quality ("CEQ"), but it has no

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and programs that serve as barriers to equal opportunity"); Joe Davidson, *Susan Rice Wants Every Federal Agency to Focus on Racial Equity*, WASH. POST (Jan. 29, 2021), https://perma.cc/7QF7-F82D (observing Rice, the head of President Biden's Domestic Policy Council, is focused on creating "a whole-of-government enterprise that goes well beyond the regular confines of diversity rhetoric about staffing and contracting, and into every program of every federal agency"); Andre M. Perry & Darrick Hamilton, *Just as We Score Policies' Budget Impact, We Should Score for Racial Equity As Well*, BROOKINGS INST. (Jan. 25, 2021), https://perma.cc/4Q3F-Y8CC.

46. Aagard, *supra* note 36, at 1257–59 (observing that NEPA implementation "becomes integrated with other, non-environmental law").

47. *Id.* at 1281. "Embedded environmental laws" are environmental laws that are situated "within larger programs that are not primarily environmental and that are usually administered by agencies not primarily engaged in environmental lawmaking." *Id.* at 1243.

48. Lee, *supra* note 41, at 589–93 (considering the range of types of expertise that agencies develop and observing that certain kinds of functional expertise justify agency action beyond the agency's core mission).

49. 42 U.S.C. § 7609(a); *Environmental Impact Statement Filing Guidance*, EPA, https://perma.cc/QX7U-HJRF (laying out procedure for EPA's NEPA review). *But see* Daniel A. Farber & Anne Joseph O'Connell, *Agencies as Adversaries*, 105 CALIF. L. REV. 1375, 1398 (2017) (suggesting that in at least some instances EPA can exert political influence to push other agencies to revise their NEPA review documents in light of EPA's comments).

power to stop the agency action.[50] Some other environmental statutes, such as the Comprehensive Environmental Response, Compensation, and Liability Act, give EPA authority over the activities of other federal agencies.[51] But EPA does not have the express power to step in any time an agency generates (or simply fails to curtail) significant environmental harms.[52] Other statutes, give environmental agencies advisory power, but these powers tend to be narrow and context specific.[53] For instance, the Endangered Species Act ("ESA") requires that federal agencies consult with the Fish and Wildlife Service and the National Marine Fisheries Service when agency actions potentially jeopardize threatened and endangered species.[54] These kinds of interagency coordination and influence mechanism can serve important roles, but they are not a perfect substitute for internalizing environmental decision-making across the federal government.[55]

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50. 42 U.S.C. § 7609(b).
51. *See id.* § 9620 (establishing that other federal agencies can be liable for environmental cleanup just as private entities are and are subject to the same cleanup protocols and standards that EPA establishes for private entities).
52. The Department of Justice has long maintained that because both the Environmental Enforcement Section and the Environmental Defense Section represent "the United States of America," EPA cannot bring environmental enforcement actions against other agencies. Charles de Saillan, *The Use of Imminent Hazard Provisions of Environmental Laws to Compel Cleanup at Federal Facilities*, 27 STAN. ENV'T L.J. 43, 77–80 (2008) (describing this history). Some statutes, such as the Endangered Species Act ("ESA"), specifically contemplate various forms of interagency oversight but still do not give environmental agencies authority to use the courts to engage in enforcement actions against other agencies. 16 U.S.C. § 1536; Farber & O'Connell, *supra* note 49, at 1390–91 (offering the ESA as an example of a law that creates a hierarchy between two environmental agencies—the Fish and Wildlife Service and the National Marine Fisheries Service—and other federal agencies that are subject to the ESA's consultation requirement). Other federal statutes give EPA certain express regulatory authority over other agencies; for instance, under the Clean Water Act, 33 U.S.C. §§ 1251–1387, EPA can reverse Army Corps of Engineers decisions. *See* Farber & O'Connell, *supra* note 49, at 1391.
53. Jody Freeman & Jim Rossi, *Agency Coordination in Shared Regulatory Space*, 125 HARV. L. REV. 1131, 1157–73 (2012) (cataloguing various mechanisms for interagency consultation where multiple agencies have overlapping regulatory jurisdiction); Farber & O'Connell, *supra* note 49, at 1398 (describing EPA's authority to comment on other agencies' NEPA processes).
54. 16 U.S.C. § 1536 (requiring consultation to ensure that agency actions are "not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of habitat of such species").
55. *See generally* Freeman & Rossi, *supra* note 53 (exploring the limits of interagency coordination to address the redundancy, inefficiency, and incoherence of overlapping regulatory jurisdictions); Keith Bradley, *The Design of Agency Interactions*, 111 COLUM. L. REV. 745 (2011) (exploring how agencies influence each other and identifying "rule-based interfac[ing]," where one agency writes enforceable rules controlling another, as one of the most effective means for this interaction); Biber, *supra* note 13, at 41–59 (putting interagency interactions on a continuum from "lobbying" to "regulating").

Despite the discretion built into the FDCA and FSMA and the need to fill the regulatory gap in this arena, FDA does not view itself as having environmental authority. To test this hypothesis, in the next Part we examine how FDA has approached NEPA compliance.

II. NEPA Compliance: An Avoidance Story

FDA's NEPA history demonstrates that FDA neither views its work as having significant environmental implications nor views itself as an environmental regulator. We review FDA's history of NEPA compliance to demonstrate its failure to take advantage of the significant opportunity for environmental reflection the statute provides.

NEPA requires that federal agencies evaluate the environmental impacts of major federal actions.[56] A procedural statute, it requires only environmental analysis, leaving decision-making agencies free to choose whichever course of action they prefer regardless of the outcomes of that analysis.[57] Nevertheless, NEPA is a potentially powerful tool due to its ability to turn the mirror on federal actors with the intent of having them grapple with the foreseeable environmental consequences of their choices.[58] NEPA provides an avenue for public participation, which can improve the accountability and responsiveness of agency decision-making.[59] It also forces information generation, which can inform both agency decision-making and future public advocacy.[60] Although commentators disagree about the extent to which the integration of these environmental insights occurs in practice, there is no question that the statute gen-

56. 42 U.S.C. § 4332.

57. *See* Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 350 (1989).

58. *See* Michael B. Gerrard, *The Effect of NEPA Outside the Courtroom*, 39 Env't L. Rep. News & Analysis 10,615, 10,615–16 (2009); Kenneth S. Weiner, *NEPA and State NEPAs: Learning from the Past, Foresight for the Future*, 39 Env't L. Rep. News & Analysis 10,675, 10,681–83 (2009); Richard Lazarus, *The National Environmental Policy Act in the U.S. Supreme Court: A Reappraisal and a Peek Behind the Curtains*, 100 Geo. L.J. 1507, 1518–20 (2012) (describing the mechanisms through which NEPA may actually change agencies' substantive decision-making); Robert W. Adler, *In Defense of NEPA: The Case of the Legacy Parkway*, 26 J. Land Res. & Env't L. 297, 300–01 (2006) (arguing that while at the extremes NEPA can be used by plaintiffs to simply delay projects and can be used by agencies to rubber stamp projects, there are many projects "that have been made more environmentally sound by routine NEPA compliance"); Env't L. Inst., NEPA Success Stories: Celebrating 40 Years of Transparency and Open Government (2010), https://perma.cc/GN2X-RA6T (offering a series of case studies of projects improved as a result of NEPA).

59. *See* William Murray Tabb, *The Role of Controversy in NEPA: Reconciling Public Veto with Public Participation in Environmental Decisionmaking*, 21 Wm. & Mary Env't L. & Pol'y Rev. 175 (1997).

60. Bradley C. Karkkainen, *Toward a Smarter NEPA: Monitoring and Managing Government's Environmental Performance*, 102 Colum. L. Rev. 903, 909–16 (2002) (describing the theoretical benefits of NEPA-generated information).

erates at least the possibility and opportunity to fold environmental ethics into agency decisions.[61]

For "major Federal actions significantly affecting the quality of the human environment," NEPA mandates that agencies draft detailed documents referred to as EISs.[62] CEQ promulgates regulations directing agencies on how to implement this directive.[63] As a precursor to the preparation of an EIS, federal actors sometimes first prepare much shorter documents called environmental assessments ("EAs").[64] Upon review, EA submissions result in either a finding of no significant impact ("FONSI") or, if the EA turns up significant environmental impacts, a decision to draft an EIS.[65] In the context of industry applications for regulatory approvals, EAs themselves are typically drafted by applicants rather than by FDA itself. After issuing a FONSI, the agency can move forward with its proposed action under NEPA; whereas, if an EIS is required, much more research and compilation of data on alternative options for that action must be prepared. Most agencies, including FDA, also generate categorical exclusions ("CEs") to NEPA. CEs identify actions that will typically have no significant environmental impact.[66] Subsequently, when an agency proceeds with such actions, absent a showing of extraordinary circumstances, it will not be required to draft either an EA or an EIS.[67] FDA regulations provide CEs for, among other things, corrections to FDA regulations, amendments to food standards, and establishment or repeal of certain labeling requirements.[68]

After NEPA's enactment in 1970, FDA initially took the position that it had no authority to "take or refrain from taking action on the basis of a determination of adverse environmental impact."[69] The U.S. District Court for the District of Columbia rejected this position, concluding that while NEPA did not require "FDA's substantive decisions to favor environmental protection over other relevant factors," the statute did provide "FDA with supplementary au-

61. *Compare* Lazarus, *supra* note 58, at 1518–20 (observing NEPA's substantive potential), *with* Sax, *supra* note 11, at 239 (arguing that NEPA was based on faulty assumptions about agency decision-making processes).

62. 42 U.S.C. § 4332(2)(C).

63. In 2020, the Trump Administration engaged in wholesale revision of these rules, rejecting decades of settled NEPA practice, but at the time of writing, the Biden Administration is still reviewing these rules. National Environmental Policy Act Implementing Regulations Revisions, 86 Fed. Reg. 55,757 (proposed Oct. 7, 2021) (to be codified at 40 C.F.R. pts. 1502, 1507, 1508).

64. In situations where an EIS is obviously required, agencies will skip the EA process and begin with the EIS itself. CEQ, A CITIZEN'S GUIDE TO NEPA 8 (Jan. 2021), https://perma.cc/LRA2-TPU7 (showing this alternate path).

65. See 40 C.F.R. § 1501.3 (2020) for the criteria used to determine the appropriate level of NEPA review and whether an EIS must be prepared.

66. *Id.* § 1508.1(d); *National Environmental Policy Act Review Process*, EPA, https://perma.cc/ZM2X-5YTG.

67. 40 C.F.R. § 1508.1(d) (2020).

68. 21 C.F.R. § 25.32 (2021) (listing CEs for foods, food additives, and color additives).

69. Env't Def. Fund, Inc. v. Mathews, 410 F. Supp. 336, 338 (D.D.C. 1976).

thority to base its substantive decisions on all environmental considerations including those not expressly identified in the [Food Drug and Cosmetic Act] and FDA's other statutes."[70] Following this decision, FDA established a policy that "the weight to be accorded environmental factors must be determined on a case-by-case basis."[71]

Despite FDA's clear authority to consider and give weight to environmental factors, it has placed little emphasis on such considerations. The leading Food and Drug Law textbook addresses environmental issues through an analysis of NEPA compliance in a five-page section at the end of the 1,500-page book.[72] According to the casebook authors, "[t]he agency has rarely taken action in which it has identified environmental effects not involving risks to human health as an influential consideration."[73] Although FDA has seldom flouted NEPA compliance entirely, its history with the statute supports the hypothesis that the agency does not view itself as an environmental regulator and does not view its work as having significant environmental implications.[74]

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70. *Id.* (rejecting an FDA rule determining that the agency need not comply with NEPA on the ground that "a determination of adverse environmental impact has no legal or regulatory effect and does not authorize the Commissioner to take or refrain from taking any action under the laws he administers" (citation omitted)); *see also* Daniel B. Rodriguez & Barry R. Weingast, *The Paradox of Expansionist Statutory Interpretations*, 101 NW. U. L. REV. 1207, 1245 n.152 (2007) (characterizing *Env't Def. Fund, Inc. v. Mathews*, 410 F. Supp. 336 (D.D.C. 1976), as an "expansionist" interpretation of NEPA).

71. Plastic Bottles for Carbonated Beverages and Beer, 42 Fed. Reg. 9227, 9228 (Feb. 15, 1977).

72. These numbers are meant not as a critique of the casebook but as evidence of the small role that environmental consideration has played in FDA decision-making. *See* PETER BARTON HUTT ET AL., FOOD AND DRUG LAW 1526–30 (4th ed. 2013); *accord* Susan A. Schneider, *Beyond the Food We Eat: Animal Drugs in Livestock Production*, 25 DUKE ENV'T L. & POL'Y F. 227, 267–73 (2015) (describing FDA's NEPA obligations and its history of skirting compliance with regard to animal drugs).

73. HUTT ET AL., *supra* note 72, at 1527.

74. Some commentators argue that FDA regularly violates, if not the letter, then at least the spirit of, NEPA. *See* Brett M. Paben, *Lack of Interest in Consumer Interests: FDA's Narrow Perspective on Food Labeling and Label Statements Undermines a Century of Agency Leadership*, 13 RUTGERS J.L. & PUB. POL'Y 174, 208–09 (2015) (suggesting that FDA avoids NEPA compliance by making decisions through guidance documents, which are not final agency action subject to NEPA, rather than through notice and comment rulemaking); Zoe M. Grant, *The Plastic Pollution Crisis: Combatting Plastics Through NEPA Challenges to FDA's Food Contact Substance Regulations*, 35 J. ENV'T L. & LITIG. 371 (2020) (laying out some possible NEPA challenges to recent FDA decisions).

A. NEPA Compliance in the Food Context

1. The Rare EIS and the Limits of FDA NEPA Compliance

In 1985, FDA formalized the view that its work is not environmental in nature in a regulation, stating that "[t]here are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS."[75] The agency's original 1973 NEPA implementing regulations contemplated that the agency would consider drafting an EIS for a variety of regulatory actions,[76] but the 1985 regulations rejected this approach, observing that "the agency could not identify any classes of actions that would routinely require the preparation of an EIS."[77] Since NEPA was enacted in 1970, FDA has drafted only a handful of EISs. We found only one done between 1970 and 1987. In this EIS, the agency evaluated the environmental impact of plastic bottles as a response to several food additive petitions submitted by industry actors to FDA to obtain clearance to use certain plastic resins in the manufacture of bottles for carbonated beverages and beer.[78] The final EIS identified a number of beneficial environmental effects for the use of plastic bottles over other non-refillable glass and metal bottles, including energy savings, a reduction in cuts caused by broken glass bottles, and advantages in disposal by incineration.[79] The EIS did take note that to the extent that plastic bottles would replace refillable glass bottles, approval would lead to increases in litter, solid waste, and manufacturing efflu-

75. 21 C.F.R. § 25.22(a) (1985); National Environmental Policy Act; Policies and Procedures, 50 Fed. Reg. 16,636, 16,639 (Apr. 26, 1985) (to be codified in scattered parts of 21 C.F.R.). In 1997, FDA again overhauled regulations, seeking to "reduce the number of NEPA evaluations" and thus to "increase[ ] the efficiency of the agency's implementation of NEPA." National Environmental Policy Act; Revision of Policies and Procedures, 62 Fed. Reg. 40,570, 40,570 (July 29, 1997) (to be codified in scattered parts of 21 C.F.R.) (repeating the conclusion that no categories of actions will routinely trigger EIS requirements and adding categories of CEs).

76. Environmental Impact Statements: Procedures for Preparation, 38 Fed. Reg. 7001, 7003 (Mar. 15, 1973) (to be codified in scattered parts of 21 C.F.R.).

77. National Environmental Policy Act; Policies and Procedures, 50 Fed. Reg. at 16,639.

78. Plastic Bottles for Carbonated Beverages and Beer, 42 Fed. Reg. 9227 (Feb. 15, 1977). Specifically, beverage companies submitted food additive petitions seeking to permit use of "certain polymeric materials with special gas barrier properties in food contact containers. These special characteristics make the materials physically suitable for packaging carbonated beverage and beer." *Id.* at 9228; *see also* FDA, DRAFT ENVIRONMENTAL IMPACT STATEMENT: PLASTIC BOTTLES FOR CARBONATED BEVERAGES AND BEER (Apr. 1975).

79. Plastic Bottles for Carbonated Beverages and Beer, 42 Fed. Reg. at 9228–29 (acknowledging that incineration of plastic bottles might expose the public to toxic gases but concluding that the danger was not any higher than that which occurred with incineration of other materials).

ent.[80] Ultimately, FDA determined that the adverse environmental effects of the action, to some extent offset by the potential beneficial effects, were not of sufficient magnitude to justify limitation or revocation of food additive regulations permitting plastic bottles for carbonated beverages and beer.[81] FDA acknowledged that its conclusion appeared to be inconsistent with EPA efforts to reduce the environmental effects of beverage containers, but it concluded that "in the absence of potentially adverse environment impact of sufficient magnitude to justify an alternate action under the authority of NEPA," it was bound by the FDCA to approve the plastic resins as food additives so long as the additives were deemed safe for their intended uses.[82]

An EPA EIS Database, which tracks EISs since 1987, contains only two entries for FDA.[83] One of the two examines the environmental impact of constructing an FDA regional office in New York.[84] The second is an EIS assessing the environmental impacts of the FSMA Produce Safety Rule.[85] This EIS is remarkable both for its depth and for its rarity. Although FDA began the FSMA rulemaking process by announcing that the rules were subject to a CE, the agency ultimately decided to draft an EIS.[86] The final EIS, a 700-page tome, carefully catalogued the many ways that the regulation of produce safety might affect agricultural environments and was published simultaneously with publication of the final Produce Safety Rule.[87] The document considered consequences for water use, wildlife habitat, and human pesticide exposure.[88] Former FDA Commissioner Margaret Hamburg referred to this as an eye-opening experience about the relationship between food production and the environ-

80. *Id.* at 9229; *see also* Complaint at 5–6, Earth Island Inst. v. Crystal Geyser Water Co., 521 F. Supp. 3d 863 (N.D. Cal. 2021) (No. 4:20-cv-02212) (discussing beverage manufacturers' role in mid-twentieth century anti-litter campaigns, such as "Keep America Beautiful," which seemed to transfer responsibility for litter-management to the end consumer failing to recycle).

81. Plastic Bottles for Carbonated Beverages and Beer, 42 Fed. Reg. at 9230.

82. *Id.*

83. *Environmental Impact Statement (EIS) Database*, EPA, https://perma.cc/X78E-KYAG.

84. *Id.*

85. *Id.*

86. Notice of Intent to Prepare an EIS for the Proposed Rule, Standards for Growing Harvesting, Packing, and Holding of Produce for Human Consumption, 78 Fed. Reg. 50,358 (Aug. 19, 2013) ("For the proposed rule, the Agency relied on a categorical exclusion from the need to prepare an Environmental Assessment or EIS under 21 CFR 25.30(j). Based on currently available information, including comments received, and upon further analysis, FDA has determined that the proposed action may significantly affect the quality of the human environment and, therefore, an EIS is necessary for the final rule.").

87. *See* FDA, Final Environmental Impact Statement (Final EIS) for the Proposed Rule: Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Proposed Rule) (2015).

88. *See id.* at 18–38, 45, 88.

ment.[89] Perhaps the most extraordinary thing about this EIS is that, despite the far-ranging environmental footprint of FDA activities, it is the most comprehensive environmental analysis that FDA has ever completed.[90]

Further, FDA has rarely changed a substantive decision as a result of a NEPA analysis. One early attempt to do so was stymied in court. In 1978, FDA denied an application for approval of an animal feed additive in part on the basis that the applicant's environmental analysis was inadequate.[91] The Fifth Circuit vacated and remanded the denial, concluding that "[a]lthough it is possible that FDA might establish separate grounds for denial of a food additive petition based on safety to the environment, it has failed to set forth any such separate grounds on this record."[92] This holding confirms the premise, first established in *Environmental Defense Fund, Inc. v. Mathews*,[93] that NEPA provides FDA authority to deny petitions on environmental grounds, but it puts a burden on FDA to establish the basis for the environmental concern.[94]

Occasionally, FDA has declined to proceed with a regulatory action because of the burden of environmental review. In the late 1970s, FDA commenced a process to set standards for use of polyvinyl chloride as a food contact substance ("FCS"), but after environmental groups called on the agency to conduct an environmental review, the agency never completed the rulemaking.[95] Similarly, in 1993, FDA stayed its 1987 amendments to food additive regulations, which had increased the maximum selenium supplementation permitted in animal feed.[96] FDA issued the stay upon finding that "the information that is

89. *See* Margaret Hamburg, Comm'r, FDA, Speech at Georgetown University Law Center Vote Food 2016: Better Food, Better Health, Panel 1: What Should the Next President's Food Agenda Look Like? (June 3, 2016), https://perma.cc/CT9T-P8ZH (noting that she had been "working the food arena for a while without appreciating the seriousness of this problem, and it was brought to [her] attention").

90. Our conclusion that FDA has not conducted any other EISs related to its food authority follows from our search of EPA's EIS database, a search of regulations.gov, a Westlaw search, and a Google search.

91. Marshall Minerals, Inc. v. FDA, 661 F.2d 409, 413–14 (5th Cir. 1981).

92. *Id.* at 424 (also concluding that "[a]ccepting the[ ] submissions at face value, it is clear that not only was [the environmental impact analysis regulation] complied with, but also that no separate environmental safety concerns prevented approval of Marshall's petition").

93. 410 F. Supp. 336 (D.D.C. 1976).

94. *Id.* at 339.

95. Interview by Suzanne Junod & Robert Tucker with Jerome H. Heckman, Partner, Keller and Heckman, in Washington, D.C. (Aug. 10, 2006).

96. Food Additives Permitted in Feed and Drinking Water of Animals; Selenium; Stay of the 1987 Amendments, 58 Fed. Reg. 47,962 (Sept. 13, 1993) (to be codified at 21 C.F.R. pts. 558, 573). Selenium is an essential element to normal growth and production; inadequate levels of selenium may result in white muscle disease, nutritional myodegeneration, exudative diathesis, pancreatic fibrosis, and cardiac myopathy. *Id.* at 47,962. It is also highly toxic, and levels as low as one part per billion have been associated with adverse biological effects in aquatic species. *Id.*

available, if accepted as accurate, would not be sufficient to permit an adequate environmental analysis, and that the information that is necessary to do an adequate environmental analysis is unavailable."[97] Following the stay, Congress passed a law allowing implementation of the stay contingent on a finding that the previously approved higher levels of selenium were non-essential, unsafe to animals, unsafe to individuals consuming those animals, did not serve the growth-promoting value intended, and that the risks could not reasonably be controlled using current manufacturing practices.[98] FDA did not make these findings and has not revisited the matter since. As a consequence, the previously approved higher level remains in place despite the agency never having completed the environmental review.[99]

In sum, FDA rarely conducts robust environmental analysis, and the limited instances in which it has have mostly been unsuccessful in changing the direction of its decision-making.

2. FDA's FONSIs: A Food Contact Notification Study

To better understand FDA's approach to NEPA compliance, we conducted a study of FDA's NEPA documents—all CEs or FONSIs—in the context of its food contact notification ("FCN") program.[100] The study provides

97. *Id.* FDA did not take this action *sua sponte*. It resulted from a request from the California Health & Welfare Agency, Micro Tracers, Inc., Natural Resources Defense Council, and three others. *See* Food Additives Permitted in Feed and Drinking Water of Animals; Selenium, 57 Fed. Reg. 33,244, 33,245 (July 27, 1992) (to be codified at 21 C.F.R. pt. 573).

98. Food Additives Permitted in Feed and Drinking Water of Animals; Selenium, 60 Fed. Reg. 53,702, 53,703–04 (Oct. 17, 1995) (to be codified at 21 C.F.R. pt. 573).

99. *Id.*

100. FDA's heavy reliance on CEs and FONSIs is not unusual, and, in fact, it may be engaging in more environmental analysis in this context than is typically done across the federal government. U.S. Gov't Accountability Office, National Environmental Policy Act: Little Information Exists on NEPA Analyses 7 (2014), https://perma.cc/A9AR-U27Z (noting that although there is no federal-government-wide data tracking NEPA compliance, CEQ estimates that 95% of NEPA analyses are CEs, less than 5% are EAs, and less than 1% are EISs). Although FDA FONSI's are occasionally challenged, these challenges are rarely successful. *See, e.g.*, Stauber v. Shalala, 895 F. Supp. 1178 (W.D. Wis. 1995) (rejecting challenge to FONSI in approval of Posilac, a milk-production enhancing synthetic bovine growth hormone drug that was approved for use in dairy cows); Ctr. for Food Safety v. Hamburg, 142 F. Supp. 3d 898 (N.D. Cal. 2015) (challenge to approval of ractopamine dismissed on exhaustion grounds), *vacated and remanded with direction to stay proceedings*, 696 F. App'x 302, 304 (9th Cir. 2017) (directing stay rather than dismissal to give plaintiffs the opportunity to exhaust remedies); Rhone-Poulenc, Inc. v. FDA, 636 F.2d 750 (D.C. Cir. 1980); Int'l Ctr. for Tech. Assessment v. Thompson, 421 F. Supp. 2d 1 (D.D.C. 2006) (rejecting challenge to FDA allowance of sale of genetically engineered, florescent zebra danio fish); *see also* Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166 (D.D.C. 2000) (rejecting challenge to FDA determination that decision to treat genetically engineered foods as generally recognized as safe ("GRAS") was not a major federal action and thus did not

helpful insight to how the agency characterizes its role as environmental steward under NEPA and more broadly.

Under the FDCA, FCSs are considered food additives (e.g., plastic polymers, adhesives, and films in packaging that touch food) and require FDA premarket clearance.[101] In the Food and Drug Administration Modernization Act of 1997, Congress streamlined the go-to-market process for producers by creating a premarket notification system, allowing manufacturers to notify FDA that they are introducing a new FCS.[102] Upon review, FDA can then take no action, in which case the substance is considered cleared for market, or it can object to the notification.[103] FDA's decisions under this program are major federal actions subject to NEPA.[104] FDA maintains a database of its FCN NEPA documents dating to 2000.[105] At the time of this study, in June 2020, the database contained 1,493 decisions; 655 ended with a FONSI; 815 were resolved by CE, and none resulted in the preparation of an EIS.[106] The numbers here are illustrative of the agency's environmental approach. Despite the volume of FDA decisions involving regulation of FCSs since 2000, none apparently warranted a harder look via an EIS. This result is particularly surprising given that the components of single-use plastic packaging, a significant source of environmental contamination, are reviewed through this process.[107] From the 655 FONSIs, we reviewed a random sample of fifty,[108] and identified several interesting patterns.

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trigger NEPA compliance at all). For a complete list of cases rejecting NEPA challenges to FDA actions, see HUTT ET AL., *supra* note 72, at 1528. For one recent successful challenge, see *Institute for Fisheries Resources v. FDA*, 499 F. Supp. 3d 657 (N.D. Cal. 2020). *See also infra* notes 148–56 and accompanying text (discussing this case).

101. 21 U.S.C. §§ 321(s), 342(a)(2)(C), 342(a)(6), 348.

102. Pub. L. No. 105-115, § 309, 111 Stat. 2296, 2354–56 (amending 21 U.S.C. § 348(a)).

103. National Environmental Policy Act; Food Contact Substance Notification System, 65 Fed. Reg. 30,352, 30,353 (May 11, 2000) (to be codified at 21 C.F.R. pt. 25) (determining that NEPA applies to FDA decisions not to object to FCNs).

104. *How to Submit a Food Contact Substance Notification*, FDA, https://perma.cc/6V3X-64PJ.

105. *Recently Published Environmental Assessments and FONSIs*, FDA, https://perma.cc/9XYE-FFHV.

106. FDA, INVENTORY OF ENVIRONMENTAL IMPACT DECISIONS FOR FOOD CONTACT SUBSTANCE NOTIFICATIONS, https://perma.cc/RK42-6422. Twenty-three decisions resulted in both a CE finding and issuances of a FONSI. *Id.*

107. *See infra* Part III.B.1 (elaborating on the environmental footprint of single-use plastic packaging, FDA's regulatory authority in this area, and avenues for reform).

108. A note on method: we used Microsoft Excel to select a random sample of fifty. The sample, including links to the EA and FONSIs, where they are available, is included as an Appendix to this Article. When we cite to individual FONSIs, we refer to them by our Sample Number. We reviewed these focusing on whether the agency engaged in any discussion of the environmental impacts of production as compared to use and disposal. We view this as a preliminary assessment and encourage a more thorough statistics-based study of environmental factors addressed within the FCN database's documents. Despite the limitations of

First, the agency placed little to no importance on the required resources for and environmental impacts of FCS production and processing. FDA mentioned production factors in only a handful of the fifty FONSI samples. In those instances, FDA typically responded to the concern by indicating that approval would lead to no net energy and resource consumption increase as the new FCS would substitute for an old one.[109] Indeed, FDA regulations governing EAs direct evaluators to "focus on relevant environmental issues relating to the use and disposal from use of FDA-regulated articles."[110] Industry trade groups have interpreted this language to mean that applicants should not prioritize any detailed discussion of environmental concerns regarding FCS production.[111] A 2013 FDA guidance document on how to prepare an EA supports that interpretation, placing no emphasis on discussing environmental consequences of manufacturing or processing as criteria for an effective EA submission.[112] The choice to downplay production concerns during environmental assessment is a logical conclusion of FDA's emphasis on product over process.

Second, on the use and disposal portion of environmental impact analysis, the agency primarily appeared to concern itself with performing toxicology calculations to ensure that if an FCS were discharged into waterways, incinerated at a landfill, or leached into soil surrounding its disposal site that there would not be significant toxic harm to aquatic and terrestrial ecosystems.[113] What is striking about FDA's analysis of disposal concerns is that the agency typically relies on the small market share or limited use of that particular FCS to determine that its environmental impact will be negligible.[114] Yet across all FCSs, disposal has significant cumulative environmental effects.[115] Therefore, evaluat-

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our study, we think the sample size was sufficient to demonstrate the pattern of FDA's reluctance to deal broadly with environmental concerns.

109. *See, e.g.*, *infra* Appendix, Food Contact Notification Sample Nos. 19, 27, 32, 39, 40.

110. 21 C.F.R. § 25.40(a) (2021).

111. *See* Keller & Heckman LLP's Packaging Practice Group, *Packaging and Environmental Legislation in the United States: An Overview*, PACKAGINGLAW.COM (July 15, 2002), https://perma.cc/T4BU-JRZH (advising industry participants that "FDA no longer requires information on environmental effects from manufacture of a food-contact material (because these effects are controlled by EPA or local or state authorities)").

112. *See generally* FDA, GUIDANCE FOR INDUSTRY: PREPARING A CLAIM OF CATEGORICAL EXCLUSION OR AN ENVIRONMENTAL ASSESSMENT FOR SUBMISSION TO CFSAN (2006).

113. *See, e.g.*, *infra* Appendix, Food Contact Notification Samples Nos. 1, 2, 3, 20, 38.

114. *See, e.g.*, *infra* Appendix, Food Contact Notification Samples Nos. 30, 39.

115. *See* Complaint, *supra* note 80. Courts have allowed similar analytical approaches in the context of climate change, where any individual project has only a miniscule impact of global climate change. *See, e.g.*, WildEarth Guardians v. Bernhardt, 501 F. Supp. 3d 1192, 1207–11 (D.N.M. 2020) (determining that the Bureau of Land Management adequately assessed cumulative impacts of individual oil and gas leasing projects when it determined that particular groups of leases would contribute less than 0.0025% of national GHG emissions and therefore did not generate significant impacts).

ing environmental effects on an FCS-by-FCS basis isolates individual FCSs' impacts and can dramatically reduce the appearance of their significance.[116] As we elaborate in Part III.A, this trend points toward the need for an FCN programmatic EIS ("PEIS"), which would afford the opportunity to engage in an environmental analysis of the cumulative impact of FCS disposal by assessing how FDA administers the FCN program at large rather than the individual decisions.[117]

Finally, a common strategy FDA takes in these FONSIs is to dismiss environmental concerns on the ground that they relate to EPA's jurisdiction. For instance, in one FONSI, FDA dismissed concerns about an FCS's environmental footprint, including GHG emissions, by noting that outputs from these

116. FDA's regulatory approach is consistent with how environmental contaminants are regulated more generally, with the emphasis on individual contaminants rather than on collective contamination. *See* ZHAO MA ET AL., MINN. DEP'T OF FOREST RES., THE INTEGRATION OF CUMULATIVE ENVIRONMENTAL IMPACT ASSESSMENTS AND STATE ENVIRONMENTAL REVIEW FRAMEWORKS 22 (2009). A report commissioned by EPA cited stakeholder concerns that risk assessment models used in regulatory decisions regarding chemicals and toxicity, including EPA decisions, inadequately capture "public-health and environmental-health questions involving multiple exposures, complex mixtures, and vulnerability of exposed populations." NAT'L RSCH. COUNCIL COMM. ON IMPROVING RISK ANALYSIS APPROACHES USED BY THE U.S. EPA, SCIENCE & DECISIONS: ADVANCING RISK ASSESSMENT 9 (2009). The report highlighted a need for cumulative risk assessments that account for "combined risks posed by aggregate exposure to multiple agents or stressors . . . [including] [c]hemical, biologic, radiologic, physical, and psychologic stressors" in EPA's decision-making. *Id.* at 10. EPA has taken steps toward broadening the scope of the risk assessments it conducts, moving away from a solely traditional isolated substance approach, but the report found that EPA risk assessments still tended to fall short in the context of cumulative risk assessment. *Id.* at 9–10, 219; *see also* John Wood, *Can We Teach Old Laws a New Risk? Federal Environmental Law, Risk Management Theory, and Contamination of U.S. Water Supplies with Pharmaceutical and Personal Care Products*, 21 N.Y.U. ENV'T L.J. 193, 202 (2014) (observing that FDA's failure to address cumulative or synergistic risks generates "systemic under-regulation of toxic interactions"); Ken Sexton, *Cumulative Risk Assessment: An Overview of Methodological Approaches for Evaluating Combined Health Effects from Exposure to Multiple Environmental Stressors*, 9 INT'L J. ENV'T RES. 370, 371 (2012) (noting that EPA typically focuses on "individual chemical agents, distinct sources or source categories, and single exposure pathways, environmental media, routes of exposure, and health endpoints").

117. CEQ describes programmatic NEPA review as follows:

> The term "programmatic" describes any broad or high-level NEPA review; it is not limited to a NEPA review for a particular program. Programmatic NEPA reviews assess the environmental impacts of proposed policies, plans, programs, or projects for which subsequent actions will be implemented either based on the [programmatic] EA or [programmatic] EIS, or based on subsequent NEPA reviews tiered to the programmatic review (e.g., a site- or project-specific document).

CEQ, EFFECTIVE USE OF PROGRAMMATIC NEPA REVIEWS 7 (2014) [hereinafter CEQ GUIDANCE], https://perma.cc/P5XB-6A3E; *see also* Final Guidance for Effective Use of Programmatic NEPA Reviews, 79 Fed. Reg. 76,986 (Dec. 23, 2014) (announcing availability).

processes were below EPA-established thresholds.[118] Likewise, FDA mentioned in some FONSIs that water discharge associated with production or disposal would be subject to Clean Water Act permitting and thus would not generate significant environmental impacts.[119] These documents reveal FDA's inclination to defer to EPA and to assume that anything EPA regulates has no significant environmental footprint. In other contexts, courts have rejected agency claims that it need not consider environmental effects simply because they are subject to another agency's regulatory scheme.[120]

In sum, our review of the FCN Environmental Decision database reveals the limitations of FDA's NEPA compliance. These documents affirm the agency's bias for discounting process, its adherence to a narrow substance-by-substance approach to assessing safety, and its deference to EPA on environmental matters.

3. FDA's CEs

The final possible outcome of NEPA analysis is application of a CE, or a category of actions that a federal agency has determined, in conjunction with

118. *See, e.g.*, *infra* Appendix, Food Contact Notification Samples Nos. 26, 35; George G. Misoko, *What's Behind FDA's Increased FCN Deficiency Letters Related to EAs and How to Respond*, PACKAGINGLAW.COM (Aug. 15, 2017), https://perma.cc/7YAT-TFVN. In 2016, CEQ issued guidance to federal agencies, including FDA, recommending that they include analyses regarding GHG emissions as part of their NEPA review processes. *See* Final Guidance for Federal Departments and Agencies on Consideration of GHG Emissions and the Effects of Climate Change in NEPA Reviews, 81 Fed. Reg. 51,866 (Aug. 1, 2016) (announcing availability), *withdrawn by* Withdrawal of Final Guidance for Federal Departments and Agencies on Consideration of GHG Emissions and the Effects of Climate Change in NEPA Reviews, 82 Fed. Reg. 16,576 (April 5, 2017), *under review per* NEPA Guidance on Consideration of GHG Emissions, 86 Fed. Reg. 10,252 (Feb. 19, 2021). Following 2016, there was increased discussion in FDA's FONSIs on this point, and FDA more frequently requested additional information from applicants. A few FONSIs also discussed recyclability of FCSs, in which case most assumed that because the substance is replacing some existing market product that it will have little to no environmental impact. *See, e.g.*, *infra* Appendix, Food Contact Notification Samples Nos. 37, 38, 39.

119. *See, e.g.*, *infra* Appendix, Food Contact Notification Samples Nos. 27, 30.

120. *See, e.g.*, Or. Env't Council v. Kunzman, 714 F.2d 901, 905 (9th Cir. 1983) ("One agency cannot rely on another's examination of environmental effects under NEPA."); Steamboaters v. FERC, 759 F.2d 1382, 1394 (9th Cir. 1985) ("The agency must independently assess the consequences of a project."); Save Our Ecosystems v. Clark, 747 F.2d 1240, 1248 (9th Cir. 1984) (holding that the Forest Service could not rely on EPA's Federal Insecticide Fungicide, and Rodenticide Act registration process as a substitute for its own NEPA review of a plan to spray an herbicide), *abrogated on other grounds by* Amoco Prod. Co. v. Vill. of Gambell, 480 U.S. 531 (1987); Gov't of Man. v. Salazar, 691 F. Supp. 2d 37, 48 n.8 (D.D.C. 2010), *clarified on denial of reconsideration*, No. CV 02-2057, 2010 WL 11595314 (D.D.C. June 17, 2010).

CEQ, "normally do not have a significant effect on the human environment."[121] These are common in the food context.[122] For example, industry actors can seek FDA approval or authorization for specific types of color additives, FCSs, and "generally recognized as safe" food additives via a CE.[123] FDA also uses CEs for certain food labeling regulations. To claim a CE, applicants must "(1) cite the section of the [Code of Federal Regulations] under which the categorical exclusion is claimed, (2) include a statement of compliance with the categorical exclusion criteria, and (3) include a statement that, to the submitter's knowledge, no extraordinary circumstances exist that require submission of an EA."[124]

Although many of these CEs appear innocuous, some implicate the concern that FDA misses the significance of its environmental impact by examining a substance on an isolated rather than cumulative basis. For instance, one exclusion applies to an FCS where the substance is "present in finished food-packaging material at not greater than 5 percent-by-weight and is expected to remain with finished food-packaging material through use by consumers."[125] This CE relies on the low levels of the component in any individual package.[126] FDA appears to write off the value of examining more closely the compounded consequences of many such FCSs ultimately being discarded and accumulating in the environment. Another excludes FCNs when "the substance is to be used as a component of a food-contact surface of permanent or semipermanent equipment or of another food-contact article intended for repeated use."[127] This exclusion assumes that, where FCSs are not themselves disposable, they have no significant environmental impacts, ignoring potential production-related impacts as well as impacts of eventual disposal.

Another troubling aspect of FDA's CEs is the agency's pattern of excluding actions on the ground that they are unlikely to generate environmental

121. 40 C.F.R. § 1508.1(d) (2020).

122. *See* FDA, *supra* note 112.

123. *See* 21 C.F.R. §25.32 (2021). Additives that are "generally recognized as safe" are not subject to premarket approval. See *infra* Part III.B.3 for additional discussion of this carveout.

124. FDA, *supra* note 112; 21 C.F.R. § 25.15 (2021).

125. 21 C.F.R. § 25.32(i) (2021).

126. FDA justified this exclusion with the following explanation:

> (1) Only very small quantities, if any, of these additives were expected to enter the environment at sites where the additives were used in the manufacture of food-packaging materials; (2) only extremely low levels of substances, if any, could be expected to enter the environment as a result of disposal of food-packaging materials; and (3) virtually no change in the use of natural resources and energy would be expected because the additives would be replacing other, currently regulated, additives and would not affect the uses of the packaging materials to which they were added.

National Environmental Policy Act; Revision of Policies and Procedures, 62 Fed. Reg. 40,570, 40,580 (July 29, 1997) (to be codified at scattered parts of 21 C.F.R.).

127. 21 C.F.R. § 25.32(j) (2021).

harm related to substance disposal. The emphasis on disposal distracts from the possibility that production of a substance may also generate significant harm.[128] For instance, FDA regulations create a CE for feed or color additives that "occur[ ] naturally in the environment," so long as approval of the additive will "not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment."[129] The environmental consequences of a manufacturer sourcing these input materials for production could be substantial even if the disposal of the product is not.

FDA retains discretion to determine that an individual action does not qualify for a CE because it involves "extraordinary circumstances."[130] These regulations open up the possibility that the agency might deny a CE in a particular context if the "[a]ctions . . . may have significant effects on solid waste management, e.g., source reduction, recycling, composting, incineration, and landfilling"[131] or if the "actions involv[e] substances derived from a plant or animal that could affect the sustainability of the source organism or the surrounding ecosystem."[132] It is unclear how often, if ever, the agency invokes this doctrine.[133]

Overall, through its broad use of CEs, FDA allows a broad range of actions that have production as opposed to disposal related impacts or those that may have minimal impact individually, but collectively, have significant environmental effects, to evade environmental review.

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128. Michael Liftik, Food, Drugs, and the Environment: How the Food and Drug Administration Has Interacted with the National Environmental Policy Act of 1969, at 29 (Apr. 7, 2000) (unpublished manuscript) (on file with Harvard Library Office for Scholarly Communication), https://perma.cc/9SZM-85BZ.

129. 21 C.F.R. § 25.32(r) (2021). For example, in 2021, FDA determined that approval of the use of selenomethionine hydroxy as an additive to feed for beef and dairy cattle was subject to this CE, presumably on the ground that selenium (for which this additive is a source) naturally occurs in the environment and the use of the additive will not significantly alter its background natural levels. Food Additives Permitted in Feed and Drinking Water of Animals; Selenomethionine Hydroxy Analogue, 86 Fed. Reg. 37,035, 37,036 (July 14, 2021) (to be codified at 21 C.F.R. pt. 573) (referring to the CE without offering any explanation as to its applicability).

130. 40 C.F.R. § 1501.4 (2020). Extraordinary circumstances are defined in 21 C.F.R. § 25.21 and can invoke production, use, or disposal considerations regarding the proposed act that could "significantly affect" the environment. *See* 21 C.F.R. § 25.21 (2021).

131. FDA, *supra* note 112.

132. *Id.* (offering the following examples: "potentially significant effects on resources resulting from changes in agricultural practices for a cultivated crop, such as changes in water, energy, agrochemical or land use; or significant effects resulting from the harvesting of wild specimens"). These potential extraordinary circumstances invoke process considerations more directly.

133. We found no examples either in the FCN Environmental Decision database or elsewhere. The FSMA EIS appears, however, to be one example. *See supra* note 86 (citing sources that describe the origins of this EIS but do not expressly use the phrase "extraordinary circumstances").

B. NEPA Compliance in the Drug Context

Although our primary focus in this Article is on FDA's role as an environmental regulator of the food system, a brief review of its NEPA compliance in the drug context reaffirms our assessment of the agency's narrow view of its environmental protection obligations. There is also overlap between its food and drug authority where drugs are approved for animals raised for food. There remains significant room for improvement, but some of FDA's NEPA compliance work in the animal drug context demonstrates that the agency is capable of employing a broader lens and incorporating a more extensive range of production- and disposal-related concerns.

FDA is responsible for ensuring the safety and effectiveness of human and animal drugs before approving them for sale. During the drug approval process, FDA focuses almost entirely on safety for the human taking the drug or consuming the animal that has taken the drug, to the detriment of its consideration of the broader consequences of pharmaceutical use.[134] The agency has only once prepared an EIS in connection with a pharmaceutical approval.[135] As in the food context, it employs CEs in a broad range of circumstances. These exclusions, among other things, set FDA up for failure in considering the cumulative effects of multiple drugs, or even of a single drug, in the environment. For instance, the agency promulgated CEs for human drugs when residual concentrations in aquatic environments are likely to be below one part per billion.[136] Although this appears to be a stringent threshold, some drugs, such as estrogen and trenbolone metabolites, can have detrimental impacts at levels as low as a few parts per trillion.[137] Moreover, as pharmaceuticals are now a common contaminant in surface water, this sort of exclusion and the agency's limited con-

134. *See* FDA, FDA Regulation of Animal Drugs (2021), https://perma.cc/WQ8P-HTDN (explaining how the agency considers safety, also giving some credence to the safety of the animal).

135. Gabriel Eckstein, *Drugs on Tap: Managing Pharmaceuticals in Our Nation's Waters*, 23 N.Y.U. Env't L.J. 37, 66–67 (2015).

136. 21 C.F.R. § 25.31(b) (2021). Agencies may promulgate CEs when the excluded class of actions will "not individually or cumulatively have a significant effect on the human environment." National Environmental Policy Act; Revision of Policies and Procedures, 62 Fed. Reg. 40,570, 40,591 (July 29, 1997) (to be codified at scattered parts of 21 C.F.R.).

137. Eckstein, *supra* note 135, at 65–66 (also critiquing the CE for substances that occur naturally in the environment on the ground that the exclusion "ignores the consequence of cumulative and chronic exposure to such substances by aquatic and other species, including humans, as well as the possible synergistic outcomes of these substance's interaction with other chemicals"). In recent guidance, FDA suggested that it might reverse course on this threshold; it suggests it will consider evidence that levels below one part per billion will have detrimental effects. FDA, Environmental Assessment: Questions and Answers Regarding Drugs with Estrogenic, Androgenic, or Thyroid Activity 4 (2016), https://perma.cc/AU2F-SH3T.

sideration of drug production, use, and disposal impacts may generate some concern.[138]

In 2014, a group of environmental organizations challenged FDA's approval of ten different combinations of the animal growth hormone ractopamine, which FDA approved under the auspices of a CE.[139] FDA originally approved ractopamine in 1999 after completing a cursory EA.[140] Banned in many countries, the drug is widely used in the United States. The European Union banned the drug based on studies demonstrating that it poses direct health risks to humans.[141] Studies also suggest the drug poses health risks to the animals to whom it is administered.[142] Ractopamine enters the environment through the animal waste stream, and drug residues can have adverse effects on aquatic environments and humans exposed via drinking water, recreational activities, and other interactions with the environment.[143] Plaintiffs in the suit alleged, among other things, that FDA's NEPA compliance was inadequate because it had failed to take into account either the dramatic increase in ractopamine use since the initial approval or the human health and environ-

138. Eckstein, *supra* note 135, at 62–68 (arguing that FDA's NEPA compliance in the pharmaceutical context has been woefully inadequate and that the justification for this particular CE is not consistent with current science); Shawna Bligh, *Pharmaceuticals in Surface Waters: Use of NEPA*, 24 NAT. RES. & ENV'T 56, 57 (2009). A 2015 study by two scientists at the University of Wisconsin found that one of the most common medical contaminants in Lake Michigan is metformin, a diabetes drug and the sixth most prescribed drug in the United States. Nicholas J. Niemuth & Rebecca D. Klaper, *Emerging Wastewater Contaminant Metformin Causes Intersex and Reduced Fecundity in Fish*, 135 CHEMOSPHERE 38, 42 (2015). According to their findings, metformin exposure at levels found in effluent can lead to hormonal problems in aquatic life and cause intersex characteristics in male fish. *Id.* This study and other scholarship regarding environmental harms from pharmaceuticals demonstrate reason for critical need to reform FDA's current approach to environmental assessment.

139. Complaint at 2, 27–28, Humane Soc'y of the U.S. v. Hamburg, No. 14CV04933, 2014 WL 10970784 (N.D. Cal. filed Nov. 6, 2014).

140. *Id.* at *24–25 (describing FDA's initial approval).

141. Eur. Food Safety Auth., *Safety Evaluation of Ractopamine*, 7 EFSA J. 1041, 1-52, 27-52 to 28-52 (2009), https://perma.cc/MTD4-FTHM (criticizing methodology of data on which Codex relied in setting ractopamine acceptable daily intake tolerance); *see* Alberto Alemanno & Giuseppe Capodieci, *Testing the Limits of Global Food Governance: The Case of Ractopamine*, 3 EUR. J. RISK REGUL. 400, 402–03 (2012) (summarizing ractopamine's human health and animal health consequences); *see also* Complaint, *supra* note 139, at 11 (alleging that its use can increase the risk of microbial contamination in pork products).

142. Eur. Food Safety Auth., *supra* note 141, at 43–52. Animal welfare groups have also raised concerns that pigs frequently have adverse reactions including trembling, lameness, inability to walk, hyperactivity, aggression, breathing difficulty, and death. Complaint, *supra* note 139, at 7.

143. Alemanno & Capodieci, *supra* note 141, at 401; Complaint, *supra* note 139, at 10–18 (alleging meat consumption related human health risks, animal health risks, worker safety risks, and threats to endangered species associated with high levels of ractopamine use).

mental impacts of combining ractopamine with other animal drugs.[144] Although the plaintiffs ultimately lost on jurisdictional grounds, the case raises concern about the seriousness with which FDA takes these environmental risks.[145]

As in the FCN context, FDA maintains a publicly accessible database of environmental decisions for animal drug approvals.[146] In a departure from the FCN program's approach, FDA's NEPA review for animal drugs often considers, albeit briefly, potential environmental contamination associated with drug production. The agency published guidance regarding how it reviews submissions and the types of considerations it makes. In this guidance, several detailed decision charts demonstrate what depth of environmental assessment is required for animal drugs, depending on a number of factors, including: type of treated animal raised and manner in raising it, whether the animals are for food purposes or not, expected environmental introduction concentrations of drugs, and many other factors that indicate whether more extensive "Phase II" tests and calculations regarding potential environmental concentrations are needed.[147] Compared to the FCN program, this category of NEPA review evidences a more honed and considered approach to the avenues of exposure and scope of environmental harms.

A few other animal drug approval NEPA compliance actions show some limited promise, suggesting that FDA incorporates environmental concerns in the context of its drug regulation more readily than it does in the context of its food regulation. For instance, FDA issued a several-hundred-page EA assess-

144. Complaint, *supra* note 139, at 16–18 (also alleging that the original assessments are no longer applicable because they are based on outdated data about how much animal manure from feedlots is applied to fields).

145. *See* Ctr. for Food Safety v. Hamburg, 696 F. App'x 302, 303 (9th Cir. 2017); Nicholas Iovino, *Lawsuit over Oft-Banned Animal Drug Dropped*, COURTHOUSE NEWS SERV. (Feb. 2, 2018), https://perma.cc/GB5C-ENQ2. As a point of disclosure, one of this Article's authors signed a professors' amicus brief supporting the challengers on a procedural question related to the requirement that challengers exhaust their remedies at FDA before challenging the agency action in court. Brief for Environmental, Administrative, and Food Law Professors as Amici Curiae Supporting Plaintiff-Appellants, *Ctr. for Food Safety*, 696 F. App'x 302 (No. 15-17510), 2016 WL 2939280. The Animal Legal Defense Fund recently filed a similar claim challenging FDA's approval of Experior, a drug that purportedly reduces ammonia emissions from cattle waste; the suit recently survived a motion to dismiss for lack of standing and for failure to exhaust administrative remedies. Animal Legal Def. Fund v. Azar, No. 20-CV-03703, 2021 WL 4477901 (N.D. Cal. Feb. 23, 2021).

146. *Drug Summaries*, FDA, https://perma.cc/99SE-CU6D (tracking environmental decisions since 1978).

147. *See* FDA, GUIDANCE FOR INDUSTRY #166: ENVIRONMENTAL IMPACT ASSESSMENTS (EIA's) FOR VETERINARY MEDICINAL PRODUCTS (VMP's) – PHASE II VICH GL38 (2006), https://perma.cc/2PV4-3S2P; FDA, GUIDANCE FOR INDUSTRY #89: ENVIRONMENTAL IMPACT ASSESSMENTS (EIA's) FOR VETERINARY MEDICINAL PRODUCTS (VMP's) – PHASE I VICH GL6 (2001), https://perma.cc/GH39-YF45.

ing the environmental impacts of approving AquAdvantage, a genetically engineered ("GE") salmon. AquaBounty Technologies, Inc. developed a line of fish "designed to exhibit a rapid-growth phenotype that allows it to reach smolt size faster than non-GE farm raised salmon."[148] FDA has regulatory jurisdiction over the approval of GE species via the agency's New Animal Drug Application process.[149] Perhaps due to AquAdvantage salmon's status as the first GE animal to enter the country's food supply and the politics surrounding this decision, FDA went to great lengths to thoroughly explore the manner in which the salmon eggs would be imported, raised, contained to their production site, and processed for sale.[150] The scrutiny on this particular regulatory action and the unique approach needed to assess a GE animal (as opposed to a pharmaceutical) likely led to a more systemic review of possible environmental impacts prior to the clearance of AquAdvantage salmon.

Notably, even with this detailed review, the decision was subject to successful litigation opposing FDA's assessment.[151] The Center for Food Safety, Earthjustice, the Quinault Indian Nation and twelve other organizations filed suit against FDA in the U.S. District Court for the Northern District of California, claiming that the agency violated its NEPA duties by failing to consider risks of the GE salmon escaping into the environment and threatening wild salmon populations.[152] Ruling in part for the plaintiffs and remanding the case to FDA "for reconsideration of the environmental assessment under NEPA," Judge Vince Chhabria stated "FDA did not adequately assess the risk of harm given establishment [of GE salmon entering the wild] before making a finding of no significant impact."[153] The court remanded without vacatur, directing

148. FDA, AquAdvantage Salmon Environmental Assessment 1 (2015), https://perma.cc/84FQ-8TCD.

149. The FDCA mandates premarket approval for new animal drugs. 21 U.S.C. § 360b(a)(1); *New Animal Drug Applications*, FDA (2021), https://perma.cc/3TKP-EL4R (describing the application process); see *Institute for Fisheries Resources v. Hahn*, 424 F. Supp. 3d 740, 744 (N.D. Cal. 2019), for a discussion of how AquAdvantage salmon falls under FDA's regulatory jurisdiction, due to the fish's rDNA construct, which when "integrated into [the] animal's genome" makes it a unique genetically engineered product. In brief, addressing a portion of the FDCA's definition of "drug" as being "articles (other than food) intended to affect the structure or any function of the body of man or other animals," the U.S. District Court for the Northern District of California ruled that FDA was capable of regulating the GE salmon through its jurisdiction over items encompassed within this term of art. *Id.* at 747 (citing 21 U.S.C. § 321(g)(1)(C)).

150. FDA, Finding of No Significant Impact in Support of an Approval of a Supplemental New Animal Drug Application to Allow the Grow-out of AquAdvantage Salmon at AquaBounty Technologies, Inc.'s Indiana Facility (2018), https://perma.cc/V6P4-S2F4.

151. *Federal Court Declares Genetically Engineered Salmon Unlawful*, Ctr. for Food Safety (Nov. 5, 2020), https://perma.cc/LKY2-5RQ5.

152. Inst. for Fisheries Res. v. FDA, 499 F. Supp. 3d 657, 661 (N.D. Cal. 2020).

153. *Id.* at 670.

FDA to revisit its NEPA assessment of AquAdvantage salmon to account for environmental hazards should the GE fish interact with wild endangered Atlantic salmon.[154] Although many retailers have declined to carry the fish, sales began in 2021.[155] FDA has not yet revisited its environmental analysis. While FDA's regulation in the animal-drug and GE animal arenas appear to demonstrate potential for a more holistic, considered approach to how to factor environmental impact into its decision-making, the agency has a long way to go in this area as well.

III. FDA, An Environmental Agency

This Part offers a roadmap for how FDA might reposition itself as an agency that incorporates environmental protection and food system sustainability into its actions. We begin with NEPA, considering the ways in which the statute might facilitate FDA's transformation. We then identify several specific areas of FDA regulatory activity where more attention to environmental issues may be merited. For each of these areas, the agency could exercise its discretion to improve environmental outcomes. We focus on two categories: regulation of food and food-adjacent production practices pursuant to FDA's authority over adulteration, and the agency's influence over consumer choices in the food system through its authority over misbranding.

A. NEPA and Environmental Ethics at a Busy Agency

The previous Part offers insight into FDA's current approach to environmental issues. The analysis reveals that, as a predicate to taking any of the actions described later in this Part, FDA must make two conceptual shifts in its understanding of its mandate. Regarding food safety, FDA needs to embrace the concept of food systems safety.[156] More specifically, FDA needs to reframe safety to include concerns related to food production and disposal processes and not just food products themselves. Further, the agency needs to move away from substance-by-substance analysis and examine the cumulative impacts of substance approvals. We also identify a third necessary conceptual shift that is a corollary of the first two. FDA needs to broaden its understanding of consumer protection. Currently, FDA views consumer protection solely as a question of

154. *Id.*

155. Sam Bloch, *America's Biggest Retailers and Foodservice Companies Have Already Agreed Not to Sell GMO Salmon*, Counter (Feb. 11, 2021), https://perma.cc/RL4P-JWVQ (noting that consumer groups have lobbied retailers to refrain from purchasing the salmon should it come onto the market, and eighty-five retailers, including several of the largest supermarket names, have signed onto a pledge to do so); Casey Smith, *Genetically Modified Salmon Head to U.S. Dinner Plates*, ABC News (May 27, 2021), https://perma.cc/SZ28-6YPG.

156. *See generally* Broad Leib & Pollans, *supra* note 7 (developing and calling for the implementation of the concept of food systems safety).

facilitating *individual* consumer safety and choice. In addition, FDA should view itself as the steward of *population-level* safety and choice. This third shift crystallizes in our analysis of FDA's nutrition labeling regulation in Part III.C.2.

How would FDA actually come to take these steps? The predicate first step is for a shift in agency culture, embracing its identity as an environmental agency. There are several significant hurdles. The first is agency inertia and perceived conflict with FDA's core mission. FDA has a strong and narrow food and drug safety mandate. Where food safety and environmental protection collide, FDA's statutory mandate limits its ability to take environmental considerations seriously. Even where the two goals do not conflict, FDA does not always have the bandwidth to address multiple goals at the same time. This is, in Eric Biber's words, the "too many things to do" problem.[157] Because success in narrow food safety is easy to measure, whereas success in environmental protection is difficult to measure, the agency is likely to continue focusing on its food safety mandate.[158] Exacerbating this problem is the fact that FDA is an under-resourced agency. Its ability to achieve even its narrow food safety mandate is extremely limited by its low funding levels.[159] Its ability to expand its regulatory functions, which may require the hiring of new personnel, is even further constrained.

Second, expansion of regulatory activity into the environmental space puts FDA in a new position—at odds with the agricultural industry, an industry that has successfully evaded most environmental regulation to this point. FSMA, which brought FDA directly onto the farm for the first time, did not have this immediate consequence because of industry support for the statute. The produce industry supported expansion of FDA authority into on-farm produce safety regulation primarily because many of the largest participants in that industry were already subject to private regulation.[160] Industry lobbyists supported federal law in order to create a more uniform regulatory environment.[161] By contrast, the food industry has historically opposed any federal effort to expand regulatory activity into the supply chain.[162] Even in the work that it already does to regulate the food system, FDA is often accused of conflicts of interest and

157. Biber, *supra* note 13, at 2 (introducing the challenges faced by multiple-goal agencies).

158. *Id.* at 14 (identifying measurability of goal achievement as one factor that may lead an agency to prioritize one goal over another).

159. Jennifer L. Pomeranz, *A Comprehensive Strategy to Overhaul FDA Authority for Misleading Food Labels*, 39 AM. J.L. & MED. 617, 646 (2013).

160. *See* Pollans, *supra* note 29, at 417.

161. *Id.* at 416–17 (discussing the history of FSMA and the rationale behind industry support for it).

162. *Cf.* Ruhl, *supra* note 17, at 293–315 (describing agricultural exceptionalism in environmental law); Carsten Daugbjerg & Peter H. Feindt, *Post-Exceptionalism in Public Policy: Transforming Food and Agricultural Policy*, 24 J. EUR. PUB. POL'Y 1565, 1566 (2017).

regulatory capture.[163] Expansion of agency mission into environmental concerns is likely to result in significant industry resistance.[164]

NEPA may offer FDA one potential path forward. Under the guise of compliance with that statutory mandate, FDA might begin reformulating its understanding of adulteration and misbranding simply by taking the process of environmental assessment more seriously.[165] Although NEPA is far from a perfect tool for regulating the environmental effects of food products, it does provide FDA a concrete opportunity to expand its analytical lens and take on a role as steward of a broader definition of food safety, not just at the point of ingestion, but across the entire food system with active consideration of the environment. Even if more robust NEPA analysis does not immediately change FDA decision-making, it can generate information that advocates, legislators, regulators at other agencies, and future FDA decision-makers might leverage to push for agency reform.

FDA's procedures for reviewing the environmental effects of final agency actions related to FCSs and new animal drugs reflect FDA's narrow understanding of its regulatory purview. Its task is to protect the safety of food eaters and drug users from harms related to eating food and using drugs. Its approach to assessing this safety is to examine these regulated substances on a substance-by-substance basis.[166] This approach spills over into environmental review, during which FDA focuses almost entirely on individual substances and their disposal, not on production processes or cumulative effects of multiple substances. We assert, however, that NEPA provides the agency a set of tools to transcend this fragmented approach. We identify two potential uses for NEPA as a transformational tool. First, through more robust NEPA analysis in individual ap-

163. Emily J. Schaffer, *Is the Fox Guarding the Henhouse? Who Makes the Rules in American Nutrition Policy?*, 57 FOOD & DRUG L.J. 371 (2002); Gabriela Steier, *Dead People Don't Eat: Food Governmentenomics and Conflicts-of-Interest in the USDA and FDA*, 7 PITT. J. ENV'T PUB. HEALTH L. 1, 6 (2012). Indeed, the Department of Health and Human Services ("HHS") and the USDA's response to the 2015 Dietary Advisory Committee's recommendations on inclusion of sustainability concerns in the Guidelines is often understood as a result of industry influence on the agencies. *See, e.g.*, Negowetti, *infra* note 325, at 179 (suggesting that the agencies' decision to exclude sustainability concerns followed at least in part from agencies' relationship to the meat industry).

164. It may also result in resistance from traditional consumer protection organizations' concern about FDA becoming distracted from its core mission of protecting consumers from unsafe food and misleading labeling.

165. *Cf.* Paben, *supra* note 74, at 208–09 (suggesting that FDA should use NEPA as a mechanism to encourage public involvement in FDA decision-making and make the agency more responsive to the range of public concerns about the food system).

166. The FDCA does invite some cumulative assessment. *See, e.g.*, 21 U.S.C. § 348(c)(5)(B) (inviting consideration of "the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet"). *But see* Complaint, *supra* note 139 (suggesting that FDA often does not do this kind of cumulative assessment in practice).

proval decisions, FDA might address the environmental impacts of the food ingredient and food packaging production and disposal processes more thoroughly. Second, FDA might use the mechanism of the PEIS to assess cumulative environmental impacts of food additive approval decisions.[167] This latter tool is particularly important in the food packaging context. It could help the agency both to assess the cumulative impacts of substance approvals and to look at population-level health as well as individual health.

1. Broadening Environmental Review of Individual Substances

The first shift in approach is relatively straightforward. Our analysis suggests that FDA's NEPA compliance efforts regarding FCSs and food additives is cursory.[168] Focusing on the FCN program, we identify areas where the agency has room for improvement. As we note above, when FDA reviews EA submissions for FCNs, it places particular emphasis on "environmental issues relating to the use and disposal from use of FDA-regulated substances."[169] Among the substances approved through the FCN process are the components of single-use plastics, yet NEPA review of FCNs typically neglects two important deficiencies in American plastic production and disposal (including recycling).

First, the agency ignores the sourcing of raw material that precedes the manufacturing of the FCS and the ultimate packaging product. By neglecting to consider where manufacturers source the materials necessary to produce their polymers for plastic packaging, FDA fails to address the issue that manufacturers frequently opt for cheaper virgin materials rather than recycled materials.[170] This choice for virgin materials increases fossil fuel reliance, since virgin plastics are fossil-fuel based. The choice also adds to the total plastic volume produced, contributes to plastic accumulation in the environment, and further cripples the supply and demand systems necessary to promote effective recycling programs.[171]

Second, the agency's examination of disposal's environmental impacts is also incomplete and leaves room for improvement. Frequently, FDA's FONSIs review whether there will be any significant environmental impact owing to an

167. *See supra* note 117 (describing and defining the PEIS).

168. *See supra* Part II.A.2; *see also* Grant, *supra* note 74 (critiquing FDA NEPA compliance in the plastic packaging context).

169. FDA, *supra* note 112.

170. Complaint, *supra* note 80, at 7; Jack Kaskey, *Rapidly Growing Backlash to Plastic Has Oil Companies Worried*, FIN. POST (Jan. 7, 2021), https://perma.cc/H6BU-PXC4; Colin Staub, *Supply Issues and Virgin Competition Jostle Resin Prices*, PLASTICS RECYCLING UPDATE (Feb. 10, 2021), https://perma.cc/CAS3-4J7Z.

171. Chantal Carriere & Rachael Beavers Horne, *The Case for a Legislated Market in Minimum Recycled Content for Plastics*, 50 ENV'T L. REP. 10,042, 10,042–46 (2020); *see infra* Part III.B.1 (elaborating on the problematic dynamics of the recycling system).

FCS's total or partial replacement of existing products. FDA often makes a finding that none exists because the FCS is not disposed of via a different means than the products it replaces—for example, new plastic soda bottle with additive *A* can be disposed of in the same way as old plastic soda bottle with additive *B* that has roughly the same shape, size, and properties, which has been reviewed and is already in the stream of commerce.[172] With plastic FCSs intended to be used in packaging, FDA also engages in a discussion of the recyclability of the new FCS and compares it to recyclability of products currently on the market.[173] While this method of review does seem productive to prevent gross incompatibility of disposal procedures between old and new materials, it does not capitalize on opportunities to further weave into the review process an agenda that could mitigate environmental consequences. To improve its methodology, the agency could request additional information from those submitting EAs to ensure it is aware of how the replacement of one type of packaging with a new variety will proceed and that there will not be an inadvertent net increase in disposed material if both forms of packaging are simultaneously manufactured during changeover periods. Additionally, where recyclable FCSs are involved, FDA could go beyond reviewing the similarity of recyclability between old and new products and investigate whether these products are, in fact, being recycled. If the agency were to find that a particular plastic resin was not being recycled, it may instead need to evaluate how that resin was being disposed of in landfills, combusted, or discharged into the environment, and perhaps reckon with whether it was wise to permit at all another FCS to accumulate in the environment.

A last point of consideration. Our review of the FCN database revealed that in environmental analyses, FDA currently prioritizes evaluating just one category of environmental harm: FCS disposal's toxicological impact on ecosystems. This framework is appropriate for certain FCSs, like aqueous disinfectants, that exhibit their toxicological effects on the environment in the near-term.[174] But plastics are different because of their longevity. Upon disposal,

172. FDA, Environmental Decision Memo for Food Contact Notification No. 1671 (2016), https://perma.cc/98WZ-MK39 ("It is intended to replace similar polyolefin materials currently used in food contact applications. Thus significant impacts to use of energy and resource are not anticipated.").

173. *See* FDA, Environmental Decision Memo for Food Contact Notification No. 1510 (2015), https://perma.cc/R3PP-4SZ3 ("In regard to the recyclability of the FCS, [polyethylene terephthalate ("PET")] articles that are fabricated from the subject FCS are expected to bear the resin identification codes currently used for PET bottles. As a result, the FCS containing bottles and articles (i.e. non-films) will be included in the same post-consumer streams as others with the same resin identification codes, and will not result in an increase [sic] the use of resources and energy."). This particular FCN was not part of our random sample, but we chose to review it in addition because PET is a common polymer used in food packaging.

174. *Identifying Greener Cleaning Products*, EPA, https://perma.cc/44V9-ZFYK.

plastic compounds used in food packaging do not necessarily immediately leach chemical compounds into the environment at concentrations that would be considered toxic to aquatic or terrestrial ecosystems.[175] The more significant threats to aquatic environments are entanglement and ingestion.[176] In addition, plastic waste in the environment accumulates other toxins that may then be ingested by wildlife.[177] Plastic materials' unique accumulating qualities are not, however, distinctly noted in the agency's FONSI issuances. Instead, the agency appears to abdicate its oversight role and defer to EPA on matters of environmental concentration and accumulation.[178] For instance, addressing plastic waste, FDA noted in one FONSI that "in light of the [EPA's] regulations governing municipal solid waste landfills, it is reasonably expected that the disposal of FCS containing articles will not result in significant introductions to the environment. Furthermore, the incineration of these articles will be mitigated by EPA regulations governing [municipal solid waste ("MSW")] combustion units."[179] This approach also indicates that FDA does not necessarily prefer that the products are recycled, so long as those products do not introduce chemicals into the environment by leaching or combustion. Such conceptions of environmental impact fail to address the fact that these plastics either persist in landfills and the environment virtually forever or are diverted to combustion facilities resulting in increased combustion byproducts.[180] FDA also fails to consider that about "40% of plastic waste is not accounted for in managed landfills or recycling facilities," meaning that a significant percentage of plastic waste never reaches EPA's regulatory jurisdiction.[181]

FDA has discretion under NEPA to look closely at which packaging materials are more readily recycled and to examine the deficiencies in the overall recycling system and how a particular FCS would benefit or harm that system. Improved NEPA review could draw public attention to plastic food packaging products. It could also facilitate FDA's use of its affirmative regulatory authority to prevent less-efficiently recycled materials from entering the

175. Boris Worm et al., *Plastic as a Persistent Marine Pollutant*, 42 ANN. REV. ENV'T & RES. 1, 11–13 (2017) (noting that toxic leaching is an issue of concern with plastics but that it appears to be a less direct risk than the risks from ingestion and entanglement).

176. *Id.* at 10–11.

177. *Id.* at 13.

178. *See supra* note 120 and accompanying text (citing cases holding that this form of agency abdication violates NEPA).

179. FDA, ENVIRONMENTAL DECISION MEMO FOR FOOD CONTACT NOTIFICATION NO. 1479 (2014), https://perma.cc/L3XE-U74T (internal citations omitted) (included *infra* Appendix, Food Contact Notification Samples No. 34).

180. Worm et al., *supra* note 175, at 9–10 (describing the persistence of plastics in aquatic environments); Rinku Verma et al., *Toxic Pollutants from Plastic Waste—A Review*, 35 PROCEDIA ENV'T SCIS. 701 (2016) (reviewing the health risks associated with incineration of plastics).

181. Worm et al., *supra* note 175, at 1.

food system in the first place. Part III.B.1 takes up the question of FDA's substantive authority to make change in this area.

2. The Programmatic EIS

FDA has historically downplayed the environmental significance of individual regulatory decisions. As we have noted, FDA tends to focus on the use and disposal of individual FCSs, with particular emphasis on toxicological effects on aquatic and terrestrial life.[182] Moreover, when considerations such as waste management, including recycling, or GHG emissions arise, the agency most typically either cites a substitution effect resulting in no net increase or defers to EPA-established thresholds.[183] These dismissive strategies ignore the collective environmental impacts of food packaging, animal drugs, and other substances within FDA's jurisdiction.

Enter the programmatic EIS. A PEIS would evaluate the environmental impact of an agency's entire program that it is acting to implement. This approach is used when an agency determines, of its own accord, to draft a PEIS.[184] For instance, in 2017, the Obama Administration's Bureau of Land Management initiated a PEIS addressing federal coal leasing. Motivated by, among other things, concerns about climate change, the PEIS was expressly intended to consider the possibility of significant programmatic reform.[185] An agency may also draft a PEIS if a court determines that proceeding with NEPA compliance regulatory-action-by-regulatory-action will miss the larger scale environmental effects of the agency's activities in a particular arena. For instance, a federal district court ordered the National Oceanic and Atmospheric Administration to complete a PEIS for its Fishery Management Plans after determining that the EIS the agency had prepared addressing specific Alaskan fisheries was too narrow and ignored cumulative effects of the entire program.[186]

CEQ identifies the possibility of a PEIS, and its regulations suggest evaluating proposals for agency action geographically or "generically, including actions that have relevant similarities, such as common timing, impacts,

182. *See supra* notes 113–16 and accompanying text.

183. *See supra* Part II.A (identifying these trends in FDA NEPA compliance documents).

184. CEQ GUIDANCE, *supra* note 117.

185. Notice of Intent to Prepare a PEIS to Review the Federal Coal Program and to Conduct Public Scoping Meetings, 81 Fed. Reg. 17,720, 17,724–25 (Mar. 30, 2016) (including as an explicit goal the need to reduce coal extraction on federal land by reducing leasing on federal lands).

186. Beth C. Bryant, *NEPA Compliance in Fisheries Management: The Programmatic Supplemental Environmental Impact Statement on Alaskan Groundfish Fisheries and Implications for NEPA Reform*, 30 HARV. ENVTL. L. REV. 441, 443 (2006); Greenpeace v. Nat'l Marine Fisheries Serv., 55 F. Supp. 2d 1248 (W.D. Wash. 1999); *see also* Thomas v. Peterson, 753 F.2d 754, 761 (9th Cir. 1985) (holding that the Forest Service must assess the environmental impacts of a lumber sale and a road built to harvest the lumber together).

alternatives, methods of implementation, media, or subject matter."[187] Although the regulations provide little direction as to when an agency should choose to conduct a PEIS,[188] CEQ guidance on *Effective Use of Programmatic NEPA Reviews* ("CEQ Guidance") offers additional direction.[189] The CEQ Guidance suggests that PEISs "have value by setting out the broad view of environmental impacts and benefits for a proposed decision."[190] It goes on to identify four categories of agency activity where a PEIS is appropriate, including adopting official policy, adopting formal plans, adopting agency programs, and approving multiple actions.[191] The CEQ Guidance is not binding, and agencies maintain a large degree of discretion as to when a PEIS is appropriate.[192]

A cumulative analysis might be particularly valuable in the FCN context.[193] PEISs allow for a "broad overview of a complex, multifaceted, interconnected program," meaning that an analysis of the cumulative impacts of the agency's actions within this program could be especially insightful and shape revision of the regulatory approach.[194] FDA could commence a PEIS to assess the environmental impacts of the FCN approval process itself, of FDA approval of single-use plastic packaging, or, most broadly, of FDA regulation of FCSs. FDA might do this either as a part of an update to the FCN program, and thus under the guide of "adopting official policy,"[195] or it might do this as a precursor to "approving multiple actions." The CEQ Guidance suggests that a PEIS is appropriate for approving multiple actions where those actions are "temporally or spatially connected," and offers as examples projects such as large scale utility corridor projects that will involve "several similar actions or projects

187. 40 C.F.R. § 1502.4(b)(1) (2020).

188. *Id.* (establishing that EISs "may be prepared for programmatic federal actions, such as the adoption of new agency programs"). Other types of EISs are project EISs and legislative EISs. In 2020, CEQ repealed several provisions that previously governed these decisions, including 40 C.F.R. § 1508.27, which defined "significance," and established that "[s]ignificance cannot be avoided by terming an action temporary or by breaking it down into small component parts." Update to the Regulations Implementing the Procedural Provisions of the National Environmental Policy Act, 85 Fed. Reg. 43,304, 43,321–22 (July 16, 2020) (to be codified at scattered parts of 40 C.F.R.).

189. *See* CEQ GUIDANCE, *supra* note 117.

190. *Id.* at 6. The CEQ Guidance also suggests that the PEIS is an underutilized tool. *Id.* at 8.

191. *Id.* at 13–14.

192. *Id.* at 15; Bryant, *supra* note 186, at 449.

193. *Cf.* Karkkainen, *supra* note 60, at 948 (identifying the use of "tiering," where individual action EAs follow a PEIS, as a useful mechanism to "identify, from an ex ante perspective, the potential cumulative effects of a series of smaller related projects, none of which individually rose to the level of 'significant'"); CEQ GUIDANCE, *supra* note 117, at 47 (charting the differences between tiered analysis and programmatic analysis).

194. Karkkainen, *supra* note 60.

195. CEQ GUIDANCE, *supra* note 117, at 13–14 (suggesting that a PEIS might be approved where an agency is "redesign[ing] . . . an existing program").

in a region or nationwide," and "a suite of ongoing, proposed or reasonably foreseeable actions that share a common geography or timing, such as multiple activities within a defined boundary."[196] Although the FCN process does not quite match either of these descriptions, to the extent that food packaging contributes to the global problem of ocean plastic pollution, separate FCN processes are arguably spatially connected.

Such an analysis could focus on the cumulative impact of approving new plastic materials and their accumulation in the environment. For example, it might emphasize that dilution of one chemical in wastewater discharge is unlikely to harm aquatic life, but cumulative discharge could impede the effective operation of wastewater treatment facilities or cause endocrine disrupting responses even at very low concentrations. Similarly, although individual review does not focus on the environmental impact of manufacturing and sourcing of materials, a PEIS would likely consider these issues and could identify patterns of unsustainable materials sourcing practices. A PEIS might then provide the data that could inform substantive regulatory decisions to curtail use of particular types of plastics because of the public health threats that they pose.[197] A PEIS might also be useful in a variety of other contexts explored below, including animal antibiotics, food additive approval processes in general, and color additives in particular.

B. Opportunities to Regulate Food Chain Environmental Impacts

Many of FDA's ongoing regulatory activities present opportunities for food safety analysis that incorporates some consideration of safety in production and disposal. When FDA examines pre-ingestion and post-ingestion risk over a food product's entire lifecycle, it can incorporate these environmental impacts into its safety assessments and mitigate adverse consequences of its regulatory decisions.[198] The following three examples of regulation where such consideration and mitigation could occur are meant not as an exhaustive list but as a preliminary exploration, demonstrating the assertion above that FDA has both the regulatory authority and the practical opportunities to take environmental concerns seriously. FSMA also offers extensive opportunities for synergistic, dual-mission regulation, but because we have addressed these in detail elsewhere, we focus here primarily on the FDCA's other adulteration provisions.[199]

196. *Id.* at 14.

197. *See infra* Part III.B.1 (identifying some opportunities for this type of substantive action).

198. For the general suggestion that food safety should be defined "beyond ingestion" and incorporate this kind of cradle-to-grave assessment, see Broad Leib & Pollans, *supra* note 7, at 1189–93.

199. Pollans, *supra* note 38, at 427–28 (describing missed opportunities for synergistic governance of environmental protection and produce safety); Broad Leib & Pollans, *supra* note 7, at 1224–30 (elaborating on these opportunities).

1. Food Packaging

Food packaging is a key component in the plastics crisis. FDA can help mitigate this crisis by facilitating adoption of reusable instead of single use packaging, fueling increased demand for recycled plastic materials, and streamlining approvals for biodegradable plastics.

Food packaging constitutes about half of all packaging sales, and packaging constitutes about 30% of municipal solid waste.[200] That number fails to encompass the massive amount of packaging waste that is littered rather than landfilled or incinerated.[201] Some of this packaging is consumer-facing—the plastic bag in the Cheerios box, the individual foil wrapping of a Peppermint Patty—but much of it is producer-facing—the cardboard box in which produce travels to market, the pallet a group of cardboard boxes rests on. While sustainability departments at many multinational food corporations acknowledge the contribution of food packaging to their significant environmental footprints and have undertaken voluntary producer-side initiatives to reduce packaging's environmental impact, consumers currently shoulder a large portion of the responsibility to address packaging excess and waste.[202]

Yet recycling, the primary option available to consumers, has fallen short. Cradle-to-grave analysis of the plastics lifecycle shows that recycling has played a minimal role in plastic waste management. Out of an estimated 8.3 billion tons of plastic ever produced, 4.9 billion tons have been discarded, 800 million tons have been incinerated, and only 500 million tons have been recycled.[203] EPA observed that the absolute amount of recycling of waste products nationwide rose from 14.5 million tons in 1980 to 69 million tons in 2018; however, the rate of recycling, as a percentage of total volume of waste disposal, which

200. Betty Bugusu, *Food Packaging and Its Environmental Impact*, Food Tech. Mag. (Apr. 4, 2007), https://perma.cc/8GZ6-ZJYK (estimating that food packaging is 50% of total packaging *sales* by weight, but almost two-thirds of packaging *waste* by volume). Other sources offer different estimates. Joe Yates et al., *PROTOCOL: Plastics in the Food System: Human Health, Economic and Environmental Impacts. A Scoping Review*, 15 Campbell Systematic Rev. 1 (2019) (estimating that packaging makes up 40% of plastic waste and that 41% of that is food and beverage packaging waste); *see also* Carriere & Horne, *supra* note 171, at 10,043 (offering a lower estimate that packaging makes up only 26% of plastic waste).

201. Catto Fellowship Program, Global Declaration on Plastic Pollution, https://perma.cc/V8WR-7VLU.

202. *See* Carriere & Horne, *supra* note 171, at 10,044–45, 10,049. Because producers exercise control over their raw material sourcing and manufacturing practices, developing systems on the producer end for utilizing reusable packaging is a more manageable logistics challenge than addressing the waste recapturing in the post-consumer portion of a product's lifecycle. See *id.* for a discussion of the numerous production-side sustainability solutions.

203. Complaint, *supra* note 80, at 6.

also increased steadily for several decades, leveled off around 2010.[204] In 2018, plastics were responsible for 12% of all MSW generated in the United States, only 4.5% of the total MSW recycled, and 18.5% of the total MSW landfilled.[205] In total, only about 14% of plastic produced globally is actually recycled.[206] Plastic ultimately makes up a disproportionate amount of landfilled and incinerated MSW.

Improperly managed plastic waste chokes aquatic ecosystems, emits GHGs, and releases a variety of toxins, including carcinogens and endocrine-disrupting chemicals that negatively impact reproductive systems and hormones of animal life.[207] Further, even where disposal-related impacts are properly mitigated, traditional plastic production is non-renewable and resource intensive.[208]

FDA can shape both producer and consumer use of plastics in three main ways. First, through its food safety regulations, it influences the choice between single-use and reusable containers. For instance, FDA's FSMA rules directed at produce harvesting require that packing material either be "designed for single use" or be "cleanable," and, "if [a farmer] reuse[s] food-packing material, [she] must take adequate steps to ensure that food contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner."[209] The burden of cleaning a container with each use may encourage many farmers to switch to single use packaging. Food safety rules can also make it challenging for consumers who want to use their own reusable packaging in various contexts.[210] These rules burden food establishments that want to offer reusable options and they reflect, in part, concerns surrounding cross-contamination resulting from consumer behavior.[211] None of the regulations discouraging reusables are specifically required by either the FDCA or FSMA. And advocates of reusable

204. EPA, Advancing Sustainable Materials Management: 2018 Fact Sheet 5 (2020), https://perma.cc/3URD-QMCC (actually showing a decline in the percentage of municipal solid waste recycled from 2017 to 2018).

205. *Id.* at 8–9.

206. Carriere & Horne, *supra* note 171, at 10,046.

207. Okunola A. Alabi et al., *Public and Environmental Health Effects of Plastic Wastes Disposal: A Review*, 5 J. Toxicology & Risk Assessment 21 (2019); Complaint, *supra* note 80, at 22–26.

208. Traditional plastics are made from fossil hydrocarbons. These hydrocarbons were formed from the exposure of organic matter to temperature and pressure conditions over the span of millions of years to form molecular chains that have immense industrial applications. *See generally Fossil Hydrocarbon*, Sci. Direct, https://perma.cc/9SE7-5SQQ (examining components of topic summary, particularly looking at contributions by Lucia M. Petkovic and Michael F. Ashby).

209. 21 C.F.R. § 112.116 (2021).

210. *See* Broad Leib & Pollans, *supra* note 7, at 1221.

211. *See* Hillary Thesmar, *The Intersection of Food Safety and Sustainability*, Oliver Wyman, https://perma.cc/M95M-XUJT; *see also* Phila. Off. of Sustainability & Circular Phila., Reusable To-Go Food Container Webinar 13 (Aug. 5, 2021), https://perma.cc/83S5-4YND.

packaging assert that single-use packaging is not strictly necessary to protect public health,[212] with organizations such as the Reusable Packaging Association stating that there have never been food safety risks detected in association with the use of reusable packaging containers.[213]

Second, through its oversight of FCSs, FDA influences the extent to which recycled and recyclable materials are used in food packaging.[214] As its website explains:

> FDA's main safety concerns with the use of [post-consumer recycled ("PCR")] plastic materials in food-contact articles are: 1) that contaminants from the PCR material may appear in the final food-contact product made from the recycled material, 2) that PCR material may not be regulated for food-contact use may be incorporated into food-contact article, and 3) that adjuvants in the PCR plastic may not comply with the regulations for food-contact use.[215]

As a result of these concerns, "FDA considers each proposed use of recycled plastic on a case-by-case basis."[216]

Even when plastic is collected and diverted into recycling streams, the capacity of recyclers to make use of most materials is quite limited. According to a recent Greenpeace study, only a small minority of the plastic types, referred to

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212. *See* M. Susan Brewer, *Reusing Food Packaging . . . Is It Safe?*, Ill. Coop. Extension Serv. 4, 5 (1992) (discussing guidelines to follow for safe reuse of food containers); *Over 125 Health Experts Defend Safety of Reusables During COVID-19 Pandemic*, Greenpeace Int'l (June 22, 2020), https://perma.cc/69CN-5U3G (responding to the rollback of single use plastic bans during the COVID-19 pandemic and noting that more than 125 health experts—"joined by Greenpeace USA and UPSTREAM, both members of the Break Free From Plastic movement—emphasize that disposable products are not inherently safer than reusables and that reusable systems can be utilized safely during the pandemic by employing basic hygiene"); Hiroko Tabuchi, *In Coronavirus, Industry Sees Chance to Undo Plastic Bag Bans*, N.Y. Times (Mar. 26, 2020), https://perma.cc/3JQZ-4L9C (arguing the plastic industry is using the pandemic to try to block laws prohibiting single-use plastic and "to quash plastic bag bans" and that the science does not clearly support this).

213. *Food Safety*, Reusable Packaging Ass'n, https://perma.cc/A9DB-MHET.

214. The FDCA's definition of adulterated food includes food whose "container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health." 21 U.S.C. § 342(a)(6); *see also id.* § 348(h)(6) (defining "food contact substance" as "any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food"); *id.* § 348(a)(3) (deeming unsafe any FCS not in conformity either with a premarket approval or an effective notification).

215. *Recycled Plastics in Food Packaging*, FDA (2020), https://perma.cc/G5AM-PPR3.

216. *Id.*; *see also* 2 James T. O'Reilly & Katharine A. Van Tassel, Food and Drug Administration § 27:6 (4th ed. 2021) ("The FDA's role in plastic recycling is that of gatekeeper of plastic reuse markets.").

as resins, actually possess viable recycling value.[217] Resins labeled #3 through #7 using the Resin Identification Code ("RIC") are "economically impossible to recycle now and will remain so in the foreseeable future"; they are collected by many recycling programs but are frequently incinerated or landfilled.[218] As for recycling polyethylene terephthalate ("PET") and high-density polyethylene ("HDPE") (RIC #1 and #2, respectively), which are economically viable to recapture given the right circumstances, the issue has become one of surplus.[219] Recycling programs in the United States are ill-equipped to handle the volume of plastic products that flow into their systems. Until 2018, the United States exported significant volumes of plastic waste to China, which would purchase the United States' plastic waste surplus and sort and process it.[220] In that year, China implemented a new policy limiting plastic waste imports.[221] The near termination of this outlet for plastic waste exacerbated the already staggering domestic issue of plastic overflow.[222] Because recycling is costly, and becoming costlier due to this increasing need to handle large volume, recyclers need more buyers to make recycling profitable.[223] But identifying buyers for that material has been challenging, particularly as fossil fuel companies continue to integrate their oil operations with polymer production facilities.[224] This integration increases the efficiency of creating polymers and plastics and has made it cheaper for major consumer goods companies, such as Coca-Cola, Pepsico, and Nestle to purchase massive amounts of packaging from manufacturers who use virgin plastics in their products rather than recycled materials.[225] Without profitable markets for recycled products, recycling programs nationwide are faltering, with municipalities forced to either subsidize recycling facilities' or shut down their programs.[226] These monetary considerations have led communities across Ten-

217. John Hocevar, Greenpeace, Circular Claims Fall Flat: Comprehensive U.S. Survey of Plastics Recyclability 27 (2020), https://perma.cc/CX5Z-83AB.

218. *Id.* at 21.

219. Carriere & Horne, *supra* note 171, at 10,047 (describing lack of domestic processing capacity as a barrier to successful recycling markets).

220. Complaint, *supra* note 80, at 33; Christopher Joyce, *U.S. Recycling Industry Is Struggling to Figure Out a Future Without China*, NPR (Aug. 20, 2019), https://perma.cc/XV5E-8UX6.

221. Howard Husock, The Declining Case for Municipal Recycling 6 (June 2020), https://perma.cc/WBD4-7ND2 (explaining that China had previously thrown away much of the waste that it imported because it was too contaminated to recycle easily and the new policy prohibited contaminated waste imports).

222. Jehan El-Jourbagy et. al., *Creating an Industrial Regulatory Framework to Reduce Plastics*, 18 Berkeley Bus. L.J. 94, 112 (2021) (describing the consequences of China's policy shift on U.S. domestic waste management).

223. Joyce, *supra* note 220.

224. Complaint, *supra* note 80, at 7; Kaskey, *supra* note 170.

225. Complaint, *supra* note 80, at 7.

226. *Id.* at 36; Husock, *supra* note 221 (surveying the economic conditions of recycling in five major U.S. cities and counties).

nessee, Minnesota, Alabama, and Pennsylvania to cancel curb-side pick-up recycling options altogether, to stop accepting plastic, or to decide to incinerate plastic products rather than recycle.[227]

Through its control of FCSs, FDA influences the scope of the market for recycled plastics and the proportion of recyclable versus non-recyclable plastic waste. FDA does not have separate regulatory standards for recycled plastics. Instead, it regulates materials by compound and expects that recycled materials meet the same standard as virgin materials.[228] Although FDA does not require manufacturers to seek pre-market approval for their recycling processes, it does invite manufacturers to submit descriptions of their processes, any safety data they have regarding incidental contamination, and intended conditions for use of the recycled material.[229] The agency also generates guidance, which it updated in July 2021, offering suggestions for how manufacturers can avoid chemical contamination in recycling processes.[230] By revisiting assessment standards for FCSs containing recycled components with the express goal of facilitating their use, FDA might enhance markets for recycled materials and help make the circular economy for plastics more fiscally sustainable. It might also consider polymer recyclability, looking at both the theoretical and actual recyclability of new plastic FCSs.[231]

The final regulatory mechanism through which FDA can influence the flow of food packaging waste is to prioritize clearances for biodegradable polymer FCSs that can replace fossil-hydrocarbon-based plastic food packaging. There is a plethora of bio-based polymers that have entered the market or are in active research and development, including items like polylactic acid ("PLA"), made from beets and sugarcane waste, and other materials composed of wood, sawdust, and genetically engineered algae.[232] Determining how to effectively deploy such technologies can be problematic, however. For example, working with bio-based materials to create FCSs implicates concerns about

227. Complaint, *supra* note 80, at 7; Michael Corkery, *As Costs Skyrocket, More U.S. Cities Stop Recycling*, N.Y. Times (Mar. 16, 2019), https://perma.cc/92MY-PF9E.

228. *See General Information for Industry on Supply Chain Communication for Recycled Plastics in Food-Contact Applications*, Plastics Indus. Ass'n, https://perma.cc/PS5S-CWA9; *see, e.g.*, 21 C.F.R. § 177.1630 (2021) (establishing standards for polyethylene phthalate polymers, the plastics used in most soft drink bottles).

229. *Recycled Plastics in Food Packaging*, *supra* note 215 (describing the submission process); FDA, Submissions on Post-Consumer Recycled (PCR) Plastics for Food-Contact Articles (July 26, 2021), https://perma.cc/5JLX-RZHT (listing 253 submissions that have received "no objection letters").

230. FDA, Use of Recycled Plastics in Food Packaging (Chemistry Considerations): Guidance for Industry (July 2021), https://perma.cc/7VNR-6ZK9.

231. *See supra* notes 172–74 and accompanying text (suggesting that FDA include similar consideration in individual FCS EAs).

232. George G. Misko, *Biobased Plastics and the Sustainability Puzzle*, PackagingLaw.com (Feb. 2, 2020), https://perma.cc/87B9-XDGD.

whether the source material—plants, algae, other organic matter—was contaminated in some way by environmental or biochemical toxins, or if it underwent some form of reaction during heating processes in the product's formation that could create undesirable byproducts.[233] Moreover, once the product has been formed, used, and discarded, it likely biodegrades, but the environmental conditions under which this decomposition occurs may also require specific control in composting facilities, and the products may also need to be strictly separated from other recycling streams as they can contaminate whole batches of plastic polymer and prevent them from being recyclable.[234]

One possible option to assist with such encouragement for adoption of biodegradable polymers would be to explore the submission requirements and process that FCS producers are subject to under the FCN program. FDA should assess opportunities to develop a fast-track program where biodegradable polymer manufacturers are able to receive FCN review in a more expedited timeline than fossil hydrocarbon polymer producers. The FCN program already has a significantly faster timeline that the traditional food additive petition program.[235] Further acceleration for bio-based plastic technology could stimulate their development and competitiveness with fossil-hydrocarbon based plastics. Moreover, just as the FCN program creates the opportunity for a "prenotification consultation" to help ensure the FCN submitter is including all of the necessary information to support clearance of its FCS,[236] a particular subprogram for bio-based plastics could provide additional guidance and support to submitters to encourage these materials.

2. Animal Antibiotics

The story of animal antibiotics provides another roadmap of how FDA can incorporate environmental impact analysis into its consideration of human health impacts. Extensively used on feedlots, animal antibiotics promote rapid growth and allow for dense, large-scale cattle facilities.[237] Seventy to eighty percent of all antibiotics used are administered to animals.[238] As a result, feedlots

233. *Id.*

234. *Id.*

235. *See* Anna P. Shanklin & Elizabeth R. Sanchez, *FDA's Food Contact Substance Notification Program*, Food Safety Mag. (Oct. 1, 2005), https://perma.cc/DG3Y-YTHR.

236. FDA, Guidance for Industry: Preparation of Food Contact Notifications (Administrative) 15 (May 2002), https://perma.cc/D3PN-UTZM.

237. Madhab K. Chattopadhyay, Opinion, *Use of Antibiotics as Feed Additives: A Burning Question*, 5 Frontiers Microbiology, art. no. 334, at 1 (discussing postulated reasons for this phenomenon).

238. *Antibiotics and Animal Agriculture: A Primer*, Pew Charitable Trs., (Dec. 19, 2016), https://perma.cc/W832-KWUF. *But see Questions and Answers: Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals*, FDA (2020), https://perma.cc/EF2W-NLHF (rejecting the value of this statistic on the ground that human and

have become a breeding ground for antibiotic-resistant bacteria, exposing workers and their families, contaminating water via runoff, and occasionally entering the food stream.[239] Currently, about 35,000 people die each year as a result of antibiotic-resistant infections, and public health experts have expressed concern that this number could rise substantially if FDA does not take steps to reduce subtherapeutic antibiotic use in animal agriculture practices.[240]

FDA has jurisdiction over this issue through its regulatory oversight of animal drugs. Pursuant to the FDCA, FDA reviews all animal drugs before they go to market, evaluating their safety for human and animal use.[241] As part of the approval process, the agency has the authority to condition use to ensure safety for both humans and animals.[242] FDA may also withdraw an existing approval after finding that new evidence shows the drug is not safe for its intended use.[243] In 2005, FDA withdrew approval for one antibiotic used for poultry, citing concerns about antibiotic resistance. Numerous antibiotics remain available, however. In 2009 and 2013, FDA published industry guidance documents seeking collaboration from animal drug manufacturers to voluntarily remove drug labels describing growth-promoting production uses.[244] The 2013 Guidance for Industry ("GFI") #213 requested that all animal drug manufacturers whose labels have approved growth-promoting production applications contact the agency within three months to notify FDA of their intentions to voluntarily remove those approved uses from their drug labels.[245] GFI #213 also

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animal physiology is different, that animals have different weights than humans, and that there are more animals than there are humans).

239. C. Lee Ventola, *The Antibiotic Crisis: Part 1: Causes and Threats*, 40 PHARMACOLOGY & THERAPEUTICS 277, 279 (2015) (describing how agricultural use contributes to the problem of antibiotic resistance). Feedlot operators often give low (subtherapeutic) doses, which contributes to the growth of antibiotic-resistant bacteria. *See* Nat. Res. Def. Council, Inc. v. FDA, 760 F.3d 151, 153 (2d Cir. 2014).

240. David Wallinga & Avinash Kar, *New Data: Animal vs. Human Antibiotic Use Remains Lopsided*, NRDC EXPERT BLOG (June 15, 2020), https://perma.cc/Z3UL-W46Y. Some estimates of deaths related to antibiotic-resistant bacteria are as high as 162,000 in the United States. *Id.*

241. 21 U.S.C. § 360b. Challenging inadequate NEPA compliance in the context of these approvals can be challenging. A 2015 federal district court decision required that plaintiffs first exhaust remedies before the agency, even under circumstances where approval processes are confidential until they are finalized due to agency evaluation of proprietary information. Ctr. for Food Safety v. Hamburg, 142 F. Supp.3d 898 (N.D. Cal. 2015).

242. 21 U.S.C. § 360b.

243. FDA has the initial burden of production in a drug approval withdrawal proceeding. MICHAEL T. ROBERTS, FOOD LAW IN THE UNITED STATES § 3.05[8][c] (2016). It must put forth evidence raising serious questions as to the drug's safety. *Id.* Once it meets this standard, the burden shifts to the drug manufacturer to show that drug is safe. *Id.*

244. FDA, FDA'S STRATEGY ON ANTIMICROBIAL RESISTANCE – QUESTIONS AND ANSWERS (2013), https://perma.cc/7EDX-PSY6 (see question nine).

245. FDA, GUIDANCE FOR INDUSTRY #213, at 6 (2013), https://perma.cc/4ABQ-HF5U.

recommended that all antibiotics administered via animal feed and water be administered under veterinarian oversight.[246] FDA implemented the Veterinarian Feed Directive ("VFD") final rule in 2015, which builds on the preceding published guidance and specifies the methods that a veterinarian can use to "judicious[ly] use . . . medically important antimicrobials."[247] Of the thirty-one drug applications that had production uses approved, all such indications have been withdrawn following GFI #213's publication.[248] According to an FDA VFD fact sheet, "[a]s a result of these changes, these products cannot be used for production (e.g., growth promotion) purposes and may only be used under the authorization of a licensed veterinarian."[249] Sales of antibiotics for animal agriculture peaked in 2015 and declined 36% over the four following years.[250] Overall use remains very high, however, and, in 2021, FDA issued GFI #263, which recommended that "sponsors of medically important antimicrobial new animal drugs that are currently approved with [over the counter ("OTC")] marketing status voluntarily . . . change the drug from OTC to Rx marketing status."[251] This recommendation covers not only medically important "antibiotics used in feed and water," but those "administered through any route."[252] FDA established a two-year timeframe for sponsors to either change the drug marketing status or withdraw the drug's application for approval.[253]

Although many critique these actions as vastly inadequate to curb the threat of antibiotic resistance, they are nevertheless significant as a rare example of FDA's embrace of cradle-to-grave food safety.[254] Antibiotic use in animals poses a threat not because risk is associated with consumption of antibiotics themselves, but because the persistent use of antibiotics in an environment full of manure generates ideal conditions for the evolution of antibiotic-resistant bacteria.[255] These bacteria then pose a threat to human health through a variety of pathways of contamination, including but not limited to ingestion of food.

246. *Id.*

247. *Fact Sheet: Veterinary Feed Directive Final Rule and Next Steps*, FDA (Feb. 11, 2021), https://perma.cc/8TTP-RM2K.

248. *Id.*

249. *Id.*

250. FDA, 2019 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals 3 (2020), https://perma.cc/2LHR-69A2 (finding a slight increase from 2018 to 2019 and noting that while 2019 was 36% below 2015 levels, it was actually only 25% below 2010 levels).

251. FDA, Guidance for Industry #263, at 3–5 (2021), https://perma.cc/PEX3-JTPG.

252. David Hyun, *FDA Will Require Veterinary Oversight for All Animal Antibiotics Important to Human Medicine*, Counter (Aug. 23, 2021), https://perma.cc/5UNZ-2257.

253. FDA, *supra* note 251, at 6.

254. Karin Hoelzer, *Antibiotic Resistance and Animal Consumption: The Case for Duration Limits in Food-Producing Animals*, Health Affs. (Mar. 12, 2020), https://perma.cc/FW8H-36W8.

255. Ventola, *supra* note 239; Timothy F. Landers et al., *A Review of Antibiotic Use in Food Animals: Perspective, Policy, and Potential*, 127 Pub. Health Rep. 4, 6 (2012).

In other words, FDA's regulatory activity recognizes that eating-adjacent safety risks are within its regulatory purview.

In a broad assessment of how to protect human safety from the misuse of animal antibiotics, FDA could weigh incidental environmental benefits as it decides whether to approve new antibiotics, as well as in its review of the efficacy of its associated enforcement and compliance assurance processes. In fact, there is a body of scientific literature arguing that the types of changes that feedlots and poultry houses would need to lower use of antibiotics would have collateral benefits for the environment.[256] For instance, antibiotics are used preventively to combat the occurrence of necrotic enteritis in broiler chickens—a bacterial disease that causes widespread flock mortality; flock management practices can proactively mitigate disease rates without requiring the high use rate of antibiotics.[257] High-density living conditions, inappropriate diet, and unsanitary litter management can all also predispose chickens to this disease and lead to safety issues.[258] As improvements to these areas of poultry production are also avenues of opportunity to make poultry production more environmentally sustainable, there is an overlap in animal antibiotic regulation for safety purposes and mitigation or improvement of environmental consequences, not to mention animal welfare.

3. Food Additives

FDA authority over food additives presents a final, if limited, opportunity to identify and regulate additives that threaten both human health, via ingestion, and the environment, via production and disposal. FDA regulates food additives to assess whether they are safe for human consumption, and it can exclude or set tolerance levels for those that pose safety risks. Foods that contain such excluded ingredients are then deemed adulterated.[259] We consider here the limited extent to which FDA might consider environmental harms as part of this risk analysis. We argue when an additive that poses some ingestion-related human health risk also generates significant environmental harm, FDA should view such harm as a plus factor toward regulation.

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256. *See* Mary J. Gilchrist et al., *The Potential Role of Concentrated Animal Feeding Operations in Infectious Disease Epidemics and Antibiotic Resistance*, 115 ENV'T HEALTH PERSPS. 313, 316 (2007) (identifying improvements to manure management as one of several essential steps to curb the spread of antibiotic resistance bacteria). *But see* TESHOME H. REGASSA ET AL., UNIV. OF NEB.–LINCOLN EXTENSION, RP196, ANTIBIOTIC USE IN ANIMAL PRODUCTION: ENVIRONMENTAL CONCERNS 6 (2009), https://perma.cc/MR9H-NV7V (identifying possible environmental benefits related to antibiotic use).

257. Pratima Adhikari et al., *An Approach to Alternative Strategies to Control Avian Coccidiosis and Necrotic Enteritis*, 29 J. APPLIED POULTRY RSCH. 515, 516 (2020).

258. *Id.* at 517.

259. 21 U.S.C. § 342(a) (defining "adulterated" to include any food additive without premarket approval pursuant to 21 U.S.C. § 348).

Certain items, such as sugar, trigger concern in both the health and environmental contexts. Most sugars are currently "generally recognized as safe" ("GRAS").[260] Pursuant to the FDCA, GRAS additives are not subject to premarket approval. Under current FDA rules, FDA can make GRAS determinations or food manufacturers can make self-determinations that their additives are GRAS.[261] FDA may, of its own accord, withdraw an ingredient's GRAS status, thus making it a per se adulterant and prohibited unless a food additive petition is successful.

The FDCA permits treatment of a product as GRAS where there is a consensus among qualified experts about the safety of the substance for its intended use.[262] This broad standard focuses primarily on ingestion-related safety concerns but might also allow for consideration of production-related safety concerns.[263] Although the word "use" suggests that the safety inquiry might be narrower than this, the FDCA and FDA's own regulations leave open the possibility of broader analysis. First, the FDCA's list of factors for assessing safety is, on its face, not exhaustive. As described in Part I.A, the FDCA includes the phrase "other relevant factors" in its safety definition, and courts have suggested that environmental factors could be relevant under some circumstances.[264] Further, GRAS notifications must include a description of "the foods in which the substance will be used, the levels of use in such foods, and the purposes for which the substance will be used, including, when appropriate, a description of a subpopulation expected to consume the notified substance."[265] The reference

260. 21 C.F.R. § 184.1854 (2021) (GRAS status for sucrose); *id.* § 184.1857 (GRAS status for corn sugar); *id.* § 184.1859 (GRAS status for invert sugar); *id.* § 184.1865 (GRAS status for corn syrup); *id.* § 184.1866 (GRAS status for high-fructose corn syrup).

261. *Id.* § 170.205 (inviting manufacturer submission of GRAS notifications); *id.* § 170.35 (allowing FDA affirmation of GRAS status on its own initiative); Substances Generally Recognized as Safe, 81 Fed. Reg. 54,959, 54,961 (Aug. 17, 2016) (to be codified at scattered parts of 21 C.F.R.) (explaining that the rule establishes a procedure whereby any person can "notify" FDA as to "the basis for a conclusion that a substance is GRAS under the conditions of its intended use"). Among other potential problems with GRAS, this mechanism allows manufacturers to evade NEPA review because the self-determination process does not involve any agency action that would trigger NEPA review. Instead, when a company makes a GRAS self-determination, it must simply provide FDA with notice. FDA acknowledged in the preamble to the final rule that the GRAS notice process does not trigger environmental assessment responsibilities and suggested to "notifiers that the lack of a requirement to submit an environmental component (e.g., an environmental assessment) with a GRAS notice does not eliminate a notifier's responsibility to comply with applicable Federal, State, tribal, and local law or requirements regarding protection of the environment." *Id.* at 55,030.

262. 21 U.S.C. §§ 321(s), 348.

263. *See generally* Broad Leib & Pollans, *supra* note 7 (calling for a broader definition of "safety").

264. *See supra* notes 23–27 and accompanying text.

265. 21 C.F.R. § 170.225(c) (2021). A GRAS notification is the regulatory mechanism by which companies can seek FDA's formal blessing of the GRAS status of their product rather than engage in a self-determination.

to "levels of use" invites consideration of production-related harms, which are also a function of use levels.

Sugar production is environmentally intensive, particularly with regard to water use and runoff.[266] At the same time, a growing body of science on ingestion-related health impacts suggests that sugar, particularly as an additive (as opposed to an inherent component of a food), is extremely harmful to health.[267] Action on a petition to withdraw the GRAS status of sugar would trigger NEPA review, giving FDA an opportunity to assess environmental impacts and consider them as an additional factor in withdrawing sugar's GRAS status.[268]

FDA might also reexamine how it considers color additives (food dyes). Color additives are subject to FDA premarket clearance through a color additive petition process.[269] During this review, the agency examines the toxicological testing information that a submitter includes with their petition. FDA guidance identifies testing protocols and toxicological thresholds of concern and also requires that petitioners submit environmental data in the form of an environmental assessment or make a CE claim.[270]

FDA has approved several dyes through this petition process, but certain public interest groups, such as the Center for Science in the Public Interest, have raised health concerns about color additives already on the market.[271] One report cites the five-fold increase in dyes consumed by Americans since 1955 and points to concerns about research on certain additives that indicates they produce metabolic, carcinogenic, and genotoxic effects in humans.[272] Color additives are also the subject of scrutiny regarding their environmental impact. During the manufacturing and processing stages of color additive production, a substantial amount of the dye may be lost and discharged into the environment

266. World Wildlife Fund, Sugar and the Environment 5 (2005), https://perma.cc/7JQ7-JP46.

267. *See, e.g.*, Robert H. Lustig et al., *The Toxic Truth About Sugar*, 482 Nature 27 (2012).

268. In the case of sugar, such a petition is currently pending. In 2013, Center for Science in the Public Interest petitioned the agency to withdraw the GRAS status for numerous types of sugar and to set limits for added sugars in certain foods. Ctr. for Sci. in the Pub. Int., Petition to Ensure the Safe Use of "Added Sugars" (Feb. 13, 2013), https://perma.cc/EZ8M-U6HD.

269. *Color Additive Petitions*, FDA (2019), https://perma.cc/E7JL-CVW2.

270. *See* FDA, Guidance for Industry: Color Additive Petitions – FDA Recommendations for Submission of Chemical and Technological Data on Color Additives for Food, Drugs, Cosmetics, or Medical Devices (July 2009), https://perma.cc/QN6Z-EC9U; FDA, Guidance for Industry: Summary Table of Recommended Toxicological Testing for Additives Used in Food (June 2006), https://perma.cc/HUF6-TM8C.

271. *See, e.g.*, Sarah Kobylewski & Michael F. Jacobson, *Food Dyes: A Rainbow of Risks* (2010), https://perma.cc/PJ6J-AFE7; *see also* Ctr. for Food Safety v. FDA, 854 F. App'x 865, 866 (9th Cir. 2021) (denying petition to review FDA approval of soy leghemoglobin as a color additive in Impossible Burgers).

272. Kobylewski & Jacobson, *supra* note 271, at 1.

as waste or effluent.[273] In addition to creating risks of carcinogenic and genotoxic effects in aquatic ecosystems exposed to the chemicals, these dyes can also interfere with the oxygen levels of water systems because of the potential for impact to photosynthesis as a result of the dye's obstruction of light absorption by organisms.[274] Here, once more, we see an interplay between health and the environment that defines an opportunity for FDA to weigh the two sets of considerations in tandem when exercising its regulatory authority over the addition of substances to food.

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Although each of these opportunities for FDA to engage in direct regulation of the food chain's environmental impacts is limited in scope, they nevertheless reflect the flexibility within FDA's regulatory authority to take environmental issues more seriously as a relevant component of food safety. Through FDA's authority over safety in food contact substances, animal drugs, and food additives, it can elevate environmental considerations and expand the safety benefits of its regulation.

C. Opportunities to Influence Food Choice

In the aggregate, food choice matters. As the United Nations Food and Agriculture Organization ("FAO") recently concluded, "[d]ietary patterns strongly influence some of the factors that are driving climate change."[275] Numerous studies support the hypothesis that switching from red meat to pork or chicken and from meat to plant-based proteins can significantly reduce GHG emissions from food production.[276] Reviewing available data, the FAO concluded that analyses relying on "life cycle assessments . . . generally conclude that alternative diet scenarios with less animal-sourced food could contribute to reducing global GHG emissions, and have positive impacts on human health."[277] Food choice has environmental consequences beyond the animal agriculture GHG example as well. For instance, some food choices are more

273. *See* Sajjad Hussain et al., *Contamination of Water Resources by Food Dyes and Its Removal Technologies*, *in* WATER CHEMISTRY (Murat Eyvaz & Ebubekir Yüksel eds., 2020), https://perma.cc/PGP2-SBZR; *cf.* Janete da Silva & Renata Fracacio, *Toxicological and Ecotoxicological Aspects of Tartrazine Yellow Food Dye: A Literature Review*, 56 BRAZILIAN J. ENV'T SCIS. 137, 145–46 (2021) (describing dye production in Brazil).

274. Hussain et al., *supra* note 273, at 2.

275. FAO, THE STATE OF FOOD AND AGRICULTURE 86 (2016), https://perma.cc/V5G7-48VM.

276. Marya Torrez, *Accounting for Taste: Trade Law Implications of Taxing Meat to Fight Climate Change*, 27 GEO. INT'L ENV'T L. REV. 61, 68 (2014) (citing several recent studies).

277. FAO, *supra* note 275, at 86.

water intensive—contrast lower-water-footprint, pea-based, non-dairy beverages with water-demanding, almond-based choices. Others are more packaging intensive—contrast individually packaged snacks, such as a trail mix, with trail mix apportioned from a bulk bin to a reusable container.

At the individual level, a variety of structural factors including availability, marketing, cultural contexts, and affordability limit food choice freedom.[278] Individual choice has nevertheless received widespread attention as a driver of change in the food system.[279] Such focus is problematic because it puts responsibility on those with the least agency in the food system.[280]

One significant barrier to individual agency is the mess of information with which consumers must contend.[281] In this particular arena, FDA has a significant amount of power to shape consumer choice by controlling the information that consumers have before them.[282] This Part considers a variety of mechanisms that FDA has at its disposal to clean up the information mess. Some of these mechanisms—regulation of label language—enhance consumer agency by meaningfully improving transparency in the food system. Others—use of the nutrition facts panel and dietary advice—simply seek to shift aggregate food choices by merging environmental considerations with nutrition considerations. In this context, we argue that FDA's narrow focus on individual nutrition, instead of population-level health, is a missed opportunity.

1. Label Language

Food manufacturers use labels as a form of advertising. From voluntary claims—such as "healthy," "natural," and "pure"—to precisely regulated food standards of identity, label language is carefully chosen to entice consumers. Regulation in this area may ultimately have limited value in generating widespread environmental benefits, and it risks putting too much responsibility on the backs of individual food consumers.[283] But these labels are a perpetual element of the food landscape. It is therefore critical to ensure that they are not

278. *See* Margot J. Pollans, *Eaters: Powerless by Design*, 120 MICH. L. REV. (forthcoming 2022) (draft on file with authors). *But see* Torrez, *supra* note 276, at 67–68 & n.45 (identifying food choice as an area where individuals can express their environmental preferences relatively easily, by contrast to transportation and energy choices).

279. Pollans, *supra* note 278.

280. *Id.*

281. *Id.*

282. FDA shares this responsibility with several other agencies including the USDA, which regulates the organic label and labels for most categories of meat and poultry, and the FTC, which regulates advertising.

283. Jason J. Czarnezki, Margot J. Pollans & Sarah M. Main, *Eco-Labelling*, *in* THE OXFORD HANDBOOK OF COMPARATIVE ENVIRONMENTAL LAW 996, 1016–20 (Emma Lees & Jorge E. Viñuales eds., 2019) (laying out functionality barriers and equity concerns about the use of ecolabels as a driver of change in the food system); Margot J. Pollans, *Bundling Public*

misleading. FDA can use its label oversight to constrain manufacturers from abusing label language to obfuscate their environmental footprints, potentially improving consumer agency over food choices.

The FDCA declares that a food shall be deemed misbranded, and is thus prohibited from sale, if its labeling is false or misleading.[284] Pursuant to its authority to police false and misleading labels, FDA can promulgate rules defining specific terms commonly used on the label. FDA takes a "reasonable consumer" approach to evaluate whether a label is false or misleading.[285] Accordingly, the role of consumer perception is essential in implementing this tool. The proliferation of various environmental claims on food packaging in recent years presents an opportunity for FDA to influence more sustainable food choices.[286] With the exception of the term "organic," which is defined and regulated by the USDA's Agricultural Marketing Service pursuant to the Organic Foods Production Act of 1990,[287] other environmental claims, such as "natural," "clean," and "pure" are regulated only by generic consumer protection laws.[288]

"Natural" invites consideration of the environmental consequences of production. Indeed, in one recent survey, the majority of respondents reported that they believe that a "natural" product is produced without the use of pesticides, growth hormones, and antibiotics.[289] In the 1970s, FDA considered promulgating a definition of "natural," but it instead developed an informal policy, defining "natural" as "meaning that nothing artificial or synthetic (including colors regardless of source) has been included in, or has been added to, the product that would not normally be expected to be there."[290] In recent decades, a steady flow of class action suits have highlighted the consumer confusion this word

and Private Goods: The Market for Sustainable Organics, 85 N.Y.U. L. Rev. 621, 640–45 (2010) (exploring limits on consumer willingness to pay for environmental benefits).

284. 21 U.S.C. § 343(a) (prohibiting labeling that is "false or misleading in any particular").

285. Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements; Availability, 67 Fed. Reg. 78,002 (Dec. 20, 2002) (announcing availability).

286. The FTC also plays an important role in regulating environmental claims through its green guides. *See* Sarah E. Light & Eric W. Orts, *Parallels in Public and Private Environmental Governance*, 5 Mich. J. Env't & Admin. L. 1, 58, 67 (2015). For a discussion of the growth of eco-labels, see generally Czarnezki, Pollans & Main, *supra* note 283, at 996–99, and in the food context, see generally Jason Czarnezki et al., *Creating Order Amidst Food Eco-Label Chaos*, 25 Duke Env't L. & Pol'y F. 281 (2015).

287. 7 U.S.C. §§ 6501–6524.

288. Czarnezki, Pollans & Main, *supra* note 283, at 1012–14 (identifying under-regulation of these terms as a barrier to consumer trust).

289. Roberts, *supra* note 243, § 4.05[8][a], at 269 (noting that a majority of respondents also believe that natural products are produced without the use of genetic engineering).

290. Food Labeling; Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60,421, 60,466 (proposed Nov. 27, 1991) (to be codified at 21 C.F.R. pts. 5, 101, 105).

causes. Many of these suits object to the use of the word to describe products that contain genetically modified ingredients.[291] Others focus on the use of particular food additives.[292] Several recent studies confirm that consumers either actively find the word confusing or misunderstand it.[293] Despite numerous industry petitions asking for a uniform definition and several requests from courts, FDA has declined every opportunity to define the term formally.[294] FDA began reconsideration of the issue again in 2015 but has not completed its review.[295]

It is not a far leap to consider potential definitions of "natural" that enhance the word's environmental content. For instance, perhaps a product is only "natural" if it was produced without single-use plastic packaging. Or perhaps a product is natural only if it is produced without the use of chemical fertilizers.[296] FDA's range of discretion is quite broad, and it could commence a

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291. Melissa Mortazavi, *Tort as Democracy: Lessons from the Food Wars*, 57 ARIZ. L. REV. 929, 949–51 (2015) (describing these suits and offering them as an example of a battlefront in the "food wars").

292. *See, e.g.*, Janney v. Gen. Mills, 944 F. Supp. 2d 806, 817 (N.D. Cal. 2013) (considering an allegation that Nature Valley products were not "natural" because they contained high fructose corn syrup and/or rice maltodextrin).

293. *See, e.g.*, *Study: Consumers Confuse Natural and Organic Labels*, PRODUCE GROWER (Oct. 12, 2015), https://perma.cc/69L6-QXFN (citing a 2015 study from the Organic & Natural Health Association, which found that one in three consumers do not "make a quality distinction" between "organic" and "natural"); Efthimios Parasidis et al., *Addressing Consumer Confusion Surrounding "Natural" Food Claims*, 41 AM. J.L. & MED. ETHICS 357, 363–66 (2015) (citing and describing a number of studies finding confusion, misunderstanding, and distrust).

294. ROBERTS, *supra* note 243, § 4.05[8][b][1], at 269; Mortazavi, *supra* note 291, at 962–64 (describing interactions between courts and FDA on this issue); Paben, *supra* note 74, at 185–86 (offering FDA's decision not to clarify the meaning of "natural" as an example of the agency's failure to align its priorities with matters of public concern).

295. Use of the Term "Natural" in the Labeling of Human Food Products; Request for Information and Comments, 80 Fed. Reg. 69,905, 69,905–09 (request for comments posted Nov. 12, 2015) (to be codified at 21 C.F.R. pt. 101). The Obama Administration never took final action on the issue, and, despite some murmurings that it would, the Trump Administration did not take up the issue. Sam Bloch, *FDA Commissioner Scott Gottlieb Wants to Define "Healthy" and "Natural"*, COUNTER (Mar. 29, 2018), https://perma.cc/6LJ6-MZ7Q. FDA is also currently reevaluating its definition of "healthy." Use of the Term "Healthy" in the Labeling of Human Food Products; Request for Information and Comments; Extension of Comment Period, 81 Fed. Reg. 96,404 (proposed Dec. 30, 2016) (to be codified at 21 C.F.R. pt. 101). This term too could present an opportunity for more robust cradle-to-grave food safety analysis; although its value is more limited because the word itself likely does not implicate for the reasonable consumer any interests other than health issues related to ingestion.

296. FDA's own 2015 request for comments cites a Consumer Union survey finding that 66% of respondents thought natural meant that "no toxic pesticides were used, 66% think no artificial ingredients or colors were used, 65% think no chemicals were used during processing and 64% think no GMOs were used." Use of the Term "Natural" in the Labeling of Human

rulemaking process seeking input on the various environmental issues that such a label could encompass. An ideal definition would be simple for consumers to understand and easy for regulators to enforce. Thus, FDA likely could not define "natural" in such a way that would provide a definitive distinction between foods produced in an environmentally sustainable manner and foods that are not, but it could address some key components of sustainability.

FDA can also enhance consumer agency in food choices through regulation of other label language. Food identity standards, for instance, are precise definitions of particular types of food that provide detailed composition requirements; some read like recipes. They prevent consumer confusion and food fraud by prohibiting use of these food names on products that do not meet the requirements.[297] FDA promulgated numerous standards in the mid-twentieth century, but, by the 1970s, it had soured on the tool.[298] In the 1990s and again in the early 2000s, the agency solicited comments on whether to abandon or modernize the tool.[299] FDA did not take action on the issue for many years and, in 2020, it reopened the comment period again but has still made no regulatory changes.[300] The agency's statutory grant, to establish standards that "will promote honesty and fair dealing in the interest of consumers," is quite broad, and invites FDA to incorporate environmental standards to the extent that consumers expect them.[301]

The milk standard of identity offers a useful case study.[302] In recent years, members of the dairy industry and their supporters have expressed concern that

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Food Products; Request for Information and Comments, 80 Fed. Reg. at 69,907. When asked what the word *should* mean, even higher percentages of respondents (between 85% and 87%) believed these things should not be allowed for "natural" food products. *Id.*

297. 21 U.S.C. § 341 (authorizing FDA to establish standards whenever "such action will promote honesty and fair dealing in the interest of consumers"). For a complete list of foods with standards of identity, see 21 C.F.R. §§ 130–169 (2021) (codifying standards).

298. JACOB E. GERSEN, MARGOT J. POLLANS & MICHAEL T. ROBERTS, FOOD LAW: CASES AND MATERIALS 155–56 (2019).

299. Food Standards; General Principles and Food Standards Modernization, 70 Fed. Reg. 29,214 (proposed May 20, 2005) (to be codified at 21 C.F.R. pt. 130) (proposing a variety of reforms to the food identity standards program); Food Standards of Identity, Quality and Fill of Container; Common or Usual Name Regulations; Request for Comments on Existing Regulations, 60 Fed. Reg. 67,492 (proposed Dec. 29, 1995) (to be codified at scattered parts of 21 C.F.R.).

300. Food Standards; General Principles and Food Standards Modernization; Reopening of the Comment Period, 85 Fed. Reg. 10,107 (proposed Feb. 21, 2020) (to be codified at 21 C.F.R. pt. 130).

301. 21 U.S.C. § 341.

302. FDA's seldom-enforced standard of milk defines milk as "the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows." 23 C.F.R. § 131.110(a) (2021). Recently, a coalition of dairy industry representatives and elected officials have put pressure on FDA to begin enforcing this definition and clamping down on the widespread use of the term "milk" by non-dairy beverage manufacturers. *See*,

FDA's failure to engage in robust enforcement and the widespread use of the word "milk" on nondairy milks has resulted in consumer confusion and loss of market share for traditional dairy.[303] The environmental choice between dairy milks and non-dairy milks is not straightforward.[304] But FDA could bring environmental considerations into future deliberations about how to enforce or modify these kinds of standards. At the most extreme, FDA could actually include environmental standards in the standard of identity itself, requiring that manufacturers meet threshold environmental protection requirements in order to use the defined identifier. For instance, the agency might define milk in part based on the carbon footprint or the water contamination potential of the production process. Although these factors are not the primary driver of the rise of non-dairy milk alternatives, 26% of non-dairy milk drinkers in one recent study identified environmental concerns as a "major reason" for making the switch.[305] A more moderate approach would require FDA to assess potential environmental impacts when deciding whether to relax or enforce standards. In the milk context, this approach might lead FDA to continue its non-enforcement of the existing standard of identity.

Ultimately, the primary benefit of FDA intervention into the realm of label language is to constrain the ability of food manufacturers to engage in greenwashing. Greenwashing undermines consumer agency in the food system by flooding consumers with appealing but often meaningless information. Cur-

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e.g., Nat'l Milk Producers Fed'n, Citizen Petition Submitted on Behalf of the National Milk Producers Federation (Feb. 21, 2019), https://perma.cc/649R-F27J; Letter from Twenty-Five Members of Congress to Robert M. Califf, Comm'r, FDA (Dec. 16, 2016), https://perma.cc/BZ6K-XC75; Beth Kaiserman, *Dairy Industry Struggles in a Sea of Plant-Base Milks*, FORBES (Jan. 31, 2019), https://perma.cc/NQ4V-KDTR.

303. Nat'l Milk Producers Fed'n, *supra* note 302.

304. *See Ask Umbra: Which Milk Alternative Is the Lightest on the Land*, GRIST (Jan. 9, 2014), https://perma.cc/589Q-BPYD (explaining that little data exists to engage in definitive cross-category comparisons). *See generally* Kiara S. Winans et al., *Life Cycle Assessment of California Unsweetened Almond Milk*, 25 INT'L J. LIFE CYCLE ASSESSMENT 577 (2020) (providing a life cycle assessment of almond milk production); M-J Yan et al., *Life Cycle Assessment of Milk Production from Commercial Dairy Farms: The Influence of Management Tactics*, 96 J. DAIRY SCI. 4112 (2013) (describing high level of variation in dairy life cycle assessment). For instance, a team of students recently conducted a comparative life cycle assessment of cow milk and almond milk, concluding that while almond outperformed on GHG emissions, emitting 0.36 kg of CO_2 equivalent per liter to cow milk's 1.67 kg of CO_2 equivalent, cow milk outperformed on water usage, using only 77 gallons per liter as compared to 1611.62 gallons for a liter of almond milk. Jacqueline Ho et al., Almond Milk vs. Cow Milk Life Cycle Assessment 3 (June 2, 2016) (unpublished report), https://perma.cc/TW8N-WURV.

305. Alyssa Meyers, *Demand for Non-Dairy Is Here to Stay, as Consumers Seek Balance Between Sustainability, Health and Taste*, MORNING CONSULT (Mar. 30, 2021), https://perma.cc/9STX-YAWX (reporting on the results of a consumer survey). Another 30% of consumers cite environmental considerations as a "minor reason" for shifting to non-dairy milk. *Id.*

rently, FDA provides industry with robust guidance on label language to the extent that this language relates to consumer health.[306] Although it has broad statutory authority to address misbranding, it does not exercise that authority for environmental claims. Instead, it defers to the Federal Trade Commission, which regulates "green" advertising claims.[307] This abdication reflects again the fact that FDA has historically emphasized product over process. Nutrition and health claims relate to the product itself, whereas environmental claims relate to the process by which the product was made.[308] Transcending this distinction would allow FDA to think more comprehensively about how food labels affect consumer health, which is of course affected both by nutrition and by the environmental footprint of food production.[309]

2. The Health-Environment Nexus: Rethinking Nutrition Information

Nutritional labels are another area of FDA labeling jurisdiction that implicates this overlap between health considerations and the environment. FDA oversees implementation of the Nutrition Labeling and Education Act of 1990 ("NLEA").[310] These labels are designed to encourage healthier dietary practices by providing consumers access to relevant dietary information about individual processed foods.[311] Recent updates highlight modern nutritional science about the health effects of sugar and fat. In 2003, FDA added a requirement that labels list trans fat separately.[312] In 2014, FDA commenced a process to over-

306. *See, e.g.*, FDA, A Food Labeling Guide: Guidance for Industry (2013) (addressing food naming, net quantity statement, ingredient list, nutrition labeling, nutrient content claims, health claims, qualified health claims, and structure/function claims). FDA's focus on nutrition follows from the Nutrition Labeling and Education Act of 1990, which mandates, among other things, that FDA standardize and limit nutrient and health terms permitted on labels. 21 U.S.C. § 343(r).

307. 15 U.S.C. § 45; Czarnezki, Pollans & Main, *supra* note 283, at 1012–14 (describing the Green Guides and the role of FTC enforcement); *see supra* Part I.B on the limitations of relying on other agencies to address the environmental footprint of the food system.

308. Paben, *supra* note 74, at 205–07; Mortazavi, *supra* note 291, at 945–51 (describing recent tort litigation addressing food production issues); Douglas A. Kysar, *Preferences for Processes: The Process/Product Distinction and the Regulation of Consumer Choice*, 118 Harv. L. Rev. 525, 560 (2004) (discussing FDA's emphasis on product over process in the context of regulation of genetically modified foods).

309. Broad Leib & Pollans, *supra* note 7, at 1233–36 (redefining food safety to include environmental concerns).

310. Pub. L. No. 101-535, 104 Stat. 2353 (codified as amended at 21 U.S.C. § 343).

311. *See* Diana R. H. Winters, *The Magical Thinking of Food Labeling: The NLEA as a Failed Statute*, 89 Tul. L. Rev. 815, 817–18 (2015) (arguing that the NLEA is a failure at this goal and that it draws scarce resources away from other FDA endeavors). Critics also argue that this strategy is not particularly effective at improving consumer dietary health. *Id.* at 843–45 (citing a number of sources making this claim).

312. Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims, 68 Fed. Reg. 41,434 (July 11, 2003) (to be codified at 21 C.F.R. pt. 101); 21

haul the entire label; the final rules require separate listing of added sugar and adjust serving sizes upward to more accurately reflect American dietary patterns.[313]

Unlike the general misbranding provisions discussed above, the mandates of the NLEA are far more specific. Labels must include a serving size, the number of servings per container, the number of calories, the number of calories derived from fat, and the amount of "[t]otal fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein."[314] FDA has only narrow discretion to add additional nutrient disclosure mandates that "will assist consumers in maintaining healthy dietary practices."[315] The statute does not, however, define the phrase "healthy dietary practices."

Historically, FDA and other agencies involved in federal education, have focused their understanding of "healthy dietary practices" around individual ingestion-related health risks. A 2015 battle over the Dietary Guidelines for Americans, nutrition advice published every five years by the USDA and the Department of Health and Human Services ("HHS"), illustrates this history. Prior to publishing new guidelines, the two agencies convene an expert committee to evaluate current nutrition science and make recommendations.[316] In 2015, that committee recommended incorporating environmental concerns into the guidelines, particularly with regard to eating meat.[317] The 2015 Advisory Committee asked in its report, "[w]hat is the relationship between population-level dietary patterns and long-term food sustainability?"[318] The committee concluded that "a dietary pattern that is higher in plant-based foods, such as vegetables, fruits, whole grains, legumes, nuts, and seeds, and lower in animal-based foods is more health promoting, and is associated with lesser environmental impact . . . than is the current average U.S. diet."[319] The committee

C.F.R. § 101.9(c)(2)(ii) (2018). In 2015, FDA withdrew the GRAS status of artificial trans fat, giving industry several years to remove it from products. Final Determination Regarding Partially Hydrogenated Oils, 80 Fed. Reg. 34,650 (June 17, 2015).

313. Food Labeling: Revision of the Nutrition and Supplement Facts Labels, 81 Fed. Reg. 33,742 (May 27, 2016) (to be codified at 21 C.F.R. pt. 101).

314. 21 U.S.C. § 343(q)(1).

315. *Id.* § 343(q)(2)(A); *see also id.* § 343(q)(2)(B) (also allowing FDA to remove a mandated disclosure from the list if the Secretary of HHS determines that the disclosure is not necessary to assist consumers in maintaining healthy dietary practices).

316. Margaret Sova McCabe, *Eating for the Environment: The Potential of Dietary Guidelines to Achieve Better Human and Environmental Health Outcomes*, 47 ENV'T L. 741, 746–47 (2017) (describing the Dietary Guidelines development process).

317. USDA, SCIENTIFIC REPORT OF THE 2015 DIETARY GUIDELINES ADVISORY COMMITTEE 5 (2015), https://perma.cc/797T-J8Y5.

318. *Id.* at 286.

319. *Id.* at 289 (recommending that Americans reduce total calories from certain animal-based foods).

further observed that sustainability "considerations provide an additional rationale" for the recommendations in the report and called for incorporation of environmental concerns into agency messaging and labeling initiatives.[320] Finally, and most importantly, the report drew a direct connection between the sustainability of population-level dietary choices and individual-level health: "Promoting healthy diets that also are more environmentally sustainable now will conserve resources for present and future generations, ensuring that the U.S. population has access to a diet that is healthy as well as sustainable and secure in the future."[321]

Industry and Congress swiftly attacked the Advisory Committee's recommendations, and the HHS and USDA rejected them.[322] The Secretaries of Health and Agriculture released a joint statement clarifying their narrow focus on individual-level diet choice.[323] They explained that "the [Dietary Guidelines] are not the appropriate vehicle for this important policy conversation about sustainability," and that the Guidelines should instead be understood as a tool to "empower Americans to take control of their health—for their families and themselves."[324]

Under this lens, "healthy dietary practices" refers to the relationship between individual food choice and individual health outcomes. But the 2015 Advisory Committee report suggests another possible path. Indeed, a variety of commentators and scientists have called for a more capacious understanding of the word "healthy" that incorporates concerns related to sustainability and planetary health.[325] Such a shift would require FDA, and other agencies with authority over nutrition education such as the USDA, to reconceive food choice as something that occurs both at the individual level and at the population level. FDA labeling has implications for both, but FDA currently regulates with only the former in mind. Considering the latter would also allow FDA to require food manufacturers to include a sustainability metric in nutrition labels. For instance, FDA might require measures of carbon footprint, quantities of water

320. *Id.*

321. *Id.*; McCabe, *supra* note 316, at 751 (characterizing this discussion as reflecting a shift in the committee's temporal lens from looking only at diets in the present to looking at the relationship between diet in the present to diet in the future).

322. McCabe, *supra* note 316, at 751–54 (describing the various reactions to the report).

323. Tom Vilsack & Sylvia Burwell, *2015 Dietary Guidelines: Giving You the Tools You Need to Make Healthy Choices*, USDA (Feb. 21, 2017), https://perma.cc/9GZV-W2DN.

324. *Id.*

325. Nicole E. Negowetti, *A Planetary Health Approach to the Labeling of Plant-Based Meat*, 75 Food & Drug L.J. 142, 173 (2020) (cataloguing some of these calls and considering how they might be used to shape approaches to labeling alternative meat products); Broad Leib & Pollans, *supra* note 7, at 1233–37 (making a similar claim about the word "safety").

used in processing, or complete life cycle assessment.[326] These metrics are essential to "maintaining healthy dietary practices" at the population level.[327]

Conclusion

The food system generates massive environmental externalities, many of which escape any meaningful regulatory oversight. FDA, which has jurisdiction over about 80% of that system, has paid little attention to these environmental concerns. FDA views its mandate narrowly. It is concerned with ingestion-related food safety and nutrition and with the dietary decisions of individuals. Taking environmental concerns seriously would require the agency to reconceptualize its role as a regulator in the food system. Although there are significant barriers to such an effort, the agency's statutory mandate is not one of those barriers. The agency has the power to make these changes and to play a productive role in curtailing some of the food system's environmental externalities. We offer FDA a menu of options to begin such a project, identifying a variety of existing FDA powers that the agency might use to directly regulate particular food system environmental impacts, to mitigate the environmental consequences of its own regulatory actions, and to encourage a population-level shift to more environmentally appropriate eating patterns. We also point the agency toward NEPA, a statutory mandate that it has almost entirely sidestepped, as a tool that will facilitate the agency's transformation. NEPA provides a useful jumping off point to help the agency find places within its existing statutory authority where it may directly regulate the environmental impacts of food production. Although NEPA does not force any of this action, it generates the information that might support it.

FDA is not alone in this position. Many other federal agencies, such as the Department of Transportation and the Department of Energy, have authority over industries that generate massive environmental externalities. And many agencies, like FDA, do not view environmental protection as a core part of their mandate. Environmental challenges such as plastics pollution, climate change, and environmental justice are broad-reaching problems that do not lend themselves to simple solutions by a single environmental agency. Instead, they are all-hands-on-deck. We offer this assessment of FDA as a model for similar assessments of other agencies. NEPA was intended to address the interconnectedness of environmental issues with other regulatory concerns, but it has never fulfilled that promise at least in part because so many agencies, like FDA,

326. *See* Czarnezki, Pollans & Main, *supra* note 283, at 999–1004 (describing various content options for eco-labels). To be sure, such metrics pose considerable methodological problems, but they might be preferable to the proliferation of private labels currently flooding the marketplace. *See id.* at 1008–11 (describing the methodological challenges with eco-labels).

327. 21 U.S.C. § 343(q)(2)(A); *see supra* note 315 and accompanying text.

do not view their work as environmental. But every agency is, at the end of the day, an environmental agency.

APPENDIX: FOOD CONTACT NOTIFICATION DATASET

Sample No.	FDA Application No.	Food Contact Substance	Analysis	Conclusion
1	1867	An aqueous mixture of peroxyacetic acid ("PAA") (Chemical Abstracts Service Registry Number ("CAS RN") 79-21-0), hydrogen peroxide ("HP") (CAS RN 7722-84-1), acetic acid (CAS RN 64-19-7), 1-hydroxyethylidene-1,1-diphosphonic acid ("HEDP") (CAS RN 2809-21-4), and sulfuric acid (CAS RN 7664-93-9).	EA	FONSI
2	1400	Chlorine dioxide (CAS RN 10049-04-4).	EA	FONSI
3	1236	A mixture of PAA (CAS RN 79-21-0), HP (CAS RN 7722-84-1), acetic acid (CAS RN 64-19-7), HEDP (CAS RN 2809-21-4), and water (CAS RN 7732-18-5).	EA	FONSI
4	645	Chlorine dioxide (CAS RN 10049-04-4).	EA	FONSI/EA Supplement
5	757	Hydrogenated polymers prepared from one or more of the following: 1-hexene (CAS RN 592-41-6), 1-octene (CAS RN 111-66-0), 1-decene (CAS RN 872-05-9), 1-dodecene (CAS RN 112-41-4), and 1-tetradecene (CAS RN 1120-36-1).	EA	FONSI
6	975	1,4-Butanediol-polytetramethylene glycol-terephthalic acid block copolymer (CAS RN 106159-00-6), reaction products with maleic anhydride.	EA	FONSI
7	818	Titanium nitride (CAS RN 25583-20-4). Replaces FCN 716.	EA	FONSI
8	34	Nylon 6/12 resins manufactured by the copolymerization of at least 80 weight percent of epsilon-caprolactam and no more than 20 weight percent of ω-aminododecanoic acid. (CAS RN 25191-04-2),	EA	FONSI
9	67	3,6,9-triethyl -3,6,9-trimethyl -1,2,4,5,7,8-hexoxonane (CAS RN 24748-23-0).	EA	FONSI
10	21	2,2'-Methylenebis(4,6-di-tert-butylphenyl) 2-ethylhexyl phosphite (CAS RN 126050-54-2).	EA	FONSI
11	546	1,3-Benzenedicarboxylic acid, 5-sulfo-, monolithium salt (CAS RN 46728-75-0).	EA	FONSI/EA Supplement
12	142	Silicones and siloxanes, dimethyl, methylhydrogen, reaction products with polyethylene glycol monoallyl ether acetate (CAS RN 70914-12-4).	EA	FONSI/EA Supplement
13	62	Amorphous hydrogenated carbon coating produced from acetylene as the carbon source in a microwave plasma. The coating is formed at reduced pressure with 0.1 mbar using acetylene microwave energy, followed by an air rinse.	EA	FONSI
14	1401	Polyethylene glycol (400) monooleate (CAS RN 9004-96-0).	EA	FONSI

Sample No.	FDA Application No.	Food Contact Substance	Analysis	Conclusion
15	561	A mixture containing PAA (CAS RN 79-21-0), HP (CAS RN 7722-84-1), acetic acid (CAS RN 64-19-7), HEDP (CAS RN 2809-21-4), and water (CAS RN 7732-18-5).	EA	FONSI/EA Supplement
16	1856	An aqueous mixture of PAA (CAS RN 79-21-0), HP (CAS RN 7722-84-1), acetic acid (CAS RN 64-19-7), HEDP (CAS RN 2809-21-4), and, optionally, sulfuric acid (CAS RN 7664-93-9).	EA	FONSI and EA Revision Sheet
17	1967	2,2-bis((pentanoyloxy)methyl)propane-1,3-diyl dipentanoate (CAS RN 15834-04-5).	EA	FONSI and EA Revision Sheet
18	166	Aromatic petroleum hydrocarbon resin, hydrogenated (CAS RN 88526-47-0), produced by the catalytic polymerization of aromatic substituted olefins from low boiling distillates of cracked petroleum stocks with a boiling point no greater than 220°C (428°F), and the subsequent catalytic reduction of the resulting aromatic petroleum hydrocarbon resin.	EA	FONSI
19	1662	An aqueous mixture of PAA (CAS RN 79-21-0), HP (CAS RN 7722-84-1), acetic acid (CAS RN 64-19-7), HEDP (CAS RN 2809-21-4), dipicolinic acid ("DPA") (CAS RN 499-83-2), and sulfuric acid (CAS RN 7664-93-9).	EA	FONSI
20	1768	A solution of silver dihydrogen citrate stabilized with sodium lauryl sulfate and citric acid.	EA	FONSI
21	1125	Starch, carboxymethyl ether, sodium salt (CAS RN 9063-38-1).	EA	FONSI
22	953	2, 4-Imidazolidinedione, 5,5-dimethyl (CAS RN 77-71-4).	EA	FONSI
23	413	Polyester-polyurethane resin-acid dianhydride adhesives.	EA	FONSI
24	357	1,3-dibromo-5,5-dimethylhydantoin (CAS RN 77-48-5).	EA	FONSI

Sample No.	FDA Application No.	Food Contact Substance	Analysis	Conclusion
25	179	Copolymers and polymers made from the reaction of dimethyl terephthalate or terephthalic acid ("TPA") with a mixture containing 99 to 0 mole percent of ethylene glycol and 1 to 100 mole percent of 1,4-cyclohexanedimethanol (70 percent trans isomer, 30 percent cis isomer). The FCS is further identified as follows: Ethylene-1,4-cyclohexylenedimethylene terephthalate copolymers (CAS RN 25640-14-6), manufactured from dimethylterephthalate ("DMT"), ethylene glycol ("EG"), and 1,4-cyclohexanedimethanol ("CHDM"). Ethylene-1,4-cyclohexylenedimethylene terephthalate copolymers (CAS RN 25038-91-9), manufactured from TPA, EG, and CHDM. 1,4-cyclohexylenedimethylene terephthalate copolymers (CAS RN 25135-20-0), manufactured with DMT and CHDM. 1,4-cyclohexylenedimethylene terephthalate copolymers (CAS RN 25037-99-4), manufactured with TPA and CHDM.	EA	FONSI
26	1167	1H-Azepine-1-carboxamide, hexahydro-2-oxo-N-[3,3,5-trimethyl-5-[[tetrahydro-3,5-bis[(5-isocyanato-1,3,3-trimethylcyclohexyl)methyl]-2,4,6-trioxo-1,3,5-triazin-1(2H)-yl]methyl]cyclohexyl]-. Replaced by FCN 1229.	EA	FONSI
27	1897	An aqueous mixture of PAA (CAS RN 79-21-0), HP (CAS RN 7722-84-1), acetic acid (CAS RN 64-19-7), HEDP (CAS RN 2809-21-4), and, optionally, sulfuric acid (CAS RN 7664-93-9).	EA	FONSI
28	26	A solid solution of 2-naphthalenesulfonic acid, 5-(((5-chloro -4-methyl-2- sulfophenyl) azo) -6-hydroxy)-, strontium salt (1:1) and 2-naphthalenesulfonic acid, 5-((4-chloro -5-ethyl -2-sulfophenyl) azo) -6-hydroxy)-, strontium salt(1:1) (C.I. Pigment Red 276).	EA	FONSI
29	1649	2-methyl-4-isothiazolin-3-one (CAS RN 2682-20-4).	EA	FONSI and EA Revision Sheet
30	739	An aqueous solution of sodium chlorite and chlorine dioxide containing up to 1200 mg/kg sodium chlorite and up to 30 mg/kg chlorine dioxide.	EA	FONSI/EA Supplement
31	1108	1,2-Benzisothiazolin-3-one (CAS RN 2634-33-5).	EA	FONSI
32	1815	An aqueous solution of PAA (CAS RN 79-21-0), HP (CAS RN 7722-84-1), acetic acid (CAS RN 64-19-7), with oxalic acid (CAS RN 144-62-7) and/or maleic acid (CAS RN 110-16-7).	EA	FONSI
33	359	Benzoic acid, 2,4-dihydroxy-, polymer with formaldehyde and 1-naphthalenol, sodium salt (CAS RN 209119-35-7).	EA	FONSI
34	1479	1-Pentene, 4-methyl-, polymer with 1-propene (CAS RN 25119-95-3).	EA	FONSI

Sample No.	FDA Application No.	Food Contact Substance	Analysis	Conclusion
35	502	Hexanedioic acid, polymer with hexahydro-2H-azepin-2-one and 1,6-hexanediamine (CAS RN 24993-04-2).	EA	FONSI/EA Supplement
36	463	1,3-Benzenedicarbonyl dichloride, polymer with 1,4-benzenedicarbonyl dichloride, 1,3-benzenediol, carbonic dichloride and 4,4'-(1-methylethylidene)bisphenol, 4-(1-methyl-1-phenylethyl)phenyl ester (CAS RN 235420-85-6).	EA	FONSI
37	1028	Isopropanol (CAS RN 67-63-0).	EA	FONSI
38	1522	An aqueous mixture of PAA (CAS RN 79-21-0), HP (CAS RN 7722-84-1), acetic acid (CAS RN 64-19-7), HEDP (CAS RN 2809-21-4), DPA (CAS RN 499-83-2), and sulfuric acid (CAS RN 7664-93-9).	EA	FONSI
39	1975	Oxirane, 2-methyl-, polymer with oxirane, ether with 1,2,3-propanetriol (3:1), polymer with 1,3-diisocyanato-2-methylbenzene and 2,4-diisocyanato-1-methylbenzene (CAS RN 68227-13-4).	EA	FONSI
40	2024	Acetic acid ethenyl ester, polymer with ethene and ethenol (CAS RN 26221-27-2).	EA	FONSI
41	558	1,4-Benzenedicarboxylic acid, dimethyl ester, polymer with 1,4-butanediol, adipic acid, hexamethylene diisocyanate and not more than 1 percent by weight of a polyhydric alcohol, as described in FCN 372.	EA	FONSI
42	1046	2-propenoic acid, sodium salt, homopolymer (CAS RN 9003-04-7).	EA	FONSI
43	1384	An aqueous mixture of PAA (CAS RN 79-21-0), HP (CAS RN 7722-84-1), sodium hydroxide (CAS RN 1310-73-2), and glycerine (CAS RN 56-81-5).	EA	FONSI
44	821	Styrene block polymer with 1,3-butadiene, hydrogenated (CAS RN 66070-58-4).	EA	FONSI
45	43	Nickel-iron alloy. Its composition is as follows: Ni (80–83% by weight), S (0–0.005% by weight), C (0–0.005% by weight), Mo (1–3% by weight), Fe (14–19% by weight).	EA	FONSI
46	1382	Oxirane, 2-ethyl, polymer with 2-methyloxirane, monododecyl ether (CAS RN 139873-90-8).	EA	FONSI
47	1486	2-Propenoic acid, polymer with ethanedial and 2-propenamide (CAS RN 65505-03-5) containing acrylamide and acrylic acid which is then reacted with not more than 30 weight percent glyoxal.	EA	FONSI
48	1068	Fatty acids, coco, sesquiesters with polyethylene glycol (CAS RN 61791-04-6).	EA	FONSI/EA Supplement
49	1148	1,2-Benzisothiazol-3(2H)-one 1,1-dioxide, sodium salt (CAS RN 128-44-9).	EA	FONSI
50	178	Polylactide polymers (CAS RN 9051-89-2). The polymers will be manufactured and characterized as described in the notification.	EA	FONSI/EA Supplement