



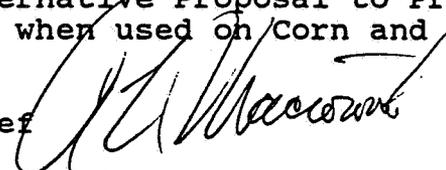
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT 7 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Response to DowElanco's Alternative Proposal to Protect
Endangered from Flumetsulam when used on Corn and
Soybeans

FROM: Anthony F. Maciorowski, Chief 
Ecological Effects Branch
Environmental Fate and Effects Division H7507C

TO: Frank Sanders, Chief
Herbicide/fungicide Branch
Registration Division H7505C

Based on current estimates of exposure, 35 endangered plant species may be affected by the registration of flumetsulam on corn and soybeans. This is a reduction from the original New Chemical Science Chapter (December 16, 1992) which identified 197 endangered plant species potentially exposed. The reason for the reduction in number is that aerial application is no longer being considered. These 35 species are those which grow in water or wetlands at least part of the time. Exposure is expected to occur through surface water runoff.

In a July 21, 1993 memorandum from EEB to RD, use limitations were proposed that would reduce, substantially, the potential for exposure to these 35 species.

On October 7, 1993, RD provided EEB with a response from the registrant of Flumetsulam, DowElanco. This response was not dated and appears to be an extract from a larger piece of correspondence. In this response, several alternatives are proposed, some reiterating previous alternatives, others are new.

These alternatives do not sufficiently reduce exposure to endangered plant species. The EEB maintains that the use limitations as discussed in the July 21, 1993 memorandum are essential to provide a high degree of protection to endangered species. The information on the specific locations of the 35 endangered plant species would provide data useful in either showing that endangered plant species are not affected, or identifying protective use limitation specific to flumetsulam.



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Without these use limitations, the EFED is obligated, by law, to formally consult with the USFWS concerning this registration. Without the specific location information, the resulting biological opinion may provide use limitations more stringent than if the location information were available.

If you have questions, please contact Mike Davy or Dan Rieder.

Frank and Steve, the following responds to a suggestion that DowElanco agree to a registration condition for flumetsulam involving an effort to identify and characterize the location of a large number of endangered plants. After considering the resources and time that would be required for such a project, it is DowElanco's conclusion that it is not equitable, feasible or practical to place such a burden on one registrant. However, we are prepared to offer an alternative proposal.

By way of background, keep in mind the following:

- As you both know, flumetsulam is a low application rate product that presents no oncogenic, developmental, mutagenic, or reproductive risk. Flumetsulam is an alternative to atrazine. It is essentially non-toxic to animals, and we believe that EPA no longer believes there is any non-target plant trigger for aquatic plants.
- DowElanco has been conducting a voluntary groundwater study. Low level detects two years after the study started occurred under quite vulnerable conditions. This information was useful to the Agency in determining whether a groundwater warning statement was needed, and in working out a practical risk mitigation statement.
- DowElanco continues to believe firmly that flumetsulam should not cause endangered plant concerns. DowElanco's modeling work does not indicate there should be a concern. DowElanco has never been provided all the details of EPA's modeling efforts so we cannot determine where the differences are. We know that at one point the Agency was using an application rate that was 10 times higher than the maximum label rate. DowElanco was recently informed that an additional error of up to 50x also occurred. Correcting for these errors brings the modeling efforts closer together but there are still differences.
- Despite the fact that DowElanco does not believe non-target plants should be an issue, the company has offered risk mitigation label language that goes far beyond what any other label that we are aware of offers. While it is not possible to quantify the extent of the risk mitigation, it is clear that the label statements will reduce risk in a qualitative sense. Taken as a whole, DowElanco believes that the label language provides state-of-the-art procedures for keeping the product "on the field"; thus, minimizing risk. At the very least, use of flumetsulam should not increase risk to endangered plants. And, in fact, with the risk mitigation measures on the flumetsulam label, risk to plants from the use of herbicides may actually be less.

DowElanco's concerns with an effort to identify the location of endangered plants are as follows:

- The cost and time to complete such an effort will be an extreme burden. We estimate that up to ten or more person-years of effort and substantial financial resources will be required.

- The benefit of this work would accrue to the registrants currently on the market who have not been asked to do similar work; the benefit will also accrue to future registrants who will not need to do the work.
- Even if such a project were undertaken, a decent data base is needed to get started. Organizations which have information may be reluctant to provide it to a pesticide registrant or even to make it available to the general public because of the concern that identifying locations could lead to harm to such plants.
- Considering recent registrations issued by EPA it is difficult to understand why flumetsulam is being picked out for additional conditions. For example, consider the recent registration of a herbicide in which the fact sheet does not say the product "may affect" endangered plants. The fact sheet says that use of the product will impact endangered plants. And yet this product was apparently not held to the same standards now being suggested for flumetsulam.
- The issue of the impact of herbicides on endangered plants is a generic problem faced by the industry and by EPA. The problem needs to be dealt with on a generic basis. Note that DowElanco is committed to being a leader in any industry-Agency effort to address the problem. DowElanco will respond fully to any EPA program designed to protect endangered plants on a generic basis.

DowElanco believes the following protective measures including some new proposals should be more than adequate to make the Agency comfortable in registering flumetsulam:

- As stated above, DowElanco will fully support generic efforts to protect endangered plants.
- The previously agreed to risk mitigation label statements will qualitatively reduce whatever the risk is.
- The previously agreed to education program will stress the fact that the risk mitigation measures on the label are key elements of a stewardship program to reduce the chance of any groundwater contamination and to reduce risk to non-target plants including endangered plants. DowElanco can stress the need to protect endangered species; following the label directions will help do this if some plants happen to be near treated fields.
- The previously agreed to non-guideline plant protection study will assist in further characterizing possible risk.
- In addition to the above, DowElanco offers the following new suggestions in lieu of an effort to identify the specific location of endangered plants. First, DowElanco will undertake a sensitivity analysis of the plants of concern in order to categorize which plants may be more sensitive and thus may need additional attention. For example, flumetsulam has minimal activity on perennials and grasses. It is effective against certain annual broadleaf plants. Literature searches and modeling work could help to

identify and characterize species of greater concern. In addition, DowElanco will conduct work to characterize the habitat of the more sensitive species. That is, rather than working on specific locations, efforts would focus on how to describe locations where the more sensitive plants might be. DowElanco can complete this work within one year after EPA provides a list of the endangered plants of concern.

- The above effort could serve as a pilot for additional work by other registrants to characterize the impact of their products. DowElanco is willing to work with EPA and other registrants to implement similar work involving other products and other plants.
- Since DowElanco believes that a project to identify the location of endangered plants will require an effort larger than one registrant can reasonably afford, and since organizations that may have needed information may be more willing to provide that information to EPA, DowElanco is willing to contribute funds individually or as a part of a larger industry sponsored program to support an EPA effort to characterize plant locations.

In conclusion, DowElanco believes the above seven-part proposal will clearly reduce any risk to endangered plants. While DowElanco believes the program elements are substantially greater than requirements placed on other registrants, the company recognizes its responsibility to keep advancing risk reduction efforts.

We would appreciate a prompt response to the above proposal.