UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

In the Matter of:	)	
	)	
REQUEST TO REDUCE PRE-HARVEST	)	**Docket No. EPA-HQ-OPP-2007-0181**
INTERVAL FOR EBDC FUNGICIDES	)	
ON POTATOES	)	

ORDER ON EPA'S MOTION FOR INTERLOCUTORY APPEAL

I. Procedural Background[1]

On March 2, 1992, the United States Environmental Protection Agency ("Agency") through the Acting Director of the Special Review and Reregistration Division, Office of Pesticide Programs ("EPA") published a Notice of Intent to Cancel ("NOIC") registrations under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") of pesticide products containing ethylene bisdithiocarbamates ("EBDCs"). 57 Fed. Reg. 7484 (Mar. 2, 1992). The NOIC stemmed from a Special Review of the risks and benefits of EBDCs initiated by the Agency in 1977, and a second Special Review initiated in 1987 based upon EPA's continued concern over carcinogenic, developmental toxicity and thyroid effects caused by ethylenethiourea ("ETU"), a common contaminant, metabolite, and degradation product of EBDCs. *See*, 42 Fed. Reg. 40617 (Aug. 10, 1977); 52 Fed. Reg. 27172 (1987). The NOIC provided that use of EBDCs on certain crops would be canceled unless registrants modified the pesticide product labels. Specifically as to potatoes, the restrictions on use included a minimum pre-harvest interval ("PHI") of at least 14 days, except that in nine states, the PHI was reduced to three days on the basis of data indicating that the late blight disease can cause significant yield losses in those states. Three months later, although the NOIC provided an opportunity for a hearing, the Agency and the registrants (pesticide manufacturers) reached a settlement, including an agreement to amend labels to require a 3-day PHI in 13 states and a 14-day PHI in the other states. *American Food Security Coalition*, FIFRA Docket No. 646 *et al.*, 1992 EPA ALJ LEXIS 862 (June 16, 1992).

Over three years later, on December 26, 1996, the EBDC/ETU Task Force ("Task Force" or "applicant"), representing certain registrants of EBDCs, submitted a request to modify the

[1] A more detailed procedural history is provided in the May 15, 2008 Order on EPA's Motion for Clarification and Reconsideration of Order Regarding Scope of Hearing in this matter.

NOIC to reduce the PHI to three days in other states to address the spread of the late blight disease in potatoes. *See*, 72 Fed. Reg. 37771, 37772 (Notice of Hearing on Request to Reduce Pre-harvest Interval (PHI) for EBDC Fungicides on Potatoes, July 11, 2007). The request not having been granted in the intervening 6½ years, on August 25, 2003, the Task Force submitted applications to amend the registrations of EBDC-containing products, requesting therein that the NOIC be modified and that the Agency initiate a hearing to allow the 3-day PHI on potatoes in all states.

During the EBDC reregistration process, the Agency evaluated the Task Force's request for a reduction of the PHI to 3 days nationwide, and "determined that the exposure that would result from a nationwide 3-day PHI for potatoes would be safe under the FFDCA [Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*.] reasonable certainty of no harm standard." 72 Fed. Reg. at 37773. On December 28, 2005, the Reregistration Eligibility Decisions ("REDs") for the EBDC-containing fungicides Mancozeb, Metiram, and Maneb were announced by the Agency in the Federal Register, stating that these products are eligible for reregistration, provided that certain risk mitigation measures and required labeling amendments are adopted, after which the Agency will make a final reregistration decision. 70 Fed. Reg. 76828, 76829, 76830 (December 28, 2005).

Two years later, on July 11, 2007, the EPA Acting Director of the Special Review and Reregistration Division of the Office of Pesticide Programs published in the Federal Register a Notice of Hearing on Request to Reduce PHI for EBDC Fungicides on Potatoes under the authority of Subpart D ("July 11 Notice"). 72 Fed. Reg. 37771 (July 11, 2007). The July 11 Notice announced EPA's determination that the EBDC/ETU Task Force's request for modification of the cancellation order "has merit" and announced the opportunity for a hearing under 40 C.F.R. Part 164 Subpart D ("Subpart D") to be held within 40 days of publication of the July 11 Notice, if an interested party requests a hearing. *Id*. The July 11 Notice stated that if no such hearing is requested, then the EPA intends to file a motion requesting accelerated decision in favor of modifying the cancellation order as requested by the Task Force. 72 Fed. Reg. at 37778. The July 11 Notice listed issues for hearing, including the current status of late blight on potatoes and whether it has changed since 1992, whether EBDCs are necessary to respond to late blight, what are the dietary risks associated with EBDC use on potatoes, whether substantial new evidence has been presented regarding the request to reduce the PHI, whether through due diligence the applicant could have discovered this evidence prior to the cancellation order, and whether the 3-day PHI meets the standard of Section 2(bb) of FIFRA.

The Natural Resources Defense Counsel ("NRDC") filed a request for hearing on August 10, 2007, stating its position with regard to each of the issues stated in the July 11 Notice in objecting to the reduction in the PHI. The Task Force and EPA are "automatically" parties to this proceeding according to the Notice of Hearing. 72 Fed. Reg. at 37778. The National Potato Council ("NPC") was subsequently granted leave to intervene. The Task Force, representing the

applicants, the NPC and EPA are all in agreement that the PHI should be reduced to 3 days.[2]

By Prehearing Order dated September 19, 2007, the parties were directed, *inter alia*, to file prehearing information supporting their respective positions on the issues for hearing identified in EPA's July 11 Notice of Hearing. EPA, the Task Force and NPC requested an extension of time to file the prehearing exchange and an early prehearing conference to discuss the scope of the hearing, which request NRDC opposed. In reply, EPA (joined by the Task Force and NPC) asserted that it had misstated in the Notice of Hearing one of the issues to be adjudicated in the Subpart D hearing, which was the question of whether the applicant (the Task Force), through due diligence, could have discovered the substantial new evidence allegedly warranting the PHI now being reduced nationwide prior to issuance of the 1992 NOIC order (the "due diligence" issue). Therefore EPA requested that the September 19 Prehearing Order be amended to delete the request for information as to the "due diligence" issue, set forth in Paragraph 2(C) of the Prehearing Order. The Reply also noted that there was a dispute between NRDC and the other parties as to whether certain risk issues are within the scope of the hearing.

By Order dated October 29, 2007, the request for an early prehearing conference to discuss the scope of issues was denied, NRDC was provided an opportunity to respond to the request to amend the Prehearing Order to remove Paragraph 2(C), and the prehearing exchange schedule was extended. On November 7, 2007, NRDC filed its response. Thereafter, a Joint Motion filed by EPA, the Task Force and NPC to defer the ruling thereon was granted, on the basis that EPA intended to publish an Amended Notice of Hearing containing an amended statement of issues and would thereafter file a motion to amend the Prehearing Order to conform it with the revised issues listed therein.

On December 12, 2007, the EPA's "Notice of Hearing Concerning a Request to Reduce the Pre-Harvest Interval for EBDC Fungicides on Potatoes; Amendment to Statement of Issues" ("December 12 Notice") was published in the Federal Register. 72 Fed. Reg. 70586. The December 12 Notice replaced the issues listed in the July 11 Notice with only two issues, eliminating the "due diligence" issue and issues as to the spread of late blight and whether EBDCs are necessary to respond to it ("benefits" issues). 72 Fed. Reg. at 70588. In addition, on December 12, EPA, joined by the Task Force and NPC, submitted a document ("December 12 Memo") which was in part a reply in support of their October 26 request to delete Paragraph 2(C) from the Prehearing Order, and in part a broader memorandum of law as to the limitation of issues for hearing. The December 12 Memo argued that the issues listed in the July 11 Notice of Hearing, as amended by those listed in the December 12 Notice, are the only issues to be

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[2] Therefore, in this proceeding the Task Force is not (or is no longer) "petitioning" EPA for relief and EPA is not "responding" *i.e.* opposing in whole or in part the petition to reduce the PHI. In fact, if the NRDC had not requested a hearing, EPA's determination to reduce the PHI and any motion for accelerated decision thereon would be unopposed and there would be no further case or controversy for adjudication by this Tribunal. Therefore, the parties are aligned in this case with the Task Force, EPA and the NPC on one side and the NRDC on the other.

adjudicated in the hearing.

On December 18, 2007, NRDC submitted a Response to the December 12 Memo requesting that this Tribunal disregard the Amended Notice of Hearing and direct the prehearing exchanges to proceed under the original Notice of Hearing. On December 20, EPA filed an opposition to NRDC's December 18 Response.

An Order Regarding Scope of Hearing was issued on January 16, 2008 ("January 16 Order"), denying the October 26 request to delete Paragraph 2(C) from the Prehearing Order, denying the December 12 request to limit the issues for hearing to the issues listed in the December 12 Amended Notice of Hearing, denying the December 12 request to amend the Prehearing Order, and denying the NRDC's request to disregard the December 12 Amended Notice of Hearing. The prehearing exchange has not yet been rescheduled, as EPA has in its various filings further challenged the scope of the Prehearing Order, and on January 25, 2008, EPA filed a Request to Defer Schedule in which EPA stated its intention to file a motion for reconsideration or clarification of the January 16 Order.

On February 19, 2008, EPA filed a Motion for Clarification and Reconsideration of the January 16 Order asserting that it changes the nature and scope of a Subpart D hearing to a "registration-eligibility" action, which is inconsistent with the statutory framework and which would be enormously resource-intensive for EPA. NRDC opposed the motion, EPA filed a reply, NRDC filed a surreply and EPA filed a reply thereto. By Order dated May 15, 2008 ("May 15 Order"), the Motion for Reconsideration was denied, but the Motion for Clarification was granted in part, clarifying that the hearing in this matter is to address the question of whether the PHI should be reduced nationwide to three days for potatoes, based on adjudication of the issues stated in 40 C.F.R. § 164.132(a), and that the outcome of this matter is a conclusion either that substantial new evidence exists that requires reversal or modification of the 1992 Order or that the earlier cancellation order must remain in effect and the application to reduce the PHI nationwide to three days may not be considered. In the May 15 Order, this Tribunal denied EPA's request to clarify that only dietary issues relevant to the dietary risks that formed the basis of the earlier cancellation order are relevant to this proceeding. Also in the May 15 Order, this Tribunal denied EPA's request to adjust the sequence of the pre-hearing exchange to submit its pre-hearing exchange after the Task Force and NRDC exchange theirs.

On June 13, 2008, EPA submitted a Motion for Interlocutory Appeal and memorandum in support (collectively, "Motion"), requesting that the January 16 Order and the May 15 Order be certified by this Tribunal for interlocutory appeal to the Environmental Appeals Board ("EAB"). In addition, EPA requests a stay of this proceeding until 30 days after a decision is made on the certification. On July 14, upon an extension of time granted to respond, NRDC filed an Opposition to the Motion ("Opp."). Also on July 14, the Task Force and NPC filed a Statement in support of EPA's Motion ("Statement"). On July 23, EPA submitted a Reply to NRDC's Opposition. On July 28, having been granted leave to file, NRDC filed a Response to the Statement.

II. Standard for Certifying Orders for Interlocutory Appeal

The procedural rules that apply to this proceeding, 40 C.F.R. Part 164 Subpart D ("Rules") do not include any provision for interlocutory appeal. The Rules provide that –

> The presiding officer shall make recommendations, including findings of fact and conclusions and to the extent feasible, as determined by the presiding officer, the procedures at the hearing shall follow the Rules of Practice, set forth in subparts A and B of this part 164.

40 C.F.R. § 164.132(b). The Rules indicate that Subparts A and B shall be followed "at the hearing", which is referenced in 40 C.F.R. § 164.131(c) as a "formal public hearing" with a discrete date of commencement, and therefore the Rules suggest that Subparts A and B do not apply to the entire proceeding. However, where Subpart D has no provision applicable to a particular procedure, it is appropriate to refer to Subparts A and B.

Subpart B provides that appeals from orders or rulings other than an initial or accelerated decision –

> shall, except as provided in this section, lie only if the Administrative Law Judge certifies such orders or rulings for appeal, or otherwise as provided. The Administrative Law Judge may certify an order or ruling for appeal to the Environmental Appeals Board when:
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> (a) The order or ruling involves an important question of law or policy about which there is substantial ground for difference of opinion; and
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> (b) either
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> (1) an immediate appeal from the order and ruling will materially advance the ultimate termination of the proceeding or
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> (2) review after the final judgment is issued will be inadequate or ineffective.

40 C.F.R. § 164.100.

III. Arguments of the Parties

A. EPA's Motion

EPA requests certification of the January 16 Order and the May 15 Order asserting that the issues addressed therein are threshold matters of fundamental importance to the hearing and without interlocutory appeal, the parties and Tribunal will likely waste substantial time and resources in unnecessary litigation. EPA asserts that issues in the January 16 and May 15 Orders as to the scope of the hearing, the question of who has authority to determine the scope, and the

relevance of a provision in FIFRA § 3(c)(5)(D), are important questions of law with broad policy significance beyond this proceeding, and that this issue is likely to arise again, because EPA has received additional petitions for amendment to registrations that would be subject to Subpart D procedures.

FIFRA § 3(c)(5)(D) sets forth the criteria for registering a pesticide, including the criterion that "it will perform its intended function without unreasonable adverse effects on the environment," and it also provides that "[t]he Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide" ("lack of essentiality" provision). EPA believes that it applies not only to registration but also to cancellation proceedings, which are governed by FIFRA § 6(b). Because of the "lack of essentiality" provision, EPA does not generally consider the benefits of a pesticide in deciding whether to register pesticides that do not pose any non-trivial risks. Motion at 6. The May 15 Order (at 16), however, stated that "EPA has not demonstrated that the 'lack of essentiality' provision applies to cancellation proceedings" and thus did not eliminate the "benefits" issues from the scope of the hearing. EPA asserts that a finding that the "benefits" issues are relevant to this proceeding is equivalent to a demand that a pesticide's essentiality be demonstrated, which could substantially impact how EPA regulates pesticides generally. EPA therefore argues that the issue of whether "lack of essentiality" applies to cancellation proceedings is an important question of law or policy.

EPA further argues that there are substantial grounds for difference of opinion as to these issues because EPA believes that previous administrative cases referenced in the January 16 Order, namely *Shell Oil Co.*, 1 E.A.D. 517, 1979 EPA App. LEXIS 8 (Judicial Officer, 1979) and *Notice of Hearing on the Applications to Use Sodium Fluoroacetate (Compound 1080) to Control Predators*, FIFRA Docket No. 502 (ALJ, Initial Decision, October 22, 1982)("*Compound 1080* case"), support its position that the Administrator (through a delegatee) determines the relevant issues for hearing through the Notice of Hearing. Motion at 8-9. EPA asserts that Federal courts appear to have interpreted the Administrator's authority to determine the scope of hearing differently than this Tribunal, citing *Northwest Food Processors Ass'n v. Reilly*, 886 F.2d 1075 (9th Cir. 1989)("the Administrator determined that, under FIFRA, the existing stock issues were not legally part of the cancellation hearing"), stating that it was cited with approval recently in *United Farmworkers of America v. Admin'r, U.S. EPA,* No. 04-099 RSM, 2008 U.S. Dist. LEXIS 40196, * 16-17 (D. Wash., May 19, 2008).

EPA also argues that this Tribunal suggests that the "lack of essentiality" provision applies only to registration actions, which is contrary to EPA's longstanding interpretation and implementation of FIFRA. EPA states that it has been operating its pesticide program under its interpretation, applying the standard of FIFRA § 3(c)(5) to both registration and cancellation actions, pointing out that the cancellation standard in FIFRA § 6(b) includes some of the same language as Section 3(c)(5). EPA argues that this "Tribunal's seemingly contrary position could lead to an absurd result: EPA could register a pesticide one day because it cannot deny for lack of essentiality, but turn around the next day and cancel it because of lack of essentiality," which would jeopardize EPA's decisions granting registrations without considering essentiality.

Motion at 12. EPA quotes the Fifth Circuit, stating that "FIFRA § 6(b) requires compliance with all other provisions of the statute, including FIFRA § 3(c)(5) which prohibits unreasonable adverse effects on the environment without regard to whether such effects are caused 'generally.'" *Ciba-Geigy Corp. v. EPA*, 874 F.2d 277, 279 (5th Cir. 1989).

In addition, EPA argues that this Tribunal's finding that "benefits" issues are relevant to this proceeding is contrary to EPA's longstanding policy and practice, reiterating its argument in a previous filing, that "the only issues for this hearing are those related to dietary risks, [and] [w]here dietary risks are the only issues, benefits, such as the necessity for EBDCs and the presence of late blight, are no longer relevant because the new reasonable certainty of no harm standard governing tolerances . . . does not allow benefits to be used to balance against dietary risks." Motion at 12-13. EPA points out that the issues presented are of first impression for this Subpart D proceeding. Motion at 8.

As to the second prong of the Section 164.100 standard to certify an order for interlocutory appeal, EPA claims that the January 16 and May 15 Orders will result in a more lengthy, expensive, broad and unfocused hearing for all parties, and the expenditure of time and resources cannot be undone. EPA is concerned that *any* issue related to risk and benefits of EBDC use may be considered in this hearing, as any party could raise new risk issues. Under the narrow scope of a Subpart D hearing, such new risks are not relevant because they were not part of the earlier cancellation proceeding, but, EPA asserts, they would be relevant to EPA staff who would consider them when making the final registration determination under FIFRA Section 3, upon a "full review of the appropriate risks and benefits." Motion at 16-17, 21. In a footnote, EPA states baldly, without citing to any policy or procedure, that if anyone submitted relevant information concerning the use of EBDCs on potatoes beyond the issues for the Subpart D hearing, EPA staff would evaluate it prior to making a determination on the amendment to reduce the PHI. Motion n. 11. EPA argues that "it is not clear what additional issues are in play" given that NRDC has not been required to identify with specificity the additional issues it believes should be included, yet EPA has the burden of presenting its direct case before NRDC, requiring EPA to either "wait for NRDC to inject issues when it presents its direct case, and rely either on cross examination or rebuttal . . . without having adequate time to prepare for litigation of the issue" or "address every conceivable issue in its direct case, presenting a great abundance of evidence on numerous issues . . . that may not even be in factual dispute, just in case the Tribunal or NRDC may determine at a later date that the issue is necessary or material . . . ." Motion at 17-18. EPA urges that if this Tribunal decides that the PHI should be modified, EPA will not have the opportunity to appeal the issue of the scope of the hearing, which likely will occur in future Subpart D proceedings. If, on the other hand, interlocutory appeal is granted, either the hearing will be more efficient if EPA prevails on appeal, or if it does not prevail, then the parties will be better able to weigh their options for hearing, and possibly increase the chances of settling certain issues prior to hearing. Motion at 20, 22.

Finally, EPA requests a stay of this proceeding until 30 days after a ruling on its Motion. Motion at 1.

B. Statement of Task Force and NPC in support of Motion

The Task Force and NPC echo some of the arguments and concerns presented by EPA in its Motion. In their Statement, they assert that without limiting the issues to those in the December 12 Notice, they face significant litigation disadvantages and potentially significant resource expenditures due to the requirement to file their prehearing exchange prior to NRDC. As to the second prong of the standard in Section 164.100, the Task Force and NPC assert that immediate appeal will materially advance the ultimate termination of the proceeding because it will eliminate issues almost certain for appeal, as to whether benefits can be considered when making the safety determination under FIFRA and the application of the "lack of essentiality" provision.

C. NRDC's Opposition and response to Task Force and NPC's Statement

NRDC agrees that this case involves important questions of law, but disagrees that there are any substantial grounds for difference of opinion on the issues. NRDC asserts that interlocutory appeal at this stage will only further delay resolution of this matter, and that EPA's arguments that it will require substantial resources to litigate this case are not credible, purely speculative and unripe for appellate review. Further, NRDC asserts that neither EPA's strong disagreement with the January 16 and May 15 Orders nor the fact that this case presents an issue of first impression justifies certification for interlocutory review. NRDC adds that EPA will have adequate and effective opportunity to seek appellate review by the EAB after a judgment in this proceeding.

NRDC argues that EPA has not demonstrated a substantial ground for difference of opinion, pointing out, *inter alia,* that *Northwest Food Processors, Shell Oil* and the *Compound 1080* case address whether an intervening party may raise new risks or claims to *expand* the scope of relief sought, which is distinct from a Subpart D proceeding in which a party seeks to raise new risk issues to *oppose* the relief sought. Opp. at 11-14. NRDC points out that while language of FIFRA § 3(c)(5) appears also in FIFRA § 6(b), the essentiality language in Section 3(c)(5) does not appear in Section 6(b), and that the inclusion of this clause in one part of the statute and its absence from another part must be given effect. Consideration of a pesticide's benefits, or usefulness, is distinct from the question of whether it is essential, or indispensable, NRDC argues, and the essentiality provision only applies to pesticide uses that meet the standard of FIFRA § 3(c)(5), which is defined in FIFRA §2(bb)(1) as "any unreasonable risk to man or the environment" when its "economic, social and environmental costs and benefits" are taken into account. Opp. at 17. NRDC asserts that the need for the 3-day PHI, announced in the July 11 Notice as new evidence submitted by the Task Force, was the ostensible motivation for the Task Force's Subpart D application, and it would be a "perverse result" if it could not be contested in this proceeding. Opp. at 18. NRDC notes that EPA has not provided any evidence of the "longstanding policy and practice" of EPA. Where arguments are found not to have merit, certification for interlocutory appeal should be denied except in exceptional circumstances,

NRDC argues; none exist here, and moreover, the January 16 and May 15 Orders turn on basic principles of statutory interpretation and the plain and clear language of FIFRA §2(bb) and 40 C.F.R. § 164.132(a). Opp. at 19-20.

As to the second prong of the Section 164.100 standard, NRDC asserts that its Request for Hearing provides reasonable notice of the issues it intends to raise at the hearing, and after NRDC files its prehearing exchange, EPA is provided an opportunity to submit a rebuttal prehearing exchange, in which it can address any issues raised in NRDC's disclosure. NRDC points out the admonition in the Prehearing Order that documents and witnesses not fairly disclosed during the prehearing exchange may not be presented at the hearing, which eliminates any concern by EPA about surprise at the hearing and inadequate time to prepare. NRDC also points out the fact that the Task Force, not EPA, has the burden of proof, so EPA's burden is self-imposed and does not establish that later review would be ineffective on the basis of EPA's expenditures. Furthermore, parties may narrow proceedings in routine ways such as by stipulation, and EPA can make a motion *in limine* to exclude any evidence that EPA does not think is relevant to the proceeding. NRDC argues that allowing this case to proceed to hearing will memorialize the witness' testimony and exhibits that would create a clear factual record for more informed and efficient appellate review. Opp. at 24.

NRDC asserts that before NRDC files its prehearing exchange, EPA's arguments about burdens of litigating are only speculations and are not ripe, so EPA is asking for little more than an advisory opinion from the EAB, particularly considering that the EAB may never need to address the scope of this hearing if EPA prevails on the merits of this case. Opp. at 22-23.

D. EPA's Reply

EPA asserts that NRDC incorrectly characterizes the standard of review applicable to its Motion, disagreeing with NRDC's position that interlocutory review should be provided only in "exceptional circumstances." As to the cases NRDC cites in support, *Dana Corp.*, EPA Docket No. V-W-90-R-14, 1994 WL 594895, 1994 EPA ALJ LEXIS 28 at *2 (ALJ, Aug. 1, 1994) and *Judicial Watch v. Nat'l Energy Policy Dev. Group*, , 233 F. Supp. 2d 16, 20 (D. D.C. 2002), EPA argues that they are not on point, interpreting the interlocutory appeal provisions of 40 C.F.R. § 22.2((b) and 28 U.S.C. § 1292(b) respectively, suggesting that interpretations of those provisions is not applicable to Section 164.100. EPA argues that under Section 164.100, "exceptional circumstances" is the test for the EAB to apply in accepting an interlocutory appeal which is not certified by the ALJ, and EAB would not accept uncertified interlocutory appeals in all circumstances which would justify an ALJ to certify it. EPA argues that "extraordinary circumstances" is the standard for staying a Part 164 proceeding pending interlocutory appeal, which would be rendered inoperative if certification by the ALJ used the test of "exceptional circumstances."

EPA characterizes as "slender" NRDC's distinctions of cases cited by EPA in support of its argument on substantial grounds for difference of opinion. Reply at 4. EPA argues that the

text in the May 15 Order (at 17), "[t]he issue of benefits raised in this proceeding are . . . whether EBDCs are *needed* to combat a serious fungal disease on potatoes . . . " (emphasis added) indicates, by virtue of the definition of "need," that the May 15 Order "flatly holds that EBDC's essentiality is an issue for the proceeding." Reply at 4.

In support of its claim of a longstanding policy and practice, EPA submits an Affidavit of Lois Rossi, Director of the Registration Division in the Office of Pesticide Programs, dated July 23, 2008 ("Rossi Affidavit"). Ms. Rossi in her Affidavit states that she has worked in the Office of Pesticide Programs for over 30 years and is "very familiar with EPA's pesticide registration policies." Rossi Affidavit ¶ 2. She states further that for more than ten years,

> EPA has generally applied the following practice in determining whether use of a pesticide will cause unreasonable adverse effects on the environment.
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> 4. . . . . If the pesticide is found to pose [human health and environmental] risks below the level of concern, EPA will generally conclude that the pesticide does not cause any unreasonable adverse effects on the environment without ever considering what benefits the pesticide may provide . . . because we generally believe that a pesticide that poses risks below the level of concern would not pose an unreasonable risk to human health or the environment, even if it had no accompanying benefits.
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> 5. Since the passage of the FQPA [Food Quality Protection Act] in August 1996, if the pesticide is found to pose risks of concern, and if none of these risks are dietary human health risks, then EPA has generally considered what benefits the pesticide might provide.
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> 6. . . . . If dietary risks exceed that standard [reasonable certainty of no harm] and a necessary tolerance cannot be granted, we do not examine benefits because we will not issue a registration if a necessary tolerance cannot be granted, regardless of the benefits associated with its use.

Rossi Affidavit ¶¶ 4-6. EPA asserts that the Rossi Affidavit "clearly illustrates that this Tribunal's determination that benefits are relevant to the proceeding is inconsistent with EPA's longstanding policies[;] [w]here there are no risks of concern, pesticide benefits are generally irrelevant to the registration process." Reply at 5.

E. NRDC's Reply to Task Force and NPC Statement

NRDC emphasizes that the arguments of the EPA, Task Force and NPC as to the scope of hearing have been found to be "without merit." NRDC asserts that any outcome of interlocutory appeal will result in a hearing requiring significant resource expenditures, and thus will not avoid a hearing. NRDC argues that the Motion and Reply do not demonstrate that any

additional expenditures would be significant. NRDC points out that the Task Force first submitted the request to alter the PHI to EPA over 11 years ago, and did not file its own motion for interlocutory appeal, yet argues that an immediate appeal is necessary to protect its interests in the proceeding.

IV. Discussion and Conclusions

The determination of whether to certify the January 16 and May 15 Orders for interlocutory appeal will be based on the criteria set forth in 40 C.F.R. § 164.100. However, adding a standard of "exceptional circumstances" is neither necessary nor clearly supported by any ALJ rulings in environmental cases. The ALJ in *Dana Corp*. merely noted a party's argument and reference to 28 U.S.C. § 1292(b), that certification of interlocutory appeal is granted in exceptional circumstances, but the ALJ did not adopt that argument in his decision to deny certification.

The first factor is whether the rulings in the January 16 and May 15 Orders involve an "important question of law or policy about which there is substantial ground for difference of opinion." The scope of hearing in this proceeding presents important questions of law and/or policy, particularly where the scope of a hearing under Subpart D Rules, or in cancellation proceedings, has been addressed in very few rulings in other cases and has not been addressed at all in circumstances in which a party intends to present evidence as to pesticide benefits and risks other than those specified by EPA, to oppose the relief sought by the applicant. In addition, these circumstances may arise in future Subpart D proceedings. The appellate tribunal of the Agency has considered as an "exceptional" circumstance warranting interlocutory appeal the situation of "fundamental issues of first impression" about the scope of discovery upon which there is a complete absence of previous decisions by the appellate tribunal. *Chautauqua Hardware Corp.*, 3 E.A.D. 616, 619 (CJO 1991).

As to EPA's assertion of a longstanding policy and practice establishing substantial ground for difference of opinion, EPA does not proffer any *written* policy or interpretation of the pertinent statutory provisions, but instead presents the Rossi Affidavit. However, the Rossi Affidavit addresses pesticide registration, and does not specifically address pesticide cancellation. *See,* Reply at 5. The statement EPA references from *Ciba-Geigy Corp. v. EPA*, 874 F.2d at 279, actually a quote of the Administrator in the underlying appeal, *Ciba-Geigy Corp.,* 2 E.A.D. 516, 522 (Adm'r 1988), that "FIFRA § 6(b) requires compliance with all other provisions of the statute, including FIFRA § 3(c)(5) . . .," refers to the compliance of a pesticide or its labeling with FIFRA, and thus to applicants and registrants, and not to a prohibition on EPA denying registration for "lack of essentiality."

Nevertheless, the question of whether there is substantial ground for difference of opinion need not be decided here, because EPA has not met the second criterion, that either an immediate appeal from the order and ruling will materially advance the ultimate termination of the proceeding or review after the final judgment is issued will be inadequate or ineffective.

Where it is clear that significant amounts of a party's time and resources, including presenting evidence and expert witness' testimony at a hearing, would be wasted if the motion for interlocutory appeal is denied and the Administrative Law Judge's order is later reversed by the EAB, an immediate appeal may materially advance the ultimate termination of the proceeding. *U.S. Army Ft. Wainwright Central Heating and Power Plant,* EPA Docket No. CAA-10-99-0121, 2002 EPA ALJ LEXIS 29 * 4 (ALJ, Order Granting Interlocutory Appeal, May 28, 2002). It is noted that the EAB has considered as an exceptional circumstance warranting interlocutory appeal the situation in which discovery requests were so broad that compliance with them would have been wasteful of EPA resources. *Chautauqua Hardware*, 3 E.A.D. at 619.

However, the ultimate disposition of this proceeding would be significantly delayed, and significant resources of the EAB and the parties would be wasted in the interlocutory appeal, if the EAB upholds the January 16 and May 15 prehearing Orders and then upon the filing of NRDC's prehearing exchange (whatever it may or may not include), a motion *in limine* is granted or stipulations are filed which exclude most or all of the evidence and testimony NRDC would present at a hearing on the issues raised in its Request for Hearing and which EPA deems irrelevant. As to EPA's argument that NRDC has "not been required to identify with specificity the additional issues it believes should be included," NRDC has stated clearly the issues it wishes to present, analogous to assertion of affirmative defenses in an answer to a complaint. It is in the prehearing exchange that parties are required to provide specific information and evidence regarding the issues, and EPA will have ample opportunity in its rebuttal prehearing exchange to provide information and evidence in response to NRDC's prehearing exchange. EPA's concerns that NRDC may present evidence on additional new issues for hearing are unfounded or at least premature, as NRDC would be required to file a motion to amend its Request for Hearing to raise any such issues for the hearing. EPA's concerns that it would have insufficient time to prepare for hearing and/or would be at a disadvantage if it submitted evidence responsive to NRDC's prehearing exchange in its rebuttal is also unfounded. In any administrative proceeding, in order to ensure fairness to all parties, sufficient time is provided after the rebuttal prehearing exchange for all parties to file motions and to prepare for hearing. EPA's argument that even if it does not prevail before the EAB, interlocutory appeal may increase the possibility of settling issues is countered by the possibility of settling issues upon completion of the prehearing exchange.

At this early point in the proceeding, prior to the prehearing exchange, it is not clear that significant amounts of EPA's time and resources would be wasted if the motion for interlocutory appeal is denied and the January 16 and May 15 Orders are later reversed by the EAB. Therefore, it cannot be concluded at this time that an immediate appeal "will materially advance the ultimate termination of the proceeding" or that "review after the final judgment is issued will be inadequate or ineffective."

The Task Force, NPC and/or EPA may file a motion *in limine* after the NRDC files its prehearing exchange, so the parties may provide focused and concrete arguments as to whether the evidence proposed by NRDC is relevant to, or within the scope of, the hearing in this matter. If Task Force, NPC and/or EPA do not prevail on such motion, a motion for interlocutory appeal

may be filed at that time.

ORDER

1. EPA's Motion for Interlocutory Appeal is hereby **DENIED.**

2. EPA's request for a stay of this proceeding for 30 days from the date of this decision is hereby **GRANTED.**

_____
Susan L. Biro
Chief Administrative Law Judge

Dated: October 6, 2008
Washington, D.C.

In The Matter of Hearing On Request to Reduce Pre-Harvest Interval For EBDC Fungicides On Potatoes, Docket No. EPA-HQ-OPP-2007-0181

CERTIFICATE OF SERVICE

I certify that the foregoing **Order on EPA's Motion for Clarification and Reconsideration of Order Regarding Scope of Hearing** dated October 6, 2008, was sent this day in the following manner to the addresses listed below.

_____
Sybil Anderson
Headquarters Hearing Clerk

Dated: October ___, 2008

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