Environmental Working Group Statement

In Advance of the Hearing "Legislative Proposals to Maintain and Improve the Public Health Workforce, Rural Health, and Over-the-Counter Medicines"

Before the Health Subcommittee

of the House Committee on Energy and Commerce

July 16, 2025

The Environmental Working Group is a national environmental health group which has advocated for safer, more effective sunscreens for two decades.

EWG strongly supports the use of sunscreens and other sun protection measures. The number of Americans suffering from skin cancer has increased dramatically in recent decades.[1] But, many sunscreens fail to adequately protect consumers from the sun's harmful Ultraviolet, or UV, rays. In addition, the use of the Sun Protection Factor, or SPF, value may lead some consumers to mistakenly believe that a sunscreen provides broad-spectrum protection against both UVA and UVB rays.[2]

[1] American Academy of Dermatology Association, https://www.aad.org/media/stats-skin-cancer

[2] During the last two decades, EWG has tested products and reviewed the results of various other studies to verify the sun protection performance of sunscreen products. An EWG peer-reviewed study found several sunscreens sold in the U.S. provide inadequate UVA protection, compared to the listed SPF claim. *See* David Q. Andrews et al., *Laboratory Testing of Sunscreens on the US Market Finds Lower In Vitro SPF Values Than on Labels and Even Less UVA protection*, 38 Photodermatology, Photoimmunology, & Photomedicine 224 (2021), https://onlinelibrary.wiley.com/doi/full/10.1111/phpp.12738. A total of 51 sunscreen products were tested for UV absorption in a laboratory using in vitro methodologies, and results showed that, on average, products reduced the UVA exposure by only half of what would be expected based on the labeled SPF. Just 18 of 51 products passed the UVA protection test required of products sold in Europe.

Some sunscreen ingredients may pose health harms, including harm to the hormone system. In particular, oxybenzone, octinoxate,[3] octisalate, octocrylene, homosalate[4] and avobenzone are systemically absorbed into the body, according to recent studies published by the FDA.[5] These studies also found that these ingredients could be detected on the skin and in the blood weeks after they had last been used. Other studies have reported sunscreen ingredients detected in breast milk, urine, and blood plasma samples.[6]

The most worrisome sunscreen active ingredient is oxybenzone, which is readily absorbed through the skin, behaves like a hormone disruptor,[7] and may be more harmful to children as they are more susceptible to the effects of chemicals.[8] One evaluation found that adolescent boys with higher oxybenzone levels had lower total testosterone levels.[9]

---

[3] Octinoxate, a non-mineral UV filter, is readily absorbed into the skin and continues to be absorbed after the sunscreen has been applied. According to the FDA's 2020 study, octinoxate has been found in blood samples at levels 16 times above the proposed FDA safety threshold. Animal studies have reported octinoxate has hormone effects on the metabolic system and affects thyroid hormone production, with some evidence for other endocrine targets, including androgen and progesterone signaling. See Dana Seidlová-Wuttke et al., *Comparison of Effects of Estradiol with Those of Octylmethoxycinnamate and 4-Methylbenzylidene Camphor on Fat Tissue, Lipids and Pituitary Hormones*, 24 Toxicology & Applied Pharmacology 1 (2006), https://pubmed.ncbi.nlm.nih.gov/16368123/. *See also* Michael Krause et al., *Sunscreens: Are They Beneficial for Health? An Overview of Endocrine Disrupting Properties of UV-Filters*, 35 International Journal of Andrology 424 (2012), https://pubmed.ncbi.nlm.nih.gov/22612478/.

[4] A recent European Commission opinion reported that homosalate has a recommended maximum concentration of 1.4 percent, because of concerns for potential hormone disruption. https://health.ec.europa.eu/system/files/2022-08/sccs_o_244.pdf. The FDA allows U.S. sunscreen manufacturers to use it in concentrations up to 15 percent.

[5] Murali K. Matta et al, *Effect of Sunscreen Application on Plasma Concentration of Sunscreen Active Ingredients: A Randomized Clinical Trial,* 323 Journal of the American Medical Association 256 (2020),https://jamanetwork.com/journals/jama/fullarticle/2759002

[6] Susie Suh et al., *The Banned Sunscreen Ingredients and Their Impact on Human Health: A Systematic Review*, 59 International Journal of Dermatology 1033 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7648445/

[7] Mayra Ghazipura, *Exposure to Benzophenone-3 and Reproductive Toxicity: A Systematic Review of Human and Animal Studies*, 73 Reproductive Toxicology 175 (2017), https://pubmed.ncbi.nlm.nih.gov/28844799/

[8] Environmental Protection Agency, Children Are Not Adults, https://www.epa.gov/children/children-are-not-little-adults (last updated June 12, 2024).

[9] Franco Scinicariello et al., *Serum Testosterone Concentrations and Urinary Bisphenol A, Benzophenone-3, Triclosan, and Paraben Levels in Male and Female Children and Adolescents: NHANES 2011-2012*, 124 Environmental Health Perspectives 1898 (2016), https://pubmed.ncbi.nlm.nih.gov/27383665/. A 2017 systematic review of 23 studies reported that there was evidence of associations between oxybenzone exposure and adverse reproductive outcomes, including birth outcomes. *See* Ghazipura et al., *supra* note 7.

Safer, more effective ingredients are available, but the current review process has so far failed to make them available to American consumers. In particular, the FDA has failed to ban or restrict potentially harmful, less effective sunscreen ingredients, and sunscreen manufacturers have so far failed to generate the studies needed to admit safer, more effective ingredients into our market. Many of these ingredients, available elsewhere, appear to be safer and are better able to provide protection against both harmful UVA and UVB rays.[10]

Potentially harmful, less effective ingredients remain in the marketplace. In particular, the FDA has failed to meet a legislative deadline to determine whether 12 active sunscreen ingredients should still be permitted, including oxybenzone, octinoxate, octisalate, octocrylene, homosalate and avobenzone. Some of these ingredients may not only pose health harms but may also provide less protection from UVA rays than alternatives that are available elsewhere. Only two active sunscreen ingredients, zinc oxide and titanium dioxide, have been determined, so far, to be safe and effective by the FDA.

Past attempts at reform have failed. Since the FDA first published standards, called a monograph, for marketing sunscreens in 1999, the FDA has tried and failed to update these standards to include new sunscreen ingredients. Congress sought to address these failures in 2014, when Congress enacted the Sunscreen Innovation Act,[11] and in 2020, when Congress

[10] The FDA has approved 16 active ingredients; the European Union has approved 27 active ingredients, some of which provide broad spectrum protection.

[11] Between 2002 and 2009, manufacturers submitted applications for eight new sunscreen active ingredients used in Europe and Asia. Several of the ingredients, including bemotrizinol (Tinosorb S), bisoctrizole (Tinosorb M), ecamsule (Mexoryl SX), and drometrolizole trisiloxane (Mexoryl XL), were UVA or UVA/UVB filters which could provide broad spectrum protection but submitted insufficient data for FDA to determine if the ingredients were safe.

enacted the CARES Act. In both cases, companies still had insufficient incentive to produce the data needed to demonstrate the safety and effectiveness of new ingredients. The short period of exclusivity provided by the CARES Act may provide insufficient reward for companies to complete needed studies.[12] Only one company has so far sought to use the process created in the CARES Act.[13]

Congress should address the need to complete safety studies. To provide the resources to finance needed safety studies, Congress should consider alternative funding mechanisms, including registration, facility, maintenance, and user fees, so that FDA can complete needed studies of existing and promising new ingredients.[14] Congress should also grant the FDA test order authority to require studies of currently available ingredients, as Congress did for other chemical safety studies in 2016.[15]

H.R. 3686, the SAFE Sunscreen Standards Act, will not address the need to complete safety studies. Rather than providing the resources needed to complete needed safety studies, H.R. 3686 would lower the bar for sunscreen safety by allowing "real world evidence" and marketing history that will not address concerns posed by the chronic risks posed by sunscreen chemicals. Allowing the use of evidence that may be relevant to acute risks, but not chronic risks, will simply repeat past policymaking mistakes.

---

[12] *See* U.S. Government Accountability Office. GAO-18-61 (2017), https://www.gao.gov/products/gao-18-61

[13] DSM is seeking FDA approval of bemotrizinol, or BEMT. If approved, BEMT would be the first new UV filter in nearly 30 years.

[14] Fees are commonly used by agencies to fill data gaps and fund other programs and services. For example, pesticide safety reviews are funded through registration and maintenance fees. https://www.epa.gov/pria-fees/pria-5-implementation. Many FDA reviews are funded by fees, including application fees, annual program fees for certain products, and registration fees. Many other agencies charge fees to fund reviews, ranging from the National Credit Union Administration to the Nuclear Regulatory Commission to the Securities and Exchange Commission.

[15] *See* 15 U.S.C. § 2603.

The current system has created a double standard that allows potentially harmful, less effective sunscreen ingredients to remain on the market while potentially safer, more effective ingredients remain off limits - even though both categories present similar safety data challenges, as indicated in feedback letters.[16] Rather than designate some promising ingredients as Category III ingredients, pending the development of new information, the FDA has created a regulatory purgatory from which certain ingredients never escape while other legacy ingredients remain available.[17]

Congress should direct the FDA to ban ingredients that are not safe. The CARES Act required the FDA to determine whether ingredients currently in use were safe. However, the FDA has failed to do so, and companies have not provided the safety data needed by the FDA to make this determination. Congress should set a new deadline by which companies provide needed safety data. If companies fail to do so, and the FDA cannot conclude that a chemical is safe, the ingredient should be removed from the market within one year.[18] In particular, Congress should end the use of four ingredients for which the industry has not sought deferred action by

[16] Food and Drug Administration, Regulatory Policy Information, Sunscreen Innovation Act, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/regulatory-policy-information-sunscreen-innovation-act (last updated Sept. 02, 2021).
[17] Category I ingredients are GRASE. Category II ingredients are not GRASE. Category III ingredients lack data needed for final classification but can continue to be marketed. In 2019 and 2021, FDA determined that two ingredients are in Category I, two are in Category II, and 12 are in Category III.
[18] If safety data is not available, the FDA has previously said it may consider deferring further action to allow additional time for data to be developed, if "the party seeking the deferral had made timely and diligent progress in trying to obtain that safety information." The FDA has also said it would move forward if it determines that studies are not progressing or otherwise productive. *See* Food and Drug Administration, An Update on Sunscreen Requirements: The Deemed Final Order and the Proposed Order https://www.fda.gov/drugs/cder-conversations/update-sunscreen-requirements-deemed-final-order-and-proposed-order (last updated Dec. 16, 2022). The sunscreen chemical manufacturers have requested that the FDA defer action on 8 of the 12 sunscreen active ingredients while data gaps are filled. But, there is no evidence that needed safety studies are being conducted.

the FDA,[19] and Congress should direct the FDA to finalize limits for spray sunscreens and conduct needed studies.[20]

Congress should also address consumer confusion about sunscreens. Consumer confusion about the protection – or lack of protection – provided by sunscreens can create a false sense of security and lead to consumers to spend more time outdoors with inadequate protection. Even though sunscreens with high SPFs provide only marginally greater protection, many consumers assume that a sunscreen with an SPF of 60 provides twice as much protection as a sunscreen with an SPF of 30.

Congress should learn from past mistakes. Consumers expect our sunscreens to be safe and effective. Unfortunately, many sunscreens do not adequately protect consumers from harmful UV rays and pose needless health risks – even though better alternatives are available. Allowing legacy ingredients that are less effective and less safe to remain on the market while more effective and safer ingredients are available makes little sense.

Congress should take steps to quickly ban harmful ingredients and take steps to ensure the production of the data needed to resolve questions, if any, about the safety and effectiveness of

[19] Manufacturers have not requested deferred action on cinoxate, dioxybenzone, padimate O, or sulisobenzone. *See* Food and Drug Administration, Proposed Order (OTC000008): Amending the Over-The-Counter (OTC) Monograph M020: Sunscreen Drug Products for OTC Human Use (Sept. 24, 2021), https://dps-admin.fda.gov/omuf/omuf/sites/omuf/files/primary-documents/2022-09/Proposed%20Administrative%20Order%20OTC000008_Amending%20M020_Sunscreen_Signed24Sept2021.pdf.

[20] The 2021 proposed order would require that all spray and power sunscreen products undergo particle-size analysis to ensure that the particles cannot be inhaled and cause damage. The proposal would require that at least 90 percent of the particles dispensed from a spray product be 10 micron or larger and that the minimum particle size dispensed from the consumer container must be no less than 5 µm. *Id.* This provision should be included in the final order. The FDA should also specify that only rutile titanium dioxide sunscreens should be allowed on the market.

promising alternatives. To avoid the policymaking mistakes of the past, Congress should consider funding mechanisms and deadlines which require the FDA to quickly complete needed studies of existing and promising new ingredients.