

Webinar Highlights

FDA's Missed Opportunities to Tackle EDCs in Food

The Food and Drug Administration (FDA) recently decided to allow continued use of nine phthalates in plastics, paper, and adhesives in food- or drink-contact applications. Phthalates are known endocrine-disrupting chemicals (EDCs). In this webinar, Dr. Maffini provided an overview of FDA's approach to endocrine disruption in the assessment of chemicals in food packaging, focusing particularly on these recent actions on phthalates and BPA.

Featured Speaker: Dr. Maricel Maffini, an independent consultant with more than 25 years of experience researching carcinogenesis, reproductive biology, and endocrine disruption, speaking July 06, 2022.

This fact sheet has been created by CHE based on information presented in an EDC Strategies Partnership webinar. Selected quotes in bold are from the webinar speaker(s). For the full set of resources provided by the webinar presenters, see the [webinar page](#), where you'll also find associated Slides & Resources.

The Problem

Studies have linked exposure to phthalates and other EDCs to a range of serious human health harms, particularly in children. Phthalates used in food contact materials are known to leach into food. Dr. Maffini identified the following known and suspected EDCs that are allowed in food contact materials or as food additives:

Known and likely EDCs allowed in food

Food contact substances

- Perchlorate
- PFAS
- BPA
- Phthalates
- Parabens

Ingredients

- Soy isoflavone extract
- Catechins from green tea extract
- Resveratrol

As EDCs, these chemicals can have cumulative effects. For example, many are known to have impacts on the thyroid.

FDA and Phthalate Regulation. FDA originally approved the use of phthalates decades ago. In response to petitions from public health advocates, FDA admitted that it has not assessed the safety of phthalates since 1985. FDA has no regular review of old decisions. Even as the science improves and more health impacts become known, FDA does not systematically reassess chemical safety.

FDA gives companies recommendations on how they should assess additives for food safety. None of FDA's recommended assessments specifically test or screen for endocrine disruption from chemicals such as phthalates. FDA considers reproductive and developmental toxicity studies as a proxy for endocrine disruption, but does not specifically suggest testing for endocrine disruption:

“The guidance for food contact substances is silent when it comes to endocrine screening or testing...Endocrine disrupting chemicals can act in incredibly low concentrations in the diet, so this is quite concerning.”

In 2012, FDA reviewed its own policies for evaluating the safety of chemicals. The review included current and former FDA employees. FDA's own review found the following areas of concern:

- The lack of processes to identify and manage endocrine disruptors.
- Data gaps on the effects of chemicals at low doses.
- The lack of understanding of chronic toxicological effects.
- Inadequate assessment of sensitive populations at greater risk (such as children).
- The need to consider exposure to mixtures and related chemicals. FDA only evaluates chemicals individually. **“There is no cumulative assessment.”**

FDA is supposed to follow the Food Additive Amendment for regulating additives. This act is intended to protect public health in the following ways:

- Require manufacturers to test potentially unsafe substances.
- Advance food technology by allowing food additives at safe levels.
- Give FDA regulatory authority.
- Require affirmation of safety before chemicals are allowed in or on food.
- Assess safety based on risk.
- Prohibit carcinogens regardless of exposure level.

Following these guidelines, additives are only to be considered “safe” if there is *reasonable certainty* that they are *not harmful* under the intended conditions of their use. The law requires that food safety assessments consider the *cumulative effects* of the chemicals, taking into account any other chemically or pharmacologically related substances in the diet.

Petition to Ban. Public health advocates have petitioned FDA to ban the use of many phthalates in food contact materials. On May 19, 2022, FDA declined to ban those phthalates. Many of these phthalates are banned from use in toys but are still allowed to be in contact with food.

“FDA left nine phthalates for use in contact with food *without doing any safety assessments.*”

FDA did agree to reevaluate the safety of BPA.

“We are asking FDA to revoke uses of BPA for adhesives and coatings and strictly limit the migration from plastics.”

Recommendations

FDA must reassess the safety of phthalates and other EDCs.

“They could easily update the guidance for both ingredients and food contact substances and recommend or...request that there is a screening for endocrine disruption.”

Many scientists and public health advocates believe that an accurate safety assessment of these nine phthalates would result in them being banned from use in food contact materials.

To Find Out More

- Watch the July 06, 2022 webinar: [FDA's Missed Opportunities to Tackle Endocrine Disrupting Chemicals in Food](#)
- Read the webinar slides: [FDA's Missed Opportunities on EDCs](#)
- Watch the latest webinar about phthalates in food: [Protecting Brain Development in Children: Phthalates in Food & the Critical Need for Policy Reform](#)

About the Speaker



Dr. Maricel V. Maffini is an Independent Consultant based in Maryland, US. She has more than 25 years of research experience in the fields of carcinogenesis, reproductive biology, and endocrine disruption. For the past eleven years, her work has focused on the safety of chemicals in food and food packaging, its regulation, and the market's influence. She has authored numerous peer-reviewed journal articles, blogs and book chapters. She co-authored a petition requesting the US Food and Drug Administration to revoke the use of phthalates in contact with food.

Before becoming a consultant, she was a senior scientist with the Natural Resources Defense Council; a senior science officer at The Pew Charitable Trust, and a Research Assistant Professor at Tufts University School of Medicine. She consults with public interest organizations and private businesses.

She is a member of the Food Packaging Forum science advisory board, a science advisor to the Breast Cancer Prevention Partners and a Fellow of Collegium Ramazzini.