

The Microplastics Crisis: Exploring Pathways for Regulation and the Growing Concern for Human Health

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I. INTRODUCTION

With over 300 million metric tons of plastic being produced in the world each year and the majority of this plastic being discarded after one use, the ocean has borne the burden of our disposal.¹ If current trends continue, the oceans are projected to contain more plastic than fish by the year 2050.² As plastic enters the water, it begins to fragment into smaller pieces and become microplastics, releasing toxic chemicals in the

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1. Jeremy L. Conkle et al., *Are We Underestimating Microplastic Contamination in Aquatic Environments?*, ENV'T MGMT. (Oct. 2018), at 1.

2. WORLD ECON. FORUM, *THE NEW PLASTICS ECONOMY: RETHINKING THE FUTURE OF PLASTICS* 17 (Len Neufeld et al. eds., 2016).

process.³ The oceans are an crucial component to maintaining human health, and microplastics, along with the toxins they release, spread throughout ecosystems that provide us with essential benefits.⁴ Though some debate exists about what exactly qualifies as a microplastic, scientists have generally come to the consensus that they exist as pieces with a diameter up to five millimeters and measurable at as little as one micrometer.⁵ Microplastics can be separated into two categories: primary, which includes plastics produced at a size that fits within the one micrometer to five millimeter range; and secondary, which includes plastics that break down to this size range as a result of the physical and chemical processes in the ocean or other bodies of water.⁶ The small size and severe proliferation of microplastics becomes a problem when attempting to measure the potential impact of microplastics on marine ecosystems, and much remains unknown about the extent of this impact because research on the matter has only recently become more common.⁷

Although this is a relatively new issue, what scientists have uncovered thus far raises red flags. Data from 800 different species and 87,000 individual organisms has indicated that 20 percent of individuals sampled contain ingested microplastics.⁸ In copepods and zooplankton, the foundation of marine food webs, multiple studies have uncovered instances of microplastic ingestion and negative health effects.⁹ Further up the food chain, negative impacts on growth and body condition have been observed in planktivorous fish, particularly when these fish ingest

3. Philip J. Landrigan et al., *Human Health and Ocean Pollution*, ANNALS OF GLOB. HEALTH (2020), at 2; Nicole Bandow et al., *Contaminant Release from Aged Microplastic*, 14 ENV'T CHEMISTRY 394, 403 (2017).

4. Landrigan et al., *supra* note 3, at 10.

5. J.P.G.L. Frias & Roisin Nash, *Microplastics: Finding a Consensus on the Definition*, 138 MARINE POLLUTION BULL. 145, 145–46 (2019) (noting that most studies monitoring microplastics are only able to measure those greater than 100 micrometers).

6. *See id.* at 145.

7. Woo Joon Shim & Richard C. Thomposon, *Microplastics in the Ocean*, 69 ARCHIVES OF ENV'T CONTAMINATION AND TOXICOLOGY 265, 266 (2015).

8. Todd Gouin, *Toward an Improved Understanding of the Ingestion and Trophic Transfer of Microplastic Particles: Critical Review and Implications for Future Research*, 39 ENV'T TOXICOLOGY AND CHEMISTRY 1119, 1122 (2020).

9. Matthew Cole et al., *Microplastic Ingestion by Zooplankton*, 47 ENV'T SCI. & TECH. 6646, 6652 (2013); Matthew Cole et al., *The Impact of Polystyrene Microplastics on Feeding, Function and Fecundity in the Marine Copepod *Calanus helgolandicus**, 49 ENV'T SCI. & TECH. 1130, 1134 (2015); K.W. Lee et al., *Size Dependent Effects of Micro-Polystyrene Particles in the Marine Copepod *Tigriopus japonicus**, 47 ENV'T SCI. & TECH. 11278, 11280 (2013).

smaller microplastics.¹⁰ Because of the small size of these plastics, fish fail to distinguish between microplastic and plankton.¹¹ This means that if plankton and other food sources become strained due to microplastics as the previously mentioned studies indicate, planktivorous fish may ingest more microplastics and experience adverse effects.¹² Together, these studies demonstrate how microplastics may damage the interactions between species at different trophic levels by beginning a chain reaction of compromised food sources starting at the base of the food chain.

Though ingestion of microplastics at individual trophic levels has negative implications, there may be further complications if microplastics begin to proliferate via trophic exchanges. The buildup of microplastic within individual trophic levels is referred to as bioaccumulation.¹³ This process opens the door for interaction and exchange of microplastics between trophic levels as organisms feed on one another, which is referred to as biomagnification.¹⁴ A meta-analysis of recent data from field observations and laboratory experiments confirms that bioaccumulation of microplastics has occurred across all trophic levels.¹⁵ Evidence of biomagnification has not been as apparent, and only studies in laboratory settings with extreme levels of microplastics have demonstrated such a process.¹⁶ Despite this, gaps in knowledge in the available data likely exist as monitoring for microplastics in the smaller range, particularly those smaller than 300 micrometers, is seldom feasible, which limits our ability to detect biomagnification.¹⁷ One thing, however, remains abundantly clear: the lack of understanding and ample warning signs of danger surrounding this ever-growing issue pose a threat to our oceans, and by extension, to human health.

10. Kay Critchell & Mia O. Hoogenboom, *Effects of Microplastic Exposure on the Body Condition and Behaviour of Planktivorous Reef Fish (Acanthochromis polyacanthus)*, PLOS ONE, March 1, 2018, at 1, 8–18.

11. *Id.* at 11.

12. *Id.* at 18.

13. Michaela E. Miller et al., *Bioaccumulation and Biomagnification of Microplastics in Marine Organisms: A Review and Meta-Analysis of Current Data*, PLOS ONE, October 16, 2020, at 1, 2. (“Trophic level” refers to the level of the food web a species occupies with primary producers being at the lowest trophic level and apex predators being at the highest trophic level of a given food web).

14. *Id.*

15. *Id.* at 6–14.

16. *Id.* at 15.

17. Conkle et al., *supra* note 1, at 7.

II. THE PROBLEM WITH THE WAY THE U.S. REGULATES MICROPLASTICS

To address the microplastics crisis, the government has implemented several solutions in the form of regulations. Although every current regulation targeted at plastics plays a part in attempting to address the crisis, they each have shortcomings, and taken together they fail to adequately provide a solution. To understand this failure, each component of plastic regulation in the United States should be considered along with its legislative history, which further illuminates the type of barriers faced when attempting to implement such regulations. From this examination, openings become clear for how future regulatory schemes may combat the ever-growing microplastics problem.

The legislation most clearly targeted toward regulating microplastics is the Microbead-Free Waters Act (“MFWA”).¹⁸ The MFWA was passed in 2015 and prohibits the “manufacture and introduction or delivery . . . of rinse-off cosmetics containing intentionally-added plastic microbeads.”¹⁹ Microbeads are a type of primary microplastic that proliferate mainly through the use of cosmetic products that flow through wastewater after domestic use and are able to pass through treatment facilities and infiltrate watersheds.²⁰ The MFWA was adopted in response to nonprofit organizations educating the public on the harmful effects of this specific type of microplastic and independent efforts by the private sector to phase out their use in order to appeal to consumers.²¹ Public awareness played a large role in the creation of the MFWA and many states had already implemented their own bans prior to its passage.²² The MFWA was particularly notable for its quick turnaround and bipartisan support, which can be considered unusual for an environmental regulation.²³ Its successes may be attributed to its conciseness, the level of public awareness regarding microbeads, and its focus on public health rather than environmental issues.²⁴ Though the MFWA was considered a success, it only targets a single form of microplastic rather than addressing

18. Microbead-Free Waters Act of 2015, Pub. L. No. 114-114, 129 Stat. 3129.

19. *Id.*

20. Jason P. McDevitt et al., *Addressing the Issue of Microplastics in the Wake of the Microbead-Free Waters Act—A New Standard Can Facilitate Improved Policy*, 51 ENV'T SCI. & TECH. 6611, 6612 (2017).

21. *Id.* at 6613.

22. David A. Strifling, *The Microbead-Free Waters Act of 2015: Model for Future Legislation*, 32 J. LAND USE & ENV'T. L. 151, 156–57 (2016).

23. *Id.* at 164–66.

24. *Id.* at 161–64.

the issue as a whole.²⁵ Simply put, microbeads are but a small fraction of the microplastics crisis and further action is required.

Next, the Clean Water Act (“CWA”) imposes regulations that may apply to plastics within industrial wastewater effluent and stormwater via the Effluent Guidelines and Standards for Organic Chemicals, Plastics, and Synthetic Fibers (“OCPSF”).²⁶ These standards are integrated into the industrial stormwater discharge permits required by the Environmental Protection Agency (“EPA”) for certain plastic manufacturers that use materials deemed toxic.²⁷ A major shortcoming of the OCPSF standards is that they do not apply to non-industrial uses and disposal of plastic. Additionally, microplastics are not explicitly mentioned by the guidelines so any of the “best technology” requirements designed to shield the environment from the toxicity of the enumerated materials under the OCPSF standards are not tailored to protect waterways from the breakdown of plastics.²⁸ Though this addresses toxicity issues identified with certain plastics, it ignores how the breakdown of plastics over time can exacerbate this problem along with the adverse impacts microplastics have to marine food chains.²⁹ Calls for incorporating microplastics into the OCPSF Standards have mounted, but the issue remains sequestered to a “contaminant of emerging concern” (“CEC”) category, effectively putting the microplastics crisis on hold in the eyes of the EPA.³⁰

The Marine Protection, Research, and Sanctuaries Act (“MPRSA”) regulates a particular type of disposal: the dumping of waste in the ocean by vessels. Again, this legislation does not specifically mention microplastics or plastic as an area of concern, but rather broadly defines “material” to not be dumped when it says: “including, but not limited to, dredged material, solid waste, incinerator residue, garbage, sewage, sewage sludge, munitions, radiological, chemical, and biological warfare agents, radioactive materials, chemicals, biological and laboratory waste, wreck or discarded equipment, rock, sand, excavation debris, and industrial, municipal, agricultural, and other waste.”³¹ However, a 1988

25. McDevitt et al., *supra* note 20, at 6611.

26. 40 C.F.R. § 414.11 (2022).

27. *Id.* § 414.4.

28. *Id.* §§ 414.21–23.

29. Bandow et al., *supra* note 3.

30. *Emerging Contaminants, Forever Chemicals, and More: Challenges to Water Quality, Public Health, and Communities Hearing Before the Subcomm. on Water Res. and Env’t of the H. Comm. on Transp. and Infrastructure*, 117th Cong. 1–7 (2021) [hereinafter *Hearing*] (testimony of Dr. Elizabeth Southerland, Former Director of the Office of Sci. & Tech., U.S. E.P.A.’s Office of Water).

31. 33 U.S.C.A § 1402(c) (1988).

amendment, referred to as the Ocean Dumping Act, requires enforcement of the MPRSA to take into account the standards provided by the London Dumping Convention, which includes persistent plastics.³² While this may sound promising, the agreement has limited jurisdiction in that it does nothing to address the sources of plastic before they are dumped from the boats.³³ Further, the Convention exempts plastic waste that is “incidental to, or derived from the normal operation of vessels,” providing room for interpretation on what plastics can be considered a part of the ban.³⁴ Overall, the incorporation of the London Dumping Convention to the MPRSA may provide a meaningful opportunity for the consideration of plastics and their breakdown when regulating dumping, but this reflects a narrow portion of plastic disposal.

Lastly, local and state plastic bans targeting single-use plastic have grown in popularity across the United States. At the state level, California, Connecticut, Delaware, Hawaii, Maine, New York, Oregon, and Vermont have instituted plastic bag bans.³⁵ Municipalities across the nation have implemented their own bans with varying results and responses from the public and state governments.³⁶ For example, South Carolina’s attempts to institute local bans were limited by the state government and the public expressed a mixed response, with coastal areas that implemented educational campaigns experiencing more support.³⁷ The overall effectiveness of the bans in modifying consumer behavior has also been called into question. For example, one study found that rather than discouraging plastic consumption, the ban drove consumers to purchase thicker plastic bags that were not subject to the same regulations.³⁸ Despite this potentially negative behavior outweighing the assumed benefits, the same study concedes that the state-wide ban in California was successful in reducing consumption of the targeted types of bags.³⁹

32. CLAUDIA COPELAND, CONG. RSCH. SERV., RS20028, OCEAN DUMPING ACT: A SUMMARY OF THE LAW (2010).

33. Mark Gold et al., Comment, *Stemming the Tide of Plastic Marine Litter: A Global Action Agenda*, 27 TUL. ENV’T L.J. 165, 182–83 (2014).

34. *Id.*; International Maritime Organization, Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter art. 3, Nov. 13, 1972, 1046 U.N.T.S. 120.

35. National Conference of State Legislators, *State Plastic Bag Legislation*, NCSL (Feb. 8, 2021), <https://www.ncsl.org> (search in search bar for “State Plastic Bag Legislation” then click on first link).

36. *See id.*

37. Madison Guyton, Comment, *Bans on Bans: Plastic Bags, Power, and Home Rule in South Carolina*, 71 S.C.L. REV. 801, 824–26 (2020).

38. Rebecca L.C. Taylor, *Bag Leakage: The Effect of Disposable Carryout Bag Regulations on Unregulated Bags*, 93 J. ENV’T ECON. & MGMT. 254, 270 (2019).

39. *Id.* at 265.

This success becomes limited further when considering that a diversity of regulations from a multitude of state governments undermines the need for centralized standards that institute the large-scale change needed to address an issue of this magnitude. Plastic bag bans capture the spirit of communities willing to take a stand against plastic consumption, but local and state efforts against a single form of plastic are far from systemic change.

While each of these solutions addresses a specific area of the microplastics crisis, they provide a disjointed array of narrowly targeted legislation that fails to adequately address the magnitude of the problem. Although the individual strategies help to combat aspects of rapidly proliferating microplastics, experts have called for a regulatory scheme that inspires a system-wide approach and instills an attitude shift surrounding the way we manufacture, use, and dispose of plastics.⁴⁰ These regulations reveal that the big picture has been overlooked to address components of the issue, but they also uncover important characteristics of legislation which have either led to swift change or an uphill battle.

For example, the MFWA demonstrates how public awareness and potential human health risks can initiate a quick movement toward targeting microplastic proliferation. Conversely, the containment of emerging concern category within the CWA demonstrates how barriers exist when introducing new restrictions to legislation oriented toward protecting the environment. From this review of existing regulations, two pathways to more comprehensive regulation of microplastics become apparent. The first pathway includes pushing for microplastics to be considered as part of the OCPSF guidelines, bolstering the CWA to a position that emphasizes a more comprehensive acknowledgement of the microplastics crisis. This pathway explicitly addresses the issue as an environmental problem, as the CWA was designed for the “restoration and maintenance of chemical, physical, and biological integrity of the Nation’s waters.”⁴¹ The second pathway utilizes a different approach: committing to a message that emphasizes the significant human health risks surrounding the microplastics crisis, particularly those linked to the food webs we rely on that are experiencing a significant environmental change. While this type of approach does not purport to achieve environmental protection on its face, the underlying mechanisms that

40. Imogen Ellen Napper & Richard C. Thompson, *Plastic Debris in the Marine Environment: History and Future Challenges*, 4 GLOBAL CHALLENGES, 2020, at 5–6; *Hearing*, *supra* note 30, at 6.

41. 33 U.S.C. § 125(a) (1987).

enable human health to be preserved are inextricably tied to a healthy environment.

III. THE CHALLENGE OF EXPANDING ENVIRONMENTAL REGULATION UNDER THE CWA: AN INABILITY TO ADOPT A PROACTIVE APPROACH

Rather than continue to expand the jumble of existing regulations, the government would benefit from streamlining its approach and focusing on formulating a proactive solution with the ability to regulate microplastics across all levels of the supply chain.⁴² Targeting a specific area of greatest efficiency will allow parties interested in lobbying for change to focus on the solution most likely to create progress. Making such a selection requires contemplating these two primary available pathways.

Under the first pathway, supporters of regulating microplastics will likely face significant obstacles based on the EPA's history of imposing such roadblocks. A case study of Per- and Polyfluoroalkyl Substances (PFAS) demonstrates how lobbying for recognition of certain substances under the CWA can be an uphill battle.⁴³ PFAS function as impenetrable layers, are found in materials such as Teflon, and appear in products like popcorn bags.⁴⁴ The substances are made up of chains of carbon and fluorine atoms, and the strength between the bonds within these chains results in extreme persistence.⁴⁵ This persistence and its effects on aquatic environments have been understood since the 1950s,⁴⁶ however, it took the EPA years to use its discretion to begin aligning itself with the science indicating the adverse effects of PFAS.⁴⁷ Though the EPA has drafted a "strategic roadmap" committing itself to certain actions through 2024, the agency neglected to set enforceable standards.⁴⁸ In the absence of such standards by the EPA, Congress resorted to crafting the 2020 National Defense Authorization Act (NDAA) in a manner that regulated PFAS

42. Napper & Thompson, *supra* note 40, at 5.

43. Chris McCarthy et al., *Ecological Considerations of Per- and Polyfluoroalkyl Substances (PFAS)*, 3 CURRENT POLLUTION REP. 289 (Sep. 18, 2017).

44. *Id.*

45. *Id.*

46. *Id.*

47. Scott Faber, *For 20-Plus Years, EPA has Failed to Regulate 'Forever Chemicals'*, EWG (Jan. 9, 2020), <https://www.ewg.org/epa-pfas-timeline/>.

48. *Id.*; See EPA, EPA-100-K-21-002, PFAS STRATEGIC ROADMAP: EPA'S COMMITMENTS TO ACTION 2021-2024 (2021).

associated with military spending.⁴⁹ Despite the status of PFAS advancing from the CEC category, the EPA has yet to fully outline the restrictions that will limit a chemical that was flagged as potentially a threat for decades then confirmed to cause adverse effects to both human health and the environment.⁵⁰

The PFAS saga illustrates how integrating a new substance into the CWA may be a challenging way to regulate, but it also reveals a dangerous progression with striking parallels to the microplastics crisis and the emerging evidence surrounding the effects on human health. In 2006, the EPA denied that studies demonstrated that levels of PFAS at the time were causally related to human health effects.⁵¹ Three years later, the agency published a “provisional health advisory” and an “action plan” recognizing the need for regulation of PFAS but again stopping short of creating enforceable standards.⁵² Over ten years before this need was officially recognized by the EPA, 3M, a company engaging in the monitoring of materials it used pursuant to the Toxic Substances Control Act (“TSCA”), notified the EPA of evidence that PFAS accumulate in blood and a separate study showing that the substances led to adverse health effects in studies on rats.⁵³ Though these studies issued prior to the EPA’s 2006 announcement were short of directly demonstrating human health effects, their existence exemplifies the inability of the EPA to act in a proactive manner under the CWA.

IV. A GROWING NEED FOR REGULATION ENSURING HUMAN HEALTH

The first regulatory pathway contains a history of unsuccessful attempts to convince the EPA to act on evolving science, but how does re-framing the issue to focus on human health compare? The second pathway requires a showing of evidence to confirm that human health is a valid concern associated with microplastics. Unfortunately, findings from recent scientific studies may be meeting this challenge. A deeper examination of the science relating to the human health implications of microplastic proliferation confirms that an obligation exists to address the potentially disastrous threats to our marine food sources. The widespread nature of microplastic ingestion by marine organisms cannot be

49. Michael Heard Snow, Comment, *Too Little Too Late: Congress’s Attempt to Regulate Forever Chemicals Through Military Appropriations*, 45 WM. & MARY ENV’T. L. & POL’Y REV. 287–88 (2020).

50. Faber, *supra* note 47.

51. *Id.*

52. *Id.*

53. *Id.*

overstated, as species in even the most remote marine sanctuaries have been found to contain microplastics.⁵⁴ The concern does not stop with marine food webs, however, because in recent years, evidence of microplastics in human tissues has been uncovered.⁵⁵ Perhaps the most alarming instance of this can be seen in a study that found microplastics within the placentas of multiple women.⁵⁶ While the study was not able to pinpoint exactly how the microplastic was introduced, it posited that ingestion was the most likely cause.⁵⁷ The researchers observing this phenomenon emphasized that the effects of microplastics lodged in this type of tissue are unknown and stressed that this condition could lead to compromised immunity mechanisms during pregnancy and dangerous adverse pregnancy outcomes.⁵⁸ The advent of such a serious human health concern highlights the need for further standards when it comes to our food.

Although the placenta study did not confirm that the presence of microplastics resulted from the ingestion of seafood, support for this hypothesis is present. A 2019 study examining human consumption of microplastics concluded that seafood is one of the top three contributors to microplastic ingestion, with risk increasing considerably in regions where seafood consumption is more common.⁵⁹ Because data quantifying the amount of microplastics in the edible tissues of fish and shellfish is scarce, the exact measure of the average human's microplastic consumption is not possible.⁶⁰ Rather than brushing over this gap in data and treating it as a harmless unknown, scientists caution that this lack of knowledge only makes us more vulnerable to poorly-understood adverse effects.⁶¹

The types of seafood that are the most contaminated by microplastics also serve as a relevant factor in determining the level of risk humans

54. A. M. Saley et al., *Microplastic Accumulation and Biomagnification in a Coastal Marine Reserve Situated in a Sparsely Populated Area*, MARINE POLLUTION BULL., June 2019, at 57.

55. Antonio Ragusa et al., *Plasticenta: First Evidence of Microplastics in Human Placenta*, ENV'T INT'L, (Dec. 2020), at 5.

56. *Id.*

57. *Id.* at 7.

58. *Id.*

59. Kieran D. Cox, *Human Consumption of Microplastics*, 53 ENV'T SCI. & TECH. 7068, 7073, (2019).

60. Luis Gabriel Antao Barboza et al., *Marine Microplastic Debris: An Emerging Issue for Food Security, Food Safety and Human Health*, MARINE POLLUTION BULL. (Aug. 2018), at 345.

61. *Id.*

currently face due to microplastics. Because contamination is more widespread in lower trophic levels, certain factors in combination with this suggest that the risks that accompany human ingestion of microplastics could be heightened in the future.⁶² One of these factors is a process referred to as “trophic downgrading.” As apex consumers at high trophic levels are removed from ecosystems, changes in dynamics throughout the rest of the food web ensue.⁶³ In the ocean, this process has caused a shifting reliance of fisheries from species at higher trophic levels to those at lower trophic levels.⁶⁴ Because overfishing has driven species at higher trophic levels to become scarcer, fisheries are forced to create or expand markets for species that remain abundant at lower trophic levels to stay in business.⁶⁵ This shifting reliance translates to a potential increase in the likelihood of microplastic ingestion for humans.

Method of harvest also plays a role in the increasing need for human health standards to combat microplastics. Though problems with supply persist, demand for seafood has increased, and in response, aquaculture has become the fastest-growing sector of the food industry.⁶⁶ The necessity of aquaculture to meet increasing demand comes with consequences. For example, the spread of disease throughout the food supply is heightened under aquaculture conditions.⁶⁷ When microplastics are added into the mix, a 2021 study found that the fragments of plastic may act as vectors because of their ability to provide a substrate for harmful bacteria.⁶⁸ This would exacerbate the already heightened risk of disease in aquaculture conditions.⁶⁹

Related to the method of harvest are the practices and tools that seafood producers employ. Contemplation of the role of fisheries in microplastic proliferation goes beyond seafood producers harvesting species contaminated by other sources. In actuality, the industry itself

62. See Cole et al., *Microplastic Ingestion by Zooplankton*, *supra* note 9; see Cole et al., *The Impact of Polystyrene Microplastics on Feeding, Function and Fecundity in the Marine Copepod Calanus helgolandicus*, *supra* note 9.

63. James A. Estes, *Trophic Downgrading of Planet Earth*, *Sci.*, (July 15, 2011), at 301.

64. Leigh M. Howarth, *The Unintended Consequences of Simplifying the Sea: Making the Case for Complexity*, 15 *FISH AND FISHERIES*, 690, 696–701 (2013).

65. *Id.*

66. Jake Bowley et al., *Oceanic Hitchhikers—Assessing Pathogen Risks from Marine Microplastic*, 29 *TRENDS IN MICROBIOLOGY*, 107, 112 (2021).

67. *Id.*

68. *Id.* at 114.

69. *Id.*

contributes to microplastics entering the ocean.⁷⁰ Fishing gear contributes to the presence of microplastics and surveys of the type of microplastics fibers and fragments in sediment suggests that the discarded gear can even account for the majority of microplastics in certain locations.⁷¹ The apparent human health risk that lies in seafood, the continually growing scope of this risk as fishing activities begin to shift, and the seafood industry's contributions to microplastics that contaminate their own product present risks and behaviors that can be mitigated by federal regulations focused on human health.

V. UTILIZING A DIFFERENT SOURCE OF REGULATION: HOW EMPHASIZING FOOD SAFETY CAN CREATE ENVIRONMENTAL CHANGE

If microplastics are considered a pressing food safety concern and seafood has been identified as one of the main culprits in microplastic ingestion by humans, then what can the federal government do to address the contamination of seafood? Seafood producers cannot simply cease to catch fish containing microplastics since the issue has become widespread and infeasible to monitor in this way. Control over the behavior of fisheries at all levels of the supply chain, however, may lead to a meaningful difference.

With the human health approach deemed a potentially favorable way to regulate microplastics, the Food and Drug Administration (FDA) becomes the agency of interest because of its responsibility for regulating seafood.⁷² The current regulation scheme the FDA uses for ensuring seafood safety is the Hazard Analysis Critical Control Point (HACCP) system.⁷³ First, the HACCP system requires a "hazard analysis" where producers decide whether it is "reasonably likely" for hazards to occur.⁷⁴ Such a decision should be made based upon "experience, illness data, scientific reports, or other information" that could allow the producer to make such a conclusion.⁷⁵ Importantly, the provision allows for a potential

70. Luka Seamus Wright et al., *Potential Microplastic Release from Beached Fishing Gear in Great Britain's Region of Highest Fishing Litter Density*, MARINE POLLUTION BULL., Oct. 2021, at 5-6; Baoming Xue et al., *Underestimated Microplastic Pollution Derived from Fishery Activities and "Hidden" in Deep Sediment*, 54 ENV'T SCI. & TECH., 2210, 2213 (2020).

71. *Id.*

72. 21 C.F.R. § 123.5 (2022).

73. Hazard Analysis and Hazard Analysis Critical Control Point (HACCP) plan, 21 C.F.R. § 123.6 (2022).

74. *Id.* § 123.6(a).

75. *Id.*

hazard to be one that occurs outside the processing plant “before, during, or after harvest.”⁷⁶ Based on this language alone, particularly the qualifying statement recognizing hazards beginning outside the processing plant, microplastics apply and may be considered as potential hazards. When determining what is a hazard, the regulation requires that seafood producers consider “chemical contamination,” “microbiological contamination,” and “physical hazards” among other factors.⁷⁷ Keeping in mind the scientific studies previously cited to, microplastics apply to all three of these considerations. Failing to comply with the HACCP is not an empty threat; § 123.6(g) provides that failure to implement the outlined standards results in the product being considered “adulterated,” and thus illegal.⁷⁸

Despite the fact that the statute outlining the HACCP requirements would seemingly encompass microplastics based on its language alone, the FDA issues “Fish and Fisheries Products Hazards and Controls Guidance” outlining hazards and appropriate actions to take to avoid them.⁷⁹ The document does not include plastics other than in reference to proper packaging.⁸⁰ *U.S. v. Chung’s Products LP*, an opinion from the United States District Court for the Southern District of Texas, demonstrates that while the guidance is non-binding, a seafood producer wishing to challenge the listed levels considered acceptable in the guidance must set forth a challenge study that explains their rationale.⁸¹ Here, the defendant did not include *C. botulinum* (a toxin) as a critical control point in a HACCP plan because he argued the type of packaging his product was sealed in precluded him from requiring such a consideration.⁸² The challenge study set forth by the defendant was produced by a third party laboratory and the court held that it was insufficient for using methods that obscured possible indications of *C. botulinum* and because the individual carrying out the study had carried out no previous research in the area.⁸³ Ultimately, the court found the defendant’s record of noncompliance required a permanent injunction.⁸⁴

76. *Id.*

77. *Id.* § 123.6(c)(1).

78. *Id.* § 123.6(g).

79. U.S. DEP’T OF HEALTH AND HUMAN SERVICES CENTER FOR SAFETY AND APPLIED NUTRITION, FISH AND FISHERY PRODUCTS HAZARDS AND CONTROLS GUIDANCE (2021).

80. *See id.*

81. *U.S. v. Chung’s Products LP*, 941 F. Supp. 2d 770, 778–79 (S.D. Tx. 2013).

82. *Id.* at 778.

83. *Id.* at 785, 797.

84. *Id.* at 806.

Chung's Products shows that the FDA's guidance has bite despite its non-binding nature.

For the current HACCP requirements to adequately address the proliferation of microplastics in seafood, the FDA would need to amend their guidelines, prompting seafood producers to acknowledge microplastics as a hazard or refute this assertion with a challenge study. If this were the case, seafood producers would be required to set critical control points for microplastics.⁸⁵ Additionally, the procedures used to reach and measure such points would be required.⁸⁶ But how can the FDA set such control points when knowledge of the level of microplastics is so difficult to measure? The HACCP is devoid of a provision that allows for a proactive approach to preventing microplastics from entering marine food webs and the seafood we eat. In this way, the regulation is inhibited from tailoring itself to emerging science.

Luckily, another regulatory scheme administered by the FDA has potential relevance to the regulation of seafood: the Food Safety Modernization Act (FSMA). The FSMA was created by the Obama Administration in 2011 with the goal of "ensur[ing] the U.S. food supply is safe by shifting focus from responding to contamination to preventing it," breathing new life into the FDA's authority.⁸⁷ The Act serves as an expansion of the Food, Drug, & Cosmetic Act (FDCA). Title I of the FSMA requires the FDA to use "scientific-based preventative measures" across the entirety of the supply chain.⁸⁸ Title II assists the FDA with the detection of new threats, allowing the agency the ability to identify emerging food safety issues.⁸⁹ Title III pertains to the safety of imported food and Title IV covers a handful of topics such as funding and compliance with international agreements.⁹⁰ Within this framework, the FSMA grants the FDA the ability to ensure enforcement through mandating timelines for inspection frequency, giving the FDA access to producer records, and requiring that certain testing be performed in specific laboratories identified by the agency.⁹¹ As a whole, the legislation

85. 21 C.F.R. § 123.6(c)(2) (2022).

86. *Id.* § 123.6(c)(4).

87. Amit Kheradia & Keith Warriner, *Understanding the Food Safety Modernization Act and the Role of Quality Practitioners in the Management of Food Safety and Quality Systems*, TQM J., (June 2013), at 348; *Food Safety Modernization Act and Animal Food*, U.S. FOOD & DRUG ADMIN. (Mar. 11, 2022), <https://www.fda.gov/animal-veterinary/animal-food-feeds/food-safety-modernization-act-and-animal-food>.

88. 21 U.S.C. §§ 2201–2206 (2011).

89. *Id.* §§ 2221–2225.

90. *Id.* §§ 2241–2252.

91. *Id.* §§ 2222–2223.

changes the tone of the FDA's regulatory ability, emphasizing the agency's duty to take proactive and informed measures before a human health crisis arises.

Three qualities of the FSMA make it an optimal strategy to implement in the regulation of microplastics. First, the legislation was designed to force the FDA to engage in a proactive analysis when it comes to food safety.⁹² Thus, the FSMA requires the FDA to act in a manner in which the EPA reserves its discretion to under the CWA, providing a unique window of opportunity for the regulation of microplastics. The second powerful quality of the FSMA is its ability to regulate all levels of the supply chain, a necessary scope of control when dealing with the ubiquitous issue of microplastics.⁹³ This means that standards related to microplastics would cover procedures implemented by the seafood industry including harvest, processing, packaging, and distribution.⁹⁴ Third, the FSMA binds the FDA to utilize the best available science when making determinations.⁹⁵ Without the rigid structure of the HACCP, which requires critical control point levels and asserts its scientific evaluation through non-binding guidelines, the FSMA provides more flexibility and allows the agency to create regulations that follow evolving scientific findings.

Because the “scientific-based” aspect of the FSMA acts as a core feature of the legislation, its meaning should be analyzed carefully. Though the inclusion of the term creates the first mandate for the FDA to require prevention-oriented action, it will be rendered ineffective if misinterpreted. No definition is provided within the FSMA to outline what constitutes a “scientific-based” decision and courts will likely refer to other legislation relied upon by the agency. This includes the HACCP plan, which refers to reliance upon scientific studies.⁹⁶ However, in context, this regulation does not call for as comprehensive of a scientific inquiry as the FSMA implies.⁹⁷ Thus, an analysis of the intentions behind the text of the FSMA may help to establish that Congress planned for the FDA to engage in a greater scientific investigation.⁹⁸

92. *See id.* § 2202.

93. *See id.* § 2204.

94. Baoming Xue et al., *Underestimated Microplastic Pollution Derived from Fishery Activities and “Hidden” in Deep Sediment*, 54 ENV'T SCI. & TECH., 2210–2217 (2020).

95. Food Safety Modernization Act, Pub. L. No. 111-353, § 418, 124 Stat. 3905 (2011).

96. Shauna Manion, *A Science-Based Endeavor: Interpreting Contamination Prevention in the Food Safety Modernization Act*, 117 PENN. ST. L. REV. 537, 553–55 (2012).

97. *Id.* at 555–59.

98. *Id.*

Questions also remain about the extent to which the FSMA may apply to seafood. Within the FSMA, there are exemptions for seafood that largely require seafood producers to defer to the HACCP standards instead of embracing the new standards set forth in the FSMA.⁹⁹ However, uncertainty exists when considering the future of FDA regulations and rulemaking in accordance with the restructuring brought about by the FSMA. For example, under Title III of the FSMA, those importing food from other countries must follow a new Foreign Supplier Verification Program, which requires importers to verify that their sources engaged in and completed a proper HACCP plan. This process requires a more in-depth analysis than the traditional HACCP process that seafood producers comply with, creating a gray area and potentially setting up the traditional process for change.¹⁰⁰ Voices within the food industry have cautioned that seafood producers should remain braced for tighter restrictions and increased enforcement aligned with the more demanding FSMA.¹⁰¹

Based on this critical review of the FDA's regulatory scheme for seafood products, certain steps would have to be taken to restructure regulation for the available framework to adequately address microplastic issues. First and most importantly, the FDA would need to take the proactive approach from the FSMA that is now considered a staple of the agency's directive and clearly apply it to the HACCP standards. This will open the door for "science-based" considerations to inform new regulations outside of setting critical control point levels. Next, the "science-based" term should be clarified by the FDA. This will ensure that the regulations being promulgated for the seafood industry are reflective of the suggestions made from scientific findings. From this restructured HACCP plan format, the FDA would be able to implement requirements for the responsible disposal of gear, the type of fish caught, and the method of harvest being used. Scientific studies confirm that these factors play a role in the microplastics crisis and by restructuring the HACCP regulatory scheme, the FDA can begin to generate systemic change by proactively addressing adverse industry behaviors.

99. Food Safety Modernization Act, Pub. L. No. 111-353, § 418(j)(1)(A), 124 Stat. 3891 (2011).

100. Food Safety Modernization Act, Pub. L. No. 111-353, § 301, 124 Stat. 3953 (2011).

101. Jacqueline Kochak, *FSMA Era Opens with Uncertainties for Seafood*, FOOD SAFETY MAG. (Dec. 1, 2012), <https://www.food-safety.com/articles/4470-fsma-era-opens-with-uncertainties-for-seafood>.

VI. RECONCILING REGULATIONS FOR HUMAN HEALTH AND
REGULATIONS FOR THE ENVIRONMENT

Regulating microplastics to protect human health has the potential to go beyond simply modifying producer behavior to improve the safety of a specific group of food products. There is also room for these adjustments to positively impact the environment. Regulations aimed at protecting human health can tend to conflict with the well-being of ecosystems and difficult debates about the ethics of prioritizing environmental conservation over people often result.¹⁰² For example, restrictions on the use of toxic chemicals as pesticides have been met with backlash for negating the benefits these chemicals provide when they eliminate insects acting as vectors for harmful diseases.¹⁰³ Situations like these carry a series of difficult balancing tests where human health often wins out over environmental protection.¹⁰⁴ The regulation of microplastics, however, presents a unique situation where the needs of the environment and human health are aligned. The trajectory of previous legislation demonstrates how this powerful opportunity can ease the burden of implementing regulation, instilling the public with a sense of urgency to ensure safety that also manifests as a win for the environment.¹⁰⁵

While human health-oriented regulations are equipped with an appeal that attracts lawmakers and easy support from constituents, they are ultimately devoid of ecosystem-oriented solutions or a purpose rooted in protecting the environment. Systemic change throughout the food industry may be achievable through the current regulatory schemes available to the FDA, but systemic change within marine food webs is a different matter. Controlling the behaviors of fisheries can act as a close proxy for remedying the adverse effects of microplastics in the ocean, but without a focus on the environment stated explicitly in the legislation providing regulatory power, fragile marine ecosystems remain vulnerable to the industry's history of failing to adequately protect natural resources.¹⁰⁶

102. David B. Resnik, *Human Health and the Environment: In Harmony or in Conflict?*, 17 HEALTH CARE ANALYSIS, 261, 262 (2009).

103. *Id.* at 272–74.

104. *Id.* at 270.

105. *See* Striffling, *supra* note 22, at 161–64.

106. Randall S. Abate, *Marine Protected Areas as a Mechanism to Promote Marine Mammal Conservation: International and Comparative Law Lessons for the United States*, 88 OR. L. REV. 255, 257–58, 307 (2009).

VII. CONCLUSION

In assessing the status of microplastics and the studies providing a factual basis for implementing regulations to solve the crisis, it becomes apparent that a lack of understanding of adverse effects paired with an abundance of warning signs calls for a proactive approach. Because of the extreme proliferation of microplastics, this proactive approach must do more than address the issue narrowly. The current set of regulatory tools the government has created for addressing this problem fail to do so. From the current framework, however, two pathways to future broad-scale change become clear: regulating for human health and regulating for the environment. Clear barriers exist when it comes to broadening environmental regulations to recognize microplastics as a contaminant worthy of attention. On the other hand, taking the human health approach may allow for a more positive reception. The regulatory scheme available under the FDA does not completely align with what is necessary for microplastic regulation, but it does contain critical characteristics: a proactive approach, a requirement for scientific-based inquiry, and the ability to regulate across all levels of the supply chain. Adjusting the behavior of fisheries using these regulatory features comes close to a systemic change as far as the industry is concerned, but the human health approach ultimately lacks the safeguards of legislation containing language explicitly requiring contemplation of ecosystem dynamics. In addressing the microplastics crisis, federal regulation should emphasize that threats exist on both the human health and environmental front while maintaining requirements binding agencies to the consideration of marine ecosystems.