



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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Dear Mr. Weinberg and Mr. Menotti:

Thank you for your letter of October 6, 2009, regarding EPA's approach for addressing the National Marine Fisheries Service ("NMFS") 2008 biological opinion on chlorpyrifos, diazinon, and malathion ("the BiOp"). In your letter and the attachment to that letter, you outlined what you describe as key conceptual points for Dow AgroSciences, Makhteshim Agan of North America, and Cheminova ("the registrants") for any agreement on their part to label changes and data submission obligations necessary to address the BiOp.

While I understand that the list of conceptual points you provided may be subject to amendment after you have heard from more of your customers and commercial personnel, I want to respond at this point to some of your statements and proposals for how EPA and the registrants might move forward to put in place necessary provisions to address the concerns identified in the BiOp. Before getting to those specifics, however, let me acknowledge on behalf of EPA your expression of the registrants' willingness to work constructively with the Agency to address the obligations of the Endangered Species Act ("ESA"). We are glad to see that the registrants have already agreed to adopt certain aspects of EPA's plan for addressing the BiOp.

One of the conceptual points you raise in your letter is that the registrants will only agree to labeling changes that require users to follow the terms of EPA Endangered Species Protection Bulletins ("bulletins") if "the process for bulletin development is expressly defined, and in doing so confirms each registrant's right to challenge any objectionable bulletin content *prior to publication of that content.*" Let me confirm what was discussed in our October 1, 2009,

meeting, but in a little more detail. It is EPA's expectation that the registrants and their formulator customers will, upon approval of the bulletin content, (1) place on all manufacturing use product labels reformulation limitations that require formulators to include on end-use product labeling a statement requiring user adherence to the bulletins; and (2) place on all end use products an instruction that applicators must follow the use limitations of the bulletins. Registrants may, at their option, limit this instruction to bulletins for the states of Washington, Oregon, Idaho and California. As we made clear, if the registrants object to adding these label statements or if they object to the content of the bulletins in whole or in part, EPA will not publish and compel compliance with unapproved portions of the bulletins unless and until EPA takes appropriate action under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") to require the adoption of such use limitations.

The attachment to your letter indicated that, in addition to the draft bulletin text, tables, figures and any other content, you would also want to review the computer code for the application to be employed by users to determine buffer size. EPA has spent considerable time and effort to safeguard the *Bulletins Live!* system so that the enforceable information produced by the system is not compromised. By providing access to underlying code, the integrity of the system could not be maintained. For this reason, EPA cannot grant access to the code. However, because the tool at issue is not a model but rather, a simple means for the pesticide user to determine buffer size without having to review four or more tables, the results displayed by the tool can be easily validated by comparing those results to the appropriate table. EPA currently has 99 of the 108 draft bulletins available for registrant review and review by our state regulatory partners in pdf format. You will be receiving these files electronically as attachments to several emails later this evening. We expect to have the remaining 9 bulletins available for review by the end of this week. It is our intention to make the functional bulletins, including the tool to determine buffer distances, available to the registrants and our state partners on a development site for inspection and quality assurance purposes in the near future. The specific date of availability of that site is dependent on some technical work to allow access outside the computer system's firewall. We are hopeful we will be able to provide that access by the end of next week. This will provide you with an opportunity to validate the buffer tool as well as having had the opportunity to review all other substantive terms of the bulletins through the pdf files.

A second conceptual point you raised is that, even if agreement cannot be reached on all elements set forth in the Agency's September 10, 2009, letter to NMFS, the registrants would be prepared to move forward on those issues for which agreement is possible, provided certain conditions are met, including (i) that EPA and the registrants develop agreeable procedures for resolving mutually identified remaining issues; and (ii) that failing agreement, the scope of any cancellation proceedings includes the basis for both NMFS' and EPA's actions.

Let me be as clear as possible in responding to these points, because your proposals go the heart of how EPA intends to proceed over the coming months to address the BiOp. While EPA is pleased that the registrants may be willing to put some use limitations in place absent agreement to implement all the label amendments and data submissions EPA is seeking, EPA will not negotiate with the registrants the terms of any necessary limitations to address the BiOp, nor will EPA negotiate the scope of any resulting FIFRA hearing should EPA proceed to take

regulatory action against the registrants' products in order to address the BiOp. EPA has set forth in the September 10, 2009, letter to NMFS the use limitations it intends to implement through FIFRA to address the BiOp. The registrants are certainly free to suggest that EPA consider alternative restrictions to those set forth in EPA's September letter. If EPA concludes that alternative restrictions are appropriate, it will adopt them in the bulletins. Insofar as any FIFRA hearings are concerned, EPA will abide by the requirements of FIFRA and the rules of practice regarding the process for and scope of any such proceedings. That process will afford the registrants with the appropriate opportunity to defend their registrations against the Agency's assertion that the products do not meet the statutory standards in FIFRA. EPA cannot, however, agree to negotiate what it will or will not include in any required statement of issues to be addressed in a hearing.

A third conceptual point in your letter is the assertion that the registrants should be involved at the earliest stages in any protocol development for a monitoring study that will implement item #6 of the BiOp Reasonable and Prudent Alternatives ("RPAs"). While it is our hope that the registrants will find acceptable both the process for protocol development as well as the protocol itself, EPA cannot, as suggested in the attachment to the letter, agree to any condition that either the process or the resulting protocol will necessarily be one that will be acceptable to registrants or other stakeholders. Further, should EPA issue a data call-in notice ("DCI") for the monitoring study under the authority of FIFRA section 3(c)(2)(B), EPA will not consent, as requested in your letter, to expand the scope of any requested suspension hearing to include consideration of the "appropriateness" of the study among the issues to be considered. Section 3(c)(2)(B)(iv) makes clear that "the only matter for resolution at [any suspension] hearing . . . shall be whether the registrant has satisfied the Administrator that the registrant has fully complied with the [required study]." EPA will not agree to modify this statutory limitation. If the registrants are dissatisfied with the terms of any DCI EPA issues, they may, as you know, challenge the DCI in Federal court.

The attachment to your letter also indicates that a key element of any registrant agreement to implement EPA's approach is that EPA "obtain NMFS revision of incidental take statement so it is consistent with the requirements specified on labels and the mutually acceptable final protocol of the 'monitoring study.'" While EPA understands your concern that discrepancies be resolved as between the actions of EPA and the terms of NMFS' Reasonable and Prudent Measures ("RPMs"), EPA cannot control or direct the actions of NMFS nor can EPA condition its obligation to address the requirements of the ESA on NMFS' agreement to modify aspects of the BiOp. EPA has an independent obligation to comply with the ESA irrespective of the actions of the Services.

We understand at this point that you are still seeking input from customers and commercial personnel regarding many of specifics of EPA's letter to NMFS outlining the Agency's plan for addressing the BiOp. As explained above, while the Agency has no intention of negotiating about the use limitations necessary to address the BiOp, the Agency will review and adopt alternative limitations that it believes are appropriate. As indicated above, we will be sending you pdf files of most of the draft bulletins by the end of the day today. EPA would then expect registrants to provide their written response to the draft bulletins within two weeks of receipt. In connection with that review, the registrants may choose to accept all, some, or none

of the terms of the bulletin. If the registrants are willing to accept all or some of those terms, EPA would expect all manufacturing and end use product registrants to submit draft labeling to EPA to amend product labels to include language that requires compliance with the bulletins. EPA is prepared to agree to a reasonable but prompt schedule for implementation of new labeling. Provided both the manufacturing use product and end use product registrants of chlorpyrifos, diazinon, and malathion are willing to add necessary labeling use limitations on all of the registrants' products released for shipment after February 28, 2010, EPA intends to permit further distribution and sale of products bearing previously approved labeling that have released for shipment prior to February 28, 2010, for a period of 18 months. EPA believes this is a reasonable accommodation if the registrants are prepared to adopt expeditiously product labeling referencing EPA bulletins that include all necessary use limitations. If, however, EPA must pursue action under FIFRA to compel adoption of any necessary limitations, EPA will evaluate whether to permit further distribution or sale of product bearing previously approved labeling in connection with that FIFRA action.

If the registrants only agree to accept some of the terms of the draft bulletins, the amendment request should set forth those terms that are and are not acceptable, and include any other conditions the registrants may have on EPA's acceptance of that amendment request. If EPA determines that it is appropriate to proceed with bulletins as limited by the registrants' requests, it will post those bulletins on *Bulletins Live!* and will then proceed to initiate appropriate action under FIFRA to impose the remaining use limitations EPA determines are necessary to address the BiOp.

If you have any questions or comments, please contact me at (703) 308-8000.

Sincerely,



Richard P. Keigwin, Jr.
Director, Pesticide Re-evaluation Division

cc: Debbie Edwards
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