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EPN Comments on the Draft Guidance Document Issued By EPA for "Evaluating the Efficacy of Pre-Saturated/Impregnated Antimicrobial Towelettes for Disinfection Claims"

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The Environmental Protection Network (EPN) harnesses the expertise of more than 650 former Environmental Protection Agency (EPA) career staff and confirmation-level appointees from Democratic and Republican administrations to provide the unique perspective of former regulators and scientists with decades of historical knowledge and subject matter expertise.

On November 20, 2024, EPA published a Notice in the Federal Register announcing the opportunity to comment on a draft guidance document, "Evaluating the Efficacy of Pre-Saturated/Impregnated Antimicrobial Towelettes for Disinfection Claims" (Guidance).[1] According to the Notice, researchers should follow a "recently standardized efficacy method for assessing antimicrobial towelettes, identified as ASTM E3363" to "assess efficacy of pre-saturated or impregnated antimicrobial towelettes to disinfect hard surfaces" (disinfecting wipes). Id. According to the Notice, "[t]est method ASTM E3363 provides a consistent means to assess the efficacy of towelettes through the combination of chemical inactivation of the test microbe and mechanical removal of inoculum from a surface." Id. The draft Guidance document appearing in the online docket[2], also describes another efficacy-related study referred to as the "Gravimetric and Wetness Determination." EPA intends to use the results of these two studies to evaluate whether a disinfecting wipe product meets a draft performance standard of 4.5-log reduction in the level of specific types of test microbes over the contact time specified in a product's labeling.[3] The draft Guidance also provides recommended ways of expressing efficacy claims for disinfecting wipes. Id., p. 7.

I. Introduction

EPN thinks that one of the most important responsibilities of EPA's pesticide regulatory program is evaluating the efficacy of pesticide products that make public health claims. To fulfill this responsibility, EPA requires applicants and registrants to conduct studies on the efficacy of such products and to submit the data for EPA to evaluate. In EPN's view, to understand how well public health products like disinfectant wipes work, efficacy studies need to use test methods that reflect how the products are actually used. The testing protocols should also be linked with a product's use directions to increase the likelihood that users will follow application methods that have been determined to provide the requisite effectiveness of these public health products.

Having reliable data on the efficacy of disinfecting wipes is especially important. Hospitals are full of patients who are ill with diseases caused by bacterial and viral pathogens. These patients and hospital staff can inadvertently transmit the pathogens to others in the facility, making them sick and sometimes causing death. These "hospital-acquired infections" (HAIs) are responsible for many deaths annually and impose enormous costs on patients and medical professionals by extending patients' stays in hospitals and requiring

[1] 89 FR 91741.
[2] https://www.regulations.gov/document/EPA-HQ-OPP-2024-0414-0001
[3] Guidance, pp. 3-4

them to receive additional medical care. Infection control specialists think that disinfecting hard surfaces is one way to limit the spread of HAIs and thereby avoid some of these costs and save lives. EPN understands that many environmental services staff in hospitals and other medical facilities rely heavily on the use of disinfecting wipes on hard surfaces as part of their infection control programs. It is important, therefore, that the use of disinfecting wipes be effective at reducing the presence of pathogens to lower the risk of transmission of disease.

EPN supports the effort by EPA to improve the quality of the data used to assess the efficacy of disinfecting wipes, but the approach described in the draft Guidance document fails to account for a critical aspect of such assessment – how disinfecting wipes are actually used. The proposed test methods for measuring efficacy do not reflect the manner in which users deploy disinfecting wipes, and therefore the results of such studies would not provide an accurate basis for predicting whether using a disinfecting wipe will actually disinfect a hard surface. As described more fully below, EPN feels EPA needs to add another type of study that will generate data from typical users on the rates at which the antimicrobial liquid in a disinfecting wipe is deposited on a hard surface wiped with a towelette and how large an area is typically treated with a single towelette. This information will be critical to the development of use directions for the labeling of disinfecting wipes. This information should also be used in the design of gravimetric and wetness determination studies.

EPN's comments are organized in three sections. The first section (section II) describes an additional type of study that should be part of EPA's evaluation of the efficacy of disinfecting wipes, a study that measures users' behavior to determine the typical amount of antimicrobial liquid left on a hard surface that has been treated by a disinfecting wipe, and the amount of surface area that a user will typically treat with a single disinfecting wipe. The second section (section III) addresses methodological aspects of the "Gravimetric and Wetness Determination" study. The third section (section IV) offers comments relating to the proposed performance standard and the content of use directions for disinfecting wipes.

II. Application Rate and Area Treated Determinations

EPA's draft Guidance does not define "a pre-saturated or impregnated antimicrobial towelette." (EPN refers to this kind of product as a "disinfecting wipe.") EPN understands that a disinfecting wipe product consists of two components: a flexible cloth substrate ("towelette") and an antimicrobial liquid containing the active ingredient(s) ("liquid"). The towelette and liquid are packaged in the same container, and when the towelette is removed from its container, it is impregnated or saturated ("wet") with the liquid. Product labeling of currently registered disinfecting wipe products generally directs the user to clean a hard surface and allow it to dry, and then to wipe the surface with the towelette, making the surface wet with the liquid. The use directions also specify the duration ("contact time") that the hard surface needs to remain wet with the antimicrobial liquid to achieve a disinfection level of microbial control[4].

Product labeling typically does not contain particularly detailed instructions regarding how to use the product to disinfect a hard surface. For example, the use directions typically do not indicate how much surface area typically could be treated with a single towelette. Also, typical use directions do not specify whether to "wipe" or "scrub" a surface with a towelette.

In the absence of more detailed use directions, users' behaviors can vary significantly in ways that will affect the "effective application rate," i.e., how much liquid is deposited per unit area on the treated surface. This might happen for several reasons. For example, some users may repeatedly wipe an area, in effect applying

[4] See, e.g., the labeling for "Clorox Disinfecting Wipes," EPA Reg. No. 5813-79.

more than one "coat" of liquid to a treated surface. Thus, users who express the same amount of liquid from towelettes may produce different application rates, to the extent that they wipe different-sized areas with a single towelette. The amount of pressure applied when wiping can also affect the effective application rate. Greater pressure – i.e., scrubbing rather than simply wiping – will release more of the liquid from a towelette. Finally, users may differ in when they think they have used up a disinfectant wipe, i.e., when all (or nearly all) of the liquid has been expressed. To the extent a user continues to wipe with a relatively drier towelette, that user would likely be depositing less liquid on the treated surface than would a user who had discarded the towelette. Collectively, these behaviors are likely to lead to a wide range in individuals' effective application rates.

Differences in users' behavior would obviously produce different amounts of liquid per unit area on the treated surface. EPN thinks the efficacy of a disinfecting wipe will depend in significant part on whether the user puts enough liquid on the treated surface to keep the surface wet for the specified contact time. In fact, when determining the efficacy of a disinfecting wipe product, EPN thinks that both the pressure exerted when wiping a surface and the amount of liquid applied per unit area may be as important, or possibly more important, than the innate antimicrobial activity of the active ingredient(s) or the concentration of the active ingredient(s) in the liquid.

In addition, if these differences have a significant impact on efficacy, it would be important for products' labeling to address them and for EPA to work with infection control programs to provide guidance on training of medical staff on the proper use of the products.

EPN contends, therefore, that it is essential to collect data on actual users' behaviors when they are employing disinfecting wipes to treat hard surfaces. If EPA does not have data to characterize the impact of different application actions on the efficacy of a product, **EPN recommends that EPA require registrants of disinfecting wipes to conduct studies with multiple human participants[5] to see how much area they treat with a single towelette and how much liquid they express from a towelette.[6] If the product is marketed with different substrates for the towelette, each substrate should be tested.[7] The study should also measure the amount of liquid in a towelette when the participant starts and stops using it.[8] Finally, the study should measure the amount of pressure applied by the user of the towelette, i.e., does the user "wipe" or "scrub" the surface. Using these results, the study should also calculate the effective application rate for each participant's trial.**

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[5] EPN recommends that the people who participate in the studies be recruited from the population of environmental services staff who routinely use disinfecting wipes in their jobs at hospitals or other medical settings.

[6] EPN does not know whether a user's effective application rate may differ depending on the composition of the surface being wiped. Because medical facilities will have many different types of hard surfaces, EPN recommends that EPA conduct research in which participants are directed to wipe horizontal surfaces composed of different materials, e.g., stainless steel, porcelain, and laminate. EPA should analyze the resulting data to see whether there are statistically significant differences in the application rates across the different types of surfaces. If so, the application rate study should include treating different types of surfaces.

[7] See comment III. 4.

[8] The towelettes in a package may differ in the amount of liquid they contain. Anecdotally, EPN volunteers who have used disinfecting wipes have noticed that the first several towelettes removed from a package appear to have somewhat less liquid than the ones in the middle of the container, and that the last several towelettes have relatively more liquid than any other towelettes in the package. The difference in "wetness" appears more pronounced when towelettes are packaged in a stack, i.e., like facial tissue, than in a roll, i.e., like toilet paper. The recommended study should also consider whether such variability in the wetness of the towelette changes the effective application rate.

EPN recognizes that the study we are recommending would be "research involving intentional exposure of a human subject," that is subject to EPA's regulations in 40 CFR part 26, subparts K - P.[9] According to these regulations, both EPA and the Human Studies Review Board (HSRB) must review and comment on the acceptability of both the proposed protocols and the final results of such studies. EPN does not anticipate that such HSRB review will be a significant impediment to conducting the recommended research. Participants would be asked to wipe surfaces the way they normally would, their exposure to the test liquid would be in the range experienced by people who routinely use such products. Thus, the research would undoubtedly pose little or no added risk to the participants, compared to non-experimental conditions. Assuming appropriate recruitment practices, an appropriate consent process, and a robust sample size, the studies should be easy to design and should win quick approval. Moreover, EPN thinks the costs of such testing would be relatively modest.

The data generated by the recommended research would be useful both in the conduct of the "Gravimetric and Physical Wetness Determination" and in the labeling of disinfecting wipe products. As discussed in the next section, the amount of liquid applied in the wetness assay should be the typical effective application rate measured in the application rate study. Also, the labeling of disinfectant wipes should routinely include an instruction suggesting the size of the area to be treated with a single towelette. That limitation should be the value generated by the treated area portion of the study.

In sum, because the efficacy of disinfecting wipe products could depend, to a significant degree, on how they are used, EPN believes it is essential for EPA to have data that quantitatively characterizes the size of the area treated and the effective application rate of the typical user who employs a disinfectant wipe to disinfect a hard surface.[10]

III. Gravimetric and Physical Wetness Determination

EPA's draft Guidance includes a proposed new type of study for disinfecting wipes, a "Gravimetric and Physical Wetness Determination" ("wetness assay"). The Guidance would direct a researcher to measure the weight of liquid initially expressed from a towelette onto a surface and the weight of liquid remaining at the end of the contact time stated on the product's labeling. In addition, the researcher is directed to confirm that the surface remained wet at the end of the contact period.

EPN agrees that a study that measures whether the liquid expressed from a towelette remains on a treated surface for the duration of the contact time is a necessary adjunct to the efficacy assessment described in the proposed ASTM E3363. EPN thinks that the durability of an application is very important. If the liquid deposited on the surface evaporates before the end of the contact time, there is a strong possibility that the product will not achieve the expected level of pathogen control. That failure, in turn, could mean that viable pathogens would be present and potentially transmissible.

EPN thinks, however, that many users, if not most, do not monitor a surface after wiping it to verify that the surface remains wet for the full contact time. Therefore, EPN strongly endorses the policy – implicit in

[9] See 40 CFR 26.1102 (e), (i).

[10] EPN notes that there is a relevant precedent for the type of study we are recommending. Efficacy studies of skin-applied insect repellents start with a dose-determination phase. The research participants are directed to apply the repellent product to themselves, and the investigators determine the amount applied by each participant, using gravimetric measurements. In a subsequent phase of the study, the human participants are treated with the mean amount of repellent applied by participants during the first phase. The participants are then exposed to insects, and the investigators assess the length of time that the insects are successfully repelled from attacking each participant.

the design of the wetness assay – that wiping a hard surface with a towelette should deposit enough liquid to keep the surface wet for the contact time specified on labeling. When users employ a product meeting such a standard, there will be a greater likelihood that the product will successfully disinfect the surface.

To ensure an accurate evaluation of efficacy, EPN thinks that the instructions for conducting a wetness assay need to be clarified, added to, and changed in some cases. Comment III.1 recommends changing how much liquid is applied to a carrier and how it is applied. Comments III.2 - 4 apply to the methodology of the wetness assay, regardless of how or how much liquid is applied to a carrier. Finally, if EPA does not accept comment III.1, EPN makes alternative recommendations for the application methodology for the wetness assay in comments III.4 - 6.

1. The quantity of the liquid applied to the treated surface in a wetness assay should match the effective application rate determined in the study recommended in section II of EPN's comments.

EPN believes that the wetness assay should evaluate how long the product keeps a surface wet under conditions that resemble, as closely as possible, the actual use of the product. A key aspect of the wetness assay is how much liquid is deposited on the treated carrier. To bring greater rigor to the study, **EPN recommends that the wetness assay should be conducted with an amount of liquid determined to be the effective application rate of most typical users.**[11] Using a pipette or a method other than wiping with a towelette, a technician should apply an amount of liquid that produces the same quantity per unit area as the effective application rate to a glass or stainless-steel carrier. The carrier should have a surface area that is at least as large as the labeling indicates would be treated with a single towelette.

Rather than take the approach recommended in this comment, the draft Guidance links the methodology for determining the amount of liquid to apply to the treated surface in the wetness assay to the methodology in ASTM E3363. Specifically, the draft Guidance states: "For each carrier, follow the prescribed wiping pattern identified in the most current version of ASTM E3363." The ASTM methodology describes in detail a standard approach to wiping Petri plates with a towelette. The first step is to fold the towelette to form a small square or rectangular packet with side dimensions between 1 and 1.5 inches. The second step is to hold the packet in fingers, contact the surface with the folded edge, and wipe in a "corkscrew" pattern from the outer edge of the Petri plate to the center of the circular dish and then to reverse the direction.

The wetness assay should not follow the application method in ASTM E3363 because the ASTM application method likely does not resemble how users employ disinfecting wipes. EPN believes that most users do not fold a towelette into a small square packet, nor do they hold the packet in their fingertips when wiping a surface. Rather, they use most of their hand to move an unfolded towelette around the surface when wiping. In addition, EPN believes the wiping motion will not necessarily involve repeated coverage of the same area, as is specified in the ASTM method. Rather, EPN thinks many users will wipe only as much as needed to make the surface appear wet; often, only one pass will suffice. These differences in application methods could lead to meaningful differences in the amounts of liquid deposited on a treated surface by a typical user vs. a lab technician following the ASTM E3633 application method.

2. The wetness assay should eliminate the use of Petri plates.

[11]Users will vary in how much liquid they deposit on a treated surface. EPA should analyze the variability and determine what percentile to use. For skin-applied insect repellents, EPA recommends using the mean value from the dose determination phase. Because the efficacy of a disinfecting wipe to achieve its intended level of control could lead to the spread of serious infections, EPA may want to select a value from the distribution that covers more users' behaviors, e.g., the effective application rate that is lower than that seen for 75% or 90% of study participants. (See section II of these comments.)

The draft Guidance gives the researcher three choices for the material "to represent the surface to be treated" with a disinfecting wipe: a pre-cleaned 12-inch by 12-inch piece of glass, a pre-cleaned 12-inch by 12-inch piece of stainless steel, or glass Petri plates, each measuring 150mm [diameter] by 20mm [height]. **EPN recommends removing the option to use Petri plates.** First, Petri plates differ from the other choices by having a side that may extend the time a measurable quantity of the liquid remains on the surface. Moreover, the surface area of a 150mm x 20mm Petri plate is approximately 28 square inches, compared to the other choices which are each 144 square inches. Because a Petri plate has a ~5x smaller surface area, wiping a Petri plate could express approximately five times more liquid per unit of surface area than on a 12-inch by 12-inch piece of glass or stainless steel (assuming the entire surface of the carrier is wiped). EPN expects that more liquid per unit of surface area would keep the surface wet for a longer period.[12]

3. The wetness assay should contain a ventilation criterion.

The draft Guidance specifies the temperature and relative humidity conditions under which the wetness assay should be conducted. EPN recommends that the guidance also specify the air changes per hour (ACH), because the rate of air flow can affect the rate of evaporation of a liquid. (EPA's awareness of this concern is evident in the instruction not to place the carriers in a fume hood or biological safety cabinet.) The effective use of disinfecting wipes is especially important in medical settings, and medical facilities typically have higher ACH than other buildings. Specifically, engineering guidance for medical settings typically calls for a higher rate of air flow than in residential and non-medical facilities.[13] **EPN recommends setting the ACH at 6 or higher to represent use in medical settings.** If the product is not labeled for use in medical settings, it may not be necessary to require a higher ACH. Nonetheless, the study report should specify the ACH conditions.

4. The Guidance should specify how many trials must be in the wetness assay.

The draft Guidance does not specify how many trials should be performed in a wetness assay. As drafted, it appears that EPA would accept the results from only a single trial. It is important that the results be reproducible, and EPN thinks that there may be unidentified variables that could affect the results. Therefore, **EPN recommends that trials be conducted in multiple, different locations to assess the potential impact of variable laboratory conditions.** Researchers should address variability in the results for each variable and provide a statistical justification for the number of trials in the wetness assay.

5. If the recommendations in section II and III. 1. are not adopted, the wetness assay should be performed with all substrates of the registered product.

The draft Guidance directs that the wetness assay should "use towelettes using the substrate with the greatest binding affinity for the active ingredient." Since there is no guidance or requirement for how to determine which substrate has "the greatest binding affinity," **EPN recommends that each towelette substrate be tested**. EPN expects it would not cost very much to conduct a wetness assay with a single substrate. Thus, the additional expense for researchers should be modest. Having data on different substrates will confirm that the product will perform as expected, no matter which substrate is treated.

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[12] EPA could choose to address this concern by specifying that a technician use a single towelette to wipe five Petri plates. If multiple Petri plates were required, the wetness assay should confirm wetness on each plate. EPN, however, does not recommend the use of Petri plates, unless EPA has data to show that the presence of a rim on the Petri plate has no effect on the length of time that the surface remains wet.

[13] See, e.g., https://smartairfilters.com/en/blog/ashrae-per-hour-office-residential-school-virus-2/ and https://www.atlenv.com/building-ventilation-the-proper-air-changes-per-hour-ach

6. If the recommendations in section II and III.1 are not adopted, instructions regarding selection of a towelette for the study should be changed in the wetness assay.

The draft Guidance states: "Distribute the liquid in the canister or package; remove and discard the first 3-5 towelettes." EPN has concerns about both instructions because they will tend to obscure any differences in the amount of liquid expressed from a towelette due to variability in the distribution of the liquid inside the container. First, **EPN strongly recommends that researchers should take the first towelette available in the container, just as any user would do**. For towelettes packaged in stacked sheets (i.e., like facial tissues), EPN expects that, because of the effect of gravity, those at the top of a package will likely retain relatively less liquid.[14] Using these towelettes will therefore give the best characterization of each towelette's capacity to express enough liquid to maintain a wet surface for the specified contact time. Further, **EPN recommends performing the efficacy test with multiple towelettes drawn from other locations in the packaging as well.**

Second, the direction to distribute the liquid in the canister or package is unclear; what does EPA expect the researcher to do? (EPN suspects the instruction means to turn the container upside down. By doing so, any unabsorbed liquid would contact all of the towelettes and thereby decrease the towelette-to-towelette variability.) Even if the product labeling instructs the user to do this, EPN believes few users will read and follow such use directions. If most users would not do it, neither should researchers. Therefore, **EPN recommends removing the instruction about distributing the liquid in the container.** Finally, **EPN suggests that researchers use towelettes from an unopened container that is representative of commercial production.**

7. If the recommendations in section II and III.1 are not adopted, EPA should revise the wiping instructions.

The ASTM method suggests the entire wiping process should last 6-8 seconds. Given that the recommended glass and stainless-steel carriers are five times larger than a Petri plate, this wiping protocol is inappropriate. Most users are unlikely to fold towelettes, and many will not wipe in a corkscrew pattern or apply two coats of the liquid.

Here are EPN's recommendations for wiping instructions: "The glass or stainless-steel carrier should have a surface area at least as large as the labeling indicates would be treated with a single towelette. A technician should wipe the carrier with a single towelette, spreading the liquid across the entire surface of the carrier as evenly as possible."

IV. Performance Standard and Labeling Guidance

To better promote the efficacy of these important products, the performance standard must also work in tandem with actual application practices, label language, and (where appropriate) additional user training to assure that products are appropriately applied in a manner to maximize their effectiveness.

The ultimate goal of the testing of these disinfecting wipe products is not to demonstrate that the pesticide active ingredient(s) can be effective under theoretical circumstances, but rather to demonstrate that the registered product will be effective when actually used in public health settings. EPN has identified a

[14] EPN thinks towelette-to-towelette variability in the amount of liquid will be greater for products that are packaged in stacks inside boxes vs. in rolls (e.g., like toilet tissue) in cylindrical containers. Nonetheless, the instruction is inappropriate no matter how the product is packaged. Since users will likely not throw away towelettes, neither should researchers.

number of areas above where it believes the proposed testing methodologies are unlikely to replicate typical user behavior when applying towelettes. While EPN's preference would be to have the methodologies accurately reflect current user behavior, if EPA believes users should modify application practices (to reflect the practices identified in the testing methodologies), labeling and training need to be appropriately revised to assure that products' use reflect the efficacy demonstrated in testing laboratories.

As an example, if a product is demonstrated to be efficacious both when "scrubbed" and "wiped," no additional labeling or training would seem to be necessary in that regard. But if the testing methodology calls only for "scrubbing" the surface, and if EPN is correct that scrubbing (when compared to wiping) would increase the effectiveness of the product (while possibly decreasing the surface coverage of individual towelettes), EPA would be without confidence that "wiping" would be sufficiently efficacious, and labeling and user training would be necessary to alter user behavior to assure the product is used in the "scrubbing" manner determined to be effective by the prescribed testing.[15]

To address this issue, **EPN recommends that the ASTM method be modified to require that the test liquid – an amount determined in human research to be the effective application rate – be applied by pipette, not by wiping.** Such an approach will evaluate the efficacy of the test liquid without the potential for removal of test organisms through mechanical action. EPN does not believe that an alternative approach – wiping a carrier with a towelette that is moistened with distilled water or some other inactive liquid – would yield reliable results. EPN feels there is potential for meaningful variability in the amount of pressure that might be applied to the test vs. control carriers, even if they are wiped by the same technician. Such variability could make it difficult or impossible to tell whether differences in log reduction were due to the amount of pressure applied to the carriers or to the innate antimicrobial activity of the liquid. More importantly, if the liquid, by itself is efficacious, it will likely be effective under conditions of use, regardless of how little pressure the user applies when wiping a surface.

Requiring testing to determine how these products are currently being used would provide significant clarity on where changes to labels, training, and/or the other testing methodologies are needed. Whatever other changes that testing might reveal, EPN submits that EPA should assure that product labeling specifies the area that can be effectively treated with a single towelette (and that this area be verified through the testing of each product at issue here).

In sum, testing is an important component of assuring the efficacy of disinfectant products. But the testing must reflect the likely use of the products. This can only be accomplished if the testing is reflective of actual use of the products. This goal can be accomplished through modifying the testing methodologies, or it could be accomplished through additional labeling use directions and training, or through a combination of modified methodologies and additional labeling and training. However EPA addresses this issue, EPN submits it is important that the testing provide the necessary assurance that the products will be efficacious not just in a laboratory setting, but when they are actually used in public health settings.

1. Efficacy Performance Standard

[15] EPA's Federal Register Notice mentions that the use of disinfecting wipes can control pathogens on hard surfaces by a "combination of chemical inactivation of the test microbe and mechanical removal of inoculum from a surface." EPN observes that the ASTM method describes how to apply the product to carriers containing the test organisms but contains relatively little helpful instruction about how much pressure to exert when wiping the carriers. Thus, EPN thinks the ASTM method will not yield reproducible results if some technicians scrub while others gently wipe the carriers.

In the draft Guidance, under the heading "Test Procedures for Developing Efficacy Data Supporting Antimicrobial Towelette Claims," summary Table 1 lists "Evaluation of Success" for various disinfectant claims. The measure of success is identical for all three situations presented. The standard for a disinfectant claim is 99.999% control of bacteria; however, the measure presented is that "[e]ach independent test should attain a minimum mean 4.5-log reduction (LR) in viable cells." This raises several questions.

First, what is EPA's performance standard for making a disinfection claim? The draft Guidance advises that a disinfecting wipe must achieve at least a 4.5-LR in the level of viable test pathogens to support an efficacy claim as a disinfectant. EPN understands that antimicrobial products used on hard surfaces, other than disinfecting wipes, have long been required produce at least a 5-LR in test pathogens to be considered a disinfectant – as the draft Guidance notes, a 99.999% level of control. A 4.5-LR is only 99.993% control. **EPN believes that the performance standard should be the same for all categories of products making efficacy claims to disinfect hard surfaces.** If "disinfecting wipe" product does not achieve the 5-log level of control, it should not be allowed to claim it disinfects surfaces. Rather, it should be characterized as a "sanitizer," assuming it can achieve at least a 3-log level of control. In addition, EPN questions why the proposed performance standard is expressed as a "minimum mean" vs. a "minimum." Table 2 also uses the descriptor "mean," rather than "minimum." This language is again used under the heading "Efficacy Test Criteria" when describing the "Evaluation of Success." **EPN recommends that the standard should read a "minimum 5-log reduction…"**

Table 1 summarizes the claims against bacteria using ASTM E3363. It is unclear why the requirements for a hospital grade disinfectant are not listed in this summary. It is suggested that that claim is presented here with *Staphylococcus aureus* and *Pseudomonas aeruginosa* listed as the test organisms since wipes are used extensively in hospital settings.

Finally, in addition to the level of pathogen reduction needed to support efficacy claim(s) for disinfecting wipes, **the performance standard should specify that the amount of liquid from a single towelette (determined as the effective application rate) should keep a hard surface visibly wet for the specified contact time**. EPN assumes that EPA's decision to require the wetness assay reflects the agency's agreement with this policy position. However, EPN thinks that the policy should also be made clear by including it in the articulation of the performance standard for this category of products.

2. Labeling

Given the relationship between the methodology for assessing efficacy and the actual use of disinfecting wipe products, it is essential that the labeling of a product contain use directions necessary to ensure the product will achieve the promised level of pathogen control. The best way to do that is to ensure that the products will be effective for all users. Unless EPA modifies the guidance for its proposed efficacy testing methodologies to reflect typical user behavior, the labeling of products should contain clear, prominent instructions about how the user should apply the product. In EPN's view, **the use instructions should include a direction about the size of the area that can be effectively treated with a single wipe, as well as an instruction to check surfaces to ensure they have remained wet for the full contact time.**

Conclusion

In conclusion, EPN recommends that EPA implement efficacy studies to use test methods that reflect how the products are actually used by consumers. This includes studying general human participant usage that commonly goes against labeling directions. If human efficacy studies cannot be conducted, EPN

recommends changing the labeling language for disinfecting wipe products. EPN also suggests adjustments be made to EPA's proposed wetness assay to better reflect common usage of the wipes.

These comments were prepared by Bill Jordan, Jack Housenger, Bob Perlis, Tina Levine, and Tim McMahon on behalf of EPN.