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June 6, 2019

Environmental Working Group Comments to the Environmental Protection Agency

Docket ID: EPA-HQ-OPP-2012-0811

Subject: Registration Review Draft Risk Assessment for Triclosan

Environmental Working Group, a nonprofit research and policy organization with offices in Washington, D.C., Minneapolis, Minn., San Francisco and Sacramento, Calif., is submitting comments on the Environmental Protection Agency's human health and ecological risk assessment for triclosan, an antimicrobial chemical used in consumer products. Examples of EPA-regulated uses for triclosan as an antimicrobial chemical in products include countertops, cutting boards, and food packaging.

EWG has researched triclosan's toxicity and, since 2007, has recommended avoiding the use of triclosan-containing products because of concerns about the endocrine-disruption potential of this chemical and its negative impact on children's health. EWG co-authored the Florence Statement, a consensus report signed by more than 200 scientists recommending against unnecessary triclosan use because of documented hazards and a lack of demonstrated benefits.¹

In 2016, the Food and Drug Administration ruled that soap products containing triclosan, such as liquid, foam or gel hand soaps, were not safe or effective and thus should not be sold as over-the-counter consumer antiseptic products.² However, triclosan continues to be used in various consumer products and, because it is not labelled as an ingredient, shoppers often cannot be sure whether the products they plan to buy might contain triclosan.

Because of the EPA's assessment of triclosan in plastics, polymers and textiles, EWG concluded that continued registration of triclosan for these uses will not provide any health benefits and may unnecessarily expose adults and children to its harmful effects. EWG finds that the agency has not fully accounted for triclosan risks from all direct and indirect exposure routes. For this reason, EWG is concerned that allowing the reregistration and continued use of triclosan, as the agency proposes, may harm public health.

Furthermore, EWG disagrees with the EPA's decision to reduce to 1 the children's health factor, also known as the Food Quality Protection Act (FQPA) safety factor. The Food Quality Protection Act, passed in 1996, required the EPA to consider children's heightened susceptibility to pesticides and to apply an additional safety factor of 10 when setting or reevaluating tolerances, unless adequate data are available to support a different factor.

Compelling research from human and animal studies raised the possibility of thyroid and reproductive hormone changes in young children exposed to triclosan. The impact of

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triclosan on thyroid hormone homeostasis is particularly worrisome, given the importance of thyroid function for fetal growth and development.

Here we highlight just two examples of the latest research, which is essential to consider in any comprehensive assessment of triclosan's risks to children. Triclosan exposure has been linked to behavioral problems in children, which underscores the risk it may pose to neurodevelopment.³ Triclosan exposures of women during pregnancy have been inversely associated with infant birth weight, length, head circumference and gestational age, which indicates that triclosan may either promote or cause adverse birth outcomes.⁴ These findings from human epidemiological studies contradict the EPA assessment that triclosan does not harm fetal and infant development.

EWG notes that for countertops and cutting boards, two uses regulated by the EPA, children and adults may ingest triclosan by eating food that was processed on or stored in those products. The EPA's dietary exposure assessment for triclosan,⁵ reported that exposure from countertops and cutting boards can contribute more than 40 percent of the reference dose for children, which is dangerously close to the maximum exposure for triclosan for children – even without the inclusion of sources of triclosan exposure from uses other than countertops and cutting boards.

In the draft risk assessment, the EPA's chosen point of departure for triclosan toxicity assessment corresponds to the level of triclosan that was associated with decreased serum thyroxine in exposed laboratory animals. Thyroxine is the main hormone produced by the thyroid gland that plays a key role in regulating the body's heart, digestive functions, metabolism and other systems. Thyroid hormones are also critical for fetal brain development.

EWG disagrees with two statements in the EPA's draft assessment about the impact of triclosan on children and the data used by the EPA for this review.

First, in section 3.5.3.2., "Evidence of Neurotoxicity," the EPA states that "the available data on triclosan for evaluation of neurotoxicity, including the 14-day neurotoxicity study in rats, developmental and reproductive toxicity studies in rats and rabbits, and subchronic and chronic data in rats and mice, do not show evidence of a neurotoxic effect of triclosan in any of these studies." Notably, the EPA has not mentioned the information from human epidemiological research on triclosan's neurotoxicity. Drawing a conclusion from animal studies alone and dismissing findings from epidemiological research, as these examples do, does not serve the goal of public health. EWG urges the EPA to include findings from human studies in its final triclosan assessment.



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Second, in section 3.5.3.3., “Evidence of Sensitivity/Susceptibility in the Developing or Young Animal,” EPA states that “the data base is complete for triclosan and there are no data gaps pertaining to developmental or reproductive toxicity. The data provided no indication of increased sensitivity of rats or rabbits to in utero and post-natal exposure to triclosan.” Again, EPA has not considered the available human data in this section and the assessment generally. Overall, the database of toxicity studies that EPA summarized is insufficient for a comprehensive assessment of triclosan’s toxicity for the developing fetus, infant and child. For this reason, in the final assessment, EPA should use a 10-fold FQPA safety factor to protect children’s health.

EWG notes that, were the EPA to apply the children’s health safety factor of 10 to the most recently calculated reference dose for triclosan of 0.27 mg/kg/day, daily exposure of triclosan from countertops and cutting boards alone would be more than four times higher than what would be considered safe for children – and therefore this specific use of triclosan would not be suitable for reregistration.

Conclusion

EWG urges the EPA to include a 10-fold Food Quality Protection Act children’s health safety factor for the triclosan human health assessment and to consider routes of triclosan exposure from all potential sources in the agency’s final assessment for this antimicrobial chemical.

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