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April 6, 2021

Ms. Susan Mayne  
Director, Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
10903 New Hampshire Ave  
Silver Spring, MD 20993-0002

Dear Director Mayne:

Like many Americans, I was shocked to learn that a preservative used in hundreds of foods, including Pop-Tarts, Cheez-Its and other products marketed to children and teens, may cause potential harm to the immune system. I have long been concerned about food safety issues, especially when it comes to what our children are eating, and the prospective ramifications these additives in our food can have on long-term health.

A new peer-reviewed study in the International Journal of Environmental Research and Public Health found that the preservative tert-butylhydroquinone, or TBHQ—which is used to extend the shelf life of food—may actually have harmful effects on the immune system. Researchers using data from the U.S. Environmental Protection Agency’s (EPA) Toxicity Forecaster (ToxCast) found that TBHQ could harm the immune system in both animal and non-animal tests.<sup>1</sup> The ToxCast data is gathered using an innovative testing method that allows the EPA to quickly and efficiently determine the level of toxicity for certain chemicals, limiting the amount of animals needed for these tests.<sup>2</sup>

Through the ToxCast evaluation, it was found that TBHQ has several immunosuppressive tendencies. This chemical affects different immune responses such as the body’s response to antioxidants, injury, and inflammation. TBHQ has been known to influence the production of T-cells, B-cells, and NK cells, which are the core components of our adaptive immune response. The impacts of TBHQ warrant additional study as there is potential that this chemical can fundamentally change specific immune functions such as defense against foreign bodies and autoimmunity.<sup>1</sup>

Many of these food chemicals, including TBHQ, were reviewed by the U.S. Food and Drug Administration (FDA) decades ago and have not been adequately reassessed to reflect new science. In fact, according to the Environmental Research and Public Health study, previous studies of TBHQ cited the potential for effects on the immune system but did not receive any further

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<sup>1</sup> <https://www.mdpi.com/1660-4601/18/7/3332/htm>

<sup>2</sup> [https://www.epa.gov/sites/production/files/2019-01/documents/toxcast\\_factsheet\\_dec2018.pdf](https://www.epa.gov/sites/production/files/2019-01/documents/toxcast_factsheet_dec2018.pdf)

investigation or review.<sup>1</sup> Many other food chemicals linked to health complications, including those causing harm to the immune system have been deemed “safe” by food and chemical companies, but not by the FDA. I am extremely concerned about the potential long-term health effects ingesting these additives will have on an entire generation of children, and urge the FDA to reassess the use of TBHQ as an additive in foods using up-to-date science and data.

The American people should not have to worry about if what they are feeding their kids, or ingesting themselves, is potentially harmful or toxic to their health. If the COVID-19 pandemic has taught us anything, it is the importance of having a healthy immune system. It is time for the FDA to consider new science when determining the safety and potential health effects of food additives to the immune system. I urge you to do an in-depth review of the safety of TBHQ and other food chemicals that may harm the immune system.

Thank you for your attention to this issue.

Sincerely,

A handwritten signature in blue ink that reads "Kirsten Gillibrand". The signature is written in a cursive, flowing style.

Kirsten Gillibrand  
United States Senator