July 7, 2017

OPP Docket
Environmental Protection Agency Docket Center (EPA/DC), (28221T)
1200 Pennsylvania Ave. NW.
Washington, DC 20460-0001

*Submitted via Regulations.gov* Docket ID No. EPA-HQ-OPP-2015-0393

Re: Registration Reviews; Draft Human Health and Ecological Risk Assessments; Notice of Availability. Docket No. EPA–HQ–OPP–2015–0393; 81 FR 85952; November 29, 2016

| **Registration review case name and No.** | **Docket ID No.** |
|---|---|
| Bifenthrin, 7402 | EPA-HQ-OPP-2010-0384 |
| Cyfluthrins (& beta), 7405 | EPA-HQ-OPP-2010-0684 |
| Cypermethrin (alpha & zeta), 7218/2130 | EPA-HQ-OPP-2012-0167 |
| Cyphenothrin, 7412 | EPA-HQ-OPP-2009-0842 |
| D-phenothrin, 0426 | EPA-HQ-OPP-2011-0539 |
| Deltamethrin, 7414 | EPA-HQ-OPP-2009-0637 |
| Esfenvalerate, 7406 | EPA-HQ-OPP-2009-0301 |
| Etofenprox, 7407 | EPA-HQ-OPP-2007-0804 |
| Fenpropathrin, 7601 | EPA-HQ-OPP-2010-0422 |
| Flumethrin, 7456 | EPA-HQ-OPP-2016-0031 |

| **Registration review case name and No.** | **Docket ID No.** |
|---|---|
| Gamma-cyhalothrin, 7437 | EPA-HQ-OPP-2010-0479 |
| Imiprothrin, 7426 | EPA-HQ-OPP-2011-0692 |
| Lambda-cyhalothrin, 7408 | EPA-HQ-OPP-2010-0480 |
| Momfluorothrin, 7457 | EPA-HQ-OPP-2015-0752 |
| Permethrin, 2510 | EPA-HQ-OPP-2011-0039 |
| Prallethrin, 7418 | EPA-HQ-OPP-2011-1009 |
| Pyrethrins, 2580 | EPA-HQ-OPP-2011-0885 |
| Tau-fluvalinate, 2295 | EPA-HQ-OPP-2010-0915 |
| Tefluthrin, 7409 | EPA-HQ-OPP-2012-0501 |
| Tetramethrin, 2660 | EPA-HQ-OPP-2011-0907 |

To whom it may concern:

CropLife America (CLA) appreciates the opportunity to provide comments on the draft ecological risk assessments for the pyrethroid insecticides, listed above and announced in the subject FR notice. These comments will be posted to each of those dockets individually.

Established in 1933, CLA represents the developers, manufacturers, formulators, and distributors of plant science solutions for agriculture and pest management in the United States. CLA member companies produce, sell, and distribute virtually all the vital and necessary crop protection and biotechnology products used by American farmers, ranchers, and landowners. CLA is committed to working with the Environmental Protection Agency (EPA or Agency), the primary federal agency responsible for the regulation of pesticides, to encourage practical, science-based regulation of its members' products.

CLA supports the extensive comments submitted to the above dockets by the Pyrethroid Working Group (PWG), the Pesticide Policy Coalition (PPC), and the Responsible Industry for a Sound Environment (RISE). Those comments include specific reference to support the safe use of pyrethroids in myriad agricultural, garden, home, and public health applications. CLA's comments will focus on the agricultural benefits of pyrethroids, their history of safe use, models and assumptions used for assessment of residues, and the risk assessment approach used by EPA in its draft preliminary environmental fate and ecological risk assessments.

**Pyrethroids offer control of a broad spectrum of pests**

Synthetic pyrethroid insecticides (pyrethroids), introduced in the 1970s, provide a low-cost, environmentally friendly, and effective insecticide class for control of a broad spectrum of pests for use in agricultural (*e.g.*, row crops, forestry, and horticulture) and non-agricultural settings (*e.g.*, public health, homeowner, and household uses). Pyrethroids are characterized by low mammalian and avian toxicity and biodegradability, and are key tools for managing pest resistance[1,2].

Pyrethroids provide significant benefit to US agriculture through higher yields and more consistent production. For example, soil-applied pyrethroids are highly effective for controlling corn rootworm and the European corn borer [in corn and other crops]. Protection against common early-season insect pests such as wireworms, cutworms and white grubs that can dramatically reduce plant stands and yield is essential, given that, collectively, these insects are among the most damaging insect pests to corn production. Without pyrethroids, yields would most likely be reduced significantly, which in turn would result in higher prices for a wide range of food products derived from corn.

Pyrethroids are a primary tool for conventional control (non-biotechnology-derived) of these and other damaging insects, and for managing these pests in fields that are at risk of developing resistance to biotechnologically-introduced traits. Pyrethroids also have well established tolerances globally, which provides an added level of assurance to growers that export agricultural goods.

**The screening-level pesticide risk assessment (PRA) for pyrethroid insecticides is overly conservative and does not reflect use of the best available science**

EPA has performed its PRA using conservative assumptions for exposure and effects estimation that may be more appropriate for situations where much less is known regarding the effects of a product on the environment. Given the wealth of data available for pyrethroids, including extensive, higher-tier data and over 30 years of safe use of the products on over 120 crops across the US, the uncertainties highlighted by the Agency in its PRA should be greatly reduced. Any remaining uncertainties should be addressed by refinements following well-established principles of tiered risk assessment.

For several decades, pyrethroid registrations have mandated use of a 10-ft Vegetative Filter Strip (VFS) buffer, adjacent to agricultural fields, intended to minimize pyrethroid exposure in aquatic environments. The impact of the long-mandated VFS on pyrethroid loading into aquatic environments has not been considered in the PRA. Moreover, in its screening assessment, EPA did not take account of the best available data for estimating freely dissolved pyrethroid concentrations, or of the best available chemical/environmental fate inputs. When these factors are considered, pyrethroids show minimal risk[3].

EPA's PRA relies on toxicity data for only the most sensitive variant of the most sensitive species, despite the wealth of available ecotoxicological data for additional aquatic species that would enable a more complete evaluation of community- and ecosystem-level effects. EPA's PRA for pyrethroids incorrectly predicts high risk to both fish and aquatic invertebrates and thus overestimates the risk to

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[1] Khambay BPS and P J Jewess. 2010. Pyrethroids. In: Insect Control. Biological and Synthetic Agents. Gilbert, LI, and SS Gill (eds). Elsevier Academic Press.

[2] Palmquist K, J Salatas, A Fairbrother. 2012. Pyrethroid Insecticides: Use, Environmental Fate, and Ecotoxicology, Insecticides - Advances in Integrated Pest Management, Dr. Farzana Perveen (ed.), ISBN: 978-953-307-780-2, InTech. www.intechopen.com/books/insecticides-advances-in-integrated-pest-management/pyrethroidinsecticides-use-environmental-fate-and-ecotoxicology

[3] Giddings J, P Hendley, C Holmes, A Ritter, D Desmarteau, M Winchell, J Wirtz. 2015. Ecological Risk Assessment of Agricultural Uses of Nine Synthetic Pyrethroids. Pyrethroid Working Group Report PWG-ERA-18. MRID 49801901.

aquatic organisms. The use of the most sensitive species end points has contributed to overly-conservative estimated exposure concentrations, leading to exaggeration of potential effects[4].

**Comparison of monitoring data with modeled estimated exposure concentrations (EEC) is not appropriate**

CLA strongly supports the use of the extensive real-world pyrethroid monitoring data to validate EPA's modeling-based risk assessments. A comprehensive pyrethroid aquatic monitoring database developed by the Pyrethroid Working Group (PWG), including a recently updated version of the 2014 monitoring database[5], has been provided to EPA. This database was referenced by EPA in its PRA for comparisons of monitoring versus modeling predictions. However, EPA's comparisons were made with extreme outlier data points representing maximal concentrations, many of which are known to be invalid.

EPA [the Environmental Fate and Effects Division of the Office of Pesticide Programs within EPA (EFED)] incorrectly concluded that the 2014 monitoring database supported its claim that "EFED's modeling is not beyond the realm of environmental realism," and that its estimated concentrations used in risk assessment are not more than an order of magnitude higher than real world concentrations. Further, EPA incorrectly calculated the freely dissolved pyrethroid concentrations in monitoring water samples for comparison with EECs. These specific comparisons and assessments are provided in the comments submitted by the Pyrethroid Working Group.

In summary, CropLife America requests that EPA revise the preliminary draft ecological risk assessments for pyrethroids using the best available data, with refinements, and using more realistic and relevant models for its risk assessment. The best available scientific information and data must be used to form the basis of any ecological risk assessment: that is not the case with these assessments, as highlighted here and in the comments provided by the PWG, the PPC, and RISE. CLA's comments highlight the fact that EPA did not fully consider the extensive data available for pyrethroids in its PRA. Higher tier data, such as the comparison of modeled and monitored pyrethroid concentrations and microcosm studies, provide several strong and independent lines of evidence confirming that real-world risks associated with uses of pyrethroids are minimal.

Thank you for your consideration of these comments. Should you have any questions, please contact me by email or telephone.

Respectfully submitted,

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[4] Giddings J, J Wirtz, D Campana, M Dobbs, G Mitchell. 2016. Derivation of combined species sensitivity distributions for acute toxicity of pyrethroids to aquatic animals. Pyrethroid Working Group PWG Report No. PWG-ERA-21. Lakewood, WA. MRID 50097002.
[5] Giddings J, J Frew, J Wirtz, D Campana. 2016. Updated analysis of monitoring data for synthetic pyrethroids in surface waters and sediments of the United States. Pyrethroid Working Group Report PWG-ERA-05A. MRID 50134601.