Short Report

The Increasing Risk of Micro- and Nano-Plastics: The Role of the U.S. Food and Drug Administration

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Recommended citation: Seifman R. The Increasing Risk of Micro- and Nano-Plastics: The Role of the U.S. Food and Drug Administration. JGPOH 2024. Posted:15.12.2024 DOI: 10.611034/JGPOH-2024-22

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Abstract

Micro and Nano Plastics (MNPs) are increasingly recognized as health risks: The United States Food and Drug Administration (FDA) has statutory authority to regulate if justified. More MNP research is needed to produce sufficient evidence of MNPs' health effects in food.

The FDA and the U.S. legal system will have to come to grips with MNPs' effects on the human health risks from food.

Keywords: Micro- and Nano-Plastics, Food and Drug Administration, Petitioner actions.

Conflict of interests: None declared
Financial disclosure: None declared

Acknowledgment: Richard Cooper JD, contributed.

Background

A 2024 article in this journal summarized the increasing risk of Micro and Nano Plastics (MNP) worldwide (1). What is known is that micro and nano plastic particles are in the water, air, land, animals, and plants, and found in food. What is unanswered is whether there is sufficient evidence of the extent to which MNPs harm human health and whether food regulated by the United States Food and Drug Administration (FDA) significantly contributes to such harm. Further, there are screening methods to detect MNPs in food, but new technology and more practical tools are needed. Requesting and succeeding in persuading FDA to take regulatory action is a complex process. It is even more urgent as the recent fifth session of the International Negotiating Committee on the control of microplastics in Busan (2) failed to reach an agreement.

Proceedings

This paper proceeds in three steps:

1) Evidence of MNPs in food and possible health effects
2) FDA statutes and regulations
3) Petitioner seeking FDA regulation of MNPs

1) Evidence of MNPs in Food and Possible Health Effects

FDA has stated as to MNPs (3): "Some evidence suggests that microplastics and nanoplastics are entering the food supply, primarily through the environment. Current scientific evidence does not demonstrate that levels of microplastics or nanoplastics detected in foods pose a risk to human health."

Others express a stronger view as to known harm (4): "Research data reveal the presence of MNPs in edible parts of plants and indicate the hazards to human health. MNPs have been reported in apple, pear, carrot, lettuce, onion, tomato, cucumber and many other commonly consumed fruits and vegetables."

Estimating the overall human exposure to microplastics via food consumption is difficult owing to the lack of studies on food items other than seafood. Also, research on processed foods, not just fresh foods, is needed to determine the contribution of food to overall human microplastic consumption (5).

There are studies planned to deepen scientific understanding, including those funded by the European Commission Research Cluster to Understand the Health Impacts of Micro- and Nano-plastics. They currently cover five collaborating research projects that may have far-reaching implications for policies and regulations on chemicals, plastics, food, and water regarding carcinogenicity, mutagenicity, reproductive toxicity, and respiratory toxicity (6).

In sum, although there are risk assessment gaps, plastic particles could very well affect apoptosis, necrosis, inflammation, oxidative stress and immune responses, and thereby

contribute to the development of diseases such as cancer, metabolic disorders, and neurodevelopmental conditions, among others. MNPs may also affect food allergies, modify the digestibility of food allergens, increase intestinal permeability, promote an intestinal inflammatory environment, or cause intestinal dysbiosis (6).

Means of Detection: There are screening methods to detect MNPs in fresh and processed foods, and new tools probably will emerge to improve the process. A recent effort by the National Institutes of Health (NIH) used fluorescence techniques and nano cytometry, together with the staining of the lipophilic dye Nile Red (NR), to demonstrate that MNPs can be accurately detected using flow cytometry. Although MNPs can be easily seen using microscopy, flow cytometry is a highly sensitive tool to study plastic nanoparticles, with advantages over other techniques. "The question is whether these technologies are practical in food processing and/or can be applied to fresh foods" (7, 8).

Other Relevant U.S. Case Law Decisions: Over time, there has been considerable litigation on related issues:

- An action sought to compel FDA to initiate proceedings to withdraw its approval of the use of certain antibiotics in livestock for non-therapeutic purposes. Although not explicitly addressing the substantive aspects, the court upheld the plaintiffs' motion and rejected the Government's argument that FDA's denials of the citizen petitions were unreviewable "decisions not to enforce": *Heckler v. Chaney* (1985) (9).

- Under the Federal Administrative Procedure Act, FDA is to act within a reasonable time frame on a submitted petition; further, the courts may compel agency action that has been improperly withheld or unreasonably delayed. *Public Citizen Health Research Group v. Commissioner, Food Drug Administration (1984).*

2) FDA Statutes and Regulations

FDA regulates about 77% of the U.S. food supply (except meat, poultry, and some egg products; and covers about 35,000 produce farms: 300,000 restaurant food establishments, about 61% of fresh fruit, 35% of vegetables, and 91% of imported seafood (10). An Independent Expert Panel for Foods submitted its Operational Evaluation of FDA's Human Foods Program to Dr. Robert Califf, Commissioner for Food and Drugs. It described FDA responsibilities with respect to food as follows:

"FDA has a broad food safety mandate, including developing and overseeing the enforcement of food safety regulations; detecting and responding to outbreaks of foodborne illness; collaborating with other federal agencies conducting food safety activities; coordinating and supporting state, local, tribal, and territorial food safety activities; conducting and supporting food safety research; and developing and disseminating food safety information to stakeholders" (11).

The Federal Food, Drug, and Cosmetic Act (FDCA) provides that a food is deemed to be adulterated "If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health" (12).

The FDCA prohibits the introduction of adulterated food into interstate commerce and expressly directs FDA to "protect the public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled" (12).

FDA can decide to recommend to the U.S. Department of Justice a variety of remedies or enforcement actions in response to violations of the FDCA.

3) Petitioner Standing

A prospective plaintiff should submit to FDA a petition seeking regulatory action, presenting scientific evidence, and citing FDA's relevant statutory authorities. The procedure is as follows:

"If the petition requests the Commissioner to issue, amend, or revoke a regulation, [the petition should state] the exact wording of the existing regulation (if any) and the proposed regulation or amendment requested" (13).

Technically, the FDCA vests regulatory authority in the Secretary of Health and Human Services. The Secretary has delegated that authority, including the authority under 21 U.S.C. § 371(a) to issue regulations "for the efficient enforcement of this chapter, except as otherwise provided in this section," to FDA. *See* FDA Staff Manual Guides ("SMG"), Volume II – Delegations of Authority, SMG 1410.10.1A(1) (Feb. 22, 2023) (14).

If FDA denies the petition or fails to act on it within a reasonable time and the petitioner sues FDA in a federal court, whether the petitioner (an individual or an organization) has the right to bring the lawsuit depends on whether the petitioner has "standing", an issue that is decided by the court. A case before the U.S. Supreme Court, *FDA v. Alliance for Hippocratic Medicine* (AHM), raises the threshold question of who can bring a lawsuit against FDA. If the Court decides that AHM; a medical organization, lacks standing, such a decision will have broad negative implications for all possible plaintiffs, including individual citizens.

Other relevant decisions include:

- An organization seeking to sue FDA and challenge a regulation as to substances generally accepted as safe for addition to foods was held to have standing (15).

- In *American Association of Pediatrics v. FDA*, a Maryland district court upheld the plaintiffs' standing to sue FDA. In this instance, the plaintiffs claimed that, if FDA did

> not compel vaping product manufacturers to submit their product marketing applications more rapidly, the plaintiff organizations would have more difficulty pursuing their public health mission because they would not have access to the +-information generated by the application review process (16).

Would a Petitioner Seeking FDA Regulation of MNPs Have a Chance? Presumably, an organization (whose members eat food within FDA's jurisdiction) or an individual (who eats such food) would have standing, FDA would have to respond in a timely manner, and there is some evidence of the health harms to humans and animals from such particles in food and means to detect their presence.

Whether the evidence of MNPs in food causing adverse health effects is sufficient and whether the means to detect are adequate are legitimately open to question. With growing national and international concern and interest in MNPs and food links, more in-depth research will probably be conducted, and new detection methods will be developed. Thus, in the near future, FDA and the U.S. legal system will have to come to grips with MNPs' effects on the human health risks from food.

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