



BEYOND PESTICIDES

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Public Information and Records Integrity Branch (PIRIB)
Office of Pesticide Programs (OPP)
Environmental Protection Agency
Rm. 119, Crystal Mall #2
1801 S. Bell St., Arlington, VA
Attention: Docket ID Number EPA-HQ-OPP-2005-0043-0073

Re: Reregistration Eligibility Decision for Pyrethrins

Dear Madam/Sir:

Thank you for the opportunity to comment on the Reregistration Eligibility Decision (RED) for pyrethrins. These comments are submitted on behalf of Beyond Pesticides/National Coalition Against the Misuse of Pesticides (Beyond Pesticides). Beyond Pesticides seeks to educate the public on the potential hazards of pesticides, restrict pesticides uses in a manner that protects public health and the environment, and advance alternatives that eliminate dependency on toxic chemicals. To that end, we would like to use this opportunity to comment and make recommendations to the RED for pyrethrins.

1. EPA must consider the health and ecological impacts of pyrethrins formulated with piperonyl butoxide (PBO)

Pyrethrins are almost always formulated with the synergist piperonyl butoxide (PBO). EPA did not consider the possible effects of these chemicals in combination. In the RED, the agency states, "EPA considered the possibility for increased toxicity due to the presence of synergists, such as MGK264 and piperonyl butoxide, in pyrethrins formulations. In order for synergistic effects to be observed in humans, the synergist must be absorbed at levels sufficient to affect mixed function oxidase enzymes. It is unlikely that these levels would occur based on the registered uses of pyrethrins. Therefore, risk quantification related to pyrethrins toxicity considered only pyrethrins."

EPA does not present adequate data on its decision to exclude formulations pyrethrins with PBO from its analysis. Studies have shown and scientists continue to warn of the hazards that pyrethrins and other insecticides formulated with PBO and other synergists pose to human health and the environment, beyond that of the active ingredient alone. While consideration of formulated products, including synergists and inert ingredients, is important in evaluating all pesticides, because of the frequency with which pyrethrins and PBO are formulated together, EPA should evaluate the combined impact for all health and ecological endpoints.

The brief comparison between the acute aquatic toxicity of technical pyrethrins and a formulated product (p 38-39) shows that the formulated product is considerably more acutely toxic to fish and aquatic invertebrates than the active ingredient alone (37-90% increase). However, the analysis is very limited, but shows the necessity of a full evaluation of pyrethrins formulated with PBO and other common synergists.

PBO is added to increase the potency of pyrethrins product. Many pyrethrins formulations contain synergists, most commonly PBO. PBO inhibits important liver enzymes responsible for breakdown of some toxins, including the active ingredients of pesticides. Specifically, it has been shown to inhibit hepatic microsomal oxidase enzymes in laboratory rodents and interfere in humans. Because these enzymes act to detoxify many drugs and other chemicals, exposure to an insecticidal synergist may make a person temporarily vulnerable to a variety of toxic insults that would normally be easily tolerated.

Furthermore, the full impact of pyrethrins combined with PBO to aquatic organisms must be considered. We encourage EPA to always consider synergists in all applicable exposure scenarios for both health and ecological impacts.

2. EPA does not have adequate data to eliminate the 10X FQPA safety factor

EPA has reduced the 10X safety factor to 1X or 3X, depending on scenario, for pyrethrins. However, EPA does not have adequate data to abandon the 10X safety factor assigned by the Food Quality Protection Act (FQPA) to protect infants and children. Congress overwhelmingly passed FQPA to address, among other concerns, the particular hazards faced by children from exposure to pesticides. Children are not little adults, and their bodies are unlikely to respond in the same manner as adults. In the case of pyrethrins, many levels of concern are already exceeded or close to being exceeded for various exposure scenarios for both adults and children. If EPA would retain the 10X safety factor, other uses may have to be cancelled or severely restricted. Beyond Pesticides disagrees with EPA's decision to abandon the 10X safety factor. We believe the decision was political, and not based on sound science. If a chemical fails the test, we cannot simply change the rules.

EPA has established pyrethrins tolerances for apples, grapes, oranges, pears, peas, peanuts, tomatoes, milk and more. Many of these foods are the favorite foods or fruit juices of children. EPA's methods for calculating exposure through food do not account for the unique diets of children. A child's diet is far less varied than an adult's. In particular children consume large quantities of milk, fruit, and fruit juices. The average one-year-old drinks twenty-one times more apple juice, per unit of body weight than the average American. This is reason alone is enough to preclude EPA from lowering the 10x safety factor for pyrethrins provided for by FQPA.

With the phasing out of certain organophosphate pesticides between 2002 and 2005, the use of pyrethrins and synthetic pyrethroids has increased and is expected to continue to increase. Clearly, pyrethrins represents a significant source of exposure to pesticides for young children given its common household uses. With the increase in use, we must carefully monitor its impacts. Unfortunately, EPA abandoned its Pesticide Incident Monitoring System (PIMS) in 1981, so there is no official record of poisoning incidents involving pyrethrins. One can only assume that if EPA had not terminated PIMS, poisoning incidents would increase with the

increase in the use of pyrethrins. The ubiquitous nature of this pesticide in the everyday lives of children, combined with the impossibility of tracking poisoning events is yet another reason to retain the 10X safety factor.

3. The Reregistration Eligibility Decision fails to take into account the possible endocrine-disrupting effects of pyrethrins.

FQPA requires EPA to screen pesticide ingredients and determine their ability to disrupt endocrine systems. EPA is also required to take action to protect public health from those chemicals found to have endocrine effects. The RED acknowledges that pyrethrins are associated with endocrine disruption. The current system of testing suspected endocrine disruptors is flawed. Because effects from endocrine disrupting chemicals do not follow the standard dose-response pattern and can affect the body at extremely low doses, often so low that they cannot be avoided, EPA must test at these levels.

For example, Frederick vom Saal, a professor at the University of Missouri, shows that exposure to endocrine-disrupting chemicals can have significant negative effects at a dose 100,000 times smaller than commonly tested in standard methods. The study looked at the effects of Bisphenol-A (BPA) at levels pronounced safe by government regulations and are said to be the equivalent of the exposure people receive in the course of everyday life. Following exposure, the mice began to show reproductive abnormalities. In some of Dr. vom Saal's experiments, low doses of the chemical actually produced the opposite result of a large dose. For example, a very small dose led to an abnormally large prostate, while a large dose led to an abnormally small prostate. Because other endocrine disruptors could cause similar effects, EPA must test for these impacts from exposure to pyrethrins and all suspected endocrine disruptors.

According to the RED, when the appropriate screening and/or testing protocols being considered under the Endocrine Disruptor Screening Program (EDSP) have been developed, pyrethrins may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption. When the EDSP is fully developed, this RED must be reevaluated and rewritten to reflect the risks of pyrethrins's endocrine disrupting potential. It must also include appropriate risk mitigation measures that will immediately change usage patterns to ensure safety.

4. EPA does not adequately mitigate the effect of pyrethrins on asthmatics.

Asthma rates in the US have reached epidemic levels, particular in young children, who are most vulnerable. Nearly 1 in 8 school-aged children have asthma, and the rate is rising. Pyrethrins have been shown to be respiratory allergens and use may result in asthma-like symptoms, especially in children with a history of asthma or allergies. Despite acknowledging the potential impact of pyrethrins on asthmatics and describing incidents involving asthma and pyrethrins, EPA fails to take into account the special vulnerability of asthmatics in its analysis.

5. Pyrethrins are toxic to bees and other beneficial insects

Pyrethrins are toxic to bees and other beneficial insects. Pyrethrins are likely to reduce and eliminate important insect populations. Pollinators provide an essential ecological function in both agricultural and wild land ecosystems. Protection of pollinators should be the highest

priority of the EPA, as without them crops would not produce harvests and wild plant communities would decline.

6. Pyrethrins are highly toxic to fish and other aquatic organisms, including endangered species

Pyrethrins is highly toxic to fish, due to the sensitivity of their nervous systems. It is also highly toxic to many aquatic invertebrate animals; its effects on insects and crustaceans are particularly severe. According to the RED, risk quotients (RQs) were above the level of concern for endangered species for freshwater and marine fish and invertebrates

7. EPA must incorporate expected increases in market share into residential exposures for all groups and scenarios

The entire market for non-agricultural insecticide use is changing as a result of the phase out of most urban uses of diazinon and chlorpyrifos (Dursban), as well as possible restrictions to other organophosphate and carbamate insecticides. A study funded by the San Francisco Bay Regional Water Quality Control Board looked at the pesticides that are most likely to replace these once widely used pesticides. Of the 45 insecticides that are possible replacements for urban uses of diazinon and chlorpyrifos, pyrethrins made the list of the top ten pesticides that appeared to be most likely to gain significant market share in the coming years, according to the study. The increase in pyrethrins use leads to increased exposure. This market increase must be accounted for in the exposure assessments. Failure to account for the market increases due to the phase out of chlorpyrifos and diazinon uses skews the results of the RED. EPA must include this predicted increase in market share in the RED. This is yet another reason the estimates fall short and EPA should retain the 10X safety factor.

Recommendations

Our analysis of the Reregistration Eligibility Decision reveals that EPA underestimated the risk that pyrethrins poses to children and the general public. Additionally, pyrethrins is an acknowledged hazard to endangered aquatic species, pollinators and other beneficial species. The agency acknowledges many data gaps as well. Until all exposure scenarios, expected increases in market share and adequate endocrine disruption data are included, the report is incomplete and EPA must, at the very least, reinstate the 10X FQPA Safety Standard. Many of the most common uses of pyrethrins have unacceptable exposure risks to many of the exposed groups, including the most vulnerable, and pose serious risks to endangered species. These uses should be cancelled immediately. Regulatory actions must be swift and not include a potentially harmful phase-out period.

Sincerely,

John Kepner
Project Director
Beyond Pesticides