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Re: Docket Control #OPP-00678B.

Date: 9/1/01

I am writing with regard to the reassessment of time-limited registrations for Bt plant-pesticides. I was a member of the FIFRA SAP on Bt Plant-Pesticides Risk and Benefit Assessment, and have carried out research on potential risks of Bt corn to non-target insects, particularly the monarch butterfly. Papers describing the results of my and others' research are in press in the Proceedings of the National Academy of Sciences. They will be released to the press on October 1, 2001 and published on October 2, 2001.

I have several concerns about the process EPA has utilized to obtain information on risks of Bt plant-pesticides. This process has not met important criteria summarized in the Federal Register (Volume 66, No. 137, pages 37227-37229), namely that the decisions on the renewal of registrations for Bt plant-pesticides are based on the most current scientific data, and that there is maximum transparency of the decision-making process. Rather, the procedure has stifled thoughtful scientific debate on this issue; scientific opposition to this technology has been excluded from access to information that is essential to making informed decisions regarding its safety. *It is important that all groups have equal access to the same information, and also have time to comment on this information before a final decision regarding re-licensing is made. The current timeline makes this impossible.* The EPA announcement of a decision should be delayed by at least a month from the current deadline of 9/30/01 to allow decisions based on current data, transparency of the decision-making process, and thoughtful scientific debate.

The results of studies conducted in the summer of 2000 clearly demonstrate that the initial licensing decisions were premature and based on incorrect assumptions about the risks to non-target organisms of Bt corn. For example, Event 176 was licensed when later toxicity studies, both in the laboratory and in the field, demonstrated that pollen from this event is lethal to monarch larvae at concentrations commonly found in the field. The contents of the *Biopesticides Registration Action Document: Preliminary Risks and Benefits Sections* were incorrect in several respects, including the degree of temporal and spatial overlap between monarch larvae and corn pollen, and the toxicity of the pollen to monarchs. While the EPA cannot be faulted for not considering data that were unavailable at the time the report was written, the document included statements that were contradictory to what was later found in field and laboratory studies. I detailed my comments during the panel meeting. It was clear that the preliminary document reflected an overly optimistic assessment of potential risks of Bt crops. If the current timeline for decision-making is followed, EPA could repeat this mistake.

Because I have been intimately involved in collecting and analyzing data that have been summarized in the industry DCI response, I know the process by which summaries of my and others' work have reached decision-makers at the EPA. The Agricultural Biotechnology Stewardship Technical Committee (ABSTC) had access to all of the papers before they were submitted for publication. They interpreted the papers and summarized them in the DCI response. Neither the EPA nor groups or individuals concerned about risks of Bt crops had official access to these papers. After incorporating our results into their response, the ABSTC sent copies of the 91-page DCI response to the senior authors of the papers, with a suggested format for a letter stating that we agreed with their interpretation of our results. I had concerns about many aspects of the response, and wrote a summary of my objections to the committee. They addressed some of these concerns, and I reviewed a revised DCI response. After two more rounds of edits and a great deal of communication between myself and members of the ABSTC, I wrote a letter that summarized my concerns about the document that was eventually submitted to EPA. This letter should be part of the public record.

My concerns about the ABSTC DCI response are summarized below.

1. There are no published studies on the results of long-term exposure to Bt corn pollen on monarch larvae. The conclusion that it is "highly unlikely that longer-term exposures of monarch larvae will result in effects on survival or fitness at environmentally relevant pollen levels" and that "sensitivity to Cry proteins decreases markedly in later larval stages" is not justified at this time. (quotes from ABSTC DCI Response Executive Summary)
2. The focus on factors that will mitigate effects of events with high levels of Bt protein in their pollen is misleading. These factors are listed in the ABSTC DCI Response Executive Summary as the "degree of temporal overlap of sensitive larvae and Bt corn pollen and the relatively low corn pollen densities beyond a few meters from cornfields that limit exposure concerns to the cornfield and the near cornfield edge." In the northern part of the monarchs' breeding range, most monarchs are larvae during the time that corn pollen is being shed (Oberhauser et al in press). There are no long-term data on the proportions of monarchs that come from different regions, so there is no way to quantify the importance of this. Low pollen densities beyond a few meters from the edge of the fields is not a mitigating factor, since Oberhauser et al. (in press) found that most monarchs probably originate in agricultural

fields. Elsewhere in the document (Data Element 10), other mitigating factors are mentioned: "the distribution of milkweeds within corn habitat and other types of habitat, and monarch feeding behavior." Neither of these will mitigate risks to monarchs from toxic pollen; milkweed is common in corn habitat, and monarchs feed on all parts of milkweed leaves, and will thus be exposed to anything on the leaves.

These issues may not be a concern for the events with low expression in the pollen (e.g. Bt11 and Mon 810), but the focus on these mitigating factors is misleading. The only reason that Event 176 does not pose a risk to monarchs is that it is rare and becoming rarer.

3. The ABSTC DCI Response suggests that "Bt corn has likely reduced the overall impact of agricultural practices on the monarch and other non-target insects" (Data Element 19). There is absolutely no evidence for this; insecticide use in field corn fields is rare. This information should only be included in EPA decisions if field studies support the contention.
4. The industry summary of the laboratory toxicity data is misleading (see table 18 in their DCI Response to element 7). For all studies in which larvae were exposed to doses of Bt 11 pollen over 1000 grains per cm^2 , the exposed larvae weighed less than control larvae, although these results were not statistically significant at the 0.05 confidence level. Given the very small sample sizes for doses over 1500 grains (n = 4), all these results say is that further studies are needed to determine effects of large doses of pollen on monarch larvae. Negative results do not prove the null hypothesis; they only fail to disprove it. In fact, the table shows that we can be 92% confident that does of over 4000 grains per cm^2 do lead to negative fitness impacts.