ECOLAB®

April 3, 2008

OPP Regulatory Public Docket (7502P)
Environmental Protection Agency, Rm. S-4400
One Potomac Yard (South Bldg)
2777 S. Crystal Dr.
Arlington, VA 22202

RE : EPA-HQ-OPP-2008-0110
40 CFR Part 158 and 161 – Data Requirements for Antimicrobial Pesticides
Proposed Rule – Federal Register, Vol. 73, No. 196 (October 8, 2008)

Dear Sir or Madam:

With sales of $6 billion and more than 26,000 associates, Ecolab is the global leader in cleaning, sanitizing, food safety and infection prevention products and services. Ecolab delivers comprehensive programs and services to the foodservice, food and beverage processing, healthcare, and hospitality markets in more than 160 countries. Therefore, Ecolab has a vital interest in ensuring that appropriate and cost effective data requirements are applicable to the registration of antimicrobial pesticides which provide public health and food safety benefits.

In general, Ecolab supports the comments provided by the Consumer Specialty Products Association (CSPA) and the American Chemistry Council (ACC) Biocides Panel. This document provides Ecolab's specific comments which, in some instances, may differ from or expand on the comments provided by ACC and CSPA.

Background

The Environmental Protection Agency (EPA or the Agency) published a proposed rule in the October 8, 2008 Federal Register, entitled "Data Requirements for Antimicrobial Pesticides" for 40 CFR 158 and 161. In the notice, EPA proposed to revise and update the existing data requirements for antimicrobial pesticides. The Agency stated the proposed revisions are needed to reflect the following:

1. current scientific knowledge
2. current Agency regulatory practices; and
3. to improve protection of the general population and as well as sensitive subpopulations.

The proposed regulation summary goes on to state that these proposed data requirements are intended to further enhance the Agency's ability to make regulatory decisions about the human health and environmental fate and effects of antimicrobial pesticide products.

In the October 8, 2008 Federal Register Notice, the Agency requested submission of comments from interested parties on or before January 6, 2009. At the request of industry, EPA extended the comment period to April 6, 2009.

General Comments:

Implementation of Part 158W

EPA states in the preamble "*Impact of this Proposal on Future and Existing Registrations*" (IV. Introduction to Subpart W, G.) that the finalized 158 data requirements would apply to all new antimicrobial registration applications submitted after the effective date of the final rule. The new data requirements would also apply to applications of antimicrobial pesticides that are undergoing Agency review when the final regulation goes into effect. When the regulation is finalized, Ecolab concurs that all new antimicrobial applications which have not been submitted to EPA would be subject to the new data requirements. However, Ecolab strongly disagrees that any registration currently under review should have the new data requirements imposed. This would result in lengthy delays and renegotiation of PRIA costs/timelines. Imposing new data requirements on registrations submitted prior to the finalization of 158W would unfairly penalize those registrations in review. Product registration data generation fees are budgeted by companies on an annual basis. To implement new requirements on a pending registration review would trigger unbudgeted and substantial data generation costs and PRIA costs, resulting in registrants withdrawing applications due to the lack of funds in this challenging economic environment. Given the onslaught of public health crises such as MRSA, *Clostridium difficile*, hoof and mouth disease, Avian Influenza, and the critical Anthrax response to bioterrorism threats, the Agency must carefully weigh the benefit of new public health technologies against imposing additional data requirements for applications submitted prior to promulgation of a final rule.

The Agency should be consistent with how the data requirements were implemented for conventional pesticides. In that instance, EPA did not impose new data requirements retroactively on pending conventional pesticide submissions.

In addition, to comply with the Administrative Procedure Act (APA), any final rulemaking on the data requirements for antimicrobials must apply only to antimicrobial pesticide registration applications submitted after the 158W rule effective date. For registrations pending at the time of final rule publication, Ecolab suggests those pending applications be given conditional registration under Section 3(c)(7) of FIFRA and that implementation of the 158W data requirements occur at the time of Periodic Registration Review. As pointed out in the ACC comments, a statutory grant of legislative rulemaking does not give the Agency the power to promulgate registrations retroactively unless that power is expressly conveyed by Congress.

EPA also states that the purpose of the new data requirements is to update and improve the scientific knowledge and current Agency practices. While this is appropriate with any data requirement rule, it is critical to ensure that all required guidance documents and protocols relative to those data requirements are finalized to help ensure registrants have appropriate information prior to data generation and to avoid registration delays. At this time, there are several relevant guidance documents which have not been finalized and published. For example, CSPA has worked extensively with EPA's Antimicrobial Division to develop 810 efficacy guidelines for 810.2000 (General Considerations), 810.2100 (Sterilants), 810.2200 (Disinfectants) and 810.2300 (Sanitizers). The last Agency draft of these guidelines has been available since 2006. Previously, the Agency had projected that the 810 guidelines would be published in draft by 1st quarter 2009 with a 60 day comment period. The Agency has recently reported that due to procedural changes there is not a projected date for the drafts to be published for public comment. In addition, there are several 810 guidelines which are either in draft or have not yet been drafted.

In addition, Part 158 addresses the issue of "down the drain" by proposing 4 new data requirements for use in screening level assessment of the fate of antimicrobials that reach Wastewater treatment plants (WWTP's). However, 158W lacks a risk assessment procedure to determine the true fate of down-the-drain products.

Having the appropriate guidelines available for reference is critical to the regulated community being able to address the data requirements, as the Guidelines identify essential components and considerations for the conduct of studies to fulfill data requirements. Comments from the ACC Biocides Panel indicate there are approximately 30 of the OPPTS Guidelines cited within the Proposal that have not yet been issued by EPA. Registrants therefore do not have the necessary guidance for evaluating whether a particular data requirement is applicable or how best to address the data requirement. This is a significant concern and clearly indicates the proposed rule is not ready for finalization without considerable revision.

Therefore, Ecolab joins the ACC Biocides Panel and CSPA in strongly objecting to the promulgation of the proposed 40 CFR 158 subpart W in the absence of necessary guidelines and protocols for data generation. Going forward without these guidelines, would result in a meaningless and ineffective rule, resulting in significant registration application delays. In addition, the Office of Management and Budget's comments to the proposed Part 158W rule, struck through "plans" and inserted "will" finalize guidelines before publishing a final rule establishing antimicrobial data requirements.

158W Urges Individual Consultation with the Registrant Rather than establishing Applicable Regulatory Requirements

A significant concern of the proposed 158W rule is that many regulatory decisions regarding required data and data generation protocols are left to case by case decisions from the Agency. There are 37 specific examples of this as outlined in the ACC Biocides Panel comments. While Ecolab agrees that case by case consultations between the registrant and the Agency are necessary from time to time to address scientific and regulatory issues, Ecolab remains highly concerned that there are 37 instances in the proposed rule addressing the need for Agency consultation. This number of consultations clearly indicates there is a significant lack of clarity to 158W. Ecolab also points out that

this will place a significantly increased burden on Agency and industry resources. Now is the time to address policy and protocol issues rather than defaulting to a case by case basis. Currently there is a lack of transparency of evolving Agency policies and decisions. In many instances, new policies emerge in registration letters which have resulted in an increased competitive disadvantage. Ecolab urges the Agency to eliminate as many case by case scenarios with clear and scientifically sound data requirement policies.

Part 158 W is not the appropriate venue to establish regulatory policies for labeling

§ 158.2003 Definitions (b)(5) states that "sanitary" implies a public health benefit. Part 158 W is a proposed data requirement rule and is inappropriate to communicate regulatory policies which impact labeling. The Agency failed to finalize the proposed 40 CFR 152 and 156 which were published in the Federal Register on September 17, 1999. That regulation would have been the correct mechanism to implement regulatory labeling policies. In that rule, EPA proposed to include the term "sanitary" as a pesticide claim. The draft rule of September 17, 1999 was never finalized. Therefore, any proposal to include this type of label policy into a data requirement rule is impractical and inappropriate.

As was pointed out to the Agency in industry comments to the 1999 draft rule, to re-classify "sanitary" as a pesticidal claim directly contradicts the Agency's former 1992 document which stated the term "sanitary" is identified as a state of cleanliness and does not carry connotation of pesticidal benefits to support reclassification. In addition, terms such as "sanitary sewer" have been in common parlance for a material extent of time. To assign additional regulatory meaning at this time is arbitrary and meaningless. The Agency has indicated there is consumer focus group data provided by one consumer product company. The Agency has not shared this data or any other evidence with the regulated community for review and comment as to the appropriateness of reclassification of "sanitary" as a pesticide claim. As stated in comments to the 1999 rule, to summarily classify "sanitary" as a pesticide claim, without opportunity for industry comment is an unfair practice. In addition, there is no consensus within industry as to the meaning of "sanitary". Therefore the proposed reclassification of "sanitary" as a pesticide claim must be removed from the draft Part 158 W rule and addressed through the appropriate regulatory policy mechanism.

The Agency proposes in the 158 W rule to disallow the terms "sanitizers" and "disinfectants" for non-public health organisms. The product performance section advocates that the term "disinfectant" implies public health uses and should not be applied to non-public health uses. This should be removed from the rule as it proposes to insert regulatory labeling policy into a data requirement rule.

The Draft 158W Rule Lacks Clarity as Data Requirement for Food Use Antimicrobials

The regulatory jurisdiction for food use antimicrobials is very complex due to unintended consequences of the Food Quality Protection Act (FQPA), the Antimicrobial Regulation Technical Corrections Act (ARTCA) and FDA's July 1999 "Antimicrobial Food Additive Guidance Document", and a regulatory policy interpretation (Legal Policy Interpretation of the Jurisdiction Under the FFDCA and EPA Over the Use of Certain Antimicrobial Substances – October 9, 1998)) between EPA and FDA which was rescinded due to the passage of ARTCA. While the Congressional intent of ARTCA was to correct the unintended consequences of FQPA, ARTCA failed to revert many instances of residue jurisdiction back to FDA as the EPA definition of pest remained unchanged to allow certain exemptions from that definition. This jurisdiction quagmire has a profound bearing on FIFRA 2 (bb), which in turn drives the FFDCA section 408 data requirements for a food use antimicrobial pesticide registration. Some 10 years after the publication of FDA's Antimicrobial Food Additive Guidance document, significant confusion remains as to where EPA has regulatory jurisdiction over food use antimicrobials, when the jurisdiction is shared with FDA, and EPA's statutory authority to require tolerances or exemptions from food tolerance for food use antimicrobials.

In 1999, EPA attempted to provide a scantly written table outlining the jurisdiction between EPA and FDA and when residue clearances were required under Sections 408 and 409 of FFDCA. The current preamble and §158.2290 Residue Chemistry section of the proposed 158W rule falls disappointingly short of providing clarity as to when EPA requires the setting of a tolerance or tolerance exemption under section 408 of FFDCA. This section needs significant improvement in order for prospective registrants to clearly understand chemistry residue requirements for food use antimicrobials subject to EPA's jurisdiction under FIFRA and Section 408 of FFDCA. In addition, this section should delineate what constitutes a processed food and a food processing facility as defined in the FDA Antimicrobial Food Additive Guidance document.

Without a detailed and in depth discussion of these critical points, the 158W food use data requirements are meaningless and will only continue to result in confusion to the regulated

community and the Agency. Ecolab supports the recommendation provided by CSPA to further improve the data requirements to align with today's understanding of when a Section 408 requirement must be met. (See the proposed table in this letter as it relates to Chemistry Residue.)

Ecolab recommends the Agency consider the following example to indicate where EPA does and does not have statutory authority to require an FFDCA 408 clearance with respect to Residue Chemistry:

1. Antimicrobial with food contact uses regulated as pesticide chemicals (subject to EPA jurisdiction under FFDCA section 408) include the following:
   - Antimicrobials applied to raw agricultural commodities (RACs) or to process water applied to RACs in the field, during transportation, or in facilities where no other processing of RACs occurs (typically washing/packing houses only where de-stemming, drying, shelling and husking may occur)
   - Antimicrobials applied to surfaces other than food packaging e.g. hard surface food contact sanitizer or disinfectant.
   - Antimicrobials included in objects or articles and intended to have an ongoing effect on the food contact surface.
   - Antimicrobial applied to food process water to reduce the count in the process water or applied to process water to reduce microbial count on the surface of fruits and vegetables.
2. Antimicrobial with food contact uses regulated as food additives (subject to FFDCA section 409, administered by FDA and registered by EPA as a pesticide) include the following:
   - Antimicrobials applied to RACs food in a food processing facility (as defined in FDA's 1999 Antimicrobial Food Additive Guidance document).
   - Antimicrobials applied as commercial sterilants for aseptic food packaging.

Draft 158 W Definition of "High" and "Low" Exposure

The use of the term "exposure" within the proposed rule is unclear, inconsistent, arbitrary, and unrelated to any scientific justification for requiring exposure and environmental data. The proposed rule divides antimicrobial pesticides into "high exposure" and "low exposure" categories. These terms were used in the 1987 Antimicrobial Data Call-In which used high, medium, and low exposure categories to indicate the general level of concern the Agency had with different uses of antimicrobials, irrespective of the true toxicity/exposure of those compounds. However, such a categorization today is indeed archaic and irrelevant, especially in light of the exposure data being generated through the CSPA AEJV and the ACC Biocides Panel AEATF II. Further, it is highly prejudicial to arbitrarily label an antimicrobial use as "high exposure" when there is neither scientific evidence to support exposure to humans or the environment, nor are there clear criteria for stating that any exposures are "high" without qualification.

The rule contains a significant increase of data requirements for exposure to humans and the environment. Where in some cases such data may be warranted, the rule unfairly and arbitrarily places a very costly data generation burden on chemicals without sound scientific

basis for data requirements for "high exposure" products. The basic scientific principle underlying all data requirements and risk assessments addresses both the nature of the hazard and the magnitude of exposure. If a compound is very toxic, there may be risks of concern if there are resulting exposures of concern. If a compound is not highly toxic or if the exposure is primarily through routes by which there is limited potential toxicity, then a high exposure would be of little concern and therefore data could well be unnecessary. As currently written the proposed rule requires 19 different toxicity studies for products categorized as "high" exposure.

Ecolab proposes a tiered approach for guiding the testing requirements proposed in the rule. In all cases, the arbitrary low and high exposure use patterns must be eliminated. However, a clear designation of use patterns similar to those defined in the environmental fate section of the rule may be a good starting point. Once acceptable use patterns are established, the Agency could then apply the risk characterization tools similar to those being applied to determine the environmental fate of conventional pesticides.

Through a risk characterization methodology, the Agency can extrapolate risk by using a either deterministic or probabilistic approach based upon predicted environmental concentrations (PEC), which would be developed around predicted rates of release into the environment from any use, followed by the predicted no effect concentration (PNEC) based upon existing data or preliminary data requirements. The resulting risk quotient (RQ) can then be used to identify whether or not further testing should be required. This is a simple, screening-level estimate that the Agency can use to establish a tiered testing format based upon the outcome of the risk quotient:

RQ = (Exposure)/(Toxicity)

The Agency would then be able to establish a threshold value for each use pattern founded upon the accepted baseline existing, or initial required toxicity data; the 6-pack for example, divided by data which more accurately characterizes exposure; physical/chemical properties, use, environmental fate, etc. In cases where the data does not meet the accepted TCCR principle (transparent, clear, consistent, and reasonable) standards, a safety factor could be applied to the risk quotient that would address uncertainty in the predictions.

A methodology characterizing risk with existing and preliminary test data is founded in objective scientific principles and provides the applicant with more clarity than the proposed arbitrary standards. As stated earlier, the exposure scenario as proposed is not well defined and only addresses one leg of risk characterization. Including a deterministic or probabilistic analysis of the hazard as well as the potential exposure provides a more objective tool for determining data requirements. This type of approach could be applied to each of the data requirements outlined in the proposed rule.

158W Needs to Address Procedures for Emerging Pathogens

The proposed regulation does not address how EPA will proactively address emerging pathogens which pose a serious public health threat. With a significant rise of hospital acquired infections (HAIs), there is an immediate need for a more efficient process to address public health threats. Over the past 10 years, there have been emerging pests such as MRSA, VRE, *Clostridium difficile*, Avian Flu, Anthrax and hoof and mouth disease. With each emerging pathogen, healthcare facilities are immediately demanding products to address pathogens.

The process to address emerging pathogens such a *Clostridium difficile* spores was an extremely slow process. While the Agency wanted expedited removal of *Clostridium difficile*

vegetative claims, it took over one year for the Antimicrobial Division to publish a guidance document for registrants to add the *C. difficile* spore claims to labels. In fact, as of the first of 2009, AD had registered only one product with a claim of effectiveness against *C. difficile* endospores.

Ecolab supports the ACC proposal for incorporation into 158W to expeditiously address emerging pathogens which would include the following elements:

- A trigger mechanism that will activate expedited review of products for control of emerging pathogens. The mechanism can be based on other federal agencies' actions, such as FDA, USDA, and CDC.

- Once expedited review has been triggered:

  A mechanism for expedited efficacy protocol development and approval, if appropriate, involving a workshop-type process;

  A mechanism for ensuring prompt review of efficacy data; and

  A mechanism for expedited review of new products with claims against emerging pathogens (this would be limited to emerging pathogen claims, other claims will be subject to usual review timelines.

Ecolab encourages EPA's Antimicrobial Division to work with ACC and CSPA to develop a more expedited program and test method development to address emerging pathogens as the Agency does not have an effective process to address emerging pathogens.

EPA's Economic Analysis – Cost of Registration and Impact to Registrants and Users

On page 59428 of the Federal Register Notice, the Agency provided a total Antimicrobial Industry Cost Per Year. EPA based its cost estimate on antimicrobial pesticide registrations that occurred from 2000-2005. The ACC Biocides Panel sponsored a more comprehensive economic analysis which was prepared by NERA Economic Consulting. NERA is a global firm with 25 offices world wide of economic and financial experts. NERA's economists create strategies, studies, reports, expert testimony, and policy recommendations for government authorities and the world's leading law firms and corporations.

NERA's economic analysis differs substantially from EPA's in several ways.

1. The costs based on registration submissions from 2000 – 2005, fails to consider the cost burden to registrants during periodic registration review of antimicrobial pesticides (mandatory 15 year cycle).
2. The NERA costs are based on more detailed information such as specific data requirements set out by a particular Agency guideline (i.e. testing with a mandatory number of species, number of lots required for testing, GLP vs. Non-GLP study costs.)

The NERA analysis demonstrates the cost to industry is far greater than the costs estimated by the Agency (by as much as 6 times). The NERA data also show that the updated average cost per company per year ranges from about $2 million to $2.2 million. This is **over thirty times** the Agency's estimated annual costs per company of $61,000. These projected costs present a significant barrier to the development and registration of new and improved antimicrobials to combat the unending emergence of new and stronger pathogens.

National Research Council Recommendations and SAP Review

Section XV Peer Review provides recommendations from the National Research Council (NRC) and the FIFRA Scientific Advisory Panel (SAP). EPA calls out recommendations from a 1993 report entitled "Pesticides in the Diets of Infants and Children). EPA cites recommendations from the Council that supports the need for acute and subchronic neurotoxicity testing for all food-use pesticides. It also encouraged further work in the area developmental toxicity. However, in 2006, the NRC evaluated current toxicity testing methods used by the Agency to assess hazards and risks. In NRC's executive summary, the Council cautioned against adding testing requirements only for the sake of theoretical thoroughness, because such an approach could result in substantial waste of animals and resources. As indicated in the CSPA and ACC comments regarding the various data tables, there are more efficient and cost effective ways to ascertain relevant data for regulatory decisions. For example, tiered testing, as opposed to requiring testing for every data requirement in the section tables.

In this section the Agency provides a discussion of a 1994 meeting with the SAP where the proposed amendments to the data requirements for antimicrobial pesticides were discussed. At a subsequent June 1997 meeting, EPA met with the SAP and presented an early version of the Part 158 W proposal. In the wake of the Food Quality Protection Act (FQPA), EPA consulted with the SAP as to the newly mandated FFDCA safety factor required under FQPA. In 2000, EPA met again with SAP regarding ecological risk assessment. Recognizing the Agency had met with the SAP up to the year 2000 regarding data requirements for 158W, it is important to note that 9 years have elapsed since the last recorded meeting. Much has changed regarding risk assessment protocols and end points, which could alter some the data requirements proposed in the October 8, 2008 proposed rule. For example and in some instances, EPA has accepted FDA's FFDCA 409 clearances rather than requiring the needless execution of a separate FFDCA 408 clearance for pesticide registration of some food use antimicrobials.

Due to the 9 year passage of time and that the SAP makeup of experts is most likely very different from the late 1990's and 2000, the Agency should again request review and comment from the SAP prior to implementation of this data requirement rule.

Section Specific Comments

158.2203 – Definitions

Ecolab also agrees with the CSPA comments regarding definitions on page 59431 section 158.2203 are inconsistent with FIFRA § 4(i)(4)(C)(i,ii, iii) and with the definitions provided by the CSPA AEG for the draft 810.2000 guideline. The Agency should revise the proposed definitions replacing them with the definitions provided in the CSPA comments for the 158W rule to be consistent with what has been recommended by the CSPA AEG.

As previously stated, Ecolab strongly objects to the Agency proposing to reclassify "sanitary" as a pesticide claim. The industry has had no opportunity to review or comment on data previously provided to determine if such a reclassification is appropriate. Also Part 158W is a data

requirement rule and is not the appropriate venue to communicate regulatory label policy decisions. This should be removed from 158 W.

Ecolab also supports the CSPA comments that it is inappropriate to disallow the term "sanitizers" and "disinfectants" for non-public health antimicrobials. The proposed part 158 advocates the view that the term "disinfectant" inherently implies public health uses and should not be used on non-public health pesticides. The Agency has not provided to industry any data or substantiation to support this assertion. Again, the Agency is attempting to insert regulatory label policies and product classifications through a data requirement rule. This should be removed from the proposed 158W rule.

158W is a new rule for antimicrobials and must be thorough in providing definitions for acronyms such as TGAI, TEP, MU, etc. In addition, the Agency should note that the terms Industrial Use Only and Commercial Use Only are being challenged by various state pesticide offices as requiring use by certified applicators only. The Agency needs to come to an agreement with the state offices as to the appropriate terms which can be used to indicate a product is not for household use but at the same time is not "Restricted Use" requiring use by certified applicators.

Section 158.2220 – Product Performance

Ecolab agrees with and supports the comments submitted by CSPA that 158W should not be finalized or implemented until all 810 guidelines are finalized. The proposed rule refers to the 91 guidelines which were proposed in 1991 and to date have not been published or finalized. The current 91 guidelines fall short of reflecting current scientific knowledge and current Agency practices. CSPA's Antimicrobial Efficacy Group (AEG) has worked closely with EPA's Antimicrobial Division to develop the 810.2000, 810.2100, 810.2200, and 810.2300 efficacy guidelines which have yet to be published for comment. In addition there are several outstanding 810 guidelines which have not be published or even drafted. As stated previously, OMB comments to the 158W rule require EPA to finalize all guidelines prior to publication of 158W as a final rule.

The proposed 158W product performance guidelines address data requirements for public health products, but remains silent as to data requirements for non-public health antimicrobial pesticides. The lack of discussion of non-public health pesticides renders the proposed rule incomplete. While data for non-public health claims do not require submission to the Agency, the registrant is required to generate the necessary data and keep it on file for Agency inspection. EPA should revise this section to include those requirements.

Section 158.2230 – Toxicology Data

As previously stated, the proposed rule divides antimicrobial pesticides into "high exposure" and "low exposure" categories in the absence of sound scientific justification. Ecolab proposes a tiered testing approach that is triggered for each use pattern through a deterministic or risk quotient methodology as presented previously.

Ecolab does not agree with the ACC Biocides Panel proposed Food/Non-food use patterns for the toxicology data requirement, but proposes use patterns that more clearly define the actually uses of the product; similar to the patterns proposed for environmental fate.

Ecolab does agree with the other components of the ACC biocides panel toxicology data requirements proposal. We particularly note that the acute neurotoxicity study not be required because the neurotoxicity component of the 90-study will address this question; the subchronic

21-day and 90-day dermal studies should be not be considered for the end-use-product, but only the active ingredient; and the mouse-carcinogenicity study should not be included because it does not add significant information over and above the 24-month male and female rat study.

Section 158,2240 – Nontarget Organisms (Ecotox)

As described previously, Ecolab proposes a tiered testing approach that is triggered for each use pattern through a deterministic or risk quotient methodology. The low exposure use pattern is subjective and arbitrary.

Section 158,2280 – Environmental Fate

Ecolab agrees with the ACC Biocides Panel in its proposed elimination of the low exposure use pattern. As stated previously, this is arbitrary and meaningless.

Indoor conventional pesticides are conditionally required to submit only hydrolysis data and are not required to conduct any other environmental fate data. Without any explanation or rational, five environmental fate studies are required for all "low"
exposure antimicrobials. In addition, higher tier testing is required for all antimicrobials without regard as to whether they are indoor or outdoor or have no potential for environmental exposure. Section 158.220 also conditionally requires monitoring of representative US waters for all "high" exposure antimicrobials uses. Again the Agency is imposing a data requirement in the absence a guideline which has not been reviewed by the SAP.

As described previously, Ecolab proposes a tiered testing approach that is triggered for each use pattern through a deterministic or risk quotient methodology. Ecolab reminds the Agency that it currently uses RQ approaches for assessing pesticide risks to terrestrial and aquatic animals and plants. Such an approach provides an objective guidance for each additional data requirement, saves applicant and Agency resources, and provides a more scientifically based foundation for evaluating hazard, exposure and risk for each use pattern.

Section 158.2290 – Residue Chemistry

Ecolab concurs with the ACC Biocides Panel and CSPA that the Agency's description of residue chemistry requirements in the proposed 158W raise many questions that must be considered before this proposal can be finalized.

The table in the proposed 158W is confusing and unclear as to when residue chemistry data is required. In order for these data requirements to be meaningful, they Agency needs to clearly identify what antimicrobial pesticide uses are subject to FFDCA 408 regulation. It is only those uses that EPA has the statutory authority to regulate under Section 408 of FFDCA.

In the preamble to Section 158.2290, the Agency needs to include specific examples of where it has statutory authority to regulate antimicrobial pesticides under FFDCA Section 408.

Also, there needs to be clarification that drying, shelling and husking of RACs does not constitute processing as explained in the 1999 Antimicrobial Food Additive Guidance Document issued by FDA. The Guidance document is clear that these activities do not constitute processing and antimicrobials applied to RAC's in the field, in a washing facility where no further processing occurs, or in transportation, or applied to process water is under EPA jurisdiction and requires a FFDCA 408 clearance. Conversely, antimicrobials applied to RAC's in a food processing facility prior to packing or further processing (cutting, peeling, cooking, slicing) may require a FIFRA registration as a pesticide and a FDA 409 FFDCA clearance.

Ecolab proposes the following to illustrate when the Agency has statutory authority under FFDCA 408 with respect to antimicrobial produce washes and antimicrobials applied to process water which contact fruits and vegetables.

1. Antimicrobial with food contact uses regulated as pesticide chemicals (subject to EPA jurisdiction under FFDCA section 408) include the following:
   - Antimicrobials applied to raw agricultural commodities (RACs) or to process water applied to RACs in the field, during transportation, or in facilities where no other processing of RACs occurs (typically washing/packing houses only where de-stemming, drying, shelling and husking may occur)

   - Antimicrobials applied to surfaces other than food packaging e.g. hard surface food contact sanitizer or disinfectant.

   - Antimicrobials included in objects or articles and intended to have an ongoing effect on the food contact surface.

   - Antimicrobial applied to food process water to reduce the count in the process water or applied to process water to reduce microbial count on the surface of fruits and vegetables.

In addition, Ecolab supports the ACC and CSPA proposed data requirement tables submitted as comment to this proposed rule.

Section 408 of FFDCA requires the establishment of a tolerance or exemption from food tolerance when pesticides are applied to foods and which will be in "interstate commerce". EPA stated at the 8th Annual Antimicrobial Workshop, that the requirements for a tolerance or exemption from food tolerance for food use antimicrobials applied in the home were not applicable. EPA based this statement on the premise that food in household setting is no longer in interstate commerce and therefore does not require the establishment of a tolerance or exemption from food tolerance for formulation components comprising a hard surface disinfectant or sanitizer. EPA went on to state that although tolerance or tolerance exemption setting is not required due to the interstate commerce issue, that the Agency would require a dietary assessment to ensure any remaining residues are addressed from a dietary/safety standpoint. Ecolab agrees with this approach and concurs that tolerance or exemption from tolerance setting is not required for hard surface antimicrobials which may have indirect contact with food in the home setting, but an extensive dietary risk assessment should be required.

In conclusion, Ecolab requests that the Agency implement the proposed 158W rule only when all required guidelines critical to data generation are completed and finalized. In addition, the recommendations provided with these comments and the comments from ACC and CSPA should be addressed prior to promulgation of a final rule.

Thank you for your attention to our concerns.

Sincerely,

James A. Westerhaus
Vice President, Government Relations
Ecolab

John G. Wood
Director, Product Registration and Compliance
Ecolab

Consumer Specialty Products Association

April 6, 2009

OPP Regulatory Public Docket (7502P)
Environmental Protection Agency
Rm., S-4400
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202

RE: Proposed Rule on Data Requirements for Antimicrobial Pesticides, 73 Federal Register 59382. Docket id number EPA –HQ-OPP-2008-0110.

Dear Sir/Madam:

These comments are submitted on behalf of the Consumer Specialty Products Association (CSPA) on the proposed rule on Data Requirements for Antimicrobial Pesticides, 73 Federal Register 59382. CSPA is the premier trade association representing the interests of approximately 240 companies engaged in the manufacture, formulation, distribution and sale of approximately $80 billion annually in the U.S. of hundreds of familiar consumer products that help household, institutional and industrial customers create cleaner and healthier environments. Our products include disinfectants and sanitizers that kill germs in homes, hospitals, industrial sites and restaurants; candles, fragrances and air fresheners that eliminate odors; pest management products for home and garden; cleaning products for use throughout the home; products used to protect and improve the performance and appearance of automobiles; and a host of other products used everyday. Through its product stewardship program Product Care®, scientific and business-to-business endeavors, CSPA provides its members a platform to effectively address issues regarding the health, safety, sustainability and environmental impacts of its products. For more information, please visit www.cspa.org.

CSPA is pleased that the Part 158 regulations have been proposed. CSPA offers the following comments on the overall framework of the rule as well as specific comments on the following areas: Product Performance Efficacy; Residue Chemistry; Toxicology; and Human Exposure. CSPA has worked cooperatively with the ACC Biocides Panel on these and other comments and support the comments submitted by the Panel.

I. Overall Framework

a. EPA's Part 158 W Data Requirements for Antimicrobials Must Reflect That They Are Unique

Congress has reminded EPA that antimicrobials are unique among FIFRA-regulated pesticides. Thus, FIFRA has its own definition of "antimicrobial pesticides". (FIFRA 2(mm)). The Food Quality Protection Act of 1996 required EPA to implement "reforms to the antimicrobial registration process" consistent with the "degrees of risk presented by an antimicrobial pesticide." (FIFRA 3(h)(1)). CSPA respectfully submits that the environmental and human hazards of antimicrobials, together with human and environmental exposure to antimicrobials, demonstrate that antimicrobials pose low risks. CSPA urges the Agency to consider these unique characteristics of antimicrobials when it adopts final Subpart W rules.

EPA's preamble to its proposed Subpart W rules states that § 3(h) "does not include provisions pertaining to data requirements." (73 Fed. Reg. at 59385). The plain language of §3(h), however, requires EPA to adopt antimicrobial regulations that "conform the degree and type of review to the risks and benefits presented by antimicrobial pesticides ... considering the use patterns of the product, toxicity, expected exposure, and product type." EPA can not meet Congress' § 3(h) mandate without assuring in the first instance that the Subpart W data requirements reflect the unique risks and benefits of antimicrobials. For this reason, CSPA submits that EPA's tiered toxicology, environmental and exposure data requirements for conventional pesticides are not in every case suitable or warranted for antimicrobials, and our comments point out those data requirements that -- while perhaps proper for conventional agricultural pesticides -- are not appropriate for antimicrobials. For example, EPA can assess the risks of a nonfood use antimicrobial, even if it presents opportunities for repeated, significant human exposure over a considerable portion of the human lifespan, with the benefit of a well conducted 90-day study in the rat.

Just as Congress has reminded EPA that the risks, benefits and human and environmental exposures to antimicrobials are unique, CSPA wishes to remind EPA that its own economic impact assessment of Subpart W data requirements confirms that the antimicrobial industry is unique. "There are about 750 unique parent antimicrobial firms. Of these, based on the SBA definition of a small business and the Dun & Bradstreet company data, EPA estimates that 500, or approximately 67 percent, are small businesses." (Economic Analysis at 16.) While some smaller businesses formulate products from registered antimicrobial active ingredients and, therefore, are exempt from more costly active ingredient data requirements, these smaller businesses will have to absorb the costs of testing active ingredients in the form of higher costs for the active ingredients. The very rationale of the formulator's exemption is based on the assumption that the price of the active technical or manufacturing use product purchased by the formulator will include the cost of testing the active ingredient.

b. Lack of Data Guidelines

The proposed Subpart 158W is intended to specify the data requirements for antimicrobial pesticides. The Agency has spent considerable time and resources in developing this proposal.

However, CSPA is concerned with the Agency's reliance on guidance documents that are not available to registrants or that have not been adopted through the public process of notice and comment.

For example, the data requirements table in § 158.2220 Product Performance lists various 91 series performance; i.e. efficacy, guidelines that have never been published. CSPA has been working with EPA over the past several years to develop a series of product performance guidelines (810) that were intended to replace a portion of the 91 series. The Agency has yet to publish these draft guidelines for public comment. In addition, there are still numerous guidelines that are in the early phases of drafting or have not begun drafting at all.

Numerous other guidelines are also lacking. Various guidelines for non-target organisms and non-target plants were made available in draft form in 1996, but have not been finalized or updated since that time. There are a number of exposure, environmental fate and residue chemistry guidelines that are not available at all.

Our lack of knowledge of the contents of many of the data requirements makes it impossible to determine the full impact of the regulation on the regulated community. Further, we do not have the ability to determine the appropriateness of the data requirements for the applicable products or know exactly what data must be generated to support product registrations. We cannot adequately comment on the appropriateness of these data requirements when we either do not know what the actual requirements are or whether the previously proposed data requirements will be applied as proposed. Additionally, it is possible that in the years since some of these guidelines have been proposed the science may have advanced so that reliance on the drafts may not provide results that would meet today's requirements.

For these reasons, CSPA believes this proposal is not ready for public comment. We ask that EPA withdraw the proposal until such time that appropriate guidance documents have been developed, vetted for public comment and peer review and are subject to final adoption. EPA must provide a transparent process in the development of guidelines. Once final guidance documents have been published the Agency can then re-propose this regulation.

c. Data Rule Should Not Be Used for Policy Modifications

The proposed rule is meant to communicate the data requirements necessary to obtain antimicrobial pesticide registration. However, EPA is proposing a number of policy changes that must not be included within the scope of the proposed regulation. These policy changes are incorporated primarily in the definitions subsection (§ 158.2203). The preamble states that these policy changes are necessary in order for the agency to determine the scope of antimicrobials claims that would be considered public health claims for the purpose of product performance data submission (see page 59391, Preamble Section VI Product Performance Data Requirements).

We are concerned that EPA is redefining the terms disinfectant and sanitizer so that only antimicrobial pesticide products that make public health claims may call themselves disinfectants or sanitizers. We do not agree with this position. This is a significant change in policy as these

terms have historically been defined in association with the level of reduction of microorganisms, not whether the microorganisms are public health or non-public health. EPA has provided no support for this position other than stating that the proposal is consistent with the September 17, 1999 proposed rule entitled "Registration Requirements for Antimicrobial Pesticide Products and Other Pesticide Regulatory Changes". The preamble indicates on page 59391 that comments were received on the previously proposed rule and considered in the current rulemaking. EPA has not disclosed nor discussed the comments previously received. If EPA is relying on comments received in connection with the previously proposed rule it should have discussed those comments in the current preamble and their relationship to the provisions included in the current proposal. The Agency provides no justification as to why they have determined that the terms disinfectant and sanitizer should be restricted only to products that are effective against public health organisms and how the Agency has determined it is appropriate to propose definitions that differ from FIFRA.

This change in status for disinfectants and sanitizers is not necessary in order for EPA to issue product performance data. Product performance data are needed for both public health and non-public health antimicrobial pesticides. The difference is in whether EPA reviews the data or not at the time of registration. What does EPA propose non-public health products be called? For example, what would be the new statement of identity for air sanitizers? These products are already defined as non-public health antimicrobial pesticides and as such must include specific statements on their labels.

EPA makes further policy changes in § 158.2203 (b) which discusses criteria EPA will use to determine when a product is making a public health claim. The Agency seems to propose in §158.2203 (b)(5)(i) that if a pesticide product contains one or more active ingredients that are effective against public health organisms then that product is considered to make a public health claim. If this is truly the intent, then EPA has misinterpreted 40 CFR 153.125(a) which clearly is written to apply to non-registered non-pesticidal products that include active ingredients effective against public health organism in other products in order to function as a pesticide without obtaining an EPA registration.

EPA further expands the definition of a public health pesticide in § 158.2203 (b)(5)(ii) by stating that other pesticide products that may be similar in composition to a public health product will be considered a public health product. How will EPA define "similar in composition"? This language leaves room for arbitrary determinations that a currently non-FIFRA regulated product may now be considered a public health pesticide without taking into account the function of the product ingredients relating to the product application. Again, EPA does not address the comments that were received in regards to the 1999 regulatory proposal and why the Agency feels these policy decisions are necessary for inclusion in the current proposal.

CSPA feels EPA should not include fundamental policy changes in a regulation that is meant to outline data requirements for registration. In particular, EPA should not change the long standing statutory definitions for disinfectant and sanitizer in order to classify any product containing those terms as public health pesticides. If EPA intends to modify statutory definitions and/or long standing policies, it should provide justification and specific information to support

the need to make such changes. EPA needs to include this justification when this rule is re-proposed.

d. EPA Should Require Higher-Tiered Testing Requirements Only If Exposure Data Justify Imposing Such Requirements

When they become effective, EPA's Subpart W Data Requirements for antimicrobials will apply to three types of registration actions: 1) an application for registration of a new product that contains an antimicrobial active ingredient that is not included in any currently registered product; 2) an application for a new product that includes the addition of an antimicrobial use pattern that is not currently registered for one or more active ingredients contained in the product, and 3) an amendment of a registration of a product that includes the addition of a use pattern that is not currently registered for one or more active ingredients contained in the product.

EPA's Subpart W data requirements propose 12 use patterns for antimicrobial pesticides. The Agency has stated that it will consider some uses as high human exposure when they result in significant repeated human exposure over a considerable portion of the human life span. As explained below, we urge EPA not to prejudge the exposure classification of any antimicrobial use except for classifying a use as a food use. When EPA implements the new Subpart W data requirements for a nonfood use of an antimicrobial, we urge EPA to impose the higher tiered data requirement only after reviewing exposure data on an antimicrobial and, together with the applicant or registrant, determining whether higher tired data are scientifically justified.

e. EPA's Economic Analysis Fails To Consider the Costs of Registration Review

EPA's economic analysis considers the cost of Subpart W for registering new active ingredients, new products and amending products. Importantly, it fails to consider the impact of Subpart W on existing registrants, even though the Agency could presently estimate the data gaps for existing antimicrobials arising out of Subpart W. (Economic Analysis at ¶ 2.5). This is a fundamental and fatal flaw in the Agency's Economic Analysis. Instead, EPA contends that "[s]takeholders and the public have opportunities for input, consultation and involvement concerning individual pesticide cases throughout the registration review process." Once EPA adopts final Subpart W data requirements, however, these requirements will serve as the benchmark for identifying data gaps during EPA's registration review, just as Part 158 served as the benchmark for identifying data gaps during reregistration for conventional chemicals. The real cost and impact of Subpart W will be felt by the industry during registration review, and EPA must evaluate and weigh these costs now, not later during registration review.

II. Product Performance/Efficacy

The expressed reason for the Agency proposing this rule in 40 CFR subpart W of part 158 is that "revisions are needed to reflect current scientific knowledge and current Agency regulatory practices." (Federal Register/Vol. 73, No. 196 Oct 8, 2008/Proposed Rules, p.59382.) It is also stated that "EPA agrees with HHS that both current antimicrobial pesticide registrants and applicants seeking an antimicrobial registration should understand the applicability of the proposed data requirements, once promulgated." (p.59426)

To that end, the members of CSPA strongly object to promulgation of 40 CFR Part 158 subpart W in absentia of the finalized 810 guidelines. The antimicrobial product performance requirements table provided on page 59432 of the Proposed Rule refers to the guidelines which were proposed in 1991 and to date have not been published and have never been finalized. The 91 guidelines do not "reflect current scientific knowledge and current Agency regulatory practices." CSPA worked jointly with the Agency to develop the following proposed guidelines:

- 810.2000 – General Considerations
- 810.2100 – Sterilants
- 810.2200 – Disinfectants
- 810.2300 – Sanitizers

The last drafts of the above guidelines available to CSPA for consideration are from early 2006. The Agency has stated that these referenced 810 guidelines will publish in draft 1st quarter of 2009 with a 60-day comment period.

In addition, there are several outstanding 810 guidelines which are either in draft form and/or have not yet been drafted. CSPA encourages the Agency to collaborate with Industry to develop these outstanding guidelines building upon the successful endeavor for the development of the 810.2000, 2100, 2200 and 2300 guidelines. It is CSPA's position that this proposed 40 CFR Part 158 rule cannot be promulgated until all 810 guidelines are published and finalized.

Furthermore, the Page 59386 IV A introduces data requirements for the proposed regulation; capturing public health but with no mention of non-public health. This is a serious omission on the part of the Agency. While Agency policy does not require submission of non-public health data, registrants are required to develop data to substantiate label claims. It is the position of CSPA that a definition, data requirements and product labeling instructions are necessary for a non-public health claim (i.e. odor-causing bacteria).

Under Product Performance §158.2220 (a) (1) it states that "The Agency may require, on a case-by-case basis submission of product performance data for any pesticide product registered or proposed for registration". Either under this section or as a footnote to the table, EPA should insert the portion of the footnote relevant to antimicrobial pesticides that is currently found at § 158.640.[1]

[1] § 158.640 footnote 1 states "The Agency has waived all requirements to submit efficacy data unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health, and whose presence, cannot readily be observed by the user including but not limited to microorganisms infectious to man in any area of the inanimate environment... However, each registrant must ensure through testing that the products are efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration.

a. **Comments on Proposed Definitions:**

The definitions provided on page 59431 section 158.2203 are inconsistent with the FIFRA § 4(i)(4)(C)(i, ii, iii)) and with the definitions that were provided in comments on the draft 810.2000 guideline submitted by CSPA to the Agency in February of 2006. CSPA strongly recommends that the Agency avoid using different definitions of terms which are defined in the statute.

Instead, CSPA recommends that the definitions provided in the Proposed Part 158W rule be replaced with the following comprehensive list of definitions. These definitions were previously provided to EPA in the draft 810.2000 guideline dated February 16, 2006.

Algicide means any substance, or mixture of substances, intended to kill the number of algae in water.

Algistat means any substance, or mixture of substances, intended to inhibit the increase of algal populations. (ASTM E35.15 Draft)

Antibacterial means any substance, or mixture of substances, intended to destroy, eliminate, reduce, mitigate or control the growth or development of bacteria in the inanimate environment.

Antifoulant means any substance, or mixture of substances, intended to prevent the biological fouling of underwater structures.

Antimicrobial Pesticide means a pesticide [substance or mixture of substances] that is intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms; or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime (FIFRA § 2 (mm)).

Antiseptic means a drug product applied topically to the skin to help prevent infection or to help prevent cross contamination (FDA Tentative Final Monograph for Healthcare Drug Products, 1994). Antiseptic products are applied on or in the living body of man or other animals. Antiseptic products are not identified as pesticides and are regulated by the Food and Drug Administration.

Aseptic means free of microbial contamination consistent with FDA 21 CFR 178 for commercial sterilants for aseptic food packaging.

Bacteriostat means a substance, or mixture of substances, intended to inhibit the growth of bacteria in the presence of moisture. (FIFRA § 4(i)(4)(C)(ii))

Biofilm means a dynamic, self-organized accumulation of microorganisms and environmental by-products immobilized on a substrate and embedded in an organic polymer mix (ASTM E35.15 Draft). This organic polymer mix is also known by the term "glycocalyx".

Biocide means any substance, or mixture of substances, intended to reduce the number of living microorganisms (e.g., virucide-virus, mycobactericide-mycobacteria, algicide-algae; bactericide-bacteria; fungicide-fungi; slimicide-slime-forming microorganisms). (see also "microbicide.")

Confirmatory data means a reduced set of data which may be used to support an application or amendment for registration of a product, or a minor formulation change of a registered product.

Deodorizer means a substance, or mixture of substances, that are of two basic types: (1) Those that intended to prevent, reduce, or delay the formation of odors by acting upon micro-organisms which produce them, and (2) those that intended to mask, chemically destroy, or neutralize odors. Products that claim deodorization by antimicrobial means are subject to registration as pesticides.

Disinfectant means a substance, or mixture of substances, intended to destroy or irreversibly inactivate bacteria, fungi, or viruses on surfaces or inanimate objects (FIFRA § 4(i)(4)(C)(iii)).

Fungicide means a substance, or mixture of substances, intended to destroy fungi (including yeasts) and/or fungal spores.

Fungistat means a substance, or mixture of substances, intended to inhibit the growth of fungi in the inanimate environment.

Microbicide mean any substance, or mixture of substances, intended to reduce the number of living microorganisms (e.g., virucide-virus, mycobactericide-mycobacteria, algicide-algae; bactericide-bacteria; fungicide-fungi; slimicide-slime-forming microorganisms). (See also "biocide.")

Microbiological water purifier means any unit, water treatment product or system intended to remove, kill or inactivate disease-causing microorganisms from the water, including bacteria, viruses and protozoan cysts so as to render the treated water microbiologically safe for drinking.

Microbistat means a substance, or mixture of substances, intended to control or temporarily prevent the growth of microorganisms (e.g., bacteriostat, fungistat, algistat).

M*ycobactericide* means a substance, or mixture of substances, intended to destroy or irreversibly inactivate mycobacteria in the inanimate environment.

One-Step Sanitizer/Disinfectant means a substance or mixture of substances intended to be effective in the presence of light to moderate soil without a preclean step in the use directions.

Preservative means a substance, or mixture of substances, intended to inhibit the growth of microorganisms capable of causing biological deterioration of a substance(s)/material(s).

Sanitizer means a substance, or mixture of substances, intended to reduce the number of microorganisms on inanimate surfaces, in water or air (FIFRA § 4(i)(4)(C)(i)).

Slime means a dynamic, self-organized accumulation of microorganisms and environmental by-products immobilized on a substrate and embedded in an organic polymer mix (ASTM E35.15 Draft). This organic polymer mix is also known by the term "glycocalyx".

Slimicide means a substance, or mixture of substances, intended to reduce the number of slime-forming microorganisms.

Sterilant means a substance, or mixture of substances, intended to destroy or eliminate all forms of microbial life in the inanimate environment, including all forms of vegetative bacteria, bacterial spores, fungi, fungal spores, and viruses.

Sporicide means a substance, or mixture of substances, intended to irreversibly inactivate bacterial spores in the inanimate environment.

Tuberculocide means a substance, or mixture of substances that destroys or irreversibly inactivates tubercle bacilli (e.g. *Mycobacterium*) in the inanimate environment.

Two-Step Sanitizer/Disinfectant means a substance or mixture of substances that has not been tested in the presence of soil. The sanitizer/disinfectant use directions must state the need to preclean surfaces prior to sanitizing/disinfecting.

Virucide means a substance, or mixture of substances that destroys or irreversibly inactivates viruses in the inanimate environment.

If all of the definitions provided above are not accepted 'as-is', CSPA requests that the use of the terms "sanitizer" and "disinfectant" provided on page 59431 be referenced in terms of efficacy level and not by target organism or intended application. This is consistent with section (2) on page 59431 which states "a claim is made for the pesticide products as a sterilant, disinfectant, virucide, sanitizer, or tuberculocide regardless of the site of use of the product, and regardless of whether specific microorganisms are identified."

b. <u>EPA's Proposal to Restrict the Term "Sanitizers" and "Disinfectants" to Public Health Antimicrobials is Inconsistent with FIFRA.</u>

CSPA recommends clarifying the term "sanitizer" and "disinfectant" to include both public health and non-public health antimicrobial pesticides. (Page 59431 Proposed 158.2203).

With EPA proposing new definitions for the terms "disinfectant" and "sanitizer" (that are inconsistent with statute), the proposed part 158 advocates the view that the term "disinfectant" inherently implies public health uses and should not be used on non-public health antimicrobials.

A sanitizer or a disinfectant is defined in terms of killing microorganisms on the surface it is applied. It is not defined by the types of microorganisms that are killed. It is a level of efficacy independent from whether or not the targeted microorganism is public health or non-public health.

Products shown to be effective against non-public health microorganisms with the level of efficacy used to define the term "sanitizer" or "disinfectant" cannot be called a "sanitizer" or "disinfectant" leaving such a product without proper identification. The current term being offered by EPA is "antimicrobial treatment". Using "antimicrobial" in this context conflicts with other EPA guidance, PR Notice 2000-1 states EPA believes the claim "antimicrobial," is inconsistent with the intent of 40 CFR 152.25(a) if it is not properly qualified as to its intended non-public health use.

This is also problematic when registering antimicrobial pesticides in California. California has determined that the term "antimicrobial" suggests a higher level of efficacy that include both "disinfectant" and "sanitizer". Industry must be able to register their antimicrobial pesticides in the states in order to sell them. When EPA and California take an opposite position on a given issue, the situation for the registrants becomes untenable; therefore we need EPA to establish clear definitions.

c. Products That Are Similar in Composition to a Registered Public Health Antimicrobial Do Not Meet the Criteria to be Classified as Antimicrobial.

Part 158.2203(b) lists several criteria that the Agency will apply in determining if a product makes a public health claim. This includes products that are similar in composition to a registered pesticide product that makes explicit health claims. (158.2203(b)(5(ii)) There are several interpretations of this definition of public health claims. One interpretation is that a non-registered, non-pesticidal product that is similar in formulary composition to a public health pesticide is also a public health pesticide. The criteria for determining if a product must be registered are provided in 40 CFR 152.15 and non-pesticidal products are not within OPP's jurisdiction. EPA must take into account the function of the product ingredients relating to the product application. This section should be clarified with "This does not apply to products that are not registered antimicrobials but use active ingredients that have been designated as having antimicrobial uses in the other registered products."

d. Comments on Data Requirements/References

The Antimicrobial Product Performance Data Requirements Table on page 59432 referencing the 91 guidelines which have never been finalized and are not publically available. As noted previously in our comments, we do not believe that it is appropriate to move forward with Part 158W until all 810 Guidelines are final. When the 810 Guidelines are complete CSPA recommends the table below, which references the 810 guidelines, replace the table currently in the Proposed Part 158W Rule.

Guideline Number*	Data Requirement (Based on Use-Site/Claim Desired)
810.2000	General Considerations
810.2100	Sterilants
810.2200	Disinfectants
810.2300	Sanitizers
810.2400	Textiles
810.2500	Air Sanitizers
810.2600	Waste
810.2700	Water
810.xxxx	Mold
810.xxxx	Biofilm
810.xxxx	Fruit/Vegetable Rinse
810.xxxx	HVAC
810.xxxx	Medical Waste
810.xxxx	Treated Articles (Public Health Claims)
810.xxxx	Other

*Numbering system may vary depending on how EPA approaches the guidelines

At this time, none of the 810 guidelines above are finalized and only 810.2000, 810.2100, 810.2200 and 810.2300 are being prepared for publication for comment this fiscal year. In the absence of 810 guidelines for each of the use-site/desired claim sets provided in the table, a non-level playing field is created. A most recent example is the registration of copper alloys with public health claims, but no guidance has been provided to registrants for how such claims can be achieved on treated articles. CSPA cannot support a proposed rule until there are finalized data guidelines in place for reference.

III. Residue Chemistry Data Requirements

EPA has proposed to adopt the basic residue chemistry data requirements as listed in Subpart O of current part 158 to support applications for antimicrobial products. However, EPA also has proposed to modify the applicability of those requirements to reflect differing risks and levels of exposure of antimicrobials. EPA uses residue data to determine the dietary risk exposure to pesticide residues from food. If there are no food uses for the antimicrobial, then no residue chemistry is required.

While EPA has stated that these proposed changes will allow EPA to better estimate human dietary exposure to ensure that food entering the commercial market meets the "reasonable certainty of no harm" standard under FFDCA, CSPA members challenge that some of these changes will allow for a "better" estimate of human dietary exposure and that the Agency has extended their authority beyond their jurisdiction..

There remains a great deal of confusion regarding areas of responsibility between EPA and FDA regarding antimicrobial substances with direct and indirect food contact uses. This requires

careful attention to EPA's statutory authority to require the setting of tolerances or exemptions from food tolerance under section 408 of FFDCA. There need to be very explicit definitions and guidance regarding antimicrobials under the jurisdiction of EPA. In the wake of FQPA, ARTCA was enacted to return jurisdiction over certain residues on processed Raw Agricultural Commodities (RAC) to FDA. However there remains ongoing confusion about antimicrobials applied to process water and RAC's. Subsequent to ARTCA, The Antimicrobial Food Additives Guidance (July 1999) was developed and published to provide additional clarity to many of the confusing issues such as what constitutes food processing and how a food processing facility is defined. The Guidance document provides additional explanation of the jurisdictional agreement between EPA and FDA. In addition, several of the past Antimicrobial Workshops provided extensive presentations based on the clarity provided thru the FDA Antimicrobial Food Additives Guidance Document.

In addition, the draft Rule for Registration Requirements for Antimicrobial Pesticide Products proposing changes to 40 CFR Part 152 and 158 and published in 1999, provided a chart which was consistent with the agreements reached through the Antimicrobial Food Additive Guidance document. In recent years, Industry has met with EPA management to discuss ways to further streamline the approval of food use antimicrobials under EPA and FDA jurisdiction. It is critical that the Agency look to the statute to ensure that any proposal to require a 408 clearance is clearly within the Agency's statutory authority to require a tolerance or exemption from food tolerance. Now is the time to provide clarity through a more detailed description as to the Residue chemistry data requirements by providing specific examples which would help to alleviate the continued confusion to EPA, industry and local and state Health Department Inspectors.

Another clarifying issue that needs to be addressed in this section is a reference to the pre-FQPA policy that a 409 clearance is sufficient for a 408 clearance for direct and indirect food additives. The clarification of this policy in the data requirements will assist in streamlining the approval of products. This should be in the preamble of the section instead of being footnoted.

§ 158.2990 Residue Chemistry Specific Comments

(a) General. – This section references the Antimicrobial Use Patters in § 158.2201. CSPA references and supports the comments proposed by the Biocides Panel in regard to relevant use patterns for antimicrobials and suggested revised footnotes in section f (test notes). Please see those specific comments in regards on how the table would be used.

(b)(1)(i) – The statutory authority to regulate products used to clean and/or sanitize eggs is unclear. To the extent that eggs are intended for processing, any product used to sanitize the shells is outside the scope of FIFRA. Until such time that EPA can clarify its statutory authority under FIFRA and/or under FFDCA Sec 408, the CSPA believes that all such uses are outside of both and should be excluded from any consideration under this proposed regulation. Also, there needs to be clarification that these direct uses are for fruit and vegetable washing for RACs and that drying, shelling and husking of RACs does not constitute processing as explain in the 1999 Antimicrobial Food Additive Guidance Document issued by FDA. The Guidance document is clear that these activities do not constitute processing and antimicrobials applied to RACs in the field, in a washing facility where no further processing occurs, or in transportation is under EPA

jurisdiction and requires a FFDCA 408 clearance for clarification purposes. Conversely, antimicrobials applied to RACs in a food processing facility may require a FIFRA registration as a pesticide and an FDA 409 FFDCA clearance.

(b)(1)(ii) – Non Exempt Treated articles should be removed from this section for clarification purposes. An additional section is recommended to be added to (b)(1) and to the section (f) table to provide a clear way to determine criteria for articles. This section should be strictly devoted to indoor commercial and institutional uses on hard surfaces.

Section 408 of FFDCA requires the establishment of a tolerance or exemption from food tolerance for pesticide chemical residues when pesticides are applied to foods and which will be in "interstate commerce". EPA stated at the 8th Annual Antimicrobial Workshop, that the requirements for a tolerance or exemption from food tolerance for antimicrobials applied in the home were not applicable. EPA based this statement on that food in household setting is not in interstate commerce and therefore does not require the establishment of a tolerance or exemption from food tolerance for formulation components comprising a hard surface disinfectant or sanitizer. EPA went on to state that although tolerance or tolerance exemption setting is not required due to the interstate commerce issue, that the Agency would require a dietary assessment to ensure any remaining residues are addressed from a dietary/safety standpoint. CSPA agrees with this approach and concurs that tolerance or exemption from tolerance setting is not required for hard surface antimicrobials used in residential settings.

(c) Definitions of low toxicity of the active ingredient or theoretical estimates of dietary exposure need to be clarified.

(e) and (f) – Table/Footnotes, see attachment 1.

IV. Comments on Toxicology Data Requirements

This section shares with EPA CSPA's comments on EPA's proposed Antimicrobial Toxicology Data Requirements. (40 C.F.R. § 158.2230). The introduction first reviews CSPA's concerns over EPA's high/low human exposure use criteria and proposes that EPA differentiate between first and second-tier testing of antimicrobial based on their food or nonfood use. CSPA then offers its comments and suggestion on particular toxicology requirements and some of the accompanying 37 test notes.

EPA's Antimicrobial Toxicology Data Requirements, in the main, adopt the Agency's Toxicology Data Requirements for conventional pesticides.[2] The Agency's March 11, 2005 Notice of Proposed Rulemaking for its toxicology requirements for conventional pesticides explained the purpose of toxicology data: "Toxicology studies are required by the Agency to assess the hazard of the pesticide to humans and domestic animals. These hazard data, when combined with exposure data, form the basis for the human risk assessment ... The duration of the toxicity study approximates the estimated duration of human exposure ... If a pesticide is

[2] EPA published its toxicology data requirements for conventional pesticides in the Federal Register on October 26, 2007. (72 Fed. Reg. 60934). They are codified now at 40 C.F.R. § 158.2230.

used on food and requires a tolerance, the dietary exposure may be over a lifetime, and thus chronic/cancer and multi-generation reproductive studies would be required."[3]

The Agency's proposed antimicrobial Toxicology Data Requirements raise two principal issues: 1) for antimicrobials, what are the scientifically appropriate criteria for differentiating among first, second and third tiered testing? 2) Within each tier what studies are reasonable and appropriate in light of the toxicity of antimicrobials and likely and realistic human exposure to antimicrobials?

a. CSPA Urges EPA To Differentiate Between First and Second Tier Testing of Antimicrobials On The Basis of Food/Nonfood Uses Rather Than High/Low Human Exposure Uses

For conventional pesticides EPA determined that the typical nonfood pesticide presents only limited opportunities for significant repeat or lifetime human exposure, while residues resulting from the agricultural uses of pesticides on food and feed present opportunities for lifetime dietary exposure. While the use criteria separating the first and second-tier testing for conventional pesticides -- food/nonfood -- makes scientific sense and are susceptible to consistent and systematic application by EPA, the Agency's counterpart use criteria for antimicrobials -- high/low -- makes less sense, as explained below.

The Agency's definition of "high" human exposure differs in material ways from its counterpart for conventional pesticides:

b. EPA's Proposed Definition of "High" Human Exposure Uses for Antimicrobials (§ 158.2230(b)(1)):

"[H]igh human exposure includes those uses which are likely to result in human exposure over a considerable portion of the human lifespan, and which are significant in terms of frequency, duration, or magnitude of exposure (i.e., uses for which there is an expectation of high, prolonged, or repeated exposure). ..."

EPA derived its definition of high human exposure antimicrobials from criteria it adopted in 2007 for determining when a registrant or applicant of a conventional nonfood pesticide must submit to EPA a chronic rat study (note 17) and/or a mouse oncogenicity study (note 20). The criteria in note 17 and note 20, however, materially differ from EPA's proposed "high human exposure use" definition for antimicrobials.

c. EPA's Note 17 accompanying § 158.500 (first of two criteria for requiring a chronic rat study for nonfood use conventional pesticide):

"The use of the pesticide is likely to result in **repeated** human exposure over a considerable portion of the human lifespan, as determined by the Agency; ..."

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[3] 47 Fed. Reg. at 12292.

d. EPA's Note 20 accompanying § 158.500 (first of three criteria for requiring a mouse oncogenicity study for nonfood use conventional pesticide):

"The use of the pesticide is likely to result in **significant** human exposure over a considerable portion of the human life span which is significant in terms of frequency, duration, or magnitude of exposure."

Not only is EPA's proposed definition of a high human exposure use for an antimicrobial missing the important and instructive qualifiers "repeated" and "significant" before "human exposure," but the "i.e." parenthetically following the Agency's definition of "high human exposure use" -- through its use of the disjunctive "or" -- incorrectly implies that EPA may classify an antimicrobial use as "high" and trigger second and third-tier toxicology testing on the basis of a single high exposure, rather than repeated and frequent exposure for additional subchronic studies and significant lifetime exposure for additional chronic studies.

The second limitation of the Agency's high/low dichotomy is that, after attempting to define "high" exposure use, EPA then arbitrarily places certain uses of antimicrobials in the high category in the absence of any data demonstrating that exposures from these uses meet the criteria that divides first and second-tier testing -- whether an antimicrobial's use in fact is likely to result in repeated or lifetime exposure, even though the Agency's Part 158W proposed antimicrobial data requirements will require applicants and registrants to submit applicator (§ 158.2260), post-application (§ 158.2270) and residue chemistry (§ 158.2290).

In using this approach, the Agency has not adequately defined the basis for its determinations, has not adequately addressed the unique exposures associated with antimicrobial pesticides, and has not taken into account the requirements of FIFRA 3(h). CSPA submits that it is mistaken to require higher tier testing of antimicrobials without first determining that there is exposure such that further information is needed to determine whether the risk is acceptable.

EPA's 200 ppb Benchmark for Residues of Indirect Food Uses of Antimicrobials: EPA proposes to treat "[i]ndirect food uses with residues equal to greater than 200 ppb" as "high' human exposure uses. CSPA concurs with the approach of using a particular value as a benchmark for separating first and second-tiered testing of antimicrobials, and believes that such an approach is consistent with EPA's "Threshold of Regulation Policy" (PR Notice 2002-2) and that it is supported by the FIFRA SAP Panel recommendations of June, 1997.

While CSPA supports the use of a benchmark, we are uncertain if that value is 200 ppb and urge the Agency to adopt a scientifically sound benchmark that reflects FDA's approach to calculating an estimated daily intake (CEDI) value which is more than one-time "residue" value. Moreover, FDA's value of 200 ppb is based on its premise that biocides are "toxic" and that a 5x safety factor is justified. Any value should be based on real data and not assumed toxicity. See, "Guidance for Industry: Preparation of Food Contact Notifications and Food Additive and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations." The CEDI is a cumulative daily exposure value, not a "residue". As noted below, CSPA recommends that EPA adopt a food/nonfood criteria for separating first and second-tiered testing requirements instead

of high and low exposure, in which case EPA would treat CEDI's of less than the benchmark as nonfood uses.

To address the above limitations CSPA proposes that EPA substitute food/nonfood for its proposed high/low paradigm for antimicrobials. The CR notes for higher tiered studies for nonfood uses of antimicrobials should then reflect scientifically reasonable and appropriate criteria for requiring higher tiered testing of nonfood antimicrobials.

1. In the preamble to the proposed rule, EPA indicates that it may require the testing of the most concentrated use-dilution for biocide concentrates. Testing may be required if the Agency believes that the use dilution may result in "significant exposure."[4] Test note #2, however, indicates that use-dilution testing is optional and at the discretion of the registrant. The Agency needs to reconcile their guidance on this matter. CSPA recommends that testing of the use-dilution of biocide concentrates remain at the discretion of the registrant. Alternatively, the Agency needs to clearly define "significant exposure" and rewrite test note #2 in order to provide clear guidance to registrants.

2. In the Label Review Manual (Chapter 7, Section IVA), the Agency allows for extrapolation of acute systemic toxicology data on product concentrates to use-dilutions. This guidance should be referenced as an alternative to requiring additional animal testing for use-solutions. The guidance will need to be updated to reflect adoption of the Up/Down test for acute oral toxicity. The Agency will also need to work with some states (e.g. California) to obtain their acceptance of this approach before this is enacted. Again, we would like to reiterate that the industry must be able to register their pesticides in the states in order to sell them. When EPA and California take opposite positions on a given issue, the situation for the registrants becomes untenable.

3. Test note # 2 does not currently apply to acute inhalation studies. It is not clear whether the omission is an oversight by the Agency or was an intentional exclusion. CSPA believes that registrants must have the opportunity to assess the inhalation toxicity potential of use-dilutions in order accurately label concentrated products.

   Many biocidal products are corrosive concentrates that are intended to be diluted prior to use. Current Agency practice requires inhalation toxicity testing on the concentrate. If classified in Toxicity Category I or II for inhalation toxicity, significant precautionary labeling and protective equipment (e.g. respiratory protection) is required.

   Once diluted, however, these products typically have a much different toxicity profile. In some segments, concentrates are diluted up to 1:1024. The labeling and PPE requirements for the concentrate can be inappropriate for the use-dilution. The PPE requirements for many concentrates are also inconsistent with common practice. For

[4] Federal Register, 73(196), 10/8/2008, p. 59394- "EPA proposes to add a test note to clarify that the currently required six acute toxicity studies are to be conducted on the product as formulated for sale and distribution. The six acute studies ***may also be needed*** for the product as diluted for use. Many antimicrobial products are diluted at the point of use, but can still lead to significant exposure."

example, it is not practical to train janitorial staff to use respiratory protection when handling diluted sanitizers or disinfectants in schools or healthcare facilities.

In these situations, registrants must be given the discretion to test the inhalation toxicity of the use-dilution in order to justify appropriate precautionary labeling and PPE requirements for the use-solution.

4. Test note #2 specifies that the "six acute toxicity studies conducted with the end-use product... must be conducted with the product formulated for sale and distribution." While CSPA essentially agrees with the Agency position on this issue, we recommend the following clarifications:

    i. The current wording of test note #2 may be perceived as prohibiting proper conduct of studies for dermal sensitization. These protocols require dilution of the test product in order to identify doses that distinguish between irritation and allergy. The irritating or corrosive natures of many antimicrobial formulations preclude testing the "product as formulated for sale and distribution" in these studies.

    ii. Secondly, there are instances where it may not be possible to test the formulated product in a humane manner. The wording of test note #2 should provide for some flexibility to allow for modification of the test material on a case-by-case basis.

        For example, in the dermal toxicity test, corrosive materials can cause significant skin injury during the 24 hours of exposure required by the study. While the study can be waived, in the absence of data, the Agency will classify the product in Toxicity Category I, require skull and crossbones and mandate the statement "Fatal if absorbed through skin." For corrosive materials, with no significant systemic toxicity, this approach can result in inaccurate labeling.

        In these instances it can be desirable to dilute the product to reduce the amount of irritation while maintaining the same overall dose of the test material. (e.g. the test product could be diluted by 50% and dosed at 10 g/kg vs. 5 g/kg). In some cases, this approach can allow the study to go forward while reducing unnecessary stress to the test animals. Of course, such procedural changes must be the exception and subject to approval by Agency toxicologists.

Therefore, CSPA recommends that FN 2 be modified as follows:

"For the six acute toxicity studies conducted with the end-use product, the test must be conducted using the product as formulated for sale and distribution except as required by study protocols or a variance is granted after consultation with the Agency".

5. Registrants and the Agency both have the desire to reduce the need for unnecessary animal testing. The increased use of bridging and study waivers can significantly reduce the number of toxicity studies that are needed to support antimicrobial registrations. Unnecessary toxicity testing imposes a significant financial and resource burden on both the registrants and the Agency. Registrants shoulder the direct cost to pay for the studies and the Agency has to dedicate resources to review the studies after submission. In addition, these studies also require the use of a significant number of experimental animals; one "six-pack" can require 70-75 test animals.

   In 2007, the ACC Biocides Panel proposed to the Agency a framework for capturing the Agency's past guidance on these topics and improving their use and acceptance.[5] CSPA requests that EPA complete their review of and implement the recommendations in the ACC Biocides Panel Framework Document. We also recommend that the Agency add a new test note that accepts waiver and bridging principles as appropriate methods to satisfy all acute toxicity data requirements.

6. There is confusion between the statement that EPA may require the testing of the most concentrated use-dilution for biocide concentrates, but in footnote 2 EPA indicates that use-dilution is optional. This apparent inconsistency requires clarification.

7. In both the preamble and in footnote 2, the Agency states that "consultation with the Agency is highly suggested to assure that the appropriate product and any appropriate dilutions are tested." CSPA believes that consultation should not be needed prior to conducting routine acute studies and that the Agency needs to clarify under what circumstances they feel that consultation is needed.

V. Human Exposure

CSPA applauds the Agency's consideration of surrogate data where appropriate. This not only conserves resources but provides consistency in assumptions and estimates when conducting risk assessments.

We are concerned that the guidance provided in the draft about toxicity and exposure triggers are so vague that the registrant would be at a loss in determining if additional data would be required or not. It is suggested that the Agency provide greater clarity on the toxicity triggers in particular in this section (158.2260 (3) (b)). The manner in which poisoning incident data are used as a trigger should be carefully considered. Often these data can be misinterpreted because they lack critical information regarding the products and the exposures thus leading to erroneous conclusions regarding the toxicity and hazards associated with a particular active ingredient.

It is important the Agency clarify the difference between applicator-, bystander- and post-application exposures as the risks associated with each of these situations can be very different. In particular, bystander and post-application exposures must be clearly delineated.

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[5] Framework for Acute Toxicity Waiver and for Acute Toxicity Bridging for Antimicrobial Pesticides. AMERICAN CHEMISTRY COUNCIL-Biocides Panel. September 17, 2007. Updated October 30, 2007.

Regarding post-application data requirements, the Agency should review its guidelines in light of antimicrobial product uses. The use of the Indoor surface residue dissipation data (guideline number 875.2300) could provide critical lead information obviating the need for additional dermal/inhalation exposure. Such information would be particularly useful in the consideration of HVAC&R uses.

It is essential that all of the applicator and post application guidelines be proposed and finalized for these requirements. Without guidance, these requirements could be highly subjective. Guidance that establishes the scope of these requirements is critical to assuring that there is consistent and reasonable implementation of these requirements.

In spite of the lack of direct guidance in the antimicrobial arena, the Antimicrobial Division of OPP has worked successfully with the Antimicrobial Exposure Joint Venture (AEJV) to develop product use and usage data collected in an observational manner. These studies consisted of in-home observations of informed/consented consumers with respect to their use of products present in their household inventory and prospective diary survey instruments provided by informed/consented consumer participants. Additionally, some surveys were recall studies which did not involve product usage. Since these data have been generated by AEJV and submitted and used by the Agency, we encourage the Agency to incorporate similar survey tool recommendations in their product use guidelines, particularly in those areas where AEJV data would not suffice.

The AEJV has worked with the Antimicrobial Division to maximize the value and utility of product use/usage data through the use of personal computer- or web-based, front-end data mining software tools (e.g., notitia™ - see www.infoscientific.com). These software tools offer powerful and user-friendly data and model management capabilities. Product use/usage data and associated "meta" information can be stored and effectively accessed and analyzed in numerous ways. Product use/usage data can also be readily applied in modeling algorithms, e.g., exposure assessment equations which include product use parameters. Desirable software features for utilizing product use/usage include viewing data in a grid format, decoding coded fields with either text descriptions or graphical representations, determining unique values in each field, querying based on structured queries, or simple text and phonetic searches, generating simple summary statistics, generating simple graphs, exporting data to familiar formats, printing data tables, using customized analytical tools (e.g., to determine the co-occurrence of multiple product use events containing an active ingredient of interest during a specified time frame that is of toxicological relevance), accessing files in local area networks and via the Internet. Desirable features of model-related functions include using a standardized approach to running models (e.g., exposure assessment standard operating procedures), constructing intuitive, icon-based collection of modules in which product use/usage data can be linked and applied, viewing model inputs through tables and customized pick lists, and viewing modeling outputs through tables, graphs, and reports.

Conclusion

CSPA appreciates the opportunity to comment on the proposed 158 W regulations. The proposed regulation refers to numerous guidance documents that are not in existence. Without those documents we are unable to provide complete and thorough comments. It is not appropriate to move forward with finalizing this proposed regulation until such time that appropriate guidance documents have been developed, vetted for public comments and published in final form.

Sincerely,

Brigid D. Klein

Brigid D. Klein
Vice President & General Counsel

Table - Antimicrobial Residue Chemistry Data Requirements

Testing Guideline Number	Data requirement	Food Use Pattern					Test substance	Footnote
		Aquatic Use for Antifouling & Aquaculture Production - Indoor/Outdoor	Raw Agricultural Commodities - Indoor/Outdoor	Commercial & Institutional Hard Surfaces - Indoor	Residential Hard Surfaces* - Indoor	Non-Exempt Treated Articles - Indoor		
Supporting Information								
860.1100	Chemical Identity	R	R	R	R	R	TGAI	
860.1200	Directions for Use	R	R	R	R	R	----	
860.1550	Proposed tolerance	R	R	R	NR	R	PAI & residue of concern	
860.1560	Reasonable grounds in support of petition for tolerance or exemption	R	R	R	NR	R	----	
860.1650	Submittal of analytical reference standards	CR	CR	CR	NR	CR	PAI & residue of concern	1
Tier 1								
	Screening level dietary exposure assessment	R	R	R	CR	R	----	2, 7, 8
Tier 2								
	Refined dietary exposure assessment	CR	CR	CR	CR	CR	TEP	2, 4, 9
Tier 3								
	Nature of residue on surface	NR	CR	CR	NR	CR	PAIRA or TGAI	1, 4, 6
	Bioaccumulation	CR	CR	NR	NR	NR	TGAI, PAI, degradate	1, 4
	Magnitude of residue	CR	CR	CR	NR	CR	TEP	1, 3, 4, 5
860.1340	Residue analytical method	CR	CR	CR	NR	CR	Residue of concern	1, 4
860. 1380	Storage Stablity	CR	CR	CR	NR	CR	TEP or residue of concern	1, 3, 4

* A 408 Tolerance Assessment is NOT required for residential food use patterns. The applicability of a dietary assessment for residential use products will be determined on a case by case basis by the

1 Not Required if exempt from tolerance provided the dietary exposure is not needed due to low toxicity or the theoretical estimates of exposure are adequate to assess dietary risk.

2 Use Appropriate models to estimates exposure by ingestion.

3 Use Appropriate protocols for residue determination.

4 Consult with Agency before conducting Tier 2 or Tier 3 Testing

5 For hard surfaces in commercial, institutional, residential and treated articles this would be a migration study.

6 For aquatic use, nature of residue is determined in the bioaccumulation test.

7 The residue estimate is for the amount leached from the treated surface.

8 Assessment conducted using estimated surface residues.

9 Assessment conducted using measured surface residues from TEP.