




Sidelining Safety: The FDA Fails to Protect the Public from Toxic Chemicals

When the Food and Drug Administration (FDA) was created more than 100 years ago, it was tasked with assuring the safety of human and animal drugs and our nation's food supply. In recent years, however, the FDA has been plagued by scandals: failing to protect patients from dangerous drugs and major recalls of contaminated spinach and eggs. Tainted imports, such as dog food and milk products containing melamine, have also shaken public confidence in the FDA. Sadly, these examples are only the tip of the iceberg of a much bigger problem that jeopardizes the health of nearly every American.

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Though Congress recently passed legislation that overhauled the nation's food safety law, it focused on bacterial contamination of food and did not address the non-biological contaminants in our food supply that also threaten public health. More reform is needed to return the FDA to its mission to protect public health. The agency's safety assessments and standards are inadequate to protect health; weak monitoring and enforcement fails to ensure food safety and provide warning of health threats; and delayed decision-making continues to expose an unprotected public to ongoing health risks.

UNSAFE SAFETY ASSESSMENTS: THE NEED TO MODERNIZE THE SCIENCE

The FDA's determinations of what level of chemical contaminants is "safe" in food and other products are based on outdated assessments that rely heavily on industry data, and result in legal but unsafe levels of contaminants. The agency's risk assessments are inconsistent and fail to incorporate scientific principles prescribed in the scientific guidance documents of other agencies, like the Environmental Protection Agency (EPA). In contrast to other agencies, in recent years, there has been no process to solicit public input

or scientific expertise on the FDA's risk assessment decision making. In addition, the FDA's assessments ignore significant advances in the science.

For example, in 2010, the FDA's safety assessment of Gulf Coast seafood affected by the BP oil spill significantly underestimated health risks and was inconsistent with modern risk assessment approaches. The FDA assumed that fish consumers weigh 80 kilograms (about 176 pounds), whereas many women and all children weigh much less, and severely underestimated shrimp consumption in high seafood consumers, like Gulf Coast residents. The FDA also ignored the cancer risks of naphthalene, a major component of oil, and failed to address the special vulnerability of pregnant women, infants, and children—thus ignoring standard risk assessment recommendations of the EPA, the National Academies, the World Health Organization (WHO), and modern scientific best practices.

The FDA's flawed safety assessments have allowed hormone disrupting chemicals—such as bisphenol A (BPA) and phthalates—to be approved as food additives, making food a major source of exposure to these chemicals. Despite overwhelming evidence from laboratory studies demonstrating that BPA is harmful to reproduction and brain development and increases the risk of hormone-sensitive cancers like breast and prostate cancer, the FDA has largely exonerated the risks based on industry-funded studies that have been widely criticized by the scientific community. Similarly, many of the phthalates approved as food additives are now known to harm the reproductive system and cause infertility. Yet, the FDA has not reassessed the safety of phthalates for more than 20 years and has ignored all the new science on these chemicals.

DELAYING DECISIONS TO PROTECT PUBLIC HEALTH

In addition to unsound safety assessments, the FDA has allowed decades-long delays in regulating chemicals with major health and environmental effects, thus allowing people to continue to be exposed at potentially unsafe levels. For example, triclosan and triclocarban are the active ingredients found in most antibacterial soaps. They are no better at killing germs than washing with regular soap and water, but both are harmful hormone disrupting chemicals and can promote antibiotic resistance. On the basis of this information, the FDA proposed in 1978 not to approve triclosan and triclocarban, which would have prohibited their use in soaps. However, since the FDA has not yet finalized its proposal more than 30 years later, these chemicals remain on the market, and antibacterial soaps now represent a billion-dollar-a-year industry dominated by triclosan and triclocarban.

INADEQUATE TESTING OF SEAFOOD AND PRODUCE

The FDA must monitor the food supply to ensure compliance with regulatory standards and to detect other potential threats to food safety. Without adequate monitoring and enforcement, the standards alone cannot protect public health. Unfortunately, the FDA conducts no comprehensive assessment of chemical contaminants in imported shrimp or other seafood despite concerns about the presence of multiple contaminants ranging from metals to hormones and antibiotics. And it's not just imported seafood. In 2010, the FDA allowed the resumption of commercial shrimp harvesting in coastal waters following the BP oil spill based on the results of only 67 samples.

The FDA's monitoring of pesticide residues on produce is no better. Current testing includes only an estimated 0.00004 percent of the fruits and vegetables available for sale and a fraction of the pesticides used on produce. Even with this minuscule sample size, the FDA finds unsafe levels of pesticide residues in two percent of domestic produce and six percent of imports, suggesting that this is a widespread and unaddressed public health issue.

REFORM NEEDED FOR PUBLIC HEALTH PROTECTION

The FDA needs the tools and science to protect public health and respond to public concerns. To get the FDA back on track towards safeguarding us from chemical contaminants, NRDC calls for the following reforms:

- Establish risk assessment practices and guidance documents consistent with modern science that provide opportunities for meaningful public participation and incorporate current recommendations from the National Academies of Science.
- Develop health protective standards for chemical contaminants in food and personal care products.
- Evaluate new food additives applications and re-evaluate currently approved food additives based on adequate testing and using modern scientific methods. Only approve those found to be safe, as required by law.
- Remove toxic chemicals, such as BPA, phthalates, and triclosan, from our food supply and personal care products and ensure that alternatives are safe.
- Finalize decisions on long-pending matters of significant public health concern, such as the decision to remove triclosan and triclocarban from soaps.
- Implement a statistically valid sampling methodology for produce and seafood that ensures adequate and representative testing and covers all relevant contaminants.
- Revise regulatory decision-making processes to be more transparent, scientifically credible, and protective of public health. This includes engaging stakeholders beyond the regulated industry (through public notice and opportunity to comment) and ensuring public disclosure of toxic chemicals in our food and drugs.