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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT: Biological Review of Public Interest Documentation Submitted by Monsanto Agricultural Company in Support of Acetochlor, formulated in the herbicide products Harness® and Top-Hand®, for weed control in corn.

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Introduction

We have reviewed the Public Interest Document submitted by Monsanto in support of the Section 3 Conditional registration of Harness® Herbicide and Top-Hand® Herbicide. We offer the following discussion and conclusions for your consideration.

Acetochlor, the active ingredient in Harness® (acetochlor only) and Top-Hand® (acetochlor [REDACTED]), is an acetanilide which is manufactured by the applicant, Monsanto. These two herbicides, applied either preemergent or preplant, control a broad spectrum of weeds.

The applicant is proposing a Section 3 conditional registration for acetochlor for use on corn to control fall panicum, foxtail species, yellow nutsedge, wild proso millet, wooly cupgrass, broadleaf signal grass, shattercane, field sandbur, pigweed, lambsquarter, common ragweed, and velvetleaf.

The proposed rates of Harness® herbicide are a maximum of 1.5 pounds AI/acre on medium-textured soils and 1.75 pounds AI/acre on fine-textured soils. On the other hand, [REDACTED] in Top-Hand® herbicide would permit use of a maximum rate of 3 pounds AI/acre of this herbicide on all soil types. There appears to be a discrepancy between the text on page 57 and the table on page 58 regarding the maximum rate for Top-Hand® (page 57 gives 3 pounds AI/A compared to the table on page 58 which gives 2 pounds AI/A for use on fine and medium soils and 1.5 pounds AI/A for coarse soils).

Monsanto used the following strategy to support their claims for benefits from the use of acetochlor. Experiments comparing the weed control efficacy of acetochlor with several alternative herbicides were conducted. The results, given as mean percent weed control provided by various rates under various conditions,

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were shown in tables. Results from several locations or rates were averaged and differences between the results of these treatments were calculated by subtraction. Regression equations developed by other researchers were then used to mathematically convert differences in weed control efficacy to differences in crop yield.

Review

We have reviewed Monsanto's document. Most of the tables were summaries of original studies. We relied on statistical review, economic analysis, review of selected literature, and personal communication with experts in the field to verify the applicant's claims and to complete our review. Our findings, in regard to Monsanto's claims of benefits from use of acetochlor, are discussed below:

1. Monsanto claims that broadleaf weed control with acetochlor is superior to that with alachlor, metolachlor, butylate and EPTC. As no supporting data is provided concerning the thio-carbamates, this aspect of the claim can not be assessed. Broadleaf weed control with acetochlor does seem to be equal to or better than that achieved by alachlor or metolachlor (Appendix E, Tables 28-41). As alachlor and metolachlor are rarely used alone for broadleaf weed control, acetochlor may provide a benefit in corn when compared to these herbicides by eliminating or reducing the need for a separate broadleaf herbicide. However, as the tables show a wide variation in the efficacy of broadleaf weed control from acetochlor, proper statistical analysis is needed to confirm this claim.

2. Monsanto claims that atrazine, when tank-mixed with acetochlor, may be used at lower rates to control velvetleaf (Appendix E, Tables 30-31). However, acetochlor's efficacy was not compared with that of atrazine alone. This comparison is needed to determine if acetochlor could replace some atrazine use. In addition, the applicant needs more data to support claims that atrazine usage would be reduced.
3. Acetochlor does demonstrate activity on triazine-resistant biotypes of pigweed, common lambsquarters, and common ragweed (Appendix E, Tables 9, 11, 12, 14-16, 18, 28, 29, 31-35). However, to claim benefits from the use of acetochlor, the applicant needs to compare acetochlor with dicamba and 2,4-D which are currently used to control triazine-resistant weeds.
4. Acetochlor provides control of difficult-to-control species of weeds (Benefits, Table 20; Appendix E, Table 21; Appendix F, Fig. 3-4, Tables 4-5). Difficult-to-control weeds include: yellow nutsedge, wild proso millet, wooly cupgrass, broadleaf signal grass, shattercane, field sandbur, common ragweed, and velvetleaf. The applicant needs to discuss other methods used to control these weeds and to compare these methods with alachlor.
5. On high (6-10%) organic matter soils the differences in weed control between acetochlor and alachlor or metolachlor are too small to support significant benefits from the use of acetochlor without comparative statistics (Appendix E, Tables 8-10; Appendix F, Fig. 2, Tables 1-2). On muck soils, acetochlor does seem to

have a clear advantage (Appendix E, Tables 11-15). However, comparative statistics are still required to quantify this advantage. There is only a small amount of acreage of corn grown on soils having organic matter greater than 4 to 5% (Gednalski, 1988).

6. Monsanto claims that acetochlor's higher biological activity under low moisture conditions allows lower rates of it to be used (Appendix E, Table 16-20; Appendix F, Fig. 2, Table 3). While the results presented for acetochlor at low rates and under dry conditions do show better average percent weed control compared with the results from equally low rates of alachlor, metolachlor, and thiocarbamates, the differences between these chemicals is too small to accept the applicant's claims without comparative statistics.
7. Our communication with experts in the corn-growing areas suggested the following from a study of no-till use of actochlor (Harness®) on corn. It appeared from the results that acetochlor would likely give better weed control than alachlor under drier conditions. However, there is limited confidence in this study because it was done without replications. If acetochlor is more soluble than alachlor, then acetochlor would likely be more active under drier conditions and give better performance (Gednalski, 1988; Weber and Peter, 1982).
8. We agree that acetochlor is active when applied to the soil surface and does not have to be incorporated into the soil. This allows for more flexibility in application than thiocarbamates. Alachlor and metolachlor also share this advantage.

9. As a preliminary step in equating pest control efficacy with crop yield, the applicant calculated the effect of each pesticide as the average of various individual rates and locations tested. However, these average percent weed control values were not presented nor is it clear which data Monsanto used to calculate them. In the few cases where aggregated means are presented, they were calculated incorrectly. For example, an unweighted mean was calculated to indicate the control of yellow nutsedge by acetochlor in Table 22. This method incorrectly gives "97" from a single test as much weight as "89" from 8 tests. A weighted mean should be calculated to account for the number of experiments and replications involved.
10. Analyses of variance were missing. Thus, it was not possible to determine if small differences (e.g., 3-5%) in weed control were due to the effect of the herbicides tested or due to random populations variations.
11. Regression equations were referenced but not provided to equate weed control with efficacy and crop yield. Neither were statistics of association between the regression equations and original data used to create them (Appendix F, Fig. 1-4). These omissions prevent verification of the registrant's calculations.
12. Note the statement in General Weed Control, pp. 57-58:
"Also, since the values shown are the means of trials established over several years at many locations, the high ratings attest to a high degree of consistency." We

disagree with this statement. A variance statistic, instead of a mean, is needed. A mean, either high or low, does not adequately describe consistency.

13. The projected market shares shown in Table 25 of the Benefit Assessment in the Monsanto Document are believed to be overstated. Because of numerous corn herbicide alternatives available it is unlikely that a single new chemical will capture 50% or more of the market share in 5 years. In that time frame other new chemicals will also enter the market to compete with acetochlor, thus reducing the market share further. It is projected that acetochlor may capture a maximum of 20% of the overall market. While acetochlor is expected to perform on high organic soils (greater than 4 to 5% organic matter), very little corn is grown on these soils, thus limiting the expected market for acetochlor.
14. Benefit estimates found in Appendix G of the Monsanto document contained mathematical errors and have been recalculated as shown in our Tables I and II.

We have the following concerns:

1. Monsanto interprets statistics in a different way from EPA. There are normal, random fluctuations of environmental conditions which affect crop yields and the data derived from these yields. Monsanto claims acetochlor improves crop yield, but evidence suggests that small yield differences may be the result of random fluctuations of the environment.

2. If acetochlor works better than tested alternatives under dry conditions, are there weather conditions where acetochlor does not work as well as alternatives?
3. Are there certain weed species controlled by alachlor and metolachlor for which acetochlor is less efficacious?
4. What kind of carry-over to rotational crops is there from acetochlor?
5. If acetochlor is active at lower rates than the alternatives, there could be potential problems from off-target drift and leaching into groundwater.
6. Lower rates may not equal lower risk. Lower application rates and residues of a more active chemical may be as toxic as higher quantities of less active chemical.

Conclusions (based on our review)

Our conclusions, were based on our analyses of the applicant's rationale submitted in support of this registration and information drawn from additional sources (Gednalski, 1988; Grube, 1988; Lueschen, et al., 1980; Lynn, 1980; Torla, 1988; Weber and Peter, 1982).

We agree that acetochlor - when evaluated along with alachlor, metolachlor, or thiocarbamates - provides the following agronomic benefits:

1. can be more flexibly applied than thiocarbamates;
2. provides control of difficult-to-control species of weeds; and
3. provides control of triazine-resistant weeds, including pigweed, lambsquarter, and common ragweed.

On the other hand, without supporting comparative statistics, we can not agree that acetochlor does the following:

1. provides general weed control at lower rates than alternatives tested [Benefits Sec., Table 19, Appendix E, Tables 1-2];
2. performs better at lower rates on high (6-10%) organic matter soils [Appendix E, Tables 8-15; Appendix F, Fig. 2 Tables 1-2];
3. performs better against certain broadleaf weeds than alachlor and metolachlor [Appendix E, Tables 28-41]; or
4. performs better under dry conditions [Appendix E, Tables 16-20; Appendix F, Fig. 2, Table 3].

Our review supports the following factors required for a public interest finding (CFR p. 7632):

1. Acetochlor meets a need not being met by alternatives in that acetochlor can be more flexibly applied than thio-carbamates.
2. Acetochlor provides benefits which exceed those of its alternatives:
 - a. Acetochlor provides control of difficult-to-control species which include: yellow nut sedge, proso millet, wooly cupgrass, broadleaf signal grass, shattercane, field sandbur, velvetleaf and triazine-resistant weeds (pigweed, lambsquarter, and common ragweed).

- b. The two acetochlor-containing products, Harness® and Top-Hand®, appear (under the conditions specified in the rationale document) to be either equivalent to or superior to alachlor, metolachlor and thiocarbamates based on information available to us at this time.
3. The projected market share for acetochlor is believed to be overstated. It is estimated that due to competition from alternative herbicides, and limited corn acreage with high organic matter, acetochlor's market share will not exceed 20%.

Table I. Cost Comparison between Top-Hand® and its Alternatives of Alachlor, Metolachlor and Thiocarbamates.

chemical	application rate (lb/acre)	chemical cost (\$/lb)	chemical cost/acre (\$/acre)	change in chemical cost/acre (\$/acre)
Top-Hand®	1.5 - 3.0	7.56	11.34 - 22.68	
alachlor	1.75 - 6.0	5.15	9.01 - 30.90	-2.33 - +8.22
metolachlor	1.5 - 4.0	6.38	9.57 - 25.52	-1.77 - +2.84
thiocabamates	4.2 - 6.0	2.90	12.18 - 17.40	+0.84 - -5.28

Table II. Cost Comparison between Harness® and its Alternatives of Alachlor, Metolachlor and Thiocarbamates.

chemical	application rate (lb/acre)	chemical cost (\$/lb)	chemical cost/acre (\$/acre)	change in chemical cost/acre (\$/acre)
Harness®	1.5 - 1.75	8.59	12.89 - 15.03	
alachlor	1.75 - 6.0	5.15	9.01 - 30.90	-3.88 - +15.87
metolachlor	1.5 - 4.0	6.38	9.57 - 25.52	-3.32 - +10.49
thiocabamates	4.2 - 6.0	2.90	12.18 - 17.40	-0.71 - +2.37

Source: Kunstman, J. L. (Compiler). 1988. Acetochlor Support Document. Rationale in Support of the Registration of Harness® Herbicide and Top-Hand® Herbicide. R. D. 879. Vol. 1 of 1. (Prepared by Monsanto Agricultural Company).

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