

ICR Response to Comments:

In its comments dated April 19, 2011, S. C. Johnson & Son, Inc. (SJC) specified its concerns about EPA's proposed collection of information:

1. The proposed research is inadequate to realize the EPA's stated goals.
2. The current EPA proposals for an efficacy mark for repellent labels could in fact cause consumers to make inappropriate choices when selecting a repellent product.
3. The current efficacy data are not appropriate for the purpose of comparing between products and would in fact be misleading.
4. Due to risk to the public, EPA must require that all pesticides making claims against public health pests meet the same efficacy and labeling requirements. FIFRA § 25(b) products should not be exempt from any of these standards.
5. Submitted an appendix with recommended changes to the questionnaire.

Concern 1: The proposed research is inadequate to realize the EPA's stated goals.

SCJ appears to have mis-understood EPA's stated goals for the survey. SCJ's comments indicate their belief that EPA is conducting this research to "cause a shift in consumer decision making." This is incorrect. As stated in the Supporting Statement for an Information Collection Request (ICR) that EPA provided in the docket EPA-HQ-OPP-2010-1085 available at <http://www.regulations.gov>, EPA had two goals:

- identify the types of information that users of insect repellents want on the label of an insect repellent product, and
- test four versions of an efficacy mark

EPA does not intend to use the information collected through this survey to attempt to shift consumer decision making, but rather to determine whether individual labels are adequately informing consumers about individual products. The proposed survey questions were deliberately designed to allow EPA to judge if the content and design of the label communicates the safety and performance information that consumers desire. If such information were required on pesticide labeling, it may impact consumer behavior because by providing information that consumers readily understand, consumers can make more informed choices.

Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), EPA works to assure that the information on pesticide labeling is neither false nor misleading. It is not EPA's intention to change consumer behavior, to influence a consumer to choose one product over another. It is not our intention to interfere in the consumer's personal decision-making process. During the focus groups, conducted by EPA in 2010, participants identified the information that they want on a label. EPA's intention is to assure that the information the consumer has asked for, as well as information necessary to safely and

effectively apply an insect repellent product is on the label, and that the consumer understands and correctly interprets that information. In the 10 focus groups conducted by EPA, participants indicated that they want clearer, more concise statements on the labels, and that they are looking for a consistent standard of measurement for evaluating the efficacy and safety of personal insect repellents.

Once EPA has assured that labels provide the appropriate and understandable information, then consumers are free to compare products and to make a personal choice based on their needs.

Concern 2: The current EPA proposals for an efficacy mark for repellent labels could in fact cause consumers to make inappropriate choices when selecting a repellent product.

In their comments, SCJ stated their belief that if icons displaying hours of protection were on an insect repellent product label, then consumers would make “shopping choices based on what product will give the longest protection for the best price.” SCJ asked instead that EPA “choose a label communication that encourages to choose repellents based on the situations in which they need repellency.” SCJ suggested using percent active ingredient instead of hours.

EPA understands that we will need to provide information to consumers on the EPA website, such as explanations of how to “read” the efficacy logo. Some of the questions in the survey will assist EPA with that purpose.

EPA agrees that the “situation” is a consideration. In fact, EPA’s website states: “Shorter protection time does not mean the product is less effective. Be sure to use a repellent product with a protection time that fits your activity, perspiration, water, temperature, and how attractive you are to insects.” (see <http://cfpub.epa.gov/oppref/insect/index.cfm>) However, EPA disagrees that percent active ingredient can serve as a surrogate for protection time. While this may be an obvious (and somewhat accurate) comparison for products with the same active ingredient, it is not an effective comparison for products with different active ingredients.

Concern 3: The current efficacy data are not appropriate for the purpose of comparing between products and would in fact be misleading.

EPA does not consider that an efficacy marker is a comparative claim. The efficacy marker would only indicate the level of efficacy supported by the efficacy data submitted to the Agency and its purpose would be explained in any education materials created by EPA. This is similar to the acute toxicity categories that are used for labeling purposes. Acute toxicity data supports the categorization of products into different hazard categories. The categories can be used by consumers to compare products, but that doesn’t make them comparative claims. In fact, any unique feature of a product label can be used to compare the product to another. But generally, EPA would not treat labeling information that doesn’t reference another product, explicitly or implicitly, as a comparative claim.

SC Johnson states that “The only practical significance of mandating an icon of hours of duration on repellent labels is the facilitation of direct comparisons between insect repellents.” First, EPA has not decided to mandate the use of an efficacy logo on an insect repellent product, and notes that rulemaking would be required for such an action. However, EPA could initiate a pilot project, or a voluntary program to encourage such efficacy logos. EPA may also decide, based on the results of the

survey, to use label information other than efficacy logos to convey this information to consumers. Second, there are reasons other than facilitating direct comparison to provide for such standardization, such as readability and understandability. During 2010, EPA conducted 10 focus groups on insect repellent labeling. Participants indicated that the claims on current insect repellent labels were variable, confusing and not always easy to read or understand. They wanted clearer, more concise statements on insect repellent labels.

EPA understands SCJ's concerns that some products would not have the efficacy data necessary to facilitate use of an efficacy logo since "methodologies vary greatly." While it may not have been true some years ago, today there is a great deal of standardization in testing for personal insect repellents given the recent finalization of the guideline for testing, and the requirement to have insect repellent testing protocols reviewed by the Human Studies Review Board (HSRB).

Additionally, EPA is in the process of preparing a proposed rule entitled: "Data Requirements for Product Performance." As described in EPA's Regulatory Plan and Semiannual Regulatory Agenda (see <http://www.epa.gov/lawsregs/documents/regagendabook-fall10.pdf> page 301),

EPA will propose to amend efficacy data requirements that specifically address the registration data needs of invertebrate pesticide product registrations as mandated by Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). This rulemaking will provide clarity, consistency, and transparency. This proposal will seek to amend the current efficacy data requirements codified in 40 CFR Part 158, which describes the minimum data and information EPA typically requires to support an application for pesticide registration or amendment; and the maintenance of a pesticide registration, e.g., as in the registration review program.

EPA expects this rule will standardize the current practices for insect repellent testing, such as number of studies and species to be tested. Thus, when these data requirements are finalized, there will be standardized data requirements, which would provide the minimum set of data needed to support providing pest and duration information in the efficacy marker. Even if the testing does have some variation, it would still all be judged by EPA/OPP who would consider the variations and the weight-of-the-evidence to determine what efficacy has been proven, and if the information to be presented in the logo is supported. Since these are not comparative claims, the mark will only be indicating that one particular product is proven to be effective as described by the logo and label claims.

Concern 4: Due to risk to the public, EPA must require that all pesticides making claims against public health pests meet the same efficacy and labeling requirements. FIFRA § 25(b) products should not be exempt from any of these standards.

At this time EPA is developing a proposed rulemaking entitled, "Reconsideration of Exemptions for Insect Repellents." As described in EPA's Regulatory Plan and Semiannual Regulatory Agenda (see <http://www.epa.gov/lawsregs/documents/regagendabook-fall10.pdf> page 250),

EPA is developing rulemaking to modify the minimum risk pesticides exemption under 40 CFR 152.25(f) to exclude personally applied insect repellents from the exemption and require an abbreviated data set for such products. EPA is taking this action because these pesticides claim to control pests of significant public health importance.

This proposed rule should publish several months after the publication of the Product Performance Rule, and would propose which data would be needed for a currently-exempt product to transition to a registered product. Additional information on this rulemaking is in the docket EPA-HQ-OPP-2010-0227 available at <http://www.regulations.gov>.

Based on comments received, EPA has made only minor clarifying changes to the Supporting Statement for an Information Collection Request (ICR) entitled “Use of Surveys in Developing Improved Labeling for Insect Repellent Products.”

Concern 5: In the table below, EPA has provided responses to SCJ’s comments (the Appendix) on the questionnaire, by adding a third column entitled “EPA’s Response.” (The first two columns are as submitted by SCJ.) Changes resulting from the comment are described.

Research Principle	Questionnaire Change Recommendations by SCJ	EPA’s Response
Proactively stating the criteria by which a decision will be made	Clearly establish which question(s) will be used to make a decision and how	Key decision-making questions are Q. 24, 26 and 31 since these are the questions where the consumer rates the efficacy marks. These questions will help determine which efficacy mark should be used on product labels. Q. 11-23, 25, 27-30 all support the key decision-making questions and provide extra information for decision-making. In particular Q. 11, 12, and 15 provide information for consideration on whether EPA may pursue placement of an efficacy mark on the label. The rest of the questions are important to provide profiles of those who preferred each mark in terms of demographics and insect repellent product use. In this regard, they also support decision-making about which mark would have the most impact on specific segments of consumers.
Randomize non-scale responses to avoid bias	Randomize responses at Qs. 3, 5, 6, 9, 10, 12, 13, 14, 25,	Randomization is automatically done for these response categories during

	<p>28, 29, 30, 33. In Qs. 24, 26, and 31 order of efficacy mark should reflect rotation order</p>	<p>questionnaire programming. We will add the instruction “RANDOMIZE” before the list for each question to convey to readers that this is done during programming. We will also note that for Q. 24, 26, and 31 the order of the efficacy marks should reflect the rotation order presented to participant.</p>
<p>Ensure content of lists is exhaustive to make information actionable</p>	<p>List at Qs. 9 and 10 should include all front label communication, including: Type of insects repellent Number of hours of protection OR instructions on when to reapply Active ingredient(s) Other ingredient(s) Scented / unscented Waterproof Expiration date Safety warning Brand Long lasting protection Dry/non-greasy skin feel Non-plasticizer= gear safe Sweat resistant Protection against West Nile Virus % of active ingredient Size Price</p>	<p>The lists for Q. 9 and 10 were compiled from the results of the 10 consumer focus groups conducted as the first phase of this study. A major purpose of the focus group study was to aid in design of the quantitative survey questionnaire. The compiled list represents what focus group participants (consumers) stated that they wanted on an insect repellent product label. There is an “Other (Specify)” response which means that survey respondents can write in other information they look for that may not be listed. Information on the labels such as brand, size, price are not relevant to this study. EPA also notes that price is rarely on the label. Other items such as sweat resistant, non-plasticizer/gear safe, protection against West Nile Virus were not mentioned by participants during the segment of the focus group where this was specifically asked, and are therefore not included. Long lasting protection is a vague phrase that focus group participants found non-specific (What does that mean?), and therefore not helpful. Percent of active ingredient is required to be on the label.</p>
<p>Include internal benchmarks</p>	<p>Provide a “none” option at Qs 24, 26, 31 Add an option without an efficacy mark at Qs. 25, 26</p>	<p>EPA determined to force a choice of which efficacy mark is preferred. Since the purpose of this question is to determine which mark is the best at communicating the desired information, offering an opt-out does not serve EPA’s need for information. This question would not determine if</p>

		<p>EPA pursues placement of an efficacy mark on the label. Therefore, if none or a visual of a repellent bottle without an efficacy mark were added to these questions it alters the question, to become somewhat equivalent to the decision to use an efficacy mark. Additionally, if a number of consumers chose the “none” response, it may be difficult to statistically determine which mark should be used. The specific marks to be tested in the quantitative survey have been vetted in the focus groups. The first four focus groups winnowed the number of efficacy marks down from five to three. These three were then re-designed based on focus group participant feedback. The next 6 focus groups gave feedback on the three revised and the new RF mark. No comments were made as to not wanting any mark at all: Focus group participants were receptive to having a mark on the label.</p>
<p>Avoid forcing respondents to make arbitrary choices</p>	<p>Q. 10 should be a scale where respondents can assign importance to each variable, since they may find +/- 2 most important</p>	<p>Focus group participants were asked a similar question, and had no challenges in responding. The purpose of this question is to determine what label information is most important to consumers. A scale will more likely result in respondents rating all or most of the items as important. Therefore, there is a need to ask survey respondents to prioritize what they consider to be the two most important pieces of information.</p>
<p>Align order of questionnaire with research objectives</p>	<p>Move Qs. 3, 4, 5, 6, 7 after Q. 31 Ask Qs. 25, 26 before Qs. 11-24 to understand real-life impact before collecting diagnostics Delete Qs. 27, 28, 29, 30, 31 since not an objective</p>	<p>EPA originally considered placing Q. 3-7 after Q. 31. However, EPA believes it is important to place Q. 3-7 (which are about usage) in the questionnaire before the questions about the labeling so insect repellent use behavior and reasons for use/non-use are not influenced/informed by the detailed label information questions. Q. 11-24 are</p>

		<p>intended to introduce survey participants to the efficacy marks, which they have never seen before, and to then obtain their reaction(s) to the marks. The marks, in a reduced size that would fit onto an insect repellent product, are then evaluated to understand if the consumer can accurately obtain information from the reduced-size. (Q. 25, 26). We believe this is the correct sequence for these questions for our purposes. Q. 27-31 relate to repellent factor (RF) logo which focus group participants found confusing and difficult to understand, and therefore less desirable than the other efficacy marks. Q. 27-31 were added to test this hypothesis from the focus groups in the large, statistically reliable quantitative survey. Therefore, it became an objective of the survey.</p>
<p>Questions should match research objectives</p>	<p>Qs. 8, 9, 10 should be asked for front label only</p>	<p>Based on our prior research, consumers do not recall whether the information on the front or the back panel. We believe that adding the phrase "front label" at this point will be confusing and not important to consumers.</p>
<p>Questions should provide meaningful data</p>	<ul style="list-style-type: none"> - Delete Q. 7 (not sure how someone could be responsible for purchasing insect repellents and not have ever looked at the label) - Rephrase Q. 11 to provide more direction (how would this information help you make a choice between mosquito repellents) - At Qs. 12, 28 ask either informative OR helpful (not both terms) - Provide context for Q. 15 (why would a consumer be looking for this label if they 	<ul style="list-style-type: none"> - EPA wants to retain Q. 7. Our previous surveys have shown that up to 25% of respondents who purchase insect repellents self-report that they do not read the product labels at purchase. - EPA intended Q. 11 as way to determine what the symbol communicates to consumers on an unaided or "cold" basis. This is precisely how some consumers could come across the efficacy mark in the store. EPA wants to understand what the symbol is communicating to consumers before they know it is an efficacy mark. Additionally, this information will help EPA to design an

	weren't aware	<p>outreach/communication program if the decision is made to include the logo on the label.</p> <ul style="list-style-type: none"> - We will delete the rating for Informative in Q. 12 and 28 and retain Helpful. Helpful is more actionable. - Q. 15 can be rephrased in the hypothetical so that it applies to all consumers, such as "Now that you have seen this efficacy mark, if you were shopping for an insect repellent product, how likely would you be to look for and consider the logo information in making a purchase of an insect repellent product?"
Maximize consumer understanding	<p>Add which specific products consumers have used in the past year</p> <p>How use product against mosquitoes vs. ticks (is there confusion if the numbers are different)</p>	<p>EPA already has consumer research data on this. Specific product use behavior is not the purpose of this study.</p> <p>EPA agrees that there may be confusion if the numbers are different, and will add a question (see below) about this issue.</p>
Ensure technical integrity	Fix skip logic at Q. 4	We will fix this.
EPA also identified the following additional issues while responding to SCJ's comments.		
	Fix skip logic at Q. 7	We will fix this.
	With regard to the "confusion" mentioned above, "if the numbers are different," what would consumers think if one of the numbers was zero?	EPA will also add a question about this issue. (see below)
	Also, may want a question about SCJ concern about always purchasing the product with the longest duration.	EPA will also add a new question on this issue. (see below)

New Qs:

Duration:

If you are comparing two products, and you are looking for a product to use while watching your son/daughter's soccer game, which would you choose:

Insert three logos (use the same design for both) it should be the logo they selected in Q26, and insert this as a new Q 27. For option 1 have M8, T8, and option 2 M4, T4 and option 3 M2, T2 and option 4 (I want a different product.)

(Randomize)

Differing Times:

How would you interpret the following: Insert logo, also the logo they selected in Q26 with M6 and T2, and insert this as new Q 28.

- The product repels insects for approximately 6 hours
- The product repels insects for approximately 2 hours
- The product repels mosquitoes for 6 hours and repels ticks for 2 hours
- I don't know.

(Randomize)

Zero:

How would you interpret the following: Insert logo, also the logo they selected in Q26 with M0 and T6, and insert this as new Q 29.

Select one answer:

- The product repels insects for approximately 6 hours
- The product repels insects for an average of 3 hours
- The product repels ticks for 6 hours and does not work on mosquitoes
- The product repels ticks for 6 hours, and must work on mosquitoes for six hours too.
- I don't know.

(Randomize)