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MEMORANDUM

Via E-Mail

DATE: July 11, 2007

TO: Firm Clients and Friends

FROM: Bergeson & Campbell, P.C.

RE: EPA Will Hold Hearing on Request to Modify EBDC Cancellation Order

Today the U.S. Environmental Protection Agency (EPA) issued a hearing notice regarding a request to modify the existing cancellation order for the use of three products containing ethylene bisdithiocarbamate (EBDC) on potatoes. The EBDC/Ethylene Thiourea (ETU) Task Force (Task Force) requested in 1996 and again in 2003 that EPA extend the preharvest interval (PHI) for potatoes from 14 days to three days nationwide to address the spread of late blight disease. EPA has determined that the request to modify the cancellation order has merit. Requests to participate in the hearing are due **August 10, 2007**. A pre-hearing conference will be held and the evidentiary hearing will commence as soon thereafter as practicable, according to the schedule outlined in the *Federal Register* notice.

In 1992, EPA issued a notice of intent to cancel (NOIC) registrations containing EBDC for use on certain crops. The NOIC stated that its use on potatoes would be cancelled unless the registrants modified their labels. On December 26, 1996, the Task Force, whose current members are Dow AgroSciences, DuPont, Griffin, Cerexagri, and BASF, submitted its first request to modify the existing cancellation order for the use of three products containing EBDC on potatoes: mancozeb, maneb, and metiram. The Task Force requested that the PHI be reduced from 14 days to three days nationwide to address the spread of the late blight disease in potatoes. On August 25, 2003, the Task Force resubmitted its request as part of the EBDC reregistration process. EPA informed the Task Force that it had to consider the impact of the Food Quality Protection Act of 1996 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act before it could take any action on the request. According to the *Federal Register* notice, to date, EPA has not taken any substantial actions on the Task Force request. The notice represents EPA's determination that the 2003 request to modify the existing cancellation order merits a hearing.



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EPA states that under Subpart D of 40 C.F.R. Part 164, the Task Force submission constitutes a petition to modify the final cancellation order concerning EBDC pesticide products. Such a petition may not be granted without an opportunity for a formal adjudicatory hearing in front of an administrative law judge. EPA states that it has concluded that the submissions by the Task Force provide a basis for modification of the order cancelling EBDC products. For EPA to find that a Subpart D hearing is warranted, it must determine:

- (1) The applicant has presented substantial new evidence that may materially affect the prior cancellation or suspension order, which was not available at the time of the final cancellation or suspension determination; and
- (2) Such evidence could not, through the exercise of due diligence, have been discovered by the parties to the cancellation or suspension proceeding prior to the issuance of the final order.

EPA states that the Task Force's 2003 petition to reduce the PHI for use of EBDCs on potatoes from 14 days to three days nationwide included a number of points described as "substantial new evidence" that could not have been known at the time of the cancellation order. The new evidence includes information on the spread of late blight to additional potato-growing states, field trial data for mancozeb and maneb use on potatoes, and EPA's revision of the cancer endpoint for the EBDC breakdown product, ETU.

According to the notice, because the purpose of such a hearing is to consider only whether to modify certain aspects of the prior cancellation decision and because a prompt conclusion to the hearing "is a requisite of meaningful relief for the applicant," the evidentiary presentation in the hearing shall be strictly confined to the issues of fact and law that the Administrator has determined are presented by the Task Force submission.

1. *Issues of fact.* The issues of fact to be adjudicated are:
 - i. What is the current status (nationwide) of late blight on potatoes?
 - ii. Has the occurrence of late blight changed since the initial cancellation order issued in 1992?
 - iii. Are EBDCs necessary to respond to late blight?



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- iv. What are the dietary risks associated with EBDC use on potatoes?
2. *Issues of law.* The issues of law to be adjudicated are:
- i. Has substantial new evidence been presented pertaining to the request to reduce the nationwide PHI on potatoes to three days?
 - ii. If it is substantial new evidence, could the applicant, through due diligence, have discovered this information prior to issuance of the cancellation order?
 - iii. Does the three-day PHI meet the FIFRA 2(bb) standard?

The notice states that the sole objective of the hearing is to determine whether or not the order cancelling all sale, distribution, and use of pesticide products containing EBDCs that do not comply with the current label restriction on the PHI for potatoes should be modified to permit a nationwide three-day PHI.

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We hope this information is helpful. As always, please call if you have any questions.