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The Plastic Pollution Crisis: Combating Single-Use Plastics Through NEPA Challenges to the FDA's Food Contact Substance Regulations

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INTRODUCTION

It is no stretch to say modern society has a love affair with single-use plastics. They are in our kitchens, bathrooms, and offices. We use them on airplanes, in coffee shops, and in schools. Yet, consumers, legislators, and regulators alike tend to focus only on the short-term uses and benefits of disposable plastics. All things considered, the United States has failed to take responsibility for the long-term environmental harms associated with throwaway plastics.

Today, plastic waste management is one of the most critical environmental issues facing our planet. Humans currently generate 300 million metric tons of plastic waste each year.[1] This refuse has caused a significant buildup of plastics in landfills, municipal waste systems, and our planet's oceans.[2] Beyond the sheer volume of plastic waste generated, plastics are particularly problematic because it takes centuries for them to decompose in the natural environment.[3] Discarded single-use plastics are responsible for a wide range of damage, from clogged pipes, to chemical contamination, to littered beaches.[4] The consequences of unchecked plastic debris are becoming more and more expensive. Studies estimate that debris-related damage to marine industries costs $1.26 billion annually across the Asia-Pacific rim alone.[5] Economic losses include damage to ship propellers and spoiled tourist developments.[6]

Such valuations often do not account for the ecological costs of plastic-related wildlife deaths. Endangered species, such as sperm whales, are particularly vulnerable to plastic marine waste.[7] Scientists

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1 *Our Planet Is Drowning in Plastic Pollution: This World Environment Day, It's Time for a Change*, U.N. ENV'T PROGRAMME, https://www.unenvironment.org/interactive/beat-plastic-pollution/ [https://perma.cc/2TE9-4BRB] (last visited Mar. 8, 2020).

2 *See generally* Laura Parker, *We Made Plastic. We Depend On It. Now We're Drowning in It.*, NAT'L GEOGRAPHIC (June 2018), https://www.nationalgeographic.com/magazine/2018/06/plastic-planet-waste-pollution-trash-crisis/ [perma.cc/BB54-JTW9].

3 Juliet Lapidos, *Will My Plastic Bag Still Be Here in 2507?*, SLATE (June 27, 2007, 6:20 PM), http://www.slate.com/articles/news_and_politics/explainer/2007/06/will_my_plastic_bag_still_be_here_in_2507.html [https://perma.cc/E9VJ-JBF9].

4 Parker, *supra* note 2.

5 McIlgorm et al., *The Economic Cost and Control of Marine Debris Damage in the Asia-Pacific Region*, 54 OCEAN & COASTAL MGMT. 643, 647 (2011).

6 *Id.* at 644.

7 *See, e.g.*, Andrea Diaz, *A Sperm Whale That Washed Up on a Beach in Spain Had 64 Pounds of Plastic and Waste in Its Stomach*, CNN (Apr. 11, 2018, 2:48 PM),

discovered sixty-four pounds of mainly plastic waste in one individual whale's stomach after it washed ashore in southern Spain.[8] Another dead sperm whale had 2 flip-flops, 115 drinking cups, 25 plastic bags, and 4 plastic bottles in its digestive tract when it was found on the coast of Indonesia near Wakatobi National Park.[9] And more recently, a young dugong named Marium died of shock after ingesting plastic, which veterinarians later found blocking her intestinal tract.[10] These deaths produce striking media images, and increasingly frequent reports of this kind mean consumers are more engaged with the plastic pollution problem than ever before. Still, many of us continue to regularly take advantage of single-use plastics. Indeed, they can prove difficult to avoid.

Possible solutions to the plastic pollution crisis range from corporate social responsibility initiatives originating in the private sector, to scientific breakthroughs in biodegradable plastics,[11] to outright bans on specific plastic products and packages.[12] Each of these alternatives comes with distinct benefits and drawbacks that this Article will not explore. Instead, discussion will focus solely on federal law and policy reform, which undoubtedly are necessary components of any approach to combating plastic waste with a realistic chance of success. Despite challenges in measuring and regulating the use of disposable plastics, legal advocates are in a prime position to take meaningful action to

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https://www.cnn.com/2018/04/11/health/sperm-whale-plastic-waste-trnd/index.html [https://perma.cc/5B2H-RWVA].

8 *Id.*

9 Trevor Nace, *Yet Another Dead Whale Found with Pounds of Plastic in Its Stomach*, FORBES (Nov. 26, 2018, 10:44 AM), https://www.forbes.com/sites/trevornace/2018/11/26/yet-another-dead-whale-found-with-13-pounds-of-plastic-in-its-stomach/#ea66e26af5d6 [https://perma.cc/9WZS-CTLE].

10 Morgan Krakow, *This Baby Sea Mammal Captured People's Hearts. She Just Died from Eating Plastic.*, WASH. POST (Aug. 17, 2019, 11:37 AM), https://www.washingtonpost.com/science/2019/08/17/this-baby-sea-mammal-captured-peoples-hearts-she-just-died-eating-plastic/ [https://perma.cc/5DFB-HSPH]; *see also* Guardian News, *Baby Dugong Becomes Thailand's National Sweetheart*, YOUTUBE (July 2, 2019), https://www.youtube.com/watch?v=DvHbGloMQrc&feature=youtu.be [https://perma.cc/R594-MAX8].

11 Merrit Kennedy, *The Lowly Wax Worm May Hold the Key to Biodegrading Plastic*, NPR (Apr. 25, 2017, 4:18 PM), https://www.npr.org/sections/thetwo-way/2017/04/25/525447206/a-worm-may-hold-the-key-to-biodegrading-plastic [https://perma.cc/3KC9-PGH5].

12 *See, e.g.*, CAL. PUB. RES. CODE § 42281 (West, Westlaw through Ch. 1 of 2020 Reg. Sess.); OR. ADMIN. R. 333-150-0000(4) (Westlaw through Feb. 2020 Oregon Bulletin) (stating "[a] food and beverage provider or convenience store may not provide a single-use plastic straw to a consumer unless the consumer specifically requests the single-use plastic straw.").

eliminate the plastic pollution crisis through inventive applications of already existing laws and regulations. This Article will discuss the history and mechanics of the U.S. Food & Drug Administration's (FDA) approval of plastic food contact substances, general obligations of federal agencies under the National Environmental Policy Act (NEPA), application of NEPA to the FDA, and it will outline potential arguments within a hypothetical NEPA challenge to the FDA's approval of particularly concerning chemical compounds. The aim of this Article is to provide advocates with a roadmap for preparing impact litigation against the FDA (and perhaps other federal agencies) to curb the growing plastic pollution crisis.

BACKGROUND

Plastics are unique in that they do not neatly fall within the regulatory purview of any one specific government agency. In fact, the Environmental Protection Agency,[13] the Consumer Product Safety Commission,[14] and the Department of Interior's Bureau of Safety and Environmental Enforcement[15] are just a few examples of agencies involved in regulating plastics. This can make it difficult for environmental advocates to concentrate their efforts and arguments toward any particular agency or set of regulations. But while plastics are pervasive throughout many facets of our daily lives, food storage, transport, and consumption accounts for a significant volume of single-use plastics. According to the United Nations Environment Programme, "[t]he most common single-use plastics found in the environment are, in order of magnitude, cigarette butts, plastic drinking bottles, plastic bottle caps, food wrappers, plastic grocery bags, plastic lids, straws and stirrers, other types of plastic bags, and foam take-away containers."[16] Also, "[n]ine of the Ocean Conservancy's top ten items retrieved from its annual beach cleanups are related to food and

13 40 C.F.R. § 63.5785 (2019).

14 16 C.F.R. § 1307.3 (2020).

15 *Marine Trash and Debris Program*, BUREAU SAFETY & ENVTL. ENFORCEMENT, https://www.bsee.gov/debris [https://perma.cc/4AD9-FS7R] (last visited Mar. 8, 2020); 30 C.F.R. § 250.300 (2019).

16 U.N. ENV'T PROGRAMME, SINGLE USE PLASTICS: A ROADMAP FOR SUSTAINABILITY, at vii (2018), https://wedocs.unep.org/bitstream/handle/20.500.11822/25496/singleUsePlastic_sustainability.pdf?sequence=1&isAllowed=y [https://perma.cc/9P4A-WC2N].

drink."[17] With these types of waste in mind, it makes strategic sense to focus on FDA regulations as a vehicle through which to address the plastic pollution crisis. Consumption of disposable plastics is deeply entrenched in all stages of our industrialized food system. Given the limited shelf life and universal demand of food items, without substantial changes to current food packaging standards our planet's plastic pollution problem will continue to worsen.

NEPA is an invaluable tool for environmental advocates focusing on the plastic crisis because of its broad applicability and public participation requirements.[18] NEPA implements a comprehensive national framework designed to promote long-term environmental protection.[19] One of NEPA's main goals is to ensure that all government agencies give appropriate consideration to environmental impacts before a government action moves forward.[20] While little to no federal statutory regulation exists explicitly controlling disposal of plastics, many plastics are approved through federal actions that are subject to NEPA requirements.[21] NEPA provides environmental advocates with a useful catchall to tackle environmental concerns not addressed through other statutes, such as the Clean Air Act, the Clean Water Act, or the Endangered Species Act. Each of these laws were crafted and passed by Congress in the 1970s with the aim of solving discrete environmental problems.[22] Although they are each landmark pieces of legislation that have been crucial to environmental protection in recent decades,[23] they often fall short as we are faced with increasingly complex and pervasive environmental issues, such as

17 Laura Parker, *Plastic Food Packaging Was Most Common Beach Trash in 2018*, NAT'L GEOGRAPHIC (Sept. 3, 2019), https://www.nationalgeographic.com/environment/2019/09/plastic-food-packaging-top-trash-global-beach-cleanup-2018/ [https://perma.cc/V5V3-W6WG].

18 *See* TODD AAGAARD ET AL., PRACTICING ENVIRONMENTAL LAW 645–47 (Robert C. Clark et al. eds., 2017).

19 *Summary of the National Environmental Policy Act*, U.S. ENVTL. PROTECTION AGENCY, https://www.epa.gov/laws-regulations/summary-national-environmental-policy-act [https://perma.cc/MP48-NDHQ] (last visited Mar. 8, 2020).

20 *Id.*

21 *See generally* 42 U.S.C.A. § 4332(2)(C) (Westlaw through Pub. L. No. 116-91).

22 42 U.S.C.A. § 7401(b)–(c) (Westlaw through Pub. L. No. 116-91); 33 U.S.C.A. § 1251(a) (Westlaw through Pub. L. No. 116-91); 16 U.S.C.A. § 1531(b) (Westlaw through Pub. L. No. 116-91).

23 *See generally* Robinson Meyer, *How the U.S. Protects the Environment, from Nixon to Trump*, ATLANTIC (Mar. 29, 2017), https://www.theatlantic.com/science/archive/2017/03/how-the-epa-and-us-environmental-law-works-a-civics-guide-pruitt-trump/521001/ [https://perma.cc/T2JC-JJHC].

plastic pollution. Since it seems Congress is unlikely to pass any new progressive environmental laws in the foreseeable future, NEPA can be applied as a gap filler for many of the glaring voids in contemporary federal environmental policy. Furthermore, NEPA demands public involvement in an agency's decision to prepare or not prepare environmental impact statements.[24] Such public input is highly desirable for promoting local community interests as well as government transparency.

NEPA is considered a bedrock piece of U.S. federal environmental legislation.[25] For more than fifty years the statute has helped protect the nation's water sources, air supply, and wildlife.[26] Notwithstanding its many legitimate critiques,[27] overall, NEPA has been so successful that it served as a model for many similar environmental laws now operating in different countries around the world.[28] However, despite this proven track record, the Trump administration has recently proposed a new federal regulation that shortens the time allowed to complete the environmental analysis required under NEPA and carves out substantial new exemptions from the NEPA review process.[29] The Council on Environmental Quality (CEQ) "proposes to add additional sections to address the level of NEPA review" and categorical exclusions. CEQ "also proposes to set presumptive time limits for the completion of NEPA reviews."[30] This proposed NEPA overhaul will almost certainly face serious court challenges from environmental organizations.[31] While the full implications of this proposed regulation

24 40 C.F.R. § 1501.4(e)(2) (2019).

25 Jeff Brady & Jennifer Ludden, *Trump Administration Proposes Major Changes to Bedrock Environmental Law*, NPR (Jan. 9, 2020, 10:48 PM), https://www.npr.org/2020/01/09/794857523/trump-administration-proposes-major-changes-to-bedrock-environmental-law [https://perma.cc/5BQK-YJUC].

26 *See, e.g.*, *Examples of Benefits from the NEPA Process for ARRA Funded Activities*, COUNCIL ON ENVTL. QUALITY (May 2011), https://ceq.doe.gov/docs/get-involved/ARRA_NEPA_Benefits_List_May122100.pdf [https://perma.cc/S9TM-JLGD].

27 *See generally* Daniel R. Mandelker, *The National Environmental Policy Act: A Review of Its Experience and Problems*, 32 WASH. U. J.L. & POL'Y 293 (2010).

28 Aliza M. Cohen, *NEPA in the Hot Seat: A Proposal for an Office of Environmental Analysis*, 44 U. MICH. J.L. REFORM 169, 193 (2010).

29 Lisa Friedman, *Trump's Move Against Landmark Environmental Law Caps a Relentless Agenda*, N.Y. TIMES (Jan. 9, 2020), https://www.nytimes.com/2020/01/09/climate/trump-nepa-environment.html [https://perma.cc/3BV4-XGLN].

30 Update to the Regulations Implementing the Procedural Provisions of the National Environmental Policy Act, 85 Fed. Reg. 1695 (proposed Jan. 10, 2020).

31 Juliet Eilperin et al., *White House Update of Key Environmental Law Would Exclude Climate Change*, WASH. POST (Jan. 3, 2020, 5:43 PM), https://www.washingtonpost.com/

remain unclear, if implemented, it will almost certainly alter the scope of future environmental impact statements completed under NEPA. The arguments presented in this Article are based on decades' worth of established federal court precedent interpreting NEPA, while acknowledging the possibility of forthcoming shifts in court rulings in the event the currently proposed regulation becomes final.

I
FDA'S REGULATION OF FOOD CONTACT SUBSTANCES

The FDA is one of the main agencies with authority to regulate single-use plastics. It is also one of the oldest federal agencies in the United States and can trace its history back to the Pure Food & Drug Act of 1906.[32] Concerns regarding sanitation in meat production facilities, unrestricted use of chemical food preservatives with limited safety tests, and false claims surrounding "patent medicines" created widespread demand for government oversight of the nation's food and drug supply.[33] Today, "the FDA estimates . . . it regulates roughly $1 trillion worth of products annually."[34]

When the FDA is not overseeing tobacco products,[35] infant formula,[36] and catfish labeling,[37] one of the core obligations of the agency is to regulate food additives under the Federal Food, Drug & Cosmetic Act (FD&C Act).[38] A food additive is any nonexempted substance, "the intended use of which . . . may reasonably be expected to result . . . in [it] becoming a component of food or otherwise

climate-environment/white-house-update-of-key-environmental-law-would-exclude-climate-change/2020/01/03/35491e10-2e89-11ea-9b60-817cc18cf173_story.html [https://perma.cc/8UFG-9SPL].

32 Andrew Glass, *Pure Food and Drug Act Passes, June 23, 1906*, POLITICO (June 23, 2014, 12:02 AM), https://www.politico.com/story/2014/06/fda-theodore-roosevelt-108164 [https://perma.cc/37JA-PGKQ].

33 Wallace F. Janssen, *The Story of the Laws Behind the Labels*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/downloads/AboutFDA/History/FOrgsHistory/Evolving Powers/UCM593437.pdf [https://perma.cc/4UPL-NTKL] (last visited Mar. 8, 2020) (originally printed in FDA CONSUMER (June 1981)).

34 Ben Panko, *Where Did the FDA Come from, and What Does It Do?*, SMITHSONIAN MAG. (Feb. 8, 2017), https://www.smithsonianmag.com/science-nature/origins-FDA-what-does-it-do-180962054/ [https://perma.cc/4WWP-3FYV].

35 21 U.S.C.A. § 387a (Westlaw through Pub. L. No. 116-91).

36 21 U.S.C.A. § 350a (Westlaw through Pub. L. No. 116-91).

37 21 U.S.C.A. § 321d(a) (Westlaw through Pub. L. No. 116-91).

38 21 U.S.C.A. § 348 (Westlaw through Pub. L. No. 116-91).

affecting the characteristics of food."[39] The FDA recognizes two categories of food additives: direct and indirect.[40] Indirect food additives include food contact substances (FCS).[41] An FCS is "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."[42] The FDA has a congressional mandate arising from the FD&C Act to regulate FCSs.[43] Under the Act, the FDA "shall consider criteria such as the probable consumption of such food contact substance and potential toxicity of the food contact substance in determining the circumstances in which a petition [for approval] shall be filed."[44] Current FDA regulations also acknowledge the potential risk of substances migrating into food from contact with utensils such as plastic forks or straws.[45] Throughout the agency's history, the FDA has used two main mechanisms for approving FCSs: (1) by promulgating compound-specific regulations and (2) through its Food Contact Notification (FCN) process. Compound-specific regulations are promulgated based on either a submitted rulemaking petition or the FDA's decision to initiate the rulemaking process itself.[46] The FCN process is an alternative to traditional rulemaking procedures under the Administrative Procedure Act, based on submission of a notification from manufacturers.[47]

A. FDA Approval of FCS Components Through Regulations

The earliest version of the FD&C Act, passed in 1938, gave the FDA broad authority to regulate food additives and packaging but did not establish any mechanism for premarket approval.[48] "A food shall be deemed to be adulterated . . . if it bears or contains any added poisonous or added deleterious substance . . . or . . . if its *container* is composed,

39 21 C.F.R. § 170.3(e)(1) (2019).

40 21 C.F.R. § 172.5 (2019); 21 C.F.R. § 174.5 (2019).

41 21 C.F.R. § 174.5(d)(5).

42 21 U.S.C.A. § 348(h)(6).

43 *Id.* § 348(h)(3)(B).

44 *Id.*

45 *See* 21 C.F.R. § 170.39(a) (2019).

46 *See* 5 U.S.C.A. § 553(b)–(e) (Westlaw through Pub. L. No. 116-91) (describing the formal rulemaking process for the FDA and other federal agencies).

47 21 U.S.C.A. § 348(h)(1).

48 Food Drug & Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1046 (codified as amended at 21 U.S.C.A. § 342(a) (Westlaw through Pub. L. No. 116-91)).

in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health."[49] The Food Additives Amendment of 1958 outlined the earliest process for approval of food additives.[50] "Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used."[51] This amendment also authorized the FDA to develop regulations specifying limitations on food additives, including appropriate quantities of additives.[52]

> The Secretary shall . . . establish a regulation . . . prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or in which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use) . . . .[53]

Based on this statutory mandate, the FDA began promulgating regulations approving chemical compounds for use in FCSs in 1977.[54] Several common compounds still found in FCSs today were approved at this time. For example, polystyrene is a main component of plastic eating utensils.[55] Polystyrene was first approved for use in FCSs through a 1977 FDA regulation.[56] "Polystyrene and rubber-modified polystyrene identified in this section may be safely used as components of articles intended for use in contact with food . . . ."[57] This is just one of the means the FDA has used to allow plastic food packaging onto the market.

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49 *Id.* (emphasis added).

50 Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1785 (codified as amended at 21 U.S.C.A. § 342(b)(1) (Westlaw through Pub. L. No. 116-91)).

51 *Id.*

52 21 U.S.C.A. § 348(c)(1)(A).

53 *Id.*

54 Indirect Food Additives: Polymers, 42 Fed. Reg. 14,572 (Mar. 15, 1977) (codified at 21 C.F.R. § 177.1520 (2019)).

55 Ashleigh Lewis, *The Life of a Plastic Fork*, L MAG. (Apr. 14, 2010, 4:00 AM), http://www.thelmagazine.com/2010/04/the-life-of-a-plastic-fork/ [https://perma.cc/62FN-Q6S5].

56 Polystyrene and Rubber-Modified Polystyrene, 42 Fed. Reg. 14,593 (Mar. 15, 1977) (codified at 21 C.F.R. § 177.1640 (2019)).

57 *Id.*

B. FDA Approval of FCS Components Through the FCN Process

In 1997, Congress passed the Food & Drug Administration Modernization Act (Modernization Act), which introduced a new procedure for allowing FCSs onto the market.[58]

> [A] manufacturer or supplier of a food contact substance may, at least 120 days prior to the introduction or delivery for introduction into interstate commerce of the food contact substance, notify the Secretary of the identity and intended use of the food contact substance, and of the determination of the manufacturer or supplier that the intended use of such food contact substance is safe . . . .[59]

Since the passage of the Modernization Act, the FCN process has become the primary mechanism for approving new FCSs, though earlier FCSs approved by regulations remain valid.[60] The FCN process is made up of two major phases: (1) notification submission and (2) FDA review.[61] To begin, a manufacturer or supplier must submit to the FDA a notification of a new use for an FCS.[62] The notification must include the following:

1. a comprehensive discussion of the notifier's determination that the FCS is safe;
2. the chemical identity of the FCS;
3. detailed information on the intended conditions of use of the FCS;
4. a determination of the minimum amount of the substance that will achieve the intended technical effect;
5. sufficient data to enable the FDA to calculate the estimated daily intake resulting from use of the substance;
6. relevant toxicological profiles;
7. either an environmental assessment or a claim for categorical exclusion from the NEPA process; and

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58 Food & Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 309(b)(2), 111 Stat. 2354 (codified as amended at 21 U.S.C.A. § 348(h)(1) (Westlaw through Pub. L. No. 116-91)).

59 *Id.*

60 *Guidance for Industry: Preparation of Food Contact Notifications (Administrative)*, U.S. FOOD & DRUG ADMIN. (May 2002), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparation-food-contact-notifications-administrative [https://perma.cc/S6ZV-PS38] [hereinafter *Preparation of Food Contact Notifications*].

61 *Id.*

62 *Id.*

8. a completed and signed FDA form No. 3480.[63]

Once this notification is received by the FDA, the agency will acknowledge receipt within thirty days.[64] Next, the FDA must review the submitted notification.[65] If the FDA does not issue a letter objecting to the notification within 120 days, the FCS is approved for market.[66] The 120-day timeframe begins when the FDA acknowledges receipt of the notification.[67] The FDA is not required to issue a letter confirming approval of the FCS, but will provide one in many cases in order to formally close the review process.[68] Alternatively, the FDA may object to an FCS if the notification is incomplete or the FDA does not agree with the manufacturer's determination that the FCS is safe.[69] If the FDA declines to object to a notification during the 120-day review period, it will add the compound to its inventory of effective FCNs.[70]

Besides significant procedural changes, introduction of the FCN process represented a notable shift in FDA policy. The previous system required the FDA to specifically approve a compound in an FCS through a new regulation. Now, under the FCN process, the public is relying on the FDA to object to a potentially dangerous compound within 120 days.[71] Initial determinations of "safety" are now the responsibility of manufacturers rather than the FDA, and silence on the part of the agency with respect to a particular compound is now equivalent to its approval.[72] An approval process incorporating the precautionary principle would better serve both environmental and consumer protection interests. The precautionary principle dictates that "[w]hen an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some

63 *Id.*

64 *Id.*

65 *Id.*

66 *Id.*

67 *Id.*

68 *Id.*

69 21 C.F.R. § 170.104(c) (2019); 21 U.S.C.A. § 348(h) (Westlaw through Pub. L. No 116-91).

70 *See Inventory of Effective Food Contact Substance (FCS) Notifications*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/fdcc/?set=FCN&sort=FCN_No&order=DESC&startrow=1&type=basic&search= [https://perma.cc/N4W2-L5ZC]. (last updated Nov. 30, 2019).

71 *Preparation of Food Contact Notifications*, *supra* note 60.

72 *Inventory of Effective Food Contact Substance (FCS) Notifications*, *supra* note 70.

cause and effect relationships are not fully established scientifically."[73] In the context of approving FCNs, adopting this principle would mean shifting the burden onto plastic manufacturers to demonstrate that a plastic compound is safe before it is approved by the FDA, rather than allowing for approval unless the FDA makes a finding that the compound is unsafe. Under such a system, the FDA would automatically deny approval to FCNs that are not proven safe within the 120-day review period, rather than automatically approving FCNs barring objection by the agency within that same timeframe.

II
FDA AND THE NATIONAL ENVIRONMENTAL POLICY ACT

Beyond its agency-specific responsibilities, the FDA must also comply with more general legal obligations that apply to nearly all federal agencies. NEPA was passed in 1969 with stated purposes to "encourage productive and enjoyable harmony between man and his environment," "promote efforts which will prevent or eliminate damage to the environment," and "enrich the understanding of the ecological systems and natural resources important to the Nation," among others.[74] NEPA requires government agencies to assess the environmental impacts of their decisions and regulations.[75] "[A]ll agencies of the Federal Government shall . . . insure the integrated use of the natural and social sciences and the environmental design arts in planning and in decisionmaking which may have an impact on man's environment."[76] NEPA is a strictly procedural statute, requiring agencies to complete environmental analysis of projects without requiring any specific response based on the finding of that analysis.[77] "NEPA itself does not mandate particular results, but simply prescribes the necessary process."[78] Government agencies will often prepare an initial environmental assessment (EA) to ascertain whether a complete environmental impact statement (EIS) is warranted.[79] However,

73 *Precautionary Principle: The Wingspread Statement*, COLLABORATIVE ON HEALTH & ENV'T, https://www.healthandenvironment.org/environmental-health/social-context/history/precautionary-principle-the-wingspread-statement [https://perma.cc/4UH3-XP7N] (last visited Mar. 8, 2020).

74 42 U.S.C.A. § 4321 (Westlaw through Pub. L. No. 116-91).

75 42 U.S.C.A. § 4332(2)(C) (Westlaw through Pub. L. No. 116-91).

76 42 U.S.C.A. § 4332(2)(A).

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

78 *Id.*

79 40 C.F.R. § 1501.4 (2019).

agencies *must* prepare a full EIS for (1) major federal actions (2) that are likely to significantly affect the quality of the environment.[80] If an agency does not find that these elements are met in the course of preparing an EA, the agency will issue a finding of no significant impact (FONSI) to move forward with the action in question.[81]

While the precise threshold of NEPA's triggers for a full EIS are highly contested and remain the subject of extensive litigation, a court should treat FDA approval of an FCS as a major federal action under NEPA. Regulations promulgated by CEQ clearly list key activities that are considered major federal actions.[82] "Actions include . . . new or revised agency rules, regulations, plans, policies, or procedures . . . ."[83] Therefore, courts have consistently adopted the view that an agency's promulgation of a regulation is a major federal action for purposes of NEPA with minimal discussion.[84] "NEPA requires the preparation of an environmental impact statement unless the regulations do not significantly affect the quality of the human environment."[85] Furthermore, agency decisions to issue permits allowing specific activities are also major federal actions.[86] CEQ regulations list "[a]pproval of specific projects" as a category of federal action.[87] "Projects include actions approved by permit or other regulatory decision as well as federal and federally assisted activities."[88] Therefore, FDA approval of an FCS is a major federal action for purposes of NEPA.

It is worth noting that the Trump administration's proposed amendments to CEQ regulations include a "clarification" of the term "major federal action."[89] "CEQ proposes to amend the first sentence of the definition [of 'major federal action'] to clarify that an action meets the definition if it is subject to Federal control and responsibility, and

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80 42 U.S.C.A. § 4332(2)(C).

81 40 C.F.R. § 1508.13 (2019).

82 40 C.F.R. § 1508.18(a) (2019).

83 *Id.*

84 Am. Pub. Transit Ass'n v. Goldschmidt, 485 F. Supp. 811, 832 (D.D.C. 1980)*; see also* Kleppe v. Sierra Club, 427 U.S. 390, 399 (1976); Andrus v. Sierra Club, 442 U.S. 347, 358 (1979).

85 *Am. Pub. Transit Ass'n*, 485 F. Supp. at 832 (alteration in original) (internal quotations omitted).

86 40 C.F.R. § 1508.18(b).

87 *Id.*

88 *Id.*

89 Update to the Regulations Implementing the Procedural Provisions of the National Environmental Policy Act, 85 Fed. Reg. 1708 (proposed Jan. 10, 2020).

it has effects that may be significant."[90] Even with this revision, FDA approval of an FCS would likely still be considered a major federal action by a court as an approval process that is subject to federal control and responsibility.

NEPA's second trigger, the significance requirement, is also defined by CEQ regulations, as well as subsequent case law. Agencies and courts must consider both the context and intensity of a proposed action or project in determining whether it will have significant effects on the environment.[91] CEQ regulations prescribe examination of site-specific impacts, adverse effects to endangered or threatened species, and level of controversy associated with an agency action in analyzing context and intensity, along with other considerations.[92] While the Trump administration's proposed amendments to CEQ regulations do make some alterations to the wording of this criteria,[93] by and large the amendments do not change the significance requirement.[94]

> Under both the current and proposed regulations, an agency must describe the environmental impacts of its proposed action and alternatives, providing enough information to support a determination to prepare either a FONSI or an EIS. The EA should focus on whether the proposed action (including mitigation) would ''significantly'' affect the quality of the human environment and tailor the length of the discussion to the relevant effects.[95]

Because courts have treated the significance requirement as a highly fact-based question, there are inconsistencies across the circuits in setting thresholds for fulfilling this requirement. On the one hand, the Ninth Circuit has held that "[a]n EIS must be prepared if 'substantial questions are raised as to whether a project . . . may cause significant degradation of some human environmental factor.'"[96] Therefore, a plaintiff is not required to prove any significant effect will actually occur, "[i]t is enough for the plaintiff to raise substantial questions whether a project may have a significant effect on the environment."[97]

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90 *Id.*

91 40 C.F.R. § 1508.27 (2019).

92 *Id.*

93 Update to the Regulations Implementing the Procedural Provisions of the National Environmental Policy Act, 85 Fed. Reg. at 1695.

94 *Id.* at 1708.

95 *Id.* at 1697.

96 Blue Mountains Biodiversity Project v. Blackwood, 161 F.3d 1208, 1212 (9th Cir. 1998) (quoting Idaho Sporting Cong. v. Thomas, 137 F.3d 1146, 1149 (9th Cir. 1998)).

97 *Id.* (internal quotations omitted).

On the other hand, the Second Circuit has construed the significance requirement more narrowly.[98]

> [I]n deciding whether a major federal action will "significantly" affect the quality of the human environment the agency . . . should . . . review the proposed action in the light of at least two relevant factors: (1) the extent to which the action will cause adverse environmental effects in excess of those created by existing uses in the area affected by it, and (2) the absolute quantitative adverse environmental effects of the action itself . . . .[99]

Despite varying standards, a court should consider the impacts of the FDA's approval of FCSs as significant based upon the extent to which environmental damage related to disposable plastics has spread, and the research-based evidence illustrating the damage. Given the wide reach and persistent nature of plastic pollution, FDA approval of plastic FCSs clearly raises substantial questions surrounding the environmental degradation resulting from these approvals, thereby satisfying the Ninth Circuit test for significance. Similarly, FDA approval of plastic FCSs also satisfies each part of the Second Circuit's test because: (1) allowing plastic FCSs onto the market creates severe environmental damage across the globe that is in excess of the damage that would occur if FCSs were not approved; and (2) these adverse effects are well documented by both anecdotal evidence and quantitative data.

When a full analysis is triggered by a major federal action with significant environmental effects, NEPA stipulates that an EIS must describe the following:

> i. the environmental impact of the proposed action,
>
> ii. any adverse environmental effects which cannot be avoided should the proposal be implemented,
>
> iii. alternatives to the proposed action,
>
> iv. the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity, and
>
> v. any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented.[100]

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98 *See* Hanly v. Kleindienst, 471 F.2d 823, 830–31 (2d. Cir. 1972).

99 *Id.* at 830.

100 42 U.S.C.A. § 4332(C)(i)–(v) (Westlaw through Pub. L. No. 116-91).

The Trump's administration's proposed regulations revising the NEPA review process include several new guidelines regarding what constitutes a full EIS, specifically regarding format, page length, and a timeline for completing the document.[101]

> CEQ intends for senior agency officials to take responsibility for the quantity, quality, and timelines of environmental analyses developed in support of the decisions of their agencies. Therefore, the senior agency official approving an EA or EIS in excess of the page limits should ensure that the final environmental document meets the informational needs of the agency's decision maker.[102]

The NEPA process outlined above applies to policies and decisions of all federal agencies, including the FDA.[103] The FDA acknowledges its own NEPA obligations in its current guidance regarding how to prepare a notification for a new FCS,[104] and through its promulgated regulations.[105] Overall, the FDA has clear legal obligations to provide adequate analysis of the environmental impacts of its decisions, which the agency cannot ignore.

III
POTENTIAL NEPA CHALLENGES TO THE FDA'S APPROVAL OF FCSS

In the face of our planet's growing plastic pollution crisis, it has become abundantly clear that single-use plastics significantly affect the quality of the human environment. Furthermore, market availability of single-use plastics was allowed and is perpetuated through major federal actions, specifically, the approval of key chemical compounds by the FDA. With this in mind, it is worth exploring the possibility of NEPA litigation challenging the FDA's approval of FCSs.

A. General Administrative and Procedural Requirements

For a NEPA claim to succeed, it is necessary to focus on discrete agency actions rather than contemplating a broader challenge to the

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101 Update to the Regulations Implementing the Procedural Provisions of the National Environmental Policy Act, 85 Fed. Reg. 1700 (proposed Jan. 10, 2020).

102 *Id.*

103 42 U.S.C.A. § 4332(2)(A).

104 *How to Submit a Food Contact Substance Notification*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/inventory-effective-food-contact-substance-fcs-notifications/how-submit-food-contact-substance-notification [https://perma.cc/H7MW-5KKB] (last updated Dec. 14, 2017).

105 21 C.F.R. § 25.22(b) (2019).

FDA's approval of plastic FCNs. Such focus is important for several reasons. First, the Supreme Court has held that NEPA contains no private right of action.[106] Therefore, judicial review of the NEPA process is available only through the Administrative Procedure Act (APA).[107] The APA controls the processes through which federal agencies craft and promulgate regulations and also outlines requirements for judicial review of agency actions.[108] Under the APA, only final agency actions are subject to judicial review.[109] In *Bennett v. Spear*, the Supreme Court put forth a practical definition to determine when agency actions become final.

> As a general matter, two conditions must be satisfied for agency action to be "final": First, the action must mark the "consummation" of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which "rights or obligations have been determined," or from which "legal consequences will flow."[110]

In order to satisfy this two-part test, a plaintiff must identify a discrete action on the part of the FDA. Second, identification of a discrete agency action is crucial to fulfilling Article III standing requirements. To establish Article III standing, a plaintiff must prove they suffered harm that is (1) concrete and particularized, (2) actual or imminent, and (3) redressable through a favorable court ruling.[111] FDA decisions regarding both polystyrene and polypropylene are discrete agency actions that advocates can focus their attention on. As described above, polystyrene is a key chemical component of plastic utensils.[112] And single-use plastic straws are commonly made from polypropylene.[113] Like polystyrene, polypropylene and other members of the broader olefin family of chemicals have also been approved for use in FCSs

106 Lujan v. Nat'l Wildlife Fed'n, 497 U.S. 871, 872 (1990).

107 *Id.* at 882–83.

108 5 U.S.C.A. §§ 701, 706 (Westlaw through Pub L. No. 116-91).

109 *Id.* § 704.

110 Bennett v. Spear, 520 U.S. 154, 177–78 (1997) (citations omitted).

111 Lujan v. Defs. of Wildlife, 504 U.S. 555, 560 (1992).

112 Lewis, *supra* note 55.

113 Christy Brissette, *Plastic Straws Aren't Just Bad for the Environment—They Can Be Bad for Your Body*, WASH. POST (July 3, 2018, 4:00 AM), https://www.washingtonpost.com/lifestyle/wellness/plastic-straws-arent-just-bad-for-the-environment—they-can-be-bad-for-your-body/2018/07/02/d682fdfe-7964-11e8-aeee-4d04c8ac6158_story.html?utm_term=.814212ae320e [https://perma.cc/QYS5-5DM2].

through FDA regulations.[114] "The olefin polymers listed in . . . this section [including polypropylene] may be safely used as articles or components of articles intended for use in contact with food . . . ."[115] The regulations approving polystyrene and olefins for use in FCSs were promulgated in 1977.[116] The harms suffered from FDA approval of FCSs, such as polystyrene and polypropylene, are concrete and particularized because approval allows these plastics onto the market where they become undesirable waste following short-term use, as intended by design. The resulting harms are also actual and imminent because plastic waste is now clogging the nation's waterways, as well as injuring prized wildlife, and will continue to do so until remedial steps are taken. Finally, redressability exists because a favorable court ruling would require the FDA to reevaluate its approval of dangerous FCSs and may ultimately reduce market availability of plastic FCSs.

B. Statute of Limitations Issue

While NEPA does apply to FDA regulations and policies, it is likely that many FDA decisions regarding specific plastic chemical compounds, like polystyrene and polypropylene, fall outside the statute of limitations for NEPA challenges. Several courts have held that because NEPA does not include any private right of action, NEPA claims are confined to the six-year statute of limitations provided by the APA.[117] Clearly, this statute of limitations has passed for potential challenges to the 1977 FDA regulations governing chemical compounds of particular concern. It is also worth noting that plaintiffs in similar environmental cases have previously argued that the continuing violation doctrine should extend to infringements of environmental statutes through claims brought under the APA.[118] The continuing violation doctrine applies when "each overt act that is part of the violation and that injures the plaintiff . . . starts the statutory period running again, regardless of the plaintiff's knowledge of the

114 Indirect Food Additives: Polymers, 42 Fed. Reg. 14,572 (Mar. 15, 1977) (codified at 21 C.F.R. § 177.1520 (2019)).

115 *Id.*

116 *Id.*

117 Friends of Tims Ford v. Tenn. Valley Auth., 585 F.3d 955, 964 (6th Cir. 2009); Jersey Heights Neighborhood Ass'n v. Glendening, 174 F.3d 180, 186 (4th Cir. 1999); *see also* 28 U.S.C.A. § 2401(a) (Westlaw through Pub. L. No. 116-91).

118 Izaak Walton League of Am., Inc. v. Kimbell, 558 F.3d 751, 759–61 (8th Cir. 2009).

alleged illegality at much earlier times."[119] But several circuit courts have rejected such arguments, holding that the general six-year statute of limitations (which begins to run when an agency decision is published in the federal register) is applicable to suits against federal agencies.[120]

However, there are alternative legal avenues available for contesting FDA regulations approving problematic FCSs. Under the APA, "[e]ach agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule."[121] Advocates could petition the FDA to revise the existing regulations or make a new regulation based on evidence highlighting the environmental concerns tied to FCSs manufactured with polystyrene and polyethylene. If such a petition were filed, there would be three possible outcomes. First, the FDA could accept the petition and begin the process of updating the relevant regulations to reflect these important environmental considerations. Second, the FDA could delay and provide no response to the petition, and subsequent litigation could arise hinging on the issue of unreasonable delay. In similar situations, courts have looked to six factors in determining whether an agency has unreasonably delayed in responding to a petition:

> (1) the time agencies take to make decisions must be governed by a "rule of reason"; (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason; (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake; (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority; (5) the court should also take into account the nature and extent of the interests prejudiced; and (6) the court need not "find any impropriety lurking behind agency lassitude in order to hold that agency action is 'unreasonably delayed.'"[122]

Third, and perhaps the most likely outcome, the FDA could choose to deny the petition. Such a denial is a final agency action, open to

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119 Midwestern Mach. Co. v. Nw. Airlines, Inc., 392 F.3d 265, 269 (8th Cir. 2004) (citations omitted).

120 *Izaak Walton League of Am.*, 558 F.3d at 761; *see also* Stupak-Thrall v. Glickman, 346 F.3d 579, 584–85 (6th Cir. 2003); Ctr. for Biological Diversity v. Hamilton, 453 F.3d 1331, 1334–35 (11th Cir. 2006).

121 5 U.S.C.A. § 553(e) (Westlaw through Pub. L. No. 116-91).

122 Telecomm. Research & Action Ctr. v. Fed. Commc'n Comm'n, 750 F.2d 70, 80 (D.C. Cir. 1984) (citations omitted).

judicial review under the APA and, therefore, is also reviewable under NEPA.[123] By presenting the FDA with a new petition, whatever the response, advocates can bring government attention to the environmental harms caused by plastics in our food system and reset the statute of limitations found within the APA. Presenting the FDA with a new petition necessitates a response (or a lack of response) from the agency that provides a basis for plaintiffs to seek judicial review.[124] Additionally, the APA requires exhaustion of all administrative remedies before judicial review is granted.[125] Plaintiffs can meet this requirement by engaging with the administrative process through filing a petition and receiving a subsequent agency response.

C. Substantive NEPA Arguments

Once all procedural obligations are fulfilled and the statute of limitations problem is overcome, advocates can concentrate on the substance of a NEPA challenge to the FDA's approval of FCSs. Here are three key arguments that might contribute to a successful substantive NEPA challenge to the FDA's approval of polystyrene and polypropylene:

1. Polystyrene and polypropylene have significant impacts on the human environment that are demonstrated through a credible body of scientific research.[126]
2. The science the FDA relied upon in approving polystyrene and polypropylene is outdated and unreliable.[127]
3. Given that plastics remain in the environment for centuries, the scope of the FDA's environmental analysis in approving polystyrene and polypropylene was inadequate.[128]

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123 *See* Bennett v. Spear, 520 U.S. 154, 177–78 (1997).

124 5 U.S.C.A. § 553(c)–(e); *Telecomm. Research & Action Ctr.*, 750 F.2d at 80.

125 *See* Abbott Labs. v. Gardner, 387 U.S. 136, 146–48 (1967).

126 *See* Irina Ivanova, *States Declare War on Styrofoam—"People Think It Breaks Down*,*"* CBS NEWS (May 1, 2019, 5:39 PM), https://www.cbsnews.com/news/styrofoam-ban-states-declare-war-people-think-it-breaks-down/ [https://perma.cc/2FSH-LYGB]; Bruce Y. Lee, *Microplastics Found in the Ocean and in Human Poop*, FORBES (Sept. 3, 2019, 3:34 AM), https://www.forbes.com/sites/brucelee/2019/09/03/microplastics-found-in-the-ocean-and-in-human-poop/#185aa5ec37a4 [https://perma.cc/ZC4K-3RHW].

127 *See, e.g.*, Indirect Food Additives: Polymers, 42 Fed. Reg. 14,572 (Mar. 15, 1977) (codified at 21 C.F.R. § 177.1520 (2019)).

128 *See* Tony Briscoe, *22 Million Pounds of Plastics Enter the Great Lakes Each Year. Most of the Pollution Pours into Lake Michigan.*, CHI. TRIB. (Sept. 4, 2019, 6:52 AM), https://www.chicagotribune.com/news/environment/ct-met-lake-michigan-plastic-pollution-20190904-2xf3qogqv5bpfco2plndapak2q-story.html [https://perma.cc/F2HD-7RSU].

Of course, plaintiffs would need to reframe each of these arguments as necessary if challenging chemical compounds that were approved by the FDA for use in FCSs other than polystyrene or polypropylene. The rest of this Article will examine each of these arguments more closely with regard to polystyrene and polypropylene, as they are main components of regularly consumed disposable plastics, such as plastic forks and straws.[129]

1. Polystyrene and Polypropylene Significantly Affect the Human Environment

FONSIs for the polystyrene and polypropylene in plastic FCSs violate NEPA because there are significant impacts to the human environment resulting from products manufactured with these compounds. Courts will often find cause to reverse an agency's FONSI.[130] In *Minnesota Public Interest Research Group v. Butz (I)*, a nonprofit organization successfully sought an injunction against timber sales by the United States Forest Service for logging in Minnesota's Boundary Waters Canoe Area.[131] On appeal, the Eighth Circuit held that qualitative harms to the environment as a result of a federal action constituted a significant impact and upheld the trial court's ruling.[132] "Logging creates excess nutrient run-off which causes algal growth in the lakes and streams, affecting water purity. Logging roads may cause erosion and water pollution and remain visible for as long as 100 years . . . ."[133] In the same case, the court also held that NEPA's significance requirement "is concerned with indirect effects as well as direct effects."[134] The environmental impacts of plastic FCS approvals by the

129 Lewis, *supra* note 55; Brissette, *supra* note 113.

130 *See generally* Minn. Pub. Interest Research Grp. v. Butz (*Butz II*), 498 F.2d 1314, 1322–23 (8th Cir. 1974) (refusing to overturn a district court's injunction on logging in northern Minnesota without the United States Forest Service filing a final EIS); McDowell v. Schlesinger, 404 F. Supp. 221, 250 (W.D. Mo. 1975) (holding that the relevant administrative record and initial EIA failed to support the United States Air Force's conclusion that construction of new housing facilities had no significant environmental impact); Ocean Advocates v. U.S. Army Corps of Eng'rs, 402 F.3d 846, 865 (9th Cir. 2005) (holding that a FONSI prepared by the Army Corps of Engineers failed to properly analyze possible increases in tanker traffic and oil spills in Puget Sound created by permitting the construction of a new platform dock at a British Petroleum facility).

131 Minn. Pub. Interest Research Grp. v. Butz (*Butz I*), 358 F. Supp. 584, 630 (D. Minn. 1973).

132 *Butz II*, 498 F.2d at 1322–23.

133 *Id.* at 1322.

134 *Id.*

FDA are at least as significant as logging in the Boundary Waters Canoe Area, if not even more so.

When it comes to polypropylene and polystyrene, both anecdotal and scientific evidence clearly show the significant impact on the human environment caused by products manufactured with these compounds. A recent survey in California found that plastic utensils rank among the state's ten most common trash items.[135] Americans use 500 million plastic straws every day, and these straws are usually not recycled.[136] In 2015, video footage of marine biologists painstakingly removing a plastic straw that was embedded in a sea turtle's nostril as the animal squealed and began bleeding went viral.[137] Such tangible records of harm to wildlife (in some cases, species specifically protected by other statutes like the Endangered Species Act or Marine Mammal Protection Act)[138] support reversal of FDA's FONSI for polypropylene and polystyrene in FCSs.

2. The Science the FDA Relied Upon to Approve Polystyrene and Polypropylene Is Outdated

The reliability of the science supporting the FDA's approval of chemical components found in polystyrene and polypropylene is questionable, since they were approved several decades ago and the FDA must consider more recent research discussing resulting environmental impacts. When it comes to judicial review, an agency's scientific determination receives a high degree of deference from courts.[139]

> When a challenge to an agency construction of a statutory provision, fairly conceptualized, really centers on the wisdom of the agency's policy, rather than whether it is a reasonable choice within a gap left open by Congress, the challenge must fail. In such a case, federal judges—who have no constituency—have a duty to respect

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135 Jenny Luna, *We Are So Forked*, MOTHER JONES (July/Aug. 2017), https://www.motherjones.com/environment/2017/07/are-alternate-utensils-for-take-out-an-envrioment-friendly-option/ [https://perma.cc/WSX3-RHXW].

136 Laura Parker, *Straw Wars: The Fight to Rid the Oceans of Discarded Plastic*, NAT'L GEOGRAPHIC (Feb. 23, 2018), https://news.nationalgeographic.com/2017/04/plastic-straws-ocean-trash-environment/ [https://perma.cc/EFK2-QDUQ].

137 Christine Figgener, *Sea Turtle with Straw up its Nostril – "No" to Plastic Straws*, YOUTUBE (Aug. 10, 2015), https://www.youtube.com/watch?v=4wH878t78bw [https://perma.cc/5HCF-PET2].

138 *See* 50 C.F.R. § 17.11 (2019); 16 U.S.C.A. § 1362(6) (Westlaw through Pub. L. No. 116-91).

139 *See* Chevron U.S.A., Inc. v. Nat. Res. Def. Council, 467 U.S. 837, 844 (1984).

> legitimate policy choices made by those who do. The responsibilities for assessing the wisdom of such policy choices and resolving the struggle between competing views of the public interest are not judicial ones . . . .[140]

However, CEQ regulations require agencies to "insure the professional integrity, including scientific integrity, of the discussions and analyses in environmental impact statements."[141] Accordingly, courts have held that NEPA is violated where agencies relied upon outdated data in reaching a decision.[142] In *Sierra Club v. USDA*, environmental advocates challenged the United States Forest Service's decision to allow oil and gas leasing within Shawnee National Forest in southern Illinois.[143] As part of their case, plaintiffs argued that projections of songbird populations included in the agency's EIS were inaccurate because they were developed using statistics that were at least ten years old.[144] The Seventh Circuit agreed with the plaintiffs, stating, "Absent a rational response to the ornithologists' criticisms and an explanation for the failure to compile more recent data . . . the Court finds . . . the reliance upon the 10-year-old Graber data to be arbitrary and capricious."[145]

Similarly, environmental advocates could also argue that the data the FDA relied upon in approving polystyrene and polypropylene is outdated. Since the relevant regulations were promulgated in 1977, some of the research at issue is even older than the data the court found lacking in *Sierra Club v. USDA*.[146] Therefore, under current case precedent, the FDA would be forced to either generate new data regarding environmental impacts of polystyrene and polypropylene or provide a reasonable explanation for why the original data remains appropriate to consider in support of its decision. However, the Trump administration's proposed revisions to CEQ regulations include the addition of language stating, "Agencies shall make use of reliable existing data and resources and are not required to undertake new

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140 *Id.* at 866.

141 40 C.F.R. § 1502.24 (2019).

142 Nw. Ecosystem All. v. Rey, 380 F. Supp. 2d 1175, 1195 (W.D. Wash. 2005); Sierra Club v. U.S. Dep't. of Agric., No. 96-2244, 1997 WL 295308, at *12 (7th Cir. May 28, 1997).

143 *Sierra Club*, 1997 WL 295308, at *24.

144 *Id.* at *9–12.

145 *Id.* at *14.

146 *See id.*

scientific and technical research to inform their analyses."[147] While this change could harm the argument that reliance on decades-old science used in FDA's approvals of polystyrene and polypropylene is invalid and violates NEPA, the future of the Trump administration's proposed regulatory amendments and subsequent court rulings remains unclear.

3. The Scope of Environmental Analysis the FDA Relied Upon to Approve Polystyrene and Polypropylene Is Inadequate

Plastic FCSs remain in the environment for centuries after their disposal and the FDA's environmental analysis has spanned much shorter timeframes, thereby underestimating the cumulative environmental impacts of their disposal. While courts have held that a federal agency need not anticipate *every* possible future environmental impact of an action to comply with NEPA, the agency must still make good faith efforts to forecast likely environmental harms resulting from a major federal action.[148]

> It must be remembered that the basic thrust of an agency's responsibilities under NEPA is to predict the environmental effects of proposed action before the action is taken and those effects fully known. Reasonable forecasting and speculation is thus implicit in NEPA, and we must reject any attempt by agencies to shirk their responsibilities under NEPA by labeling any and all discussion of future environmental effects as "crystal ball inquiry."[149]

Therefore, the timeline of the FDA's environmental analysis in approving polystyrene and polypropylene should extend beyond this century, as the products manufactured from these compounds are anticipated to remain in the environment for hundreds of years.[150] For context, some of the environmental analysis cited by the FDA in support of amendments to 21 C.F.R. § 177.1520 spanned a timeframe of just ten days.[151] A court should hold that the FDA is shirking its responsibilities in failing to provide research discussing the

147 Update to the Regulations Implementing the Procedural Provisions of the National Environmental Policy Act, 85 Fed. Reg. 1721 (proposed Jan. 10, 2020) (to be codified at 40 C.F.R. § 1502.24).

148 *See* Scientists' Inst. for Pub. Info., Inc. v. Atomic Energy Comm'n, 481 F.2d 1079, 1092 (D.C. Cir. 1973).

149 *Id.*

150 *See* Lapidos, *supra* note 3.

151 *See* Keller & Heckman, Petition Letter on Amended Environmental Assessment (Jan. 13, 1988), https://www.regulations.gov/document?D=FDA-1987-F-0123-0002 [https://perma.cc/65AN-GLV6].

environmental impacts of polystyrene and polypropylene into future centuries.

CONCLUSION

Disposal of single-use plastics has become one of the most pressing and visible environmental concerns of our time. One possible mechanism environmental advocates can use to address this problem through existing law is a NEPA challenge to the FDA's approval of compounds in FCSs designed for disposal. The FDA has employed two different procedures to approve chemical compounds for use in FCSs. First, the FDA promulgated regulations to approve particular compounds found in FCSs. Second, the FDA has more recently used the FCN process to approve chemical compounds intended for FCSs. Following the passage of the Modernization Act in 1997, the FDA has largely switched to the FCN process. The FDA is subject to the statutory requirements of NEPA regardless of which mechanism is used by the agency.

Even though many FDA regulations approving compounds for use in FCSs are several decades old, hypothetical plaintiffs could overcome statute of limitations arguments by filing a petition with the FDA to amend or promulgate new regulations on pertinent chemicals. After overcoming this procedural barrier, there are legitimate substantive arguments that the agency did not complete appropriate environmental analysis regarding FCSs to comply with NEPA. The FDA has historically placed a heavy emphasis on human health implications in conducting NEPA-required analyses without considering the foreseeable disposal of plastics used to package commonly consumed food items. From an environmental management perspective, such a narrow evaluation is wholly inadequate. The FDA should account for the full lifecycle of the plastic compounds it approves for use in FCSs. At a time when government leaders have failed to collectively confront the plastic pollution crisis at the federal level, alternative avenues and creative legal solutions are now required to address this important issue.