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EPN Comments on the Proposed Registration of Pesticide Products Containing the New Active Ingredient, Veratrine

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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 October 31, 2024, EPA initiated a public comment period on its proposed decision to approve applications submitted by McLaughlin Gormley King Company (MGK) to register five pesticide products containing the new active ingredient, veratrine. Specifically, EPA proposed to register one manufacturing-use product and four end-use products, two of which also contain pyrethrins. EPA posted several documents in the public docket in connection with its proposed decision. The docket included various EPA human health and ecological risk assessment documents, as well as EPA's Memorandum Supporting Proposed Decision to Approve Registration for the New Active Ingredient Veratrine ("Decision Document"). The Decision Document helpfully summarizes the agency's risk assessments and explains the basis for the proposed registrations. However, the docket initially did not include the draft labeling for the products proposed for registration. EPN asked EPA for an opportunity to review the labeling for the end-use products in connection with the proposed decisions. On November 13, 2024, EPA notified EPN that it had posted the draft labeling of the four end-use products to the public docket.

The draft labeling provides additional information about the end-use products that EPA proposes to register, beyond that in the draft Decision Document and risk assessments. Some of the key information is summarized below.

Name of proposed product	**MGK Formula 31422 Aerosol**	**MGK Formula 31731**	**MGK Formula 3159**	**MGK Formula 31421**
Active ingredient(s)	Pyrethrins (0.2%) Veratrine (0.1%)	Veratrine (0.1%)	Veratrine (4.2%)	Pyrethrins (0.2%) Veratrine (0.1%)
Likely market[1]	Consumer use	Consumer use	Commercial pest control	Consumer use

[1]These products' labeling does not (and legally cannot) limit who purchases and uses the products. EPN's identification of the likely market for the products is based on the way it appears the products will be packaged for sale, as well as on the complexity of the use instructions.

Application technique	Spray with aerosol spray can	Spray with "Pre-filled pump spray bottle[,] handheld trigger spray[, or] bag on valve (BOV) spray can"	Spray in "Hand-held compressed air sprayers such as a pump up sprayer [or] low pressure backpack sprayer"	Spray with "Pre-filled trigger spray bottle, or bag on valve (BOV) spray can"
Target pest(s)	House flies	Box elder bugs, brown marmorated stink bugs, various ants, & house flies	Box elder bugs, brown marmorated stink bugs, various ants, & house flies	Box elder bugs, brown marmorated stink bugs, various ants, & house flies

The rest of these comments will refer to the different products using the formula numbers, i.e. 31422, 31731, 3159, and 31421, in the products' names.

EPN has reviewed the Decision Document, selected risk assessment documents, and the draft labeling for the four end-use products. EPN feels that, if the products were used as EPA assumes, they seem unlikely to cause unreasonable adverse effects on the environment. However, EPN has some concerns with the labeling and the scope of EPA's risk assessments for these products, and that EPA's apparent assumptions on use may be unjustified. Our comments below detail our concerns with labeling (Section I) and the risk assessments (Section II). If the agency addresses these concerns, EPN would support the registration of these products.

I. Veratrine Product Labeling

As EPA knows, the labeling of a pesticide product is a critically important component of the registration of a product. The labeling is the means whereby the agency communicates to product users how to store, mix, load, apply, and dispose of the product, as well as any other steps users may need to take to protect themselves, others, and the environment. Further, under FIFRA sec. 12(a)(2)(G), it is unlawful for any person to "use a registered pesticide in a manner inconsistent with its labeling." This statutory provision is aptly summarized as "the label is the law." All pesticide products' labeling must bear a statement immediately beneath the "Directions for Use" heading that reads: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." In sum, the labeling of a pesticide product communicates how a product is safely and effectively used. It conveys science-based regulatory decisions made by EPA and how users can enforce them.

EPN has several comments on the draft labeling of the four end-use products containing veratrine. EPN has chosen to focus on the proposed end-use products because the labeling is, ultimately, the most important distillation of EPA's regulatory work. To the extent these comments are relevant to MGK's manufacturing-use product, EPN recommends that changes be made to the labeling of that product, as well.

A. EPA needs to direct MGK to add a clear FIFRA sec. 2(ee)(2) statement to the labeling of all four end-use products prohibiting the use against unnamed pests, and EPA needs to make a finding to justify this prohibition.

Although not stated explicitly, it plainly appears that EPA assumed the veratrine products would be used only against the pests specified on the products' labels. This assumption is stated in the draft Decision Document (p. 16), which contains the following statement in the concluding "Labeling Requirements" section:

> "The human health and environmental risks assessments were based on the label mitigations below:
> 1. All end use products are labeled for direct spray application to brown marmorated stink bug, boxelder bug, house flies, or ants (excluding carpenter, harvester, pharaoh, fire) in spot, crack and crevice sites on the exterior vertical surfaces of the listed man-made structures only …"

This conclusion is also supported by two different parts of the label. First, three of the products, 31731, 3159, and 3122, indicate that the product may be used to control "Ants (excluding carpenter, harvester, pharaoh, and red-imported fire ants)." This is an express statement that the product is <u>not</u> to be used against certain species of ants. Second, all four labels contain unusual language that purports to go beyond the statement, mandatory on all pesticide labels, "It is a violation of Federal Law to use this product in a manner inconsistent with its labeling." Immediately beneath the mandatory statement, each label contains additional text: "READ ALL DIRECTIONS COMPLETELY BEFORE USE AND FOLLOW ALL DIRECTIONS AND PRECAUTIONS WHEN USING PRODUCT" (31422), "Read and follow ALL directions when using [applying, treating with] this product." (31731 and 31421), and "APPLY THIS PRODUCT ONLY AS SPECIFIED ON THIS LABEL" (3159). These additional statements would be unnecessary if they were intended to mean nothing more than the mandatory statement concerning pesticide misuse that appears immediately above the text. Therefore, EPN infers that EPA expects users to apply the product only against the named target pests.

However, the statements appearing on the four labels are not adequate to prohibit the use of veratrine products against unlisted pest species. As EPA is aware, FIFRA sec, 12(a)(2)(G) makes it unlawful "to use any registered pesticide in a manner inconsistent with its labeling." FIFRA sec. 2(ee) contains a definition of the phrase, "to use any registered pesticide in a manner inconsistent with its labeling." The definition makes clear that certain practices are not unlawful under FIFRA sec. 12(a)(2)(G), even though they might appear not to follow directions in the labeling. FIFRA sec. 2(ee)(2), in particular, allows:

> "[use against any] pest not specified on the labeling if the application is to the crop, animal, or site specified on the labeling, unless the Administrator has the required that the labeling specifically state that the pesticide may be used only for the pests specified on the labeling after the Administrator has determined that the use of the pesticide against other pests would cause an unreasonable adverse effect on the environment."

Thus, to impose a limitation on the pests treated, the statute expressly requires a prohibition against treating unspecified pests and a finding that such use would cause "an unreasonable adverse effect on the environment." The proposed label does not contain an adequate prohibition; thus, EPA should revise the label text to "specifically state" the restriction against treating unspecified pests. Moreover, the Decision Document does not contain such a finding; **EPA should include such a conclusion in its final Decision**

Document. In the absence of such a finding, EPN questions whether the anticipated label mitigation would be legally binding on users.

EPN questions the legal adequacy of the additional language quoted above – "follow all directions" and "apply this product only as specified on the label" – to create an enforceable prohibition against use of these products against pests not identified on the label. FIFRA sec. 2(ee)(2) requires language to "specifically state" the prohibition against using the product to kill unspecified pests. The text currently on the label may not have the requisite specificity. **EPN recommends, therefore, that EPA direct MGK to revise the labeling to include the following statement wherever target pests are named: "Use of this product against any other target pests is illegal."** For example, such a statement should appear both in the labeling section, PESTS KILLED, and in the table with "Application Site," "Pest," and "Dilution in Water and Application Rate" columns, as well as in any efficacy claims made for the product.

Further, EPN thinks the agency may have difficulty making the statutory finding required by FIFRA sec. 2(ee)(2). Obviously, EPA would need to support such a finding with an assessment of the risks created by using veratrine products against unspecified pests. EPN has not fully considered the ways in which such use might potentially cause unreasonable adverse effects on the environment but recommends that EPA consider the following observations. The pest species listed are primarily nuisance pests. Absent a clear, prominent prohibition, users may decide to use the product against public health insects such as wasps and yellow jackets. There is no indication, however, that MGK has provided EPA with data on the products' efficacy against public health pests. (Given the products' toxicity to bees, it seems likely to be effective against at least some public health insects.) Further, three of the end-use products will probably have a consumer market, and even if there is a prominent and clear prohibition, EPN expects consumers will use the product against any type of insect pest they encounter. Such use probably would be more widespread than the relatively limited usage envisioned in the human health risk assessment. For example, use to control insects in food handling areas of home kitchens, cafeterias, and restaurants could lead to dietary exposure – an exposure route that EPA did not assess. Potentially greater exposure and/or exposure by different routes could cause risks that do not meet the statutory standard.

Finally, EPN appreciates that, on review, EPA may decide it is not necessary or supportable to impose a FIFRA sec. 2(ee)(2) prohibition on veratrine products. If so, **EPA should consider requiring the labels to include restrictions against uses that contact food, feed, and food handling surfaces.** In addition, it may be appropriate to warn users that EPA has not evaluated the product's efficacy against public health pests. Examination of such use may identify other risks that EPA could address with labeling restrictions short of a FIFRA sec. 2(ee)(2) prohibition.

B. EPA needs to direct MGK to add a clear FIFRA sec. 2(ee) statement to the labeling of the "3159" product prohibiting use except in the specified application equipment.

The labels for all four end-use veratrine products specify that the product must be applied as a spray. EPN is concerned about the equipment that could be used to spray the 3159[2] product. Unlike the three products

[2] EPN does not have this concern for the other three products. The draft labeling of the 31422, 31731, and 31421 products indicate that the formulations will be packaged in pre-filled spray containers. EPN thinks it highly unlikely users would remove the contents of a package and place it in another type of spray equipment. Thus, it is reasonable for EPA to expect users of these products will apply the product using the application equipment that is part of their container packaging.

likely to be marketed to consumers, the 3159 product requires the user to prepare a use dilution by mixing the product contents with water. The "APPLICATION METHODS" [sic] section of the 3159 label reads: "Direct spray treatment to pests in spot, crack and crevice sites," and the "APPLICATION EQUIPMENT" section lists two types of devices for spraying the use dilution – "Hand-held compressed air sprayers such as a pump up sprayer [or] Low pressure backpack sprayer."

Our concern is that the current 3159 label may allow use of other types of spray application equipment, and that using other types of equipment could pose greater risks. The two types of equipment listed in the 3159 label dispense the use dilution at a very low pressure. Either type would deposit only a small amount of the use dilution on the treated surface. Moreover, consistent with the assumptions apparently used in EPA's risk assessments, the amount of "splash back" on the applicator and the amount deposited outside the spot or crack/crevice being treated would be limited. However, if a user chose high-pressure spray equipment, the amounts deposited on the handler and the surrounding environment would likely far exceed the exposure assumptions used in the agency's human health and ecological risk assessments.

Under FIFRA sec. 12(a)(2)(G) and sec. 2(ee)(3), it is lawful to use an application method that is not specified on the label unless "the labeling specifically states that the product may be applied only by the methods specified on the labeling" (emphasis added). For the reasons discussed earlier, EPN strongly questions whether the unusual additional label text quoted in section I.1. provides the requisite specificity. Therefore, **EPN recommends EPA direct MGK to revise the APPLICATION METHODS text of 3159 label product to read: "Direct spray treatments to pests in spot, crack and crevice sites using only one of the following types of application equipment: a hand-held, pump-up, compressed air sprayer or a low-pressure backpack sprayer. Application by any other method or use of any other equipment is prohibited."**

C. EPA should direct MGK to add pictures of the target pest species to the labels of the veratrine products and give greater prominence to the requirements to spray a limited area of a vertical surface only when a pest is present.

One reason that EPN would support the registration of these veratrine products is that following the labeling use directions should result in very little human health or environmental exposure. Two aspects of the use directions are critical to limiting the overall exposure. First, the user is to spray a vertical surface only when a target pest is present. Second, a user is to apply the spray only to a small area – no more than 2 square feet.

The likelihood for greater (and potentially riskier) exposure increases if the user makes a mistake in pest identification or in the size of the area treated. However, better label graphics and text could lessen the chances of such mistakes. EPN makes the following recommendations:

- First, **EPA should direct MGK to add photographs of the target pest species to the label** – at least box elder bugs and brown marmorated stink bugs, but possibly also ants and houseflies. This will help the typical consumer know whether the product is approved for use against the insect they see.
- Second, **EPA should direct MGK to add another example for determining the size of a treated area**. Since most spray nozzles dispense in a conical shape, the bullet for spot treatments in

the APPLICATION RESTRICTIONS section should read: "Spot treatments must not exceed two square feet in size (for example, 2 ft by 1 ft or 4 ft by 0.5 ft or a circle that is 19 inches across)."

- Third, the **two critical use restrictions relating to the presence of the target pest and the limited area to be sprayed in spot treatments should be in large letters and placed in the USE RESTRICTIONS sections** of the products' labels.

D. EPA should direct MGK to revise the labeling of the 3159 product to include better information about preparing the right amount of diluted material to treat a given surface area.

EPN feels the instructions about preparing a mixture of water with the 3159 product are inadequate. The formulation in a container of the 3159 product is not ready to use. Rather, the labeling requires a user to prepare a mixture by diluting between "0.3 fl. oz. (9 ml)" and "0.6 fl. oz. (18 ml)" of the formulated product with "12.8 fl. oz. (378 ml)" of water. The labeling contains no further information regarding the amount of diluted material needed. EPN has two concerns about the adequacy of the labeling of the 3159 product concerning the preparation of the diluted material.

EPN's first concern is that the use directions provide no information on how much surface area the diluted material will cover. Following these instructions literally, the user would create a volume between 13.1 fl. oz. and 13.4 fl. oz. Would this cover 2 sq. ft. or 20 sq. ft.? While EPN appreciates that the answer might depend on the type of application equipment chosen, EPN thinks that users will need some guidance on how much diluted material to prepare so as to avoid making significantly more than would actually be needed. This additional guidance is vital because preparing a greater quantity of the diluted material than is eventually applied for pest control leads to a disposal issue (see also comment I. 5, below).

EPN's second concern is that the instructions to measure the quantities of formulation and water put into the use dilution are unrealistically precise. EPN recognizes that the 3159 product will probably be marketed to commercial users and that many such customers will likely have had considerable experience in preparing dilutions of formulated products. But EPN suspects that many commercial users cannot measure either the formulated product or water in milliliters or tenths of a fluid ounce. Thus, EPN expects such users could easily prepare a mixture that is more concentrated than EPA's risk assessments assume. This may lead to greater exposure than assumed in EPA's risk assessments.

EPN recommends that **EPA direct MGK to revise the Dilution in Water instructions to give guidance on the amount of diluted material needed to treat a given square footage of surface area.** For example, the directions might say: "A quart of the resulting use mixture will be sufficient to make X spot treatments of 2 square feet each or to make crack and crevice treatments totaling Y linear feet." **EPN also recommends that EPA direct MGK to revise the Dilution in Water instructions to use whole numbers and to provide a ratio of water to product formulation.** For example, the directions might say: "Mix 1 fl. oz. of product with 25 - 45 fl. oz. of water."

E. EPA should direct MGK to relocate and revise the instruction for rinsing application equipment in the ENVIRONMENTAL HAZARDS section of the 3159 label to make it consistent with other parts of the labeling.

The ENVIRONMENTAL HAZARDS section of the 3159 label contains the following instruction: "Rinsing application equipment over the treated area will help avoid run off to water bodies or drainage

systems." Apart from the perplexing location of this instruction and its lack of enforceability, EPN believes it is inconsistent with other, mandatory directions on the label. The label has several directions which seem to conflict: 1] apply to external, vertical surfaces, 2] "Do not apply to the point of runoff," and 3] apply only to a limited area. EPN feels it is impractical (if not impossible) to rinse the application equipment over a vertical surface. EPN's understanding of the process of rinsing application equipment is that there would be copious runoff. Finally, EPN expects that rinsing application equipment would require water that would cover more area than permitted by the use instructions.

In view of these issues, **EPN recommends that the instruction regarding rinsing application equipment be removed from the ENVIRONMENTAL HAZARDS section and once revised, placed in a new separate CLEANING APPLICATION EQUIPMENT section or in the STORAGE AND DISPOSAL section. EPN further recommends that the instruction be revised to read: "Rinse application equipment only at a site with an impermeable pad that collects rinsate."**

F. EPA should consider whether the instruction on the 3159 label regarding refillable containers is sufficiently clear.

The STORAGE AND DISPOSAL section of the label of the 3159 product contains the following instruction: "Refill this container with pesticide only." The instruction does not require that the pesticide be the same one originally placed in the container. Given that the 3159 product also prohibits tank mixes of the 3159 product with other pesticides, **EPN questions whether this instruction is sufficiently specific.**

G. EPA should direct MGK to revise the use directions on all of the veratrine products to present the information in a more logical, consistent, and efficient manner.

EPN has several issues with the location of important labeling requirements on the veratrine products. The likelihood of users understanding and complying with all relevant parts of the labeling would improve by better organization of the labeling contents. EPN has the following recommendations:

- All four products' labeling have three separate sections with similar headings: "USE RESTRICTIONS," "APPLICATION RESTRICTIONS," and "Use Restrictions." **EPN strongly urges EPA to direct MGK to put the content of these three sections in a single section at the start of the DIRECTIONS FOR USE section of the label**. Moreover, given the critical nature of following these restrictions to minimize human and environmental exposure, EPN recommends putting the most important use restrictions in a larger font size than the rest of the use directions. EPN feels the most important use restrictions are: "Do not use indoors"; "Apply only to outdoor exterior vertical surfaces of listed man-made structures"; "Do not apply to point of runoff"; "Spot treatments must not exceed two square feet in size"; and "Crack and crevice treatment must not exceed 1 ft. by 100 linear ft."
- The labels of the two consumer use products, 31421 and 31731, authorize use against multiple pest species. Each label also contains a table with separate Application Rate directions by species – information which is identical for all pest species. Since the rest of the information in the table appears elsewhere on the label, **EPN recommends eliminating the table and putting the Application Rate information in a separate section**. Further, there is no need to repeat the information for each target species.
- The label for the 3159 product also authorizes use against multiple pest species. It has a table that lists instructions for "Dilution in Water and Application Rate." Like the 31421 and 31731 products,

the table repeats the identical directions for preparing the use dilution and applying the use dilution for each type of target pest. The rest of the information in the table appears elsewhere on the label. **EPN recommends eliminating the table, putting the instructions about diluting the formulation with water in the MIXING INSTRUCTIONS section, and putting the Application Rate information in a separate section**. As with the other products, there is no need to repeat the application rate information for each target species.

H. Given the potential for widespread misuse of veratrine consumer use products, EPA should consider the need for additional restrictions in product labeling and claims.

As is customary, EPA's regulatory decisions for the consumer products containing veratrine assume that the users will largely, if not fully, comply with the use directions and restrictions on the products' labels – an assumption that may be incorrect. EPN appreciates that the proposed labels for the 31421, 31422, and 31731 products contain clear use restrictions regarding how the products are to be used. Exposures to people and the environment should be very limited when the users comply with the restrictions to apply the product only to exterior, vertical surfaces and to limited areas of those surfaces only when the target pests are present. Further, the labels instruct the user not to over-apply the product in a way that results in runoff. As noted earlier, the labels also bear statements stressing the user's legal duty to comply with the label. While appropriate, the label text may not be sufficient.

EPN believes there is a significant likelihood these products will be misused by some, if not many, consumers. It is well-recognized that many consumers do not carefully read the entire labeling of pesticide products, especially those that, like the veratrine products, have familiar methods of application. Because consumers are accustomed to spraying insecticides wherever they encounter crawling or flying insects, EPN foresees that these products will be sprayed both outdoors and indoors, on vertical and horizontal surfaces, against both specified target pests and many other types of insects. Moreover, EPN does not expect that users will consistently limit the size of treated areas, minimize spray to prevent runoff, or limit use of the product to 12 times per year.

If EPA agrees the potential for misuse is significant and thinks the exposures resulting from foreseeable, widespread misuse would pose risks of concern, EPA should further strengthen the labeling requirements. At a minimum, **EPN recommends that EPA require MGK to include the key restrictions in any claim regarding the efficacy of the products.** For example, the claim for the 31422 Aerosol now reads: "Kills house flies." EPN believes EPA should direct MGK to revise the claim to read: "Kills house flies present on external, vertical surfaces of man-made structures."

II. Veratrine Risk Assessments

While EPA scientists have considered many different aspects of the safety of the proposed veratrine pesticides, EPN suggests that revised and additional risk assessments are needed before the agency reaches its final decision on MGK's applications. EPA proposes to register the veratrine products under the authority of FIFRA sec. 3(c)(5). This section provides that:

> (5) The Administrator shall register a pesticide if the Administrator determines that …
> (C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

In effect, these separate statutory determinations require EPA to consider the risks and benefits of a pesticide when used according to its labeling [FIFRA sec. 3(c)(5)(C)] and when used according to "widespread and commonly recognized practice" [FIFRA sec. 3(c)(5)(D)]. As was pointed out above, there is a high likelihood of misuse of these products by residents/consumers. Thus, pursuant to FIFRA sec. 3(c)(5)(D), the likely misuse scenarios warrant their own evaluation to determine whether they pose unacceptable risks. In addition, EPN has questions about the adequacy of the risk assessments to support the finding required by FIFRA sec. 3(c)(5)(C). Consequently, **EPN believes that it is necessary that EPA review, revise, and add a number of elements to the human health risk assessment of the products proposed for registration.** Further, to the extent these comments are relevant to environmental exposures, **EPA should consider revising the ecological risk assessment for veratrine products.**

A. EPA mistakenly asserts that there is no endpoint for dermal toxicity to base a dermal risk assessment and therefore has failed to conduct necessary risk assessments.

EPA documents state that available data on the dermal toxicity of veratrine do not show that any adverse effects result from dermal exposure. For example, EPA states in the Executive Summary (p.7) and elsewhere:

- "Short-term residential handler dermal exposure and risk were not assessed, as *no dermal hazard has been identified* (emphasis added)."
- "Short-term residential post-application dermal exposures and risks were not assessed, as post-application dermal exposure is considered negligible for the proposed uses, and *no dermal hazard has been identified* (emphasis added)."
- "Short- and intermediate-term occupational handler dermal exposure and risk were not assessed, as *no dermal hazard has been identified* (emphasis added)."
- "Short-term dermal occupational post-application exposure and risk were not assessed, as post-application dermal exposure from the proposed use is considered negligible, and *no dermal hazard has been identified* (emphasis added)."

However, according to the information provided in the July 13, 2023, Human Health Risk Assessment, these statements are incorrect. In Table A.2.2 "Subchronic, chronic and other toxicity profile," there is a summary of the results of the 28-day dermal study in rats. It states that there is a dermal NOAEL of 500 mg/kg/day and a dermal LOAEL of 1000 mg/kg /day "based upon microscopic findings observed in the treated skin (minimal to moderate epithelial hyperplasia, minimal to mild parakeratosis, and minimal to mild ulcer) in both sexes." Because the data reveal a dermal toxicity endpoint, EPA must use the NOAEL from the 28-day dermal toxicity to assess quantitatively the risks of short-term dermal exposures for residential and occupational handlers, as well as intermediate-term dermal exposure for occupational handlers. Finally, EPA should likewise assess residential and occupational risks from short-term, post-application dermal exposure.

EPA must include dermal exposure assessments for all relevant exposure scenarios: occupational and residential/consumer. Furthermore, the agency also must conduct aggregate exposure/risk assessments for

each residential and occupational exposure scenario to characterize the risk for the combined routes (dermal and inhalation).

B. EPA should conduct risk assessments that reflect the likely, real-world use practices of the veratrine products, including practices that may be inconsistent with the products' labeling.

EPN believes that many users will apply veratrine products in ways that violate the use directions and restrictions on the proposed labels. While EPN thinks that EPA should strengthen the labeling to communicate the limitations more clearly and prominently, EPN doubts that labeling changes will fully address the potential for misuse. Therefore, because EPN expects some types of misuse to be widespread and commonly recognized, the agency should address at least the following four misuse practices that are likely to occur:

- Applying the product not just legally on vertical surfaces, but also applying it illegally on adjacent horizontal surfaces. If one sees the pest(s) on a vertical structure, the impulse to also apply to the adjacent horizontal surface will be very strong. Thus, **the exposure assessments should reflect application in both dimensions.**
- Applying the product to actively flying insects, especially house flies, despite the label stating that a user should apply the product to a target pest on a vertical surface. EPN notes that both stink bugs and box elder bugs also are capable of flight. **The exposure assessments should account for possible inhalation and spray drift exposures when the product spray is not directed at a surface.**
- Applying more of the product than allowed by the label. Although the label says to treat only a limited surface area, avoid over-application that results in runoff, and apply the products to a site no more than 12 times a year, EPN thinks many users will not comply with those restrictions. Therefore, **the exposure assessments should reflect greater use than is specified by the label.**
- Using veratrine indoors. While EPN recognizes that the proposed registrations of the veratrine products do not currently involve food uses, EPN believes that some consumers may choose to use these products outdoors or indoors, on or near surfaces where contact with food could occur directly or via spray drift. If outdoors, this unlawful food use could be occurring coincidentally with or independently from the lawful use. **EPN thinks that EPA should conduct an assessment of the indoor misuse scenario and, separately, an aggregate assessment of the outdoor misuse and lawful use scenario to address the aggregate exposure/risk.**

C. EPA should reconsider its conclusion that no other pesticide shares a common mechanism of action with veratrine.

EPA should conduct a cumulative risk assessment with products containing other pesticide active ingredients that may share a common mechanism of action (MOA) with veratrine. Two of the products proposed for registration contain a combination of veratrine and a pyrethrin. Both veratrine and the pyrethrins interact with sodium channels in nerve cells. Thus, they share the same Molecular Initiating Event (MIE). Furthermore, they elicit some of the same manifestations of neurotoxicity. Therefore, available data indicate that pyrethrins and veratrine may be capable of producing the same types of adverse outcomes. Given the extensive research that has been conducted on the pyrethroid's MOA, the intervening key events are well-described. Being mindful that well-described MOAs don't necessarily obligate EPA to fill in every key event of an adverse outcome pathway (AOP) when evaluating a new chemical, **EPA should direct the**

registrant to provide data on a subset of key events in the AOP for veratrine that are simpler to confirm and take less time to evaluate. Then, the question of whether the pyrethroids and veratrine share a common MOA would be settled. If, on the other hand, EPA is convinced that the available data already demonstrate veratrine will not have a cumulative impact with pyrethrins, EPA should explain in a revised risk assessment why EPN's assessment laid out in this paragraph is incorrect.

D. Conclusion

In conclusion, EPN has suggested revisions and/or additions to the exposure and risk assessments for all exposure scenarios along with changes to the labeling of veratrine products. Absent these revisions and additions, EPN would assert that any approval of registration for the requested products would be premature.

These comments were prepared by Penny Fenner-Crisp and William Jordan, with input from Tina Levine, Robert Perlis, and Jack Housenger, on behalf of EPN.