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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DATE: June 15, 2000

MEMORANDUM

SUBJECT: Disulfoton (PC Code 032501): HED's Response to Comments Submitted During Phase 5 (Risk Management). DP Barcode D266111.

FROM: David Anderson, Toxicologist 6/14/00
Christina Jarvis, Environmental Protection Specialist Christina M. Jarvis 6/15/00
Reregistration Branch II
Health Effects Division (7509C)

THROUGH: Alan Nielsen, Branch Senior Scientist 6/15/2000
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TO: Christina Scheltema, Chemical Review Manager
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Special Review and Reregistration Division (7508W)

INTRODUCTION:

The Health Effects Division (HED) acknowledges the comments received during the 60-day risk management public comment period (Phase 5) for disulfoton. The majority of the comments received were from the North Carolina Christmas tree growers and Bayer Corporation (the registrant). Comments were also received from the American Nursery and Landscape Association, the North Carolina Cooperative Extension Service, and the American Bird Conservancy. Input has been provided by Jonathan Becker (occupational and residential exposure) and David Anderson (toxicology).

Comment: A number of Christmas tree growers in North Carolina provided comments relating to their use practices, farm sizes, the number of acres they treat with disulfoton, the frequency of their applications, the number of workers involved in disulfoton application activities, and the length of time it takes to make the pesticide applications.

HED Response: After careful review of the comments, Health Effects Division (HED) has not identified additional information that would necessitate a revision of the human health risk estimates presented in its revised occupational and residential exposure and risk assessment.

Comment: The Registrant (Bayer Corporation and Bayer-Pursell, LLC) commented that the revised risk assessment did not consider that Bayer is switching 8E formulation to a closed transfer system for mixing and loading (SecuraLink-G transfer system).

HED Response: The revised occupational and residential risk assessment did include an assessment of mixing/loading liquids using engineering controls using surrogate data from PHED. The Health Effects Division does not know of any specific SecuraLink-G transfer system data relating to handler exposures that have been submitted to the Agency for review.

Comment: The Registrant stated that they will propose additional dermal toxicity and/or exposure testing to refine homeowner risk.

HED Response: Additional data relating to dermal toxicity and residential exposure would be useful to refine the exposure and risk assessment for disulfoton. Protocols for all studies should be submitted to the Agency for review prior to the initiation of any study.

Comment: The Registrant commented that the revised risk assessment for disulfoton did not consider PPE listed on the current label (specifically the chemical resistant apron for mixer/loaders).

HED Response: PPE appearing on end-use product labels is generally based on 1) the acute toxicity of the formulated product, 2) the sub-acute, sub-chronic, and chronic risks posed by the active ingredient, and 3) additional information, such as incident data, that suggests additional protection is needed for a product. Because exposure assessments conducted for a RED consider the risks posed by the active ingredient and not the potential risk posed by each end-use product, the occupational and residential exposure assessments do not evaluate all PPE that appears on product labels. Rather the occupational and residential exposure assessments evaluate the risks from exposure to the active ingredient first at baseline protection (long sleeved shirt, long pants, shoes and socks), then with PPE, and finally with engineering controls.

Comment: The Registrant disagrees with the respiratory protection factors used by EPA to estimate inhalation exposure from the use of respirators.

HED Response: HED acknowledges that there have been significant advances in respiratory protection technology. However, HED is also aware of differing opinions as to the appropriate protection factors to use with the various types of respirators based on their performance in the field. Currently, HED uses a 5-fold protection factor (80% reduction in exposure) for a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) rather than a 10-fold protection factor (90% reduction in exposure). HED would consider additional monitoring data that shows that these respirators offer a 10-fold protection factor when used in agricultural settings.

Comment: The Registrant notes that the Outdoor Residential Exposure Taskforce (OREFT) has submitted surrogate exposure data for the scenario of loading/applying granules with a push-type spreader (MRID 44972201) and maintains that these data are of higher quality than PHED data used in revised risk assessment.

HED Response: HED acknowledges that the Agency has received these studies but is not aware of the proposed review schedule for these data. Currently the quality of the ORETF data cannot be evaluated. However, taking the values presented by the registrant at face value (and assuming that these values are in units of ug/lb ai and not mg/lb ai as stated), then the exposures can be evaluated as follows: inhalation exposure – approximately the same; dermal exposure (for occupational work clothing) approximately a 17-fold reduction. This would result in estimated short-term risks for this scenario ranging from 0.9 to about 80. Changes in the residential exposures for this scenario cannot be estimated with the information presented.

Comment: The Registrant commented that the exposure rates and doses appear to be wrong in tables 4,6,7, 8 and 9 of revised risk assessment (wrong units of measure).

HED Response: HED was not able to identify these potential errors in the tables. Please describe the errors in more detail.

Comment: The Registrant want to know why DFR study on potatoes (MRID 44688001) doesn't meet guideline requirements.

HED Response: This study contained several deficiencies, such as having numerous deviations from the QA/QC and method protocols and sampling after only one application was made at any of the test sites (rather than after 3 foliar applications as stated on the product label). The most serious deficiency was that the sampling intervals were too far apart to develop a meaningful

dissipation curve. The first post-application DFR samples were collected at 24 hours and are (with one exception) uniformly negative for disulfoton. As a result, the data presented are inadequate to permit the plotting of a dissipation curve or calculation of an accurate residue half-life.

Comment: The Registrant (Bayer Corporation and Bayer-Pursell, LLC) disagrees with the assumptions of area (or number of roses) treated by residential handlers.

HED Response: In a meeting between the Registrant and the Agency on April 17, 2000, the Registrant verbally presented summarized results from a 1999 Brushkin-Goldring consumer study and a 1995-1996 Gallup survey on the consumer dynamics of the rose marketplace. These survey data will be incorporated into the residential risk assessments once the complete surveys have been submitted to the Agency, reviewed, and verified by the Biological and Economic Analysis Division (BEAD).

Comment: The Registrant commented that the dermal exposures for residential exposure from loading/applying granules with a shaker can, spoon, etc. are gross overestimates; Bayer derived much lower values using PHED.

HED Response: HED disagrees but suggests that this topic be discussed further in meetings between the Agency and the registrant.

Comment: The American Nursery and Landscape Association commented on pest management issues in nursery industry; that the use of disulfoton allows nurserymen to use less pesticide overall; worker exposure in production of nursery field stock, apply disulfoton to maple and birch by "knifing in" to soil; urge EPA to allow time for development of data to refine worker risk assessment.

HED Response: HED acknowledges that additional data would likely allow for the refinement of the risk estimates presented in the original chapter. Scheduling is determined by OPP management.

Comment: Dr. Jill Sidebottom from the North Carolina Cooperative Extension Service, commented on the worker assessment for treatment of Christmas trees with disulfoton.

HED Response: Information provided by Dr. Sidebottom collaborated many of the assumptions made in the occupational exposure assessment chapter as to the magnitude of worker's exposure to disulfoton.

Comment: Asparagus grower groups in California commented on the use of disulfoton in asparagus and provided information about cultural practices in this crop.

HED Response: After careful review of the comments, HED has not identified additional information that would necessitate a revision of the human health risk estimates presented in its revised occupational and residential exposure and risk assessment.