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Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
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Citizen Petition to the U.S. Food and Drug Administration (FDA) to Ban Triclosan

The undersigned submits this petition to the Food and Drug Administration (FDA) pursuant to Title 21 C.F.R. 10.30 under the Federal Food, Drug and Cosmetic Act, to request the Commissioner of Food and Drugs to immediately ban all non-medical uses of the antibacterial agent triclosan.

This petition is filed by: Beyond Pesticides/National Coalition Against the Misuse of Pesticides, the Center for Environmental Health, Advocates for Environmental Human Rights, Alaska Community Action on Toxics, Breast Cancer Action, Breast Cancer Fund, the Campaign for Safe Cosmetics, Citizens' Environmental Coalition, Environmental Health Fund, Indigenous Environmental Network, Maryland Pesticide Network, Natural Resources Defense Council, Northwest Indiana Toxics Action Project, San Diego Oceans Foundation, Seventh Generation, Inc., Women's Voices for the Earth, and David Kriebel, Sc.D.

The Petitioners base this petition on scientific evidence, including evidence compiled recently, which demonstrates that triclosan's continued registration will result in dangerous consequences for public health and the environment.

I. ACTION REQUESTED

A ban on all non-medical uses of triclosan, also known as Irgasan.

II. STATEMENT OF GROUNDS

A. Antibacterial Resistance

A large number of recent studies have found substantial evidence that triclosan and triclosan-containing products promote the emergence of bacteria resistant to

antibiotic medications and antibacterial cleansers.[1] These studies have found resistance in a number of different bacteria strains, including some potentially deadly strains, such as *Escherichia coli*.[2] Resistance effects have been shown at low, bacteriostatic and sub-biocidal levels, such as residues that remain hours after tooth-brushing or hand-washing, or in wastewater effluents.[3] Data shows that bacteria will become resistant to antibacterial products like triclosan, rendering the products useless to those who actually need them for medical purposes, such as people with compromised immune systems. Because triclosan's mode of action and target site in the bacteria is similar to antibiotics, bacteria that become resistant to triclosan may also become resistant to antibiotics. There are also at least two other proven resistance mechanisms that are similar for both triclosan and antibiotics.[4] Triclosan does not actually cause a mutation in the bacteria, but by killing the normal bacteria, it has been shown to create an environment where mutated bacteria that are resistant to triclosan are more likely to survive and reproduce.[5] With so many products on the market containing triclosan, scientists predict that the speed with which resistance develops is likely to be increased.[6]

Laboratory studies with triclosan have found a number of different strains of mutated bacteria that are resistant to triclosan.[7] These mutant strains of bacteria also showed resistance to certain antibiotics, including a drug widely used for treatment of tuberculosis, an experimental antibiotic currently under development, and a number of other "clinically relevant" antibiotics.[8] While most resistant bacteria grow more slowly than sensitive bacteria, *E. coli* strains that are resistant to triclosan actually have increased growth rates. Constant exposure to triclosan will cause these resistant strains to tolerate it better, become increasingly hardy, and ever more resistant.[9] Because antibiotic resistance has become an increasingly serious problem worldwide, the link to antibacterials is very important.[10] In a recent review of the subject, one researcher concluded, "It is therefore quite possible that widespread use of triclosan may indeed compound antibiotic resistance."[11]

B. The Dioxin Link

Triclosan is listed as "could be" and "suspected to be" contaminated with dioxins in EPA's draft Dioxin Reassessment.[12] Dioxins are highly carcinogenic and can cause health problems as severe as weakening of the immune system, decreased fertility, altered sex hormones, miscarriage, birth defects, and cancer.[13] Because of its chemical structure as a polychloro phenoxy phenol, dioxins are found in triclosan as synthesis impurities.[14] In addition to being formed during the manufacturing process, dioxins may also be formed upon incineration of triclosan.[15]

Researchers who added triclosan to river water and shined ultraviolet light on the water found that between one and twelve percent of the triclosan was converted to dioxin in the water, suggesting that sunlight could transform triclosan to dioxin naturally.[16] An even more serious health threat stems from treatment of triclosan-

tainted water at water treatment plants—sunlight could convert chlorinated triclosan into highly toxic forms of dioxins.[17] Exposure to sunlight in the solid state of triclosan, such as on commercial textile products, also causes the formation of dioxins, albeit in smaller amounts than aqueous solutions.[18]

A study by researchers at the Virginia Polytechnic Institute and State University found that triclosan reacts with free chlorine in tap water to form a number of chlorinated triclosan intermediates, including 2,4 dichlorophenol, which photochemically generates highly chlorinated dioxins, which are some of the most toxic forms of dioxin.[19] The researchers found that these chlorinated intermediates can be formed in kitchen sinks, when using dishwashing liquid containing triclosan.

C. Triclosan Reacts with Tap Water to Form Carcinogen

The same study that found that triclosan reacts with tap water to form dioxins also found that the combination produces chloroform gas. When imitating dishwashing conditions, researchers found that triclosan reacts with free chlorine in tap water to form significant quantities of chloroform.[20] Chloroform is classified as a probable human carcinogen.[21] This raises serious concerns about other types of triclosan-containing products, such as toothpastes and hand soaps, which can be expected to similarly produce chloroform when they come in contact with tap water.

D. Acute Toxicity

There are reports of contact dermatitis, or skin irritation, from exposure to triclosan.[22] There is also evidence that triclosan may cause photoallergic contact dermatitis (PACD), which occurs when the part of the skin exposed to triclosan is also exposed to sunlight.[23] PACD can cause an eczematous rash, usually on the face, neck, the back of the hands, and on the sun-exposed areas of the arms.[24] There is also a reported case of an immunotoxic and neurotoxic reaction to triclosan.[25]

E. Triclosan Body Burden

Triclosan is lipophilic, so it bioaccumulates in fatty tissues. A Swedish study found high levels triclosan in three out of five human milk samples, indicating that triclosan does in fact get absorbed into the body, often in high quantities.[26] A 2005 study finds triclosan in umbilical cord blood of infants, demonstrating that babies are exposed to triclosan while still in the womb.[27]

F. Triclosan Is Ineffective at Preventing Disease and Unnecessary for Everyday Use

Under the appropriate settings and conditions, such as in hospitals to prevent hospital-acquired infections, triclosan has been proven to be effective.[28] Yet the

current widespread use of triclosan-containing products and their promotion of triclosan-resistant bacteria will decrease the effectiveness of triclosan for those people with compromised immune systems who depend on triclosan-containing products for health protection. No current data demonstrate any extra health benefits from having antibacterial-containing cleansers in a healthy household.[29] For example, a study of over 200 healthy households found that those households that used antibacterial products did not have any reduced risk for symptoms of viral infectious diseases.[30] According to the American Medical Association, "Despite their recent proliferation in consumer products, the use of antimicrobial agents such as triclosan in consumer products has not been studied extensively. No data exist to support their efficacy when used in such products or any need for them…it may be prudent to avoid the use of antimicrobial agents in consumer products…"[31] The Centers for Disease Control and Prevention say that antibacterial soaps are not necessary in everyday use, and washing hands with ordinary soap and warm water is an effective way to ward off infections.[32]

Most recently, on October 20, 2005, at a meeting of the Nonprescription Drugs Advisory Committee, which advises FDA, the committee voted 11-1 that antibacterial soaps and washes were no more effective than regular soap and water in fighting infections—both work equally as well.[33]

G. Representative Information of Views Supporting Triclosan Usage

In response to material that Beyond Pesticides published in the fall of 2004 along with a press release, the Soap and Detergent Association (SDA) issued its own press release supporting the use of triclosan.[34] The SDA stated, "Triclosan has been safely and effectively used in hygiene products for nearly 40 years… In recent years, several national, regional, and inter-governmental agencies have reviewed the available data on antibiotic resistance. None have identified resistance associated with the use of antibacterial products or compounds as a concern under current conditions of use." The SDA supported their claims with a handful of studies, the first of which was a review by a European Commission Scientific Steering Committee, which the SDA quoted as reporting that, "There is no convincing evidence that triclosan poses a risk to humans or to the environment by inducing of transmitting antibacterial resistance under current conditions of use." The conclusion was based specifically on examining triclosan products in their pure form at "high biocidal concentrations." However, the Committee also reported that at sub-biocidal and bacteriostatic levels resulting from normal use, such as residues that remain up to 12 hours following a hand-washing or tooth-brushing, triclosan is capable of promoting antimicrobial resistant bacteria.[35]

The SDA also cited a study by British researchers Gilbert and McBain as showing that bacterial resistance stemming from triclosan use is not as bad as once thought.[36] However, while this study did not find resistance in all bacterium, it did find that

repeated exposure to triclosan caused resistance in two potentially deadly types of bacteria, *E. coli* and *Klebsiella* bacteria. Additionally, SDA cited another UK study about antibiotic resistance by researcher Denver Russell which stated that "comprehensive environmental surveys" have not shown resistance.[37] However, the same study also called for an elimination of "frivolous and unnecessary" uses of triclosan, based on lab studies demonstrating resistance. The Petitioners consider non-medical uses of triclosan to be frivolous and unnecessary, in light of section II-F of this petition.

III. ENVIRONMENTAL IMPACT

Triclosan seeps into soil, surface water, and groundwater, wreaking havoc on aquatic ecosystems:

A. Environmental Fate of Triclosan

Over 95% of the uses of triclosan are in consumer products that are disposed of down residential drains.[38] Since wastewater treatment plants fail to remove triclosan from the water and the compound is highly stable for long periods of time,[39] a huge amount of triclosan is emitted into waterways. Research has confirmed this: in a U.S. Geological Survey study of 95 different organic wastewater contaminants in U.S. streams, triclosan was one of the most frequently detected compounds, and in some of the highest concentrations.[40] A study of triclosan in bodies of water in Switzerland also found high concentrations of the chemical in several lakes and rivers, as well as lower levels of methyl triclosan, its breakdown by-product.[41] Methyl triclosan, which is formed by biological methylation, is actually more lipophilic than its parent compound, and thus more bioaccumulative. [42] The large quantities of triclosan effluents in waterways that do not get removed by wastewater treatment plants may cause a number of unforeseen hazards, such as production of dioxin when sunlight shines on the water, and production of resistant bacteria populations.

B. Ecological Effects

Triclosan can have detrimental effects on aquatic ecosystems. Triclosan has been found to be highly toxic to different types of algae.[43] Triclosan effluents affect both the structure and the function of algal communities in stream ecosystems.[44] Because algae are the first-step producers in aquatic ecosystems, high levels of triclosan discharged into the environment may cause widespread negative consequences, including "the possible destruction of the balance of the ecosystem."[45] The risks are especially high immediately downstream from wastewater treatment plants.[46]

Because of its lipophilic nature and resistance to degradation, triclosan in waterways is readily available for absorption and bioaccumulation by aquatic organisms in the

environment.[47] Researchers in Sweden found high levels of triclosan were present in the bile of fish that were placed in cages downstream of sewage treatment works in Sweden.[48] Methyl triclosan, a transformation product of triclosan, has also been found in fish.[49] Although little is known about the effects on fish, triclosan has been found to be highly toxic to Japanese medaka fish in their early life stages, and may cause weak endocrine disruption as well.[50]

IV. CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner that are unfavorable to the petition.

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