HOUSEHOLD & COMMERCIAL PRODUCTS ASSOCIATION

Innovative Products For **Home. Work. Life.**

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Subject: HCPA Preliminary Feedback on the Initial Staff Draft Proposal for the Crawling Bug Insecticide Product Category[1]

Dear Mr. Berghouse,

The Household & Commercial Products Association (HCPA) appreciates the opportunity to participate as an active stakeholder in the California Air Resources Board (CARB) Regulatory Strategies Work Group and the Regulatory Definitions Work Group, to discuss possible amendments to the Consumer Product Regulation. This document conveys HCPA member companies' preliminary feedback on the CARB staff initial draft volatile organic compound (VOC) limit for the Crawling Bug Insecticide product category.

HCPA member companies have serious concerns that a VOC limit lower than 10% by weight may not be technologically and commercially feasible. Further, manufacturers and formulators may not have enough time to reformulate crawling bug insecticides to comply with the proposed VOC limit by 2023 because of the registration process timelines with both the U.S. Environmental Protection Agency (EPA) and California Department of Pesticide Regulation (CDPR) before reformulated products enter the marketplace.

Crawling bug insecticide products are typically labeled to control pests of significant public health importance.[2] For example, cockroaches are found in all types of buildings and all kinds of

[1] On November 7, 2019, CARB held the second public workshop to discuss staff's initial draft regulatory strategies for meeting the commitments for VOC reductions set forth in the 2016 State Strategy for the State Implementation Plan. A copy of the CARB staff's PowerPoint presentation is found at: https://ww3.arb.ca.gov/consprod/regact/workshop_november2019.pdf

[2] U.S. EPA Pesticide Registration (PR Notice) Notice 2002-1. Section 28(d) of the Federal Insecticide Fungicide and Rodenticide Act [7 U.S.C. § 136w–3(d)], requires EPA, in coordination with the U.S. Department of Health and Human Services and the U.S. Department of Agriculture to identify pests of significant public health importance and, in coordination with the Public Health Service, to develop and implement programs to improve and facilitate the safe and necessary use of chemical, biological and other methods to combat and control such pests of public health importance.
See https://www.epa.gov/sites/production/files/2014-04/documents/pr2002-1.pdf.

neighborhoods. The saliva, feces and shedding body parts of cockroaches can trigger both asthma and allergies when these allergens kicked-up in the air; and cockroaches also contaminate food that they come in contact with.[3] Other crawling insects can spread microorganisms that can cause illness. The efficacy of crawling bug insecticide products is critically important as several pests that are included in the crawling bug category can carry infectious diseases (*e.g.,* ticks,[4] fleas, spiders). Thus, the EPA standard for products with claims to kill or control pests of significant public health importance must provide at least 90% efficacy in laboratory trials.[5] HCPA members have serious concerns that a product that is reformulated to meet the initial staff draft proposal of a 6% VOC limit would not be sufficiently effective to meet this high efficacy standard. Research has been performed on aerosol products showing that changes in droplet size, even in the range of 14-30 microns, significantly changes the efficacy of an aerosol pesticide.[6] Therefore, any change in the propellant resulting in droplet size changes will require additional efficacy testing.

A. <u>On average, it takes approximately five years to reformulate a crawling bug insecticide product</u>.

Research and development is a lengthy process that includes both product formulation and physical property testing, all under Good Laboratory Practices (GLP) requirements, to ensure the new formulation meets the standards for product stability and control of pests of significant public health importance; this is required by both EPA and CDPR:

- 1 year for developing new formulation
- 1 year efficacy, physical chemistry and toxicity testing
- 1 year (and possibly two years)[7] for storage stability testing
- 1 year for EPA to evaluate any new formulation (which can take longer if EPA requires additional information/tests), longer if inert ingredient registration is also required
- 1 year to register the product in California through CDPR (which could take longer due to CDPR's new reporting requirement

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[3] American College of Allergy, Asthma & Immunology, *see* https://acaai.org/allergies/types/cockroach-allergy.

[4] Various tick species transmit diseases such as Lyme disease, tick-born relapsing fever, ehrlichiosis, and Rocky Mountain spotted fever.

[5] Guidance on Efficacy Testing for Pesticides Targeting Certain Invertebrate Pests (EPA), see https://www.epa.gov/pesticide-registration/guidance-efficacy-testing-pesticides-targeting-certain-invertebrate-pests.

[6] "Effect of different droplet size on the knockdown efficacy of directly sprayed insecticides," Masaaki Subira, Yoshihiro Horibe, Hitoshi Kawadab and Masahiro Takagi, SCI (wileyonlinelibrary.com) DOI 10.1002/ps.2157 (May 11, 2011). *See* http://www.tm.nagasaki-u.ac.jp/medical/PDF/Pest%20Manag%20Sci%2067%201115-1123.pdf

[7] EPA requires one year of stability testing. [Product Properties Test Guidelines: OPPTS 830.6317 Storage Stability [EPA 712-C-02-026]: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0151-0019 [*see* (b)(2)(ii)]. However, many companies perform two years of testing to ensure that the product will continue to perform until the contents in the can are completely used.

The associated timing of the listed actions is a best-case scenario that rarely occurs; this timeline is premised on the initial reformulation and all other requirements being met without failure. If at any point in this timeline the formulation does not meet the necessary requirements, the process will have to be started anew; this means that the formulation will change, resulting in a significantly longer timeframe than five years. The following provides some detail to explain the complexities of registering a reformulated insecticide product.

Developing a new formulation - requires creating the formulation and then conducting screening/pilot tests for stability, efficacy, and application parameters, which takes a minimum of one year to complete. Application parameters can be different for products, depending on the label directions and insects to be killed or controlled. A reformulation entails more than simply reducing the VOC level (usually the propellants) and replacing it with greater levels of ingredients already in the formulation. It may require an increased level of solvent(s) to meet efficacy requirements as polar solvents/VOCs help to penetrate the cuticle of insect pests. The aerosol delivery form is a complex system – both the formulation's physical and chemical properties and container stability must be retested after any formulation modification. Further, altering the formulation can modify how the product sprays (*i.e.,* particle size distribution). More importantly, particle size distribution can negatively impact efficacy, even if the active ingredient remains unchanged. If consumers don't see the quick results they're used to (even if the ≥90% efficacy threshold is met, albeit slower), there may be an unintended consequence of over-application on the part of the consumer, thereby resulting in greater exposure to the consumer. Changing the mindset of the consumer is difficult and would require greater education and outreach – not necessarily a bad thing but again takes time and resources.

The changes to the product formulations required to meet the CARB staff's initial draft proposed limits are significant enough that EPA would likely not consider them alternate formulations; therefore, all new data would be required to support the new formulations. As stated above, a reduction in VOC propellants will most likely result in an increased level of solvents, which leads to the need to redo flame extension tests and eye irritation studies.

Available alternatives to VOC propellants are not ideally suitable for all types of formulations. For example, changing to HFC-152a is significantly more expensive but, more importantly, by utilizing HFC-152a we're seeing a conflict in regulations. While HFC-152a is currently excluded from CARB's definition of a VOC under the Consumer Products Regulations, it does have global warming potential (GWP). Switching to CO_2 can cause active ingredient stability issues and affect the pH of a product. Not all manufacturing facilities are equally equipped. For example, switching to nitrogen may be slower to manufacture causing capacity issues that may lead to environmental impacts such as running plants longer, requiring more energy to produce the same product. There are also limitations to using bag-on-valve technology as far as spray patterns and fill size are concerned. The current fill limit is 15 ounces, creating more waste and recyclability issues, as bags are 3 or 4-ply made of multiple plastics. Any of these alternatives to VOC propellants creates issues such as changes in pH, flammability/flame extension, changes in pressure (increase or

drop), changes in spray pattern, package compatibility (need to retest all gaskets, may need to change to DOT 2Q cans.[8])

Inert registration - the initial staff draft proposal would require significant reduction in the VOC content of these products. Thus, most manufacturers will have to use new inert ingredients (or increased amounts of other existing inert ingredients) to meet the technology-forcing VOC limits. Inert ingredients include any substance in a pesticide formulation other than the labeled pesticide active ingredient. Propellants are inert ingredients. Inert ingredients require development of data packages, preferably from publicly available data, to support the registration and approval. New inert ingredients for use in or around food (such as kitchens) may receive a Pesticide Registration Improvement Act (PRIA) category of I001. The category I001 has a 13-month review time with the EPA.[9] Final testing on new formulations would likely not begin until the new inert ingredients are approved, due to risk. If for some reason, EPA decides not to register the new inert ingredient for the specific use, the product could not be registered (consequently, all the time, effort, cost would be wasted).

Efficacy, physical chemistry and acute toxicity testing -- EPA generally takes one year to complete its review of efficacy, physical chemistry, and toxicology testing. The actual conduct of efficacy testing could take longer than one year depending on residual label claims and/or insects listed, as some insects might only be available at certain times of year (*e.g.*, spring and summer). For products with claims against pests of significant public health importance, including spiders, scorpions, roaches, fire ants and bed bugs, new efficacy data will be required to maintain support for the claims. All tests must follow the EPA Product Performance guidelines,[10] especially OCSPP 810.3500: Premises Treatments guidelines.[11] In instances where the formulation is not considered similar to a currently registered product, EPA will likely require new acute toxicology testing, which would result in the additional animal testing; this is something EPA is working actively to reduce (and HCPA members support EPA's actions).[12]

Stability testing - is required to provide evidence on how the quality of a product varies with time under the influence of environmental factors such as temperature, humidity and light. The evidence provided by this testing provides an indication of the effect these factors may have on product quality, safety and performance (efficacy) of the pest management product. The main objective of testing is to determine how long the product will retain the percent active ingredient in its packaging. Stability testing requires at least one year to complete.

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[8] 49 C.F.R. § 178.33a. *See* https://www.govinfo.gov/content/pkg/CFR-2011-title49-vol3/pdf/CFR-2011-title49-vol3-sec178-33a.pdf.

[9] "PRIA Fee Category Table - Inert Ingredients," EPA. *See* https://www.epa.gov/pria-fees/pria-fee-category-table-inert-ingredients

[10] Series 810 - Product Performance Test Guidelines, EPA. *See* https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-810-product-performance-test-guidelines.

[11] *See* https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2009-0150-0037&contentType=pdf

[12] *See* https://www.epa.gov/research/efforts-reduce-animal-testing-epa

EPA registration – based upon member companies' experience, EPA generally requires six to 10 months to complete the registration process. [13] The time varies, depending on the volume of information companies submit to support the modification of existing formulations. Moreover, additional time is often required as a result of adjusted label claims.

California registration -- Once a product is registered at EPA it then needs to be registered in California. The CDPR's registration timelines were typically a minimum of 1 year. However, with a new system with additional requirements under CEQA, which has been mandated by the courts, it is uncertain at this time as to how long it will take a manufacturer to obtain a registration.

Moreover, even if a company has a formulation already developed (in the lab) that could meet the 10% VOC limit, it would be exceedingly difficult for that formulation to be reviewed and approved by both EPA and CDPR in time to meet the 2023 compliance date. Furthermore, if the reformulated product contains a new inert ingredient, it would then take approximately 21 months for the EPA to complete the review and approval process.

B. <u>HCPA member companies have serious concerns that the initial draft 6% VOC limit may not be commercially and technologically feasible</u>.

Complying with this extremely low VOC limit would likely require product manufacturers to move away from using hydrocarbon propellants, which allow product formulators to precisely tailor the pressure in the container to achieve the desired safety, efficacy and spray characteristics. While propellants are the majority of the VOCs in these products, there are also solvents that aid in the delivery and the efficacy of the active pesticidal ingredient to control the target pest. These products are used to control many pests that can pose a risk to public health; therefore, it is imperative that the products are effective.

Manufacturers have expressed concerns that the use of liquefied non-VOC propellants could raise the pressure in the product containers, which could have a negative effect on safety. Higher aerosol container pressure will cause more breakup of the spray pattern creating smaller particles. This combination of smaller particles and greater pressure in the delivery could create a situation in which the particles would "bounce-back" towards the applicator (*i.e.*, the consumer). Furthermore, the use of compressed gasses or very low amounts of hydrocarbon propellant may not produce a sufficient amount of dispersant energy to completely empty the contents of the container. While this consideration is outside of the scope of the VOC regulations, it is an important consideration for product manufacturers as this can divert containers intended to be recyclable into the household hazardous waste stream and negatively impact product sustainability profiles.[14]

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[13] R319 PRIA Fee Category - PRIA 4 Fee Determination Decision Tree: Conventional New Product Registration - New End Use. *See* https://www.epa.gov/pria-fees/r319-pria-fee-category.

[14] https://www.calrecycle.ca.gov/metals/paintcans

C. Reformulating aerosol crawling bug insecticide products will impose significant cost burdens on manufacturers.

HCPA member companies that manufacture these products estimate that it will cost between $ 225,000 to $ 350,000 to reformulate a single aerosol crawling bug insecticide product, depending on the insects claimed on the label. Using the CARB survey data,[15] the aggregate estimated industry costs are detailed below:

Possible threshold	Total number of reported products that meet threshold	Number of products that must be reformulated	Estimated Cost Range	
			$ 225,000 for each product	$ 350,000 for each product
15% VOC	113	0	0	0
10% VOC	40	73	$ 16,425,000	$ 25,550,000
8% VOC	28	85	$ 19,125,000	$ 29,750,000
6% VOC	18	95	$ 21,375,000	$ 33,250,000

In addition to the costs identified above, companies may also incur significant costs for buying new (or modifying existing) manufacturing equipment to produce compliant products. The net result of these additional expenses is that consumer potentially will pay a higher price for crawling bug insecticide products.

Conclusion

HCPA member companies respectfully request that CARB require one reformulation to comply with the 10% VOC limit with an effective date of 2027.

HCPA member companies look forward to meeting with CARB staff on February 5 to present technical facts to substantiate our concerns about the commercial and technological feasibility of the initial staff draft proposed VOC limits and compliance dates for this product category.

Respectfully,

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[15] CARB Regulatory Strategies Work Group Webinar (Oct. 17, 2019) at Slide # 84. *See* https://ww3.arb.ca.gov/consprod/regact/work_group_presentation_101719.pdf

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HCPA Air Quality Council