UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

The Honorable Edward J. Markey
Chairman, Subcommittee on
Energy and Environment
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your letter of January 5, 2010, to EPA Administrator Lisa Jackson regarding triclosan and triclocarbon. Administrator Jackson asked me to respond to the questions and concerns you have raised as my office is responsible for the regulation of pesticides.

Triclosan is an antimicrobial active ingredient that is contained in a variety of bacteriostats, fungistats, mildewstats, and deodorizer products. There are currently 20 antimicrobial registrations, which EPA regulates under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Triclocarban is not a pesticide active ingredient and there are no uses regulated by EPA under the Toxic Substances Control Act (TSCA). There are also consumer uses of both triclosan and triclocarban, such as its use in soaps and cleansers that are regulated by the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act (FFDCA). The following respond to the specific questions provided in your letter.

Question 1: What is EPA's status in reviewing the existing data on triclosan and triclocarban? Has the EPA made any decisions regarding the need for further assessment of these chemicals?

Response: In 2008, EPA completed a Reregistration Eligibility Decision (RED) for triclosan. This RED describes the conclusions of EPA's comprehensive review of the potential risks to human health and the environment resulting from the registered pesticidal uses of triclosan. The Agency determined that, with the exception of preservative use of triclosan in paints and stains, pesticides containing triclosan met the statutory safety standard in FIFRA, provided that risk mitigation measures as outlined in the RED were implemented, confirmatory data gaps were addressed, and label amendments were incorporated as presented in the RED document. Subsequent to the issuance of the RED, the registrant of triclosan products for use in paints and stains voluntarily requested cancellation of the registration of products for these uses.

In conducting the review for the RED, EPA considered all available data on triclosan, including data on endocrine effects, developmental and reproductive toxicity, chronic toxicity, and carcinogenicity. The 2008 EPA assessment relied in part on the 2003-2004 data available from the National Health and Nutrition Examination Survey (NHANES) measurements of urinary concentrations of triclosan in the U.S. population. Therefore, the 2008 EPA assessment

is inclusive of all triclosan-related exposures (*i.e.,* EPA and FDA regulated uses). EPA is updating its 2008 assessment of triclosan exposure using the newly released 2005-2006 NHANES urinary monitoring results. Once completed, EPA will provide its revised assessment in the public docket, and revisit its regulatory decision, if the science supports a change.

The 2008 RED considered new research data on the thyroid effects of triclosan in laboratory animals made available through the EPA's Office of Research and Development (ORD). Since the 2008 assessment, additional data on effects of triclosan on estrogen have also been made available from ORD. As discussed in the response to Question 4b, the ORD studies on the thyroid and estrogen effects led EPA to determine that additional research on the potential health consequences of endocrine effects of triclosan is warranted. This research is underway and will help characterize the human relevance and potential risk of the results observed from initial laboratory animal studies. The Agency will pay close attention to this ongoing research and will amend the regulatory decision if the science supports such a change. Also, the Agency has previously indicated that because of the amount of research being planned and currently in progress, it will undertake another comprehensive review of triclosan beginning in 2013.

With respect to triclocarban, EPA's Office of Pollution Prevention and Toxics (OPPT) in April of 2009 published its assessment of triclocarban. This assessment presented the environmental and human hazard characterization for triclocarban based on the available data. During the evaluation process, OPPT determined that there are no uses under TSCA.

Question 2: Will EPA need to alter its regulations under the Federal Insecticide, Fungicide, and Rodenticide Act for pesticides that contain triclosan and triclocarban in light of biomonitoring studies that reveal the presence of these chemicals in 75% of the U.S. population? If so, please describe your plans, and if not, why not?

Response: As noted in the 2008 RED document for triclosan, the human health assessment took into account the exposures received by the general US population from all sources, as reflected by the 2003-04 NHANES data. These sources included the use of triclosan as a preservative in paint and stains, which EPA determined was not to be eligible for reregistration and for which the registrant subsequently requested a voluntary cancellation of their products' registrations. The Agency determined that the other registered uses of triclosan were eligible for reregistration, provided that risk mitigation measures as outlined in the RED were implemented, confirmatory data gaps were addressed, and label amendments were incorporated as presented in the RED document. As noted in the response to Question 1, EPA is currently analyzing the NHANES 2005-06 results for triclosan and will revise its assessment based on these newer data. As also noted in response to Question 1, EPA plans to reexamine the potential risks to human health in light of the new and planned research on the effects of triclosan on the endocrine system.

Question 3: Given the fact that triclosan has been detected in 60% of U.S. streams, has EPA determined the impact of triclosan on wildlife, such as fish and amphibian species? If so, please provide an explanation of your findings. If not, please explain why EPA has not taken action to determine triclosan's impact.

Response: The Agency conducted a comprehensive assessment of available data on any ecological hazard and risk, which is summarized in the 2008 RED on triclosan. Based on

available information, EPA concluded that, for antimicrobial pesticidal uses, estimated environmental concentrations of triclosan do not exceed levels of concern for fish or aquatic animals. However, based on monitoring data, there is potential for toxicity to aquatic plants. The Agency has identified additional studies that it will require triclosan registrants to perform to better characterize acute and chronic ecological risks.

It should be noted that EPA required pesticide registrants to add labeling statements indicating that triclosan is toxic to fish and other aquatic animals, and that any discharges into waterways need to conform to the requirements of the National Pollutant Discharge Elimination System (NPDES).

Question 4: As you know, in 1996, Congress passed amendments to the Safe Drinking Water Act, which contained provisions calling for the screening and testing of chemicals and pesticides for possible endocrine disrupting effects. In response, the EPA established the Endocrine Disruptor Screening Program (EDSP), which is aimed at using validated methods for the screening and testing of chemicals to identify potential endocrine disruptors and determine safe exposure levels to these chemicals.

(a) Does the EPA have plans to evaluate triclosan, triclocarban, and other potentially endocrine-disrupting substances that are used in soaps, detergents, and other consumer products under EDSP? If so, please describe such plans in detail, and if not, why not, since these substances could clearly end up in the nation's drinking water?

Response (a): Under section 408(p) of the FFDCA, EPA was directed to develop "a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate." Since triclosan is a pesticide chemical, EPA will review it under the EDSP program.

The Agency notes that some data are already available to characterize the endocrine disrupting potential of triclosan. EPA's Office of Research and Development has conducted at least six of the eleven EDSP Tier I screening assays with triclosan. Based on these screening studies, EPA has additional work underway to further characterize the early results of these studies. EPA will use the results of the ongoing ORD studies (discussed in the response to Question 4(b)), along with other research from the public literature, in its comprehensive reassessment of triclosan.

(b) Has the EPA reviewed the scientific literature regarding the endocrine disrupting nature of triclosan and triclocarban? If yes, what has the EPA concluded? If not, why not?

Response (b): EPA has reviewed the existing scientific evidence regarding the endocrine disrupting effects of triclosan and discussed these findings in the RED that was issued in 2008. From review of the existing evidence, EPA concluded that there is evidence that triclosan disrupts thyroid hormone levels in laboratory animals. Additionally, there are initial EPA research findings that show triclosan has the potential to affect the estrogen system in rats. EPA analyzed the available data on thyroid hormone effects of triclosan and concluded that there were

no risks of concern from the exposures considered in the 2008 RED document. Additional work, however, is needed to better understand the initial observations of the effects of triclosan on estrogen observed in the Tier 1 assays.

Because triclosan has already been evaluated in many of the Tier 1 EDSP screening level assays, the focus of additional work should be on more definitive higher levels of testing rather than further screening. EPA has several planned studies designed to aid both EPA and FDA in better characterizing these endocrine related effects, including toxicological effects, human relevance, and the doses at which they occur to determine if levels of human exposure are safe or not. EPA also has ongoing additional studies to reaffirm its conclusions regarding thyroid effects. The Agency will pay close attention to this ongoing research and will amend the regulatory decision if the science supports such a change.

Unlike triclosan, there are no published data showing any interference with thyroid hormones by triclocarban. In fact, unpublished research data from EPA did not find any effects on the thyroid up to very high doses (1 gram/kg/day) of triclocarban. In the published literature, triclocarban was reported to have effects on testosterone in both *in vitro* and *in vivo* studies. ORD has a number of ongoing studies in *in vitro* and *in vivo* (both ecological and mammalian tests) systems to better characterize the endocrine effects triclocarban.

Question 5: Is EPA concerned that simultaneous exposure to these antimicrobial agents via different pathways such as drinking water, eating food and dermal exposure might magnify the potential for adverse effects? Why or why not?

Response: In the case of triclosan, the 2008 assessment used the 2003-04 NHANES biomonitoring data which reflect the body burden from all different sources and routes of exposure. Additionally, the assessment included separate estimates of dermal and inhalation routes of exposure for products that might be used by only a small percentage of the population. Therefore, all pathways and routes of exposure were thoroughly assessed.

With respect to risk posed by multiple chemicals, the FFDCA requires EPA to consider cumulative exposure to pesticides and other substances that share a common mechanism of toxicity. With respect to exposure to both triclosan and triclocarban, there are no available data to indicate that triclosan and triclocarban share a common mechanism of toxicity or that simultaneous exposure to triclosan and triclocarban would pose an increased risk compared to separate exposures. Thus, EPA has not concluded at this time that simultaneous exposure to triclosan and triclocarban would magnify any of the adverse effects observed in experimental studies conducted so far with these two chemicals. As stated above, additional research is needed to better characterize the effects of these individual chemicals.

Question 6: Has the EPA itself monitored triclosan or triclocarban in public water systems?

(a) If yes, please provide a copy of all data collected and EPA's interpretation of these findings.

Response (a): While EPA has itself not monitored triclosan or triclocarban in public water systems, it has obtained publicly available monitoring data on the presence of triclosan in drinking water. EPA used these data to conduct a human health drinking water risk assessment and found no human health risk concern for triclosan in drinking water.

(b) If not, does the EPA plan on including these compounds on the Candidate Contaminant List (CCL) to monitor these compounds under the Safe Drinking Water Act? If so, when will these efforts be completed, and if not, why not?

Response (b): EPA evaluated triclosan and triclocarban for inclusion on the third contaminant candidate list (CCL3). However, EPA did not list these compounds because the limited available data showed that in comparison to other contaminants under consideration, triclosan and triclocarban were not as likely to be present in drinking water at levels that may require regulation.

The CCL 3 was published on October 8, 2009 (74 FR 51850) and includes contaminants that are currently unregulated in drinking water, that are known or anticipated to occur in public water systems, and which may require regulation under the Safe Drinking Water Act. EPA developed the CCL 3 using a multi-step process recommended by the National Academies of Science and the National Drinking Water Advisory Council. EPA considered the best available occurrence and health effects data to evaluate a universe of approximately 7,500 contaminants, from which EPA identified the list of 116 contaminants that present the greatest public health concern in drinking water. Triclosan and triclocarban were included in the universe of contaminants evaluated. However, EPA determined that these contaminants did not present as great a public health concern in drinking water as the contaminants that were selected for the CCL 3 list. EPA evaluated occurrence data in ambient water for triclosan from USGS studies and found the highest concentrations of triclosan in ambient water do not approach levels of health concern derived from the health effects data used in CCL 3. Other studies have presented data from monitoring of wastewater influent and effluent concentrations of triclosan and triclocarban. These higher concentration levels also do not approach levels of health concern. EPA will continue to evaluate unregulated contaminants including triclosan and triclocarban for future CCLs and will utilize any new data that become available. The next CCL is expected by 2014.

The Safe Drinking Water Act provides authority for EPA to require public water systems to monitor for up to 30 contaminants every 5 years under the Unregulated Contaminant Monitoring Rules (UCMR). EPA did not include triclosan or triclorban on the first two UCMRs. EPA is currently developing its third UCMR and is focusing efforts on the CCL 3 contaminants. EPA expects to issue the UCMR 3 in 2012.

(c) Generally speaking, could the potential for increased widespread antibiotic resistance be a safety contribution that is assessed when determining of a chemical should be placed on the CCL?

Response (c): EPA did not consider antibiotic resistance as a factor when evaluating whether to list contaminants on the CCL 3. EPA relied on quantitative occurrence and health effects data to evaluate contaminants for the CCL 3. More research is needed to assess and identify those contaminants that would have the greatest potential for increased widespread antibiotic resistance. More research would also be needed to develop methodologies for how this type of data could be used to modify the CCL process to allow for evaluation and comparison of health effects data amongst contaminants.

Question 7: Is the EPA aware of any studies that have investigated the potential for triclosan to leach from cutting boards, kitchen utensils, and toys when washed? If so, what was found?

Response: In the RED document for triclosan, EPA concluded that human exposure resulting from the use of triclosan in cutting boards, kitchen utensils, toys, and other products did not pose unacceptable risks to human health, including risks to infants and children. Standard methods developed by the Food and Drug Administration were used to estimate the potential for triclosan to leach from the materials into which triclosan is incorporated. EPA also estimated dietary exposure and risk from triclosan used in adhesives, pulp and paper, ice-making equipment, countertops, and cutting boards. Exposures and risks were assessed for both adults and children. The results showed that for both adults and children, risks were below the Agency's level of concern for exposure to triclosan.

Question 8: In 2008, an EPA Reregistration Eligibility Decision (RED) required label changes to reflect the environmental hazards posed by end-use products containing triclosan. This labeling requirement states:

> *"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authorities are notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."*

Does EPA believe that all products that contain triclosan and have the potential to discharge into sewer systems such as antimicrobial soaps and handwashes should be labeled in this fashion? Please explain your response.

Response: The Clean Water Act (CWA) prohibits the discharge of a "pollutant" from a "point source" into a "water of the United States" unless the discharge is authorized under a permit issued under the National Pollutant Discharge Elimination System (NPDES). As part of its review of pesticidal uses of triclosan during the reregistration process, EPA determined that triclosan pesticides are used in a manner that could result in the discharge of a pollutant from a point source to a water of the United States. The specific products for which the Agency required the addition of a label statement concerning NPDES permitting involve the use of triclosan in the manufacture of pulp and paper products or as a material preservative in manufacturing settings (*e.g.,* the incorporation of triclosan in finished textiles and plastic products). EPA determined that there was potential in these settings for manufacturing effluents regulated under the CWA to contain triclosan. Accordingly, EPA determined that triclosan pesticides should bear a statement advising users of their obligations under the CWA.

Again, thank you for your letter. If you have further questions, please contact me or your staff may call Ms. Christina Moody in EPA's Office of Congressional and Intergovernmental Relations at (202) 564-0260.

Sincerely,

Stephen A. Owens
Assistant Administrator