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 REGARDING SCOPE OF HEARING

I. Background

A Notice of Hearing on Request to Reduce Pre-Harvest Interval ("PHI") for EBDC Fungicides ("EBDCs") on Potatoes was published in the Federal Register on July 11, 2007, by the Acting Director of the Special Review and Reregistration Division of the Office of Pesticide Programs, United States Environmental Protection Agency ("EPA"), under the authority of 40 C.F.R. Part 164 Subpart D ("Subpart D"). 72 Fed. Reg. 37771 (July 11, 2007). The Natural Resources Defense Counsel ("NRDC") filed a request for hearing on August 10, 2007. The EBDC/ETU Task Force ("Task Force"), representing certain registrants of EBDCs, 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 granted leave to intervene. By Prehearing Order dated September 19, 2007, the parties were directed, *inter alia*, to file prehearing exchanges.

On October 15, 2007,[1] EPA, the Task Force and NPC ("Movants") jointly moved for an extension of time to file their prehearing exchanges and requested an early prehearing conference to discuss the scope of the hearing, which NRDC opposed. In its Reply, dated October 26, Movants asserted that in the Notice of Hearing, EPA misstated as an issue to be adjudicated *at hearing* the question of whether the applicant, through due diligence, could have discovered the substantial new evidence prior to issuance of the cancellation order (the "due diligence" issue), which is instead an issue that the EPA Administrator determines *before* issuing the Notice of Hearing. Therefore, Movants 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. Movants also indicated that there is a dispute between Movants and NRDC as to whether certain risk issues are within the scope of the hearing.

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[1] All dates herein refer to the year 2007 unless otherwise indicated.

By Order dated October 29, the request for an early prehearing conference to discuss the scope of issues was denied, NRDC was provided an opportunity to respond to the Movants' request to amend the Prehearing Order to remove Paragraph 2(C), and the prehearing exchange schedule was extended. On November 7, NRDC filed such a response ("November 7 Submittal"), opposing Movants' request to remove Paragraph 2(C) from the Prehearing Order, on the basis that the issue of "due diligence" is within the scope of this hearing and must be adjudicated by this Tribunal under the Part 164 Subpart D regulations and basic notions of fairness and due process.

On November 15, Movants filed a Joint Motion to Defer Ruling, announcing EPA's intention, by publishing an *Amended* Notice of Hearing, to alter EPA's statement of issues and explain therein that the "due diligence" issue is a threshold issue for the Administrator to decide and thus unnecessary for adjudication after hearing. Movants requested that if this Tribunal was uncertain as to the correctness of EPA's position on whether "due diligence" was an issue within its jurisdiction for adjudication, they be granted leave to reply to NRDC's arguments before this Tribunal ruled on the matter. Moreover, Movants requested deferral of any ruling on the "due diligence" issue until the amended Notice of Hearing was issued, and suggested that a ruling as to any amendments to the Prehearing Order be deferred until after filing of their motion to amend the Prehearing Order, and the response and reply thereto. On November 19, NRDC opposed the motion.

On November 30, EPA submitted a Motion for Extension of Time to File Prehearing Exchanges, stating that EPA will be filing a motion to amend the Prehearing Order to conform it with the issues listed in its soon-to-be-published Amended Notice of Hearing, and that time is needed for this Tribunal to review the Notice and any subsequent motions and responses.

On December 3, an Order was issued granting the Movants' request to defer ruling, suspending the deadlines for the Prehearing Exchange until further notice, and providing Movants until December 12 to respond to NRDC's November 7 submittal.

On December 12, Movants submitted a Response ("December 12 Memo") to the December 3 Order, which is in part a reply to NRDC's November 7 opposition to Movant's 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. Also on December 12, the EPA's Amended Notice of Hearing was published in the Federal Register. 72 Fed. Reg. 70586.

On December 18, NRDC submitted a Motion for Leave to Respond to the December 12 Memo and a Response to December 12 Joint Memorandum ("December 18 Response"), 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 Motion for Leave to Respond ("December 20 Opposition"), opposing both the request to respond and the December 18 Response. On December 21, NRDC filed a Reply in Support of Motion for Leave to Respond to the December 12 Memo ("December 21

Reply").

The July 11 (original) Notice of Hearing listed the issues to be adjudicated as follows:

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?
>
> (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 3 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 3-day PHI meet the FIFRA 2(bb) standard?

72 Fed. Reg. at 37778 (July 11, 2007) (italics added).

The Amended Notice of Hearing published on December 12, 2007 stated that the original Notice of Hearing "incorrectly identified an issue of law to be adjudicated by the Court," namely that of "due diligence," and "did not provide a sufficiently clear explanation of the scope of the issues to be considered in the hearing." 72 Fed. Reg. at 70587. The Amended Notice continued as follows:

> In light of the two issues stated above, EPA is amending the Statement of Issues by consolidating the issues of fact and law into the two relevant questions that must be determined by the ALJ consistent with 40 C.F.R. 164.132 and the 1992 cancellation action. EPA believes the amended statement of issues provides necessary clarifications that will allow for a more efficient and effective hearing.

Id. Accordingly, EPA replaced the seven issues for hearing identified in the July 11 (original) Notice of Hearing with the following two issues to be adjudicated in this proceeding:

> 1. Is there substantial new evidence not considered in the 1992 cancellation that relates to whether the dietary risks associated with nationwide use of EBDCs on potatoes with a 3-day PHI satisfy the relevant statutory standard for registration under FIFRA? For the purposes of this hearing, the relevant portion of the FIFRA standard for registration is whether the human dietary risk meets the safety standard in section 408(b)(2) of FFDCA [Federal Food, Drug and Cosmetic Act].
>
> 2. Does the substantial new evidence with respect to dietary risk require the modification of the existing cancellation order, i.e., does it support a finding that the dietary risks associated with nationwide use of EBDCs on potatoes with a 3-day PHI satisfy the relevant statutory standard for registration under FIFRA? In other words, do the residues that result from EBDCs on potatoes meet the safety standard in Section 408(b)(2) of FIFRA?

72 Fed. Reg. at 70588.

II. Parties' Arguments

In its November 7 Submittal, NRDC opposes Movants' request to delete Paragraph 2(C), concerning the "due diligence" issue, from the Prehearing Order. NRDC argues that if the "new evidence" was or could have been available, through exercise of due diligence, at the time of the prior cancellation proceeding, it is not "new evidence," and it could not "require reversal or modification of the existing cancellation" within the meaning of 40 C.F.R. § 164.132(a). NRDC asserts that this is analogous to waiver of the right to present evidence or arguments in support of reconsideration of an order where such argument or evidence could have been presented in the prior proceeding. NRDC further argues that EPA's position that the Administrator has "unreviewable" authority to decide the issue of due diligence - *i.e.* that no one has the opportunity to challenge that decision in a formal hearing, is inconsistent with the purposes of Subpart D proceedings, which are to protect the public interest in the finality of cancellation orders by requiring production of substantial new evidence not available at the time of the original proceeding, and to protect the integrity of public participation rights by requiring a formal hearing process as indicated in the preamble to the Subpart D regulations (40 Fed. Reg. 12261, 12264 (March 18, 1975). Excluding the due diligence issue from judicial review is contrary to the interests of justice, allowing parties a second "bite at the apple," undoing the entire cancellation determination, wasting administrative resources, and allowing evidence that was available in the prior cancellation proceeding but was not submitted for strategic reasons, NRDC asserts.

On the other hand, it is EPA's position that Subpart D at 40 C.F.R. § 164.131(a) sets forth the threshold issues for the "*Administrator*" to determine: whether the "applicant has presented substantial new evidence which may materially affect the prior cancellation or suspension order and which was not available to the Administrator at the time he made his final cancellation or

suspension determination and, (2) such evidence could not, through the exercise of due diligence, have been discovered by the parties . . . prior to issuance of the final order." EPA in the Amended Notice of Hearing states that these issues determine whether a petition to amend a cancellation order has merit. Amended Notice of Hearing, 72 Fed. Reg. 70586, 70588 (December 12, 2007). EPA points out that 40 C.F.R. § 164.132(a), on the other hand, sets forth the issues for the *Administrative Law Judge* ("ALJ") to decide in the hearing, to determine whether or not the earlier order should in fact be modified. *Id.* These issues are whether substantial new evidence exists and whether such evidence requires reversal or modification of the existing cancellation order. Because Section 164.132(a) does not include the "due diligence" issue, and the preamble to the regulation also indicates the separate issues to be determined by the Administrator and ALJ, EPA asserts that the "due diligence" issue is a determination to be made by the Administrator *before* any hearing is convened. *Id.*

Acknowledging that in the Amended Notice of Hearing, it has not only eliminated the "due diligence" issue from the list of issues for hearing, but has also eliminated consideration of factual issues such as the need for EBDCs and the presence of late blight nationwide, EPA states that these issues are not relevant to the "risk-only safety standard" set forth in FFDCA § 408(b). 72 Fed. Reg. at 70588-89. EPA explains that the 1996 Food Quality Protection Act amendments to FIFRA require that dietary risks now be evaluated under the "risk-only" safety standard in the FFDCA § 408(b), namely, whether there is a "reasonable certainty that no harm will result from aggregate exposure to the chemical pesticide residue, including all anticipated dietary exposures." FFDCA § 408(b)(2)(A)(ii), 72 Fed. Reg. at 70589.

Furthermore, pointing out that there was no hearing or detailed cancellation order in the original cancellation proceeding for EBDC's because the parties agreed to a settlement prior thereto, EPA asserts that the 1992 Notice of Intent to Cancel ("NOIC") must be used to determine the issues for hearing. 72 Fed. Reg. at 70589. EPA points out that in the "Special Review" process that led to the NOIC, the issues of concern were carcinogenic, developmental and thyroid effects of ethylenethiourea (ETU), as stated in the NOIC, 57 Fed. Reg. 7484, 7487 (March 2, 1992). EPA asserts that these would have been the issues for hearing, and therefore, that "[o]nly information related to these three risks, or to dietary exposures related to these three risks, is material to the issue of whether the 1992 cancellation order should be modified to allow for a shorter PHI than called for in the NOIC." 72 Fed. Reg. at 70589.

Movants' position is that the list of issues that EPA set out in its Amended Notice of Hearing cannot be contested, and that the Administrative Law Judge "is limited in its decision to the matters asserted in the [Amended] Notice [of Hearing]." December 12 Memo at 6. Therefore, Movants state that "the Pre-Hearing Order must be revised accordingly." *Id.* Movants further assert that the "Administrator," acting though EPA trial staff (of the Office of Pesticides, Prevention and Toxic Substances) pursuant to EPA Delegation 5-7, is required to set forth issues to be adjudicated in a notice of hearing, under 40 C.F.R. §§ 164.131(c) and 164.23(a), and may amend the statement of issues under 40 C.F.R. § 164.23(b). Movants quote an Administrative Law Judge's statement in a decision rendered in a 1984 Subpart D proceeding,

that "the Administrator controls the issues to be adjudicated therein in accordance with 40 C.F.R. § 164.131(c) and has ample discretion to preclude the re-opening of issues considered to have been properly determined in previous proceedings." *Notice of Hearing on the Applications to Use Sodium Fluoracetate (Compound 1080) to Control Predators*, FIFRA Docket No. 502 (ALJ, Initial Decision 1984), slip op. at 43-44. Movants also cite to a 1979 pesticide cancellation proceeding under 40 C.F.R. Part 164 Subpart B, in which the Chief Judicial Officer, predecessor to the Environmental Appeals Board, stated that "matters falling outside the scope of the notice [of hearing] are of no relevance to the proceeding." *Shell Oil Company*, 1 E.A.D. 517, 1979 EPA App. LEXIS 8 at *13-14 (CJO 1979). Finally, Movants quote the April 28, 1994 EBDC Subpart D Notice of Hearing, in which EPA stated, "[b]ecause the purpose of such a hearing is only to consider whether to modify certain aspects of the Administrator's prior cancellation decision and because a prompt conclusion to the hearing is a requisite of meaningful relief to the petitioners, the evidentiary presentation at the hearing shall be strictly confined to the issues of fact and law *which the Administrator has determined* . . ." 59 Fed. Reg. 22106, 22109 (April 28, 1994) (emphasis added).

NRDC argues in its Motion for Leave to Respond that the December 12 Memo raises new legal issues bearing on the appropriate scope of the hearing on which NRDC had not yet been heard. These issues, as discussed in NRDC's December 18 Response, are: (1) whether the Amended Notice of Hearing should be disregarded by the ALJ on the basis that it was issued by EPA trial staff, in violation of the principle of the separation of functions and due process; and (2) whether the amended list of issues is consistent with the applicable statute and regulations.

As to the first issue, NRDC points out that the same EPA trial staff prosecuting this proceeding also prepared and issued the Amended Notice of Hearing under a general delegation of authority from the Administrator. NRDC disagrees with Movants' position that neither the ALJ nor any party may question the trial staff's reinterpretation of applicable law and regulations in the Amended Notice of Hearing. NRDC asserts that the EPA trial staff's attempt to use the Federal Register amendment procedure in 40 C.F.R. § 164.23(b) to shield issues from judicial review violates the"separation of functions" embodied in 40 C.F.R. § 164.7, which prohibits *ex parte* discussion of the merits of the proceeding between the "Administrator" and trial staff. NRDC argues that this separation of functions is inconsistent with the general delegation to EPA trial staff to act for the Administrator, in the context of amending a Notice of Hearing after a proceeding has commenced, which inherently involves consideration of the merits of the proceeding. The regulation with the force of law, Section 164.7, rather than the general delegation, controls, NRDC argues. In support, NRDC cites, *inter alia*, to *Envtl. Def. Fund v. EPA*, 548 F.2d 998, 1006 (D.C. Cir. 1976)(finding that *ex parte* contacts between EPA trial staff and the Administrator regarding enlarging a statement of issues to the benefit of a registrant did not prejudice the registrant in that case, but noting "the danger of abuse in such consultations"). NRDC argues that if EPA trial staff, who have an adversarial role in the proceeding, exercise powers of the Administrator to change the scope of the hearing to their advantage, NRDC is denied its right to due process.

As to the second issue, the term "specify" in the regulatory requirement of the Administrator "to *specify* . . . the issues of fact and law to be adjudicated at the hearing," (40 C.F.R. § 164.131(c)(emphasis added)), means to mention or name explicitly, and does not empower the Administrator to exempt adjudication of issues through the Notice of Hearing procedure, NRDC argues. The Subpart D regulations and the interests of justice require that the "due diligence" issue be permitted to be contested by NRDC and considered by the ALJ, regardless of whether it is included in the operative Notice of Hearing. NRDC points out that an ALJ in 1994 considered due diligence in *Notice of Hearing Concerning Application to Modify the Final Cancellation Order for Pesticide Products Containing EBDCs,* FIFRA Docket No. 657 (ALJ, Initial Decision 1994).

The limitation of the scope of this proceeding to considering just the dietary risks arising from a 3-day PHI is also inconsistent with applicable law, NRDC asserts. FIFRA prohibits registration of a pesticide that will not perform its intended function without "unreasonable adverse effects on the environment," including any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide. 7 U.S.C. §§ 136a(c)(5)(C), 136(bb). NRDC asserts that the Food Quality Protection Act amended Section 136(bb), to require, within any inquiry into "unreasonable adverse effects on the environment," consideration of "human dietary risk from residues that result from a use of a pesticide in or on any food." NRDC asserts that the amendment thus expands rather than contracts issues relevant to this proceeding. December 18 Response at 9. NRDC requests that the Amended Notice of Hearing be disregarded and that the parties be directed to proceed with their Prehearing Exchanges as directed in the prior Prehearing Order.

EPA opposes NRDC's Motion for Leave to Respond on the basis that the December 12 Memo did not introduce new legal issues that bear on the scope of hearing. In its December 20 Opposition, EPA responds to the December 18 Response, maintaining that the amendment to the Notice of Hearing by EPA trial staff was a proper exercise of the Administrator's delegation of authority, and was not an attempt to change the scope of the hearing to its advantage. EPA notes that its practice is consistent with its practice in previous Subpart D hearings, and that a Notice of Hearing is like a complaint that can be amended. December 20 Opposition n. 1. EPA disagrees with NRDC's "conflation of the *ex parte* regulations" with those that authorize amendment of EPA's statement of issues. EPA argues that under the *ex parte* prohibition, the Administrator could not both frame the issues (amend the statement of issues) and serve as the final decision maker. *Id.* n. 2. EPA disagrees that the 1994 EBDC Initial Decision included findings as to due diligence, pointing out that the term does not appear in the Decision or the Notice of Hearing.

In its December 21 Reply, NRDC maintains that the Amended Notice of Hearing dramatically changes the scope of the hearing to Movants' advantage by insulating from judicial review multiple issues of fact and law that NRDC seeks to contest. NRDC asserts that EPA's statement that its practice is proper and consistent with prior practice is unsupported, and that its past practices do not have the force of law. NRDC argues that a comparison of EPA trial staff to complainant amending a complaint is inapt in light of separation of functions and due process

concerns, and for these reasons EPA trial staff is barred by regulation from performing certain functions.

III. NRDC's Motion for Leave to Respond

Movants' request in the December 12 Memo (at 6) that the Pre-Hearing order "be revised accordingly," together with their argument in support of a finding that EPA's amended list of issues cannot be contested, constitutes a motion to revise the Pre-Hearing Order to conform to the amended list of issues. NRDC is entitled to respond to such motion, and its December 18 Response does respond to the motion on grounds that there is no basis for EPA's attempt to limit the scope of the hearing and thus for revising the Pre-Hearing Order. Accordingly, the Motion for Leave to Respond is granted.

Although NRDC acknowledges Movants' request that the Pre-Hearing Order "be revised accordingly" (December 18 Response at 4), NRDC states (December 18 Response n. 7) that Movants have not yet moved for modification of the September 19, 2007 Prehearing Order in response to the EPA's second limitation of the list of issues (as to the human dietary risks), and if such a motion is filed, NRDC requests leave to submit further briefing on this issue.

The parties have sufficiently briefed the issue, and as discussed below, NRDC's position prevails. Therefore further briefing from NRDC on the issue is unnecessary.

IV. Discussion and Conclusions

A. The "Due Diligence" Issue

The issues to be addressed at the hearing are set out in 40 C.F.R. § 164.132(a) as follows:

> The issues in the hearing shall be whether: (1) substantial new evidence exists and (2) such substantial new evidence requires reversal or modification of the existing cancellation . . . . order. The determination of these issues shall be made taking into account the human and environmental risks found by the Administrator in his cancellation . . . determination and the cumulative impact of all past and present uses, including the requested use, and uses which may reasonably be anticipated to occur in the future as a result of granting the requested . . . modification. * * * *

Section 164.132 does not define the term "substantial new evidence" but requires that in determining whether it exists, certain factors be taken into account. The requirement that a determination "shall be made taking into account" certain factors does not necessarily preclude consideration of other factors. That is, the text of Section 164.132 does not indicate that the determination of whether "substantial new evidence" exists must be made *solely* on the basis of

the risks found in the original cancellation order and the cumulative impact.[2] It may not be possible to determine whether the evidence is *new* from reading the cancellation order and the risks found therein, as the evidence in a cancellation hearing is often too voluminous to reference all of it in the cancellation order eventually issued. Therefore, Section 164.132 does not rule out but rather suggests referring to the description of "substantial new evidence" in Section 164.131(a) as that "which may materially affect the prior cancellation . . .order and which was not available to the Administrator at the time he made his final cancellation . . . determination." The words "not available to the Administrator at the time . . ." explains the word "new." While the Administrator, acting through delegated authority, makes an initial, or *prima facie,* determination of whether reconsideration is warranted by determining whether "substantial new evidence" exists, clearly the regulations require the ALJ also to determine the same issue, which presupposes that the issue may be contested by a party at the hearing. The preamble to the Subpart D Final Rule states, "the Administrator will *initially* determine, on the basis of the application and supporting data, whether there is substantial new evidence which may materially affect the prior order and whether such evidence could not have been discovered by due diligence . . . ," and that if he determines there is such evidence, then the ALJ determines whether "substantial new evidence exists" based on a formal hearing. 40 Fed. Reg. 12261, 12264 (Final Rule, March 18, 1975)(emphasis added). Thus, Sections 164.131 and 164.132 are to be read together in reference to each other, rather than as separate distinct sets of issues.

The question is whether the "due diligence" issue also may be contested by a party at the hearing and adjudicated. Reading Sections 164.131 and 164.132 together, there is nothing in the regulatory text that suggests that of the two issues to be determined by the Administrator, *i.e.,* whether "substantial new evidence" exists and the "due diligence" issue, the ALJ may adjudicate the first issue but may not adjudicate the second issue. The "due diligence" issue, that is, whether the evidence could, through exercise of due diligence, have been discovered by the parties prior to the issuance of the final order, may in some cases be relevant to the ALJ's determination of whether "substantial new evidence" exists and whether it requires reversal or modification of the cancellation order. As noted above, the text of Section 164.132 does not indicate that the determination of whether "substantial new evidence" exists must be made solely on the basis of the risks found in the cancellation order and the cumulative impact. Similarly, the regulatory text does not indicate that the determination of whether the evidence requires reversal or modification of the cancellation order must be made solely on those bases. The ALJ generally has authority "to hear and decide questions of fact, law or discretion," which includes questions of EPA's abuse of discretion. 40 C.F.R. § 22.4(c)(7); *see,* 40 C.F.R. § 164.40(d)(the ALJ "shall have power to take actions and decisions in conformity with statute or in the interests of justice."). If an allegation is made that the Administrator's delegate abused his discretion in making a determination as to the "due diligence" issue, the ALJ has authority to rule on the allegation. Therefore, the regulatory text does not preclude the ALJ's consideration of the due diligence issue, albeit the "due diligence" issue is not mentioned in Section 164.132.

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[2] This issue is further discussed below.

The preamble to Subpart D further supports this analysis. The preamble does not specifically state the basis for requiring the ALJ to take into account the risks found in the prior cancellation order, but EPA makes clear in the preamble its general concern that cancellation orders not be modified or reversed lightly. 40 Fed. Reg. at 12264. The preamble states that the hearing is convened to determine whether the evidence "materially affects the prior order and requires its modification," which determination must be made "on the basis of the record in the hearing and the recommendations of the administrative law judge, taking into account the human and environmental risks found by the Administrator in his prior order and the cumulative impact . . . ." 40 Fed. Reg. at 12264. There is no indication in the preamble that those risks are to be considered exclusively.

NRDC in its Request to Participate in the Hearing, dated August 10, 2007, challenged the determination of "due diligence," thereby raising the issue in this proceeding. Accordingly, the request to delete the "due diligence" issue from the Pre-Hearing Order is denied.

B. Issues of Need for EBDCs and Spread of Late Blight

EPA states that the presence of late blight in certain areas was relevant to the reduction of the PHI to three days in 1992. 72 Fed. Reg at 70589. The question is whether the 1996 Food Quality Protection Act amendments to FIFRA limit the issues to be heard and adjudicated to the dietary risks, and thus render immaterial to this proceeding the issues as to the need for EBDCs and presence of late blight . Section 3(c)(5)(C) of FIFRA, 7 U.S.C. § 136a(c)(5)(C), provides that the "Administrator shall register a pesticide if the Administrator determines that . . . it will perform its intended function without unreasonable adverse effects on the environment . . . ." The term "unreasonable adverse effects on the environment" is defined in Section 2(bb) of FIFRA, 7 U.S.C. § 136(bb) as:

> (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or
> (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of Title 21.[3]

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[3] Section 346a of Title 21, Section 408(b)(2)(A)(ii) of the FFDCA provides:

> . . . the term "safe," with respect to a tolerance for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

The Food Quality Protection Act ("FQPA") of 1996 added the second prong to the definition above, but did not eliminate the first prong, so the economic, social and environmental costs and benefits are still valid considerations for registration of a pesticide. In general, the FQPA amended the EPA's regulation of pesticides by, among other things, "*increasing* the number of factors that the EPA must consider in establishing a tolerance or exemption." *American Farm Bureau v. EPA*, 121 F. Supp. 2d 84, 89 (D.D.C. 2000)(emphasis added). EPA does not provide any argument or authority indicating that the first prong of the definition cannot be considered in this case. While EPA is correct that *dietary* risks are evaluated under the standard in FFDCA, EPA does not provide any supporting authority for its assertion that other issues such as the need for EBDCs and presence of late blight are "not relevant to the applicable standard." 72 Fed. Reg. at 70589. These issues appear to be encompassed by "economic, social and environmental costs and benefits," which must be taken into account under the first prong of the statutory standard.

EPA has not demonstrated that any issues listed in the July 11 Notice of Hearing are immaterial or irrelevant to the applicable standard. Accordingly, the issues listed in the July 11 Notice are properly within the scope of the hearing in this matter.

C. Additional Dietary Risks

While the two issues listed by EPA in the Amended Notice of Hearing do not limit the scope to any particular dietary risks, EPA states that only information related to carcinogenic, developmental and thyroid risks is material to this proceeding. 72 Fed. Reg. at 70589. NRDC's position, stated in its Request to Participate in the Hearing, dated August 10, 2007, as to dietary risks is that EBDC use on potatoes causes unreasonably high risks of carcinogenic and adverse developmental, reproductive, thyroid and endocrine disruption effects in humans through dietary exposure to EBDCs and their metabolites, and that the dietary risk is inconsistent with the standard under Section 408 of the FFDCA. EPA's position would thus eliminate presentation of evidence regarding two types of dietary risks, namely reproductive and endocrine disruption effects, which NRDC considers are material to this proceeding.

The fact that EPA mentioned the three risks in the NOIC, and EPA's assertion that these three were the concerns in the Special Review and would have been the only risks at issue in the cancellation hearing had one taken place, indicate that they be taken into account in determining whether the Task Force has presented "substantial new evidence" and whether any such evidence requires modification of the cancellation order.[4] However, the text of 40 C.F.R. Part 164 does not support a limitation of the scope of a Subpart D hearing to risks referenced in a NOIC where

[4] The Accelerated Decision and Order and the Settlement Agreement incorporated therein provide very little information as to the underlying issues in the EBDC cancellation proceeding. *See, American Food Security Coalition*, FIFRA Docket No. 646 et al., 1992 EPA ALJ LEXIS 862 (June 16, 1992).

no cancellation hearing was held and the parties settled the cancellation proceeding. A NOIC may only refer to the one or few risks of concern in a Special Review, whereas the rule applicable to cancellation proceedings, 40 C.F.R. § 164.23, does not limit a cancellation hearing to those issues.

Furthermore, to limit the issues in the present proceeding to the three risks mentioned in the NOIC from *sixteen (16) years* ago is inconsistent with the fact that the science of assessing risks and benefits of pesticides is continually evolving, upon which fact Congress required EPA under FIFRA § 3(g) and the FQPA to review pesticide registrations every *15 years*. *See*, H.R. CONF. REP. NO. 104-669 part 1 (1996)("It has become apparent that the rapid development of science and the subsequent application of that knowledge in how it impacts human health and the environment is not only important but continuing to evolve."); 70 Fed. Reg. 40251, 40253 (Proposed Rule, July 13, 2005)("The science underlying the risk-benefit assessments of pesticides is continually evolving."); 40 C.F.R. Part 155.

The additional dietary risks presented by NRDC may be relevant to the issues for hearing as stated in Section 164.132(a). Allowing NRDC to present such evidence of risks that may not have been known or sufficiently evaluated many years ago is consistent with the purposes underlying the issuance of Notices of Hearing and utilizing formal hearing procedures, *i.e.,* to avoid relitigating issues from the cancellation proceeding, to encourage public notice and opportunity to participate, and to avoid inefficiency in proceedings. *See*, 40 Fed. Reg. at 12264. To initiate another Special Review and cancellation process based on evidence of these additional risks would take far more Agency resources and time than considering them in a Subpart D proceeding. *See*, 40 C.F.R. Part 154.

Therefore, it is concluded that no basis has been shown or otherwise found in relevant laws and regulations, and their underlying purposes, to preclude hearing on and adjudication of the issues as to the additional dietary risks presented by NRDC. Accordingly, there is no basis for amending the Pre-Hearing Order to delete those issues.

D. EPA's Authority to Limit Issues by Amending Notice of Hearing

The next question is whether EPA trial staff have authority to eliminate issues from the hearing that are otherwise properly within the scope of the hearing, by means of an Amended Notice of Hearing.

The regulations governing the Federal Register provide in pertinent part as follows:

> § 5.9 Categories of documents.
> Each document published in the Federal Register shall be placed under one of the following categories, as indicated:
> * * *

> (b) Rules and regulations. This category contains each document having general applicability *and legal effect*, except those covered by paragraph (a) of this section. This category includes documents subject to codification, general policy statements concerning regulations, interpretations of agency regulations, statements of organization and function, and documents that affect other documents previously published in the rules and regulations section.
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> (c) Proposed rules. This category contains each notice of proposed rulemaking submitted pursuant to section 553 of title 5, United States Code, or any other law, which if promulgated as a rule, *would* have general applicability *and legal effect*. This category includes documents that suggest changes to regulations in the Code of Federal Regulations, begin a rulemaking proceeding, and affect or relate to other documents previously published in the proposed rules section.
>
> (d) Notices. This category contains miscellaneous documents applicable to the public and not covered by paragraphs (a), (b), and (c) of this section. This category includes announcements of meetings and other information of public interest.

1 C.F.R. § 5.9 (italics added).

Section 5.9 specifies that rules and regulations have legal effect and that proposed rules would have legal effect if promulgated as a rule. In contrast, Section 5.9 does not indicate that Notices have legal effect. A Notice of Hearing, or an amendment thereto, is merely an announcement of an event and related information and has no binding legal effect.

NRDC's point is well taken that the regulatory requirement of the Administrator "to *specify* . . . the issues of fact and law to be adjudicated at the hearing," (40 C.F.R. § 164.131(c)(emphasis added)), does not empower the Administrator to exempt adjudication of issues through the Notice of Hearing procedure that are to be adjudicated under applicable law and regulations.

Movants cite to *Shell Oil Company*, 1 E.A.D. 517 (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")[5] in support of their position. In *Shell Oil,* the Judicial Officer stated that a NOIC "serves much the same function as a complaint in any other administrative proceeding, and as such it 'set[s] a standard of relevance which shall govern the proceedings at the hearing," and therefore, "matters falling outside the scope of the notice . . . are of no relevance to the proceeding." The Judicial Officer based this conclusion on policy reasons, and stated that a limitation on the right

[5] *Aff'd with modifications,* 1 E.A.D. 792 (Adm'r, Final Decision Oct. 31, 1983); *aff'd, sub nom. National Cattlemen's Association v. U.S. EPA*, 773 F.2d 268 (10th 1985).

to file objections is necessarily implied from FIFRA § 6. However in that proceeding, the party sought to have the pesticide unconditionally cancelled for all uses rather than conditionally cancelled as sought by EPA. That is, the party sought relief different from that sought in the NOIC, and the Judicial Officer held that it could not expand the scope of the cancellation hearing to support alternative relief.

In the *Compound 1080* case, the ALJ stated that "the issues in a suspension or cancellation proceeding may not be expanded to include uses or restrictions not proposed in the notice issued by the Administrator," citing *Shell Oil*, and that "the rationale for this decision is that under the statute only the Administrator or his delegate can issue a notice of intent to cancel or suspend and that such a notice necessarily sets the standard of relevance for the conduct of the hearing." *Compound 1080* case, slip op. at 47-48. The ALJ also noted that "the Administrator controls the issues to be adjudicated therein in accordance with 40 CFR 164.131(c) and has ample discretion to preclude the reopening of issues considered to have been properly determined in prior proceedings." *Id*. at 43-44. These two aspects of the Administrator's control over the issues for hearing are not analogous to the issues in the present proceeding.

In the present matter, NRDC does not seek alternative relief, to include uses or restrictions not proposed in the Notice of Hearing, or to relitigate issues, but rather, opposes the relief sought by the Task Force and supported by EPA. The Notice of Hearing is somewhat analogous to a complaint, setting forth proposed relief and factual allegations in support thereof, setting out the issues for a hearing. NRDC's Request to Participate in the Hearing is to some degree analogous to an answer, denying the allegations and setting forth factual allegations to oppose the proposed relief, which are relevant and responsive to the issues listed in the July 11 Notice of Hearing. EPA's Amended Notice of Hearing is similar to an amendment to the complaint which eliminates several allegations from the complaint. While a complaint may be amended to eliminate allegations, such amendment does not necessarily render immaterial the allegations set forth in the answer to oppose the proposed relief. The *Shell Oil* case, on the other hand, involved a party similar to an intervenor who seeks to impose a more stringent relief than the complaint seeks, and the *Compound 1080* case involved a party similar to an intervenor who seeks an additional type of relief to that sought in the complaint. [6]

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[6] As noted in a previous order, the scope of trial in federal court is determined initially by the allegations in the complaint which are not admitted in the answer and any affirmative defenses. The scope then may be narrowed by rulings on pretrial motions, agreements and stipulations of the parties, and orders issued pursuant to Federal Rule of Civil Procedure ("FRCP") 16(e). *E.g., Valdes v. Leisure Resources Group, Inc.*, 810 F.2d 1345, 1357 (5th Cir. 1987)(FRCP 16(e) "instructs judges to enter pre-trial orders to define the scope of issues for trial); *Fararo v. Sink LLC*, No. 01 C 6956, -6957, 2004 U.S. Dist. LEXIS 5367 * 4 (N.D. Ill. March 29, 2004)(plaintiffs draft pre-trial order defining issues for trial, and defendant writes objections to it, or parties agree to issues for hearing at a prehearing conference); *Biglow v. Boeing Co.*, 174 F. Supp 2d 1187, 1195 (D. Kan. 2001)(court determines scope of issues for trial

(continued...)

E. Whether to Disregard the Amended Notice of Hearing

NRDC's request to disregard the Amended Notice is denied. The Amended Notice serves as EPA's position in this matter and includes legal argument which was considered herein. It is therefore not appropriate to disregard it. Furthermore, NRDC is granted relief upon issues as discussed above, and therefore there is no need to disregard the Amended Notice in furtherance of ruling on the issues, and no need to address the issue regarding separation of functions and due process.

ORDER

1. The NRDC's Motion for Leave to Respond to the December 12 Memo is hereby **GRANTED**.

2. The Movants' October 26 request to delete Paragraph 2(C) from the Prehearing Order is **DENIED.**

3. The Movants' December 12 request that the issues set forth in the July 11, 2007 Notice of Hearing, as amended by the December 12, 2007 Amended Notice of Hearing, are the only issues to be adjudicated in this hearing, is **DENIED** to the extent that it limits the hearing to the issues listed in the December 12 Amended Notice.

4. The Movant's December 12 request to amend the Pre-Hearing Order is **DENIED.**

5. NRDC's request to disregard the December 12 Amended Notice of Hearing is **DENIED.**

Susan L. Biro
Chief Administrative Law Judge

Dated: January 16, 2008
Washington, D.C.

[6](...continued)
by ruling on pretrial motions).

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 Regarding Scope of Hearing**, dated January 16, 2008, was sent this day in the following manner to the addresses listed below.

____
Sybil Anderson
Headquarters Hearing Clerk

Dated: January 16, 2008

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