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OFFICE OF
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TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT: Response to Comments on Review of Fipronil-treated Onion Seed Protocol

TO: Ann Sibold
Registration Division (7505P)

FROM: Stephen Wente, PhD, Biologist
Nancy Andrews, PhD, Branch Chief
Environmental Risk Branch I
Environmental Fate and Effects Division (7507P)

Thru: Edward Odenkirchen, PhD, Senior Scientist
Environmental Risk Branch I
James Hetrick, PhD, Senior Scientist
Environmental Risk Branch III
Environmental Fate and Effects Division (7507P)

The registrant (BASF) has submitted a report, entitled "Protocol for Experiments to Understand the Movement of Fipronil from Treated Onion Seeds", for EFED's review in order to generate supplemental data to address ecological concerns associated with the use of fipronil on onion seeds. Previous EFED modeling of this use resulted in acute and chronic risk quotients that exceed levels of concern for aquatic invertebrates for fipronil and two of its degradates (MB 46136 and MB 45950). After reviewing the proposed protocol, EFED concluded that the study *as proposed* would *not* materially affect EFED's modeling assumptions and would *not* affect EFED's conclusions concerning environmental risk (D353645).

Subsequently, the registrant submitted comments concerning the EFED review of the registrant's protocol. This document is EFED's response to those comments. After reviewing the registrant's comments, EFED's conclusion remains unchanged.

BASF Comment #1 (general comment). BASF requests an MRID number for the protocol. The submission was made in accordance with PR Notice 86-5. A MRID number would be useful for reference purposes.

EFED Response. An MRID number is not given to protocol documents. The final study will be given an MRID.

BASF Comment #2 (general comment). The protocol design originated from a teleconference with BASF and EPA on September 5, 2007. Participants in the teleconference for BASF were Dr. Bob Paulik, Dr. Scott Jackson, and Dr. Dave Bolin. Participants for EPA were Dr. Ed Odenkirchen, Dr. Jim Hetrick, and Ms. Ann Sibold.

A lengthy discussion was conducted on the design of the Inverted Field Scenario used in experiments #3 and #4. Dr. Odenkirchen contributed significantly to the discussion, including the point about analyzing the soil at the bottom of the funnel for fipronil content.

The study is non-guideline and unique in nature. We believe it would be helpful if the EPA would include participants from the original discussion in the review process and analysis of preliminary data.

EFED Response. The review (D353645) should have indicated that EFED's protocol review document had been reviewed by Drs. Odenkirchen and Hetrick before it was forwarded to Ann Sibold and, subsequently, transmitted to the registrant. Dr. Odenkirchen made several edits to the document prior to its release. EFED apologizes for this omission.

BASF Comment #3. "*Therefore, fipronil on the seeds is placed where it is most susceptible to runoff and erosion if dissolved or bound to soil particles or organic material entrained in runoff water*" (page 1, paragraph 2, line 4 of D353645).

The EPA point of view is 100% of the onion fields are at risk for the scenario AND 100% of the fipronil is those fields will wash off to surface water.

Assuming 100 percent runoff is an extremely conservative position and clearly is not realistic. We understand that if EPA does not use the unrealistic 100% value it does require a basis for choosing a different value. The results clearly show that in the presence of soil, the actual value in the field will be less than 1%. Regardless of the relatively shallow depth at which onions are planted, there are many factors associated with onion production that more than compensated for seedling depth. These include the following:

1) Onion fields tend to be flat.

2) The soil types almost always have low potential for runoff, because onion do NOT grow well in hard compactable soils. Most soils are muck or porous and light.
3) In arid regions drip irrigation is common and runoff events are unlikely.
4) Cover crops are used in some regions for onion production.

EFED Response. There appears to some misunderstanding between the registrant and EFED at a conceptual level both of the interpretation of the registrant's onion seed experiments and how the results of these experiments would be used to estimate risk. The registrant appears to interpret experiments 1 through 4 as representing a series of successive refinements that produce the best estimate of relevant environmental exposure in experiment #3 or #4. Whereas, EFED interprets the results of the series of experiments to represent the amount of fipronil released from the onion seed coat at different levels of seed coat degradation with experiments #3 and #4 representing the least amount of seed coat degradation and experiment #1 representing the most. (The only difference between experiments 3 and 4 is the amount of time the seeds are allowed to "soak" in water in the inverted Buchner funnel apparatus with experiment #3 soaking for 1 day and #4 soaking for 5 days.)

Concerning the misunderstanding between the registrant and EFED at a conceptual level on how the results of these experiments would be used to estimate risk, the registrant has designed the onion seed wash-off experiment to measure only the fraction of fipronil washed off the seeds over 1 or 5 days (experiments 3 and 4). The fate of the fipronil and degradates that did not wash off is not further investigated.

In the registrant's comments on the protocol review, the registrant supplied a PRZM/EXAMS-based analysis using what appears to be the application rate scaled down to the fraction that washed off the seeds in experiments 3 and 4 (tables on protocol document page 13). This analysis simply ignores (does not include) the fractions of the fipronil and degradates that did not wash-off and, therefore, is still attached to the seed coat or adsorbed to the soil as bound residues (soil bound fipronil that is not extracted during the acetonitrile/acetone extraction). By not including these fractions (the vast majority of the fipronil applied), this PRZM/EXAMS analysis does not include erosion of the fraction of that vast majority of fipronil that might have become bound residues, does not include any subsequent wash off of the fraction of that vast majority of fipronil that would still be bound to seed coats, and does not allow fipronil concentrations from the vast majority of the fipronil applied to build up in the soil and be eroded in the years subsequent to its application.

EFED's standard method of evaluating aquatic risk, PRZM/EXAMS, predicts estimated environmental concentrations (EECs) over typically a 30 year time period. Therefore assuming the first seeds are planted halfway through the first year, these first seeds will be subject to 29 ½ years of degradation by the end of the simulation, while the seeds planted in the last year are subject to a half year of degradation. After 29 ½ years of degradation, it seems likely that very little fipronil or its degradates will be attached to any remnants of the seed coat of the first seeds planted. Even the last seeds planted would

likely be degraded to a greater extent than the seeds soaked for 1 day (experiment 3) or 5 days (experiment 4) and, therefore, would be expected to release much more fipronil/degradates from the seed coats than that released in either experiments 3 or 4.

In EFED's protocol review, EFED used preliminary data from both experiments #1 and #2 to show that if this data is considered to be the total fipronil released from seed coats over the period of time simulated by PRZM/EXAMS, the risk to aquatic invertebrates will exceed levels of concern (LOCs). From this perspective (EFED's), the problem with the registrant's experiment is that the fipronil/degradates washed off under different degrees of seed coat degradation can't be related to time since planting.

Concerning the characteristics of the onion fields described by the registrant, the Regent® TS label (Reg. No. 7969-223) does not appear to geographically limit or limit the characteristics of the onion fields that can be planted with the fipronil treated seeds.

BASF Comment #4. "*The experiment is performed in a laboratory but uses a complex apparatus to 'include the environmental factors of soil adsorption and translocation'.*" (page 2, paragraph 3, line 3 of D353645).

The fact previously stated is that the design came from a teleconference of EPA and BASF. To characterize the laboratory equipment as "complex" is misleading. The equipment involved is a Buchner funnel and filtration flask. These common items can be found in virtually any college organic chemistry laboratory.

EFED Response. EFED agrees to not characterize the apparatus as "complex" in future correspondence.

BASF Comment #5. "*Preliminary results included in the protocol indicate approximately 0.015% (average of replicates) wash-off under these conditions (measured from water only; no soil measurements in preliminary data).*" (page 2, paragraph 3, line 7 of D353645)

Soil analysis was included in the results per suggestion of Dr. Odenkirchen. The description of the soil extraction is provided in the second paragraph on page 12. Moreover, the results table on page 13 clearly indicates water, soil, and combined totals for the experimental values.

EFED Response. EFED should have used the term "bound residue" rather than "soil". The EFED reviewer was merely indicating that there is no estimate of the fipronil bound to the soil that was not extracted by the acetonitrile/acetone extraction. The EFED review used the combined % washoff values (water leachate and soil column extraction) when discussing these experiments. EFED apologizes for the confusing terminology.

BASF Comment #6. "*Preliminary results included in the protocol indicate approximately 0.055% (average of replicates; water only).*" (page 2, paragraph 4, line 2 of D353645)

Again, soil analysis was ignored by the reviewers. The soil results are clearly shown in the table on page 13 for results of experiment #4.

EFED Response. See response to comment #5.

BASF Comment #7. "*EFED would argue that the key variable that controls the availability of fipronil and its degradates is the degree to which the seed coat has degraded. EFED's assumption of 100% availability can be thought of as an assumption of what is available after the seed coat has completely degraded. If the seed coat quickly degrades, the assumption of 100% availability is likely an acceptable approximation; if the seed coat degrades slowly, the assumption of 100% availability will over-estimate fipronil and its degradates concentrations (at least in the near-term).*" (page 4, paragraph 4, line 1-7 of D353645)

Disrupting the seed coat intentionally and extracting with solvent (acetonitrile) was the purpose of Experiment #1. Under vigorous conditions, intentionally trying to extract the maximum amount of fipronil, only 39% of the amount of the treated label rate could be recovered.

Experiment #2 demonstrated that fipronil could only be extracted at 13% of the amount of the treated label rate with water (as fipronil is less soluble in water than in acetonitrile). Again under vigorous conditions of mechanical shaking and sonication with the intent to extract the maximum amount of fipronil, the disparity between actual and EPA assumption was a factor of 7.7 X difference.

Seeds coats will NOT be vigorously disrupted in the environment as described in Experiments #1 and #2. Fipronil used in the seed treatments is bound to seeds with polymers. The seeds are placed in the soil. Fipronil movement can realistically be expected to be limited due to binding to seed and soil. Experiments #3 and #4 were designed to quantitatively estimate fipronil exposure / risk under environmental conditions.

BASF made conservative assumptions and built in a 10 X planting factor for the amount of seed / soil.

EFED Response. EFED assumes seed coats will decay/degrade almost completely over the 30 year duration of the PRZM/EXAMS simulation. The argument put forward by the registrant seems to imply that a very large fraction of the fipronil applied to an onion field is bound with polymers to seed coats in a way that would render the majority of the pesticide's active ingredient an inert ingredient. If this interpretation is correct, it would seem more logical to lower the amount of fipronil applied to each seed and bind this fipronil with weaker polymers.

BASF Comment #8. "*Potentially, a better way to design the study might be to measure the release of fipronil and its degradates from treated seeds as they degrade.....*" (page 4, paragraph 5, line 1 of D353645)

The suggestion of improvements /additional studies do not appear warranted at this time. We believe that EPA should more thoroughly evaluate the protocol and preliminary data along with our comments. It is also not clear how the additional studies described in the review would be used in the model.

BASF has provided a realistic assessment of the data obtained using PRZM/EXAMS modeling. Assessments were based on Experiments #3 and #4 with a exaggerated planting rate (10x) AND a safety factor for the result (10x – results indicate 0.1% max for fipronil and the calculations are based upon 1.0% fipronil washoff).

EFED Response. The information presented in the registrant's comments on EFED's protocol review does not change the conclusions reached in EFED's protocol review. If the registrant wants to claim that a large portion of the fipronil applied is inert, then the registrant's study needs to provide evidence that that is indeed the case. Therefore after reviewing the proposed protocol and registrant response to the protocol review, EFED concludes that the study *as proposed* would *not* materially affect EFED's modeling assumptions and would *not* affect EFED's conclusions concerning environmental risk.

Please contact Steve Wente at (703) 305-0001 (wente.stephen@epa.gov) with any comments or concerns.