UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

IN THE MATTER OF **Elf Atochem of North America, Inc. and Griffin Corporation** Petitioners **Notice of Hearing Concerning Application to Modify the Final Cancellation Order for Pesticide Products Containing EBDCs**	**FIFRA Docket No. 657** Judge Greene

INITIAL DECISION [1]

Petitioners herein seek modification of the final cancellation order for pesticide products which contain ethylene bisdithiocarbamates (EBDC), pursuant to section 6 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA or the Act), 7 U.S.C. § 136d, and the rules of practice issued under the Act, 40 C.F.R. § 164.20.[2]

---

[1] The Rules of Practice Governing Hearings Under the Federal Insecticide, Fungicide, and Rodenticide Act, Arising from Refusals to Register, Cancellations of Registrations, Changes of Classifications, Suspensions of Registrations, and Other Hearings Called Pursuant to Section 6 of the Act, 40 C.F.R. Part 164, specify that an "initial decision" shall be prepared and filed after the close of a hearing. The Administrator's Federal Register Notice of April 28, 1994, specifies that "the presiding administrative law judge shall transmit recommended findings of fact and conclusions of law. . . . " within 70 calendar days from the date of publication of the notice. 56 Fed. Reg. 22106, 22110.

[2]The ethylene bisdithiocarbamates (the EBDCs) are a group of fungicides consisting of mancozeb, maneb, metiram, and nabam.

On March 2, 1992, the Administrator of the U. S. Environmental Protection Agency (EPA) issued a Notice of Intent to Cancel (NOITC) and Conclusion of the EBDC Special Review (PD4). 57 Fed. Reg. 7484 (1992). This Notice announced EPA's intent to cancel registrations and to deny applications for registration for all pesticide products containing EBDCs as an active ingredient unless the registrations/applications complied with the terms and conditions of that Notice. One requirement was that, to avoid cancellation, all EBDC labels and product registrations bearing agricultural uses were to be amended to include the following statement: "If this product is used on a crop, no other product containing a different EBDC active ingredient may be used on the same crop during the same growing season." 57 Fed. Reg. 7523 (1992). This requirement prohibits the use of more than one EBDC active ingredient per crop per season, and was intended to "avoid the potential overuse of EBDCs through active ingredient switching." 59 Fed. Reg. 22106, 22107 (1994). The prohibition, however, "was not based on specific risk concerns or on the risk calculations underlying the Agency's EBDC regulatory decision." Id.; see Declaration of Richard P. Dumas at 7. Further, it has been stipulated that Petitioners did not have notice of this requirement prior to issuance of the NOITC and PD4. Stipulations at 2.

On December 1, 1993, subsequent to the NOITC becoming an effective Order of Cancellation, Petitioners requested amendment

of the Order. Citing what they termed the negative impacts on industry and growers, Petitioners requested that EPA: 1) amend the labels of seven EBDC pesticide products which were subject to the Cancellation Order and which contain the active ingredients of mancozeb or maneb (Manex™, Maneb 75DF, Maneb 80, Maneb Plus Zinc F4, Penncozeb, Penncozeb DF and Pro-Tex); and 2) allow all EBDC registrants to modify their end use product label(s) in the same manner as Petitioners have proposed to amend theirs.

In lieu of the current labeling, Petitioners propose the following language:

> Foliar Applications
>
> Where EBDC Products Used Allow the Same Maximum Poundage of Active Ingredient Per Acre Per Season
>
> If more than one product containing an EBDC active ingredient (maneb, mancozeb or metiram) is used on a crop during the same growing season and the EBDC products used allow the same maximum poundage of active ingredient per acre per season, then the total poundage of all such EBDC products used must not exceed any one of the specified individual EBDC product maximum seasonal poundage of active ingredient allowed per acre.
>
> Where EBDC Products Used Allow Different Maximum Poundage of Active Ingredient Per Acre Per Season
>
> If more than one product containing an EBDC active ingredient is used on a crop during the same growing season and the EBDC products used allow different maximum poundage of active ingredient per acre per season, then the total poundage of all such EBDC products used must not exceed the lowest specified individual EBDC product maximum seasonal poundage of active ingredient allowed per acre.
>
> Seed Treatment

> In addition to the maximum number of foliar applications permitted by the formula stated above, a single application for seed treatment may be made on crops which have registered seed treatment uses.

59 Fed. Reg. 22106, 22106-07 (1994). While the proposed amendment seeks to allow the use of more than one EBDC active ingredient per crop per season, Petitioners assert that it would not change the current **maximum** allowable amount of EBDCs. Consequently, as discussed infra, EPA's objective of "avoid[ing] the potential overuse of EBDCs through active ingredient switching"[3] would not be compromised.

On April 28, 1994, pursuant to 40 C.F.R. 164.131(c), the Administrator issued a notice of hearing which specified the issues of fact and law to be adjudicated, as required by 40 C.F.R. § 164.23.

Issues of fact to be adjudicated are as follows:

> 1. What will the economic impacts on growers, processors, and consumers be if the lack of a provision for a seed treatment application and the present restriction on using multiple EBDC active ingredients on the same crop during the same growing season continue?
>
> 2. What have been the use practices regarding the use of more than one EBDC active ingredient per crop per season prior to the current restriction?
>
> 3. What will be the effect of the present restriction on using multiple EBDC active ingredients on the same crop during the same growing season if this restriction is maintained? Likewise, what would be the effect on efficacy of EBDC use and other pest control practices if the lack of a provision for a seed treatment application continues?

---

[3] 59 Fed. Reg. 22106, 22107 (1994).

4. Assuming the validity of the analysis of the toxicity of EBDCs and the methodology for analysis of exposure to EBDCs upon which the cancellation order was based, what quantitative effect would adoption of the proposed language have on the total risk associated with EBDC use?

The issues of law to be adjudicated are as follows:

1. Has substantial new evidence been presented pertaining to the use of more than one EBDC active ingredient per crop per season and allowance in certain cases for a single seed treatment application per crop per season in addition to foliar applications and the impact of the current restriction?

2. Assuming the validity of the analysis of the toxicity of EBDCs and the methodology for analysis of exposure to EBDCs upon which the cancellation order was based, does the evidence presented demonstrate that the benefits of allowing use of more than one EBDC active ingredient per crop per season and allowing in certain cases a single seed treatment application per crop per season in addition to foliar applications are likely to outweigh the risks of such use? [i.e. Based on the evidence presented, should the Agency revise its prior determination that allowed use to be limited to one active ingredient per crop per season and that a single seed treatment should not be allowed in certain cases in addition to the foliar application?]

The Administrator's notice continued as follows:

The sole objective of this hearing is to determine whether or not the order canceling all sale, distribution, and use of pesticide products containing EBDCs which do not comply with the current label restriction on multiple EBDC use should be modified to permit the use of more than one EBDC active ingredient per crop per season and allow a single seed treatment in addition to foliar uses where there is a registered seed treatment use.

59 Fed. Reg. 22106, 22109 (1994).

On May 31, 1994, a group known as the EBDC/ETU Task Force, comprised of four companies (BASF, Dupont, Elf Atochem, and Rohm

and Haas) moved for leave to intervene in this proceeding. There being no opposition from Respondent EPA or from Petitioner Elf Atochem North America, Inc.,[4] and the requirements of the rules of practice pertaining to motions to intervene having been met by the movant, the motion was granted.

On June 7, 1994, the parties submitted their witnesses' direct testimony in written form.[5] Respondent's sole witness, Richard P. Dumas, stated that "assuming the record presented [at the] hearing supports Petitioners' requests, the Agency has no objections to the requested label language changes being allowed as a notification to the EBDC Cancellation Order." Declaration of Richard P. Dumas at 12. The parties were able to stipulate extensively with respect to the facts herein.[6]

A formal adjudicatory hearing was held on June 20, 1994. In its summary of the case, Respondent EPA reiterated its acceptance of Petitioners' proposed amendments, "so long as the record that we assemble as a result of today's hearing and the documents that are associated with it . . . support their request." Transcript at 10.

The record in this matter discloses substantial new evidence of negative impacts resulting from implementation of and

---

[4]No response to the motion was received from petitioner Griffin Corporation.

[5] See 40 C.F.R. § 164.81(a), (g).

[6] The stipulations of the parties are attached hereto and made a part of this decision. (See Appendix).

adherence to the label restrictions. As previously stated, it has been stipulated that Petitioners did not have notice of the restrictions in the cancellation order prior to issuance of the NOITC and PD4. Stipulations at 2. Consequently, evidence of the impact of the restriction could not have been produced prior to implementation of the restriction.

The substantial new evidence relates to three areas. First, the prohibition limits the flexibility of a grower to change products during the growing season -- for instance, whether to respond to disease pressures, or whether to respond to supply/price variations. The lack of flexibility forces growers to choose between either higher priced or less effective products for use on crops.

Second, the restriction has caused confusion in the marketplace as to its exact meaning. It could be interpreted to prohibit switching among active ingredients or, alternatively, to prohibit use of more than one commercial brand containing the same active ingredient.

Finally, the record discloses that the proposed amendments would not compromise EPA's stated objective of ensuring seasonal limits on the application of EBDCs to a particular crop, because the changes would not increase the current maximum allowable amount of EBDCs that can be applied to any crop during a growing season. Moreover, the evidence demonstrates that there would be

no increased risk from adoption of the proposed language,[7] and that the benefits would be substantial. In short, the evidence presented demonstrates that the benefits of allowing use of more than one EBDC active ingredient per crop per season and allowing in certain cases a single seed treatment application per crop per season in addition to foliar applications will outweigh the risks, if any, of such use.[8]

The following discussion analyzes and evaluates each of these factors.

I. Growers' Lack of Flexibility

Under current label restrictions, a grower is precluded from switching to a different EBDC active ingredient product during the same growing season. The record reveals that this prohibition limits a grower's ability to: A) respond to disease pressures as they arise; and B) respond to variations in price and/or supply of pesticide products.

A. Disease Pressures

During the course of a growing season, a grower may need the

---

[7] As previously stated, the Agency's decision to implement the restriction "was not based on specific risk concerns or on the risk calculations underlying the Agency's EBDC regulatory decision." 59 Fed. Reg 22106, 22107 (1994); see Declaration of Richard P. Dumas at 7.

[8] See second issue of law set forth by the Administrator in 59 Fed. Reg. 22106, 22107. (P. 5 supra).

flexibility to switch to a pesticide containing a different EBDC active ingredient in order to effectively combat unanticipated fungal problems associated with a given crop. Declaration of Gale E. Hazen at 3-4; Declaration of Thomas F. Mueller at 3-4. Prior to implementation of the current restriction, growers typically used more than one EBDC per crop per growing season. Declaration of H. Arthur Lamey at 2; Declaration of Todd Michael at 1-2; Declaration of Keith Masser at 1-2; Declaration of Gale E. Hazen at 2; Declaration of Thomas F. Mueller at 2; Declaration of Richard A. Jaeger at 1.

Under the current label language, however, growers are limited to using only one EBDC active ingredient per crop per growing season. This new language "may restrict a grower's ability to address effectively the fungal problems . . . by using the most effective EBDC product to treat a particular problem." Stipulations at 6; see Declaration of Gordon D. Bowman, II at 2. As Dr. Janet Ollinger stated at the hearing in this matter: "there can be cases where a grower may start with Maneb, and find out later in the season that he has a late blight . . . and so it would be advantageous to be able to use Ridomil MZ [the only Ridomil/EBDC combination is Ridomil with mancozeb], but because the original treatments were with Maneb, that switch is not possible." Testimony of Dr. Janet Ollinger, Transcript at 88; Declaration of H. Arthur Lamey at 4. "Essentially, growers are forced to choose between a treatment regime that is effective against early blight -- for example, maneb plus zinc -- and a

regime that is more effective against late blight -- such as Ridomil MZ 58 (mancozeb plus metalaxyl). Stipulations at 4. "A grower that cannot use Ridomil MZ 58, the most cost-effective treatment for late blight, because of use of a different EBDC earlier in the season, faces the possibility of reduced yields and/or greater costs to control late blight." Id.; see Declaration of Lynn Olsen at 3.

Similarly, the current language forces growers to choose either an effective seed treatment (maneb, the only EBDC that is formulated as a dry powder treatment), or the most effective late-blight foliar treatment (Ridomil MZ, which contains mancozeb). Growers prefer dry formulations for seed treatments because wet treatments tend to promote bacterial growth. Declaration of Todd Michael at 2.

B. Variations in Price and/or Supply

Variations in availability and pricing of EBDC products may make it necessary for growers to switch among EBDCs during the growing season. Testimony of Gary R. Sandberg, Transcript at 28; Declaration of Gary R. Sandberg at 4-5; Declaration of Todd Michael at 2. Under the current label restrictions, however, if the supply of a grower's initially selected EBDC product falls, and, as a consequence, the price rises, the grower will be precluded from switching to any other product containing a different EBDC active ingredient during the growing season. This

factor is compounded by the fact that the principle manufacturers and marketers of EBDCs in the United States are dependent on foreign manufacturing plants, work forces and shipping companies for their supply. Testimony of James M. Loar, Transcript at 61; Declaration of James M. Loar at 2; Testimony of Dr. Janet Ollinger, Transcript at 84.

These variations in price and/or supply, in conjunction with growers' inability to efficiently respond to unanticipated disease pressures, could produce substantial economic impacts on growers, processors, and consumers. It is estimated that the current restrictions could result in total revenue losses to growers of as much as $227.2 million annually on a nationwide basis for the following crops: apples, tomatoes, grapes, potatoes, onions, cucumbers, and sweet corn. Declaration of John M. Urbanchuk at 14, Table 2; Stipulations at 3. It is further estimated that processor costs for these crops could increase by as much as $71.2 million annually, and consumer expenditures by $46.8. Declaration of John M. Urbanchuk at 14, Table 2; Stipulations at 3.

II. Confusion in the Marketplace

The current label language has been interpreted differently, creating confusion among growers. Declaration of Charles H. Matthews, Jr. at 3; Stipulations at 7. One interpretation has been that the label language prohibits switching among products containing different active ingredients. Declaration of Charles

H. Matthews, Jr. at 3. For example, if a grower initially uses a product containing maneb, the grower would not be able to switch during the same growing season to a product with the active ingredient mancozeb. This has been the Agency's interpretation.

Another interpretation holds that the label language prohibits switching among commercial brands of the same active ingredient. Declaration of Dr. Janet Ollinger at 5. This interpretation has been promoted by, inter alia, the Wisconsin Potato and Vegetable Growers Association, which stated in its newsletter that: "In the course of the EBDC food safety debate and subsequent label change, the EPA has mandated that in using the EBDC compounds you can only use one brand all season. For example, if you use Dithane you must stick with Dithane all season."[9]

III. Proposed Amendments Are Compatible with Agency's Stated Objective, and Benefits Outweigh Risks

As previously stated, Petitioners' proposed amendments seek to allow the use of more than one EBDC active ingredient per crop per season. They would not, however, change the **current maximum allowable** amount of EBDCs. The proposed amendments are unambiguous in this regard:

Where EBDC Products Used Allow the Same Maximum Poundage of Active Ingredient Per Acre Per Season

If more than one product containing an EBDC active

[9] Insight, An inside Report to the Members of the Wisconsin Potato and Vegetable Growers Association, February 8, 1993.

ingredient (maneb, mancozeb or metiram) is used on a

crop during the same growing season and the EBDC products used allow the same maximum poundage of active ingredient per acre per season, then the total poundage of all such EBDC products used must not exceed any one of the specified individual EBDC product maximum seasonal poundage of active ingredient allowed per acre.

Where EBDC Products Used Allow Different Maximum Poundage of Active Ingredient Per Acre Per Season

If more than one product containing an EBDC active ingredient is used on a crop during the same growing season and the EBDC products used allow different maximum poundage of active ingredient per acre per season, then the total poundage of all such EBDC products used must not exceed the lowest specified individual EBDC product maximum seasonal poundage of active ingredient allowed per acre.

59 Fed. Reg. 22106, 22106-07 (1994) (emphasis added). Consequently, the Agency's objective of "avoid[ing] the potential overuse of EBDCs through active ingredient switching"[10] would not be compromised. Indeed, under the proposed label language, overall potential dietary risk,[11] as well as worker risk,[12] may be reduced. Clearly, then, reliable and probative evidence in the record establishes that substantial benefits[13] from adoption of the proposed language would outweigh any risks.

---

[10]59 Fed. Reg. 22106, 22107 (1994).

[11]Declaration of Gail Arce at 4; see Stipulations at 7-8

[12]Declaration of Gail Arce at 4; Stipulations at 8.

[13]Discussed supra, pp. 7-11.

RECOMMENDED FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. On March 2, 1992, the Administrator issued a Notice of Intent to Cancel ("NOITC") and Conclusion of the EBDC Special Review, which announced EPA's intent to cancel registrations and deny applications for registration for all EBDC products unless the registrants/applicants complied with certain terms, including limiting seasonal maximums for EBDC use. (Stipulation No. 1; Declaration of Richard P. Dumas at ¶ 5.)

2. One requirement of the cancellation order was that, to avoid cancellation, all EBDC product labels and registrations bearing agricultural uses be amended to include the following label statement: "If this product is used on a crop, no other product containing a different EBDC active ingredient may be used on the same crop during the same growing season." (Stipulation No. 2; Dumas Declaration at ¶ 6.)

3. The current label language was not included in any prior decision document before the PD4 regarding EBDCs and the registrants and the grower community did not have any notice prior to issuance of the NOITC that such a restriction was to be mandated. (Stipulation No. 3; 59 Fed. Reg. 22106, 22109 (April 28, 1994).)

4. Evidence of actual impacts resulting from implementation of the label restriction was necessarily unavailable prior to the effective date of the cancellation order, which put the label

restriction into effect. (Stipulation No. 4; 59 Fed. Reg. at 22109.

5. If the present restriction on using multiple EBDC active ingredients on the same crop during the same growing season continues and growers are forced to switch to non-EBDC fungicides because of unanticipated disease pressure, or inability to obtain adaquate supplies of EBDCs, available information suggests that they may experience lower yields due to reduced disease control, higher costs, and lower revenues. (Stipulation No. 5; Sandberg Testimony at p. 18, line 19; Jaeger Declaration at ¶ 3; Matthews Declaration at ¶ 6; Mellinger Declaration at ¶ 6; Mueller Declaration at ¶ 7; Olsen Declaration at ¶ 9; Hazen Supplemental Declaration at pp. 3-5; Loar Testimony at p. 57, lines 11-14.)

6. Some of the adverse impacts of the current label restriction are potential impacts that may occur in the event of particular market conditions or crop disease pressures. In some cases, product shortages, and resulting harm to growers has already occurred. (Jaeger Declaration at ¶¶ 3-4; Michael Declaration at ¶ 9; Loar Testimony at p. 55, line 8-p. 56, line 2, p. 56, line 5- p. 57 line 14; Hazen Supplemental Declaration at p. 5.)

7. Estimates of the economic impact of EBDC cancellation or the "worst case" adverse impacts of the current label restriction vary. EPA's 1992 estimates of the impact of cancellation of EBDCs included in the PD4 were as follows: $16.7 to $51.8

million loss for apples; $32 to $45 million for tomatoes; $1.8 to $17.5 million for grapes; $40.4 million for potatoes; $1.4 to $6.1 million producer impacts for cucumbers; $4.2 to $5.5 million for onions; and $2.1 to $8.6 million for sweet corn. (Dumas Declaration Exhibit A; 57 Fed. Reg. 7484, 7512-15 (March 2, 1992).)

8. The current estimates prepared by Mr. Urbanchuk for his definition of a possible worst case impact of the current label restriction on growers, processors, and consumers of the seven crops considered were that the impact on a national basis could be as high as $345 million. The numbers show a potential economic impact from the current provision restricting the use of multipe EBDCs. (Urbanchuk Declaration at p. 14.)

9. Prior to the current restriction, growers often rotated among EBDC products during a single growing season. This enabled growers to address specific disease conditions as they arose. Alternating among EBDC products also helped to avoid pest or disease resistance. (Stipulation No. 10; Loar Declaration at p. 2-3; Olsen Declaration at ¶ 5; Michael Declaration at ¶ 4; Masser Declaration at ¶¶ 4 and 6.)

10. Prior to the current restriction, growers chose EBDC products based on price, availability, and particular conditions during the growing season, including but not limited to the particular disease or pest pressure, efficacy, and timing of treatment. (Stipulation No. 11; Michael Declaration at ¶ 4;

Masser Declaration at ¶ 4; Ollinger Declaration at ¶ 7; Mueller Declaration at ¶ 5; Sutton Declaration at ¶ 5.)

11. The current label provision precludes growers from switching among EBDC active ingredients for any reason. This prohibition is absolute and applies even if a particular product is not available or is higher priced due to its short supply. (Stipulation No. 12; Dumas Declaration at ¶ 21; 59 Fed. Reg. at 22107.)

12. Because growers can no longer alternate among EBDC active ingredients during a single growing season, there is a concern that increased pest or disease resistance may occur. (Stipulation No. 13; Loar Testimony at p. 67, line 14-p. 68, line 2; Olsen Declaration at ¶ 8; Masser Declaration at ¶ 6; Matthews Declaration at ¶ 12; Mellinger Declaration at ¶ 7; Hazen Supplemental Declaration at p. 3; Masser Supplemental Declaration at ¶ 3.)

13. Early blight and late blight are two diseases that are of particular concern to potato and, to a lesser extent, tomato growers. Despite the names, either disease can occur at any time during the growing season. Early blight occurs during warm weather, while late blight is a cooler weather disease. (Stipulation No. 14; Lamey Supplemental Declaration at p. 1.)

14. Essentially growers are forced to choose between a treatment regime that is effective against early blight -- for example, maneb plus zinc -- and a regime that is more effective

against late blight -- such as Ridomil MZ 58 (mancozeb plus metalaxyl). (Stipulation No. 15; Lamey Declaration at p. 3; Hazen Declaration at pp. 2-3; Jaeger Declaration at ¶¶ 3 and 5; Mueller Supplemental Declaration at ¶ 2.)

15. A grower that cannot use Ridomil MZ 58, the most cost-effective treatment for late blight, because of use of a different EBDC earlier in the season, faces the possibility of reduced yields and/or greater costs to control late blight. (Stipulation No. 16; Lamey Declaration at pp. 4-5; Olsen Declaration at ¶ 9; Ollinger Declaration at ¶ 8; Hazen Supplemental Declaration at pp. 3-4.)

16. Under the current restriction, in order to preserve the option of using Ridomil MZ 58 to control late blight, a grower must use the more expensive mancozeb formulations throughout the season. (Stipulation No. 17; Michael Declaration at ¶ 7; Olsen Declaration at ¶¶ 6-7; Masser Declaration at ¶ 5; Hazen Supplemental Declaration at p. 4.)

17. Where a supplier does not stock adequate inventory and runs out of a particular EBDC, a grower may have to pay additional costs to obtain the material or use a less-effective, non-EBDC product. (Stipulation No. 18; Ollinger Testimony at p. 88, line 10-p. 89, line 3; Matthews Supplemental Declaration at ¶ 3; Sandberg Declaration at ¶ 9; Ollinger Declaration at ¶ 7; Michael Declaration at ¶ 9; Mellinger at ¶ 5.)

18. Suppliers of EBDC products face problems in forecasting

inventory needs and increased costs. This may be further complicated because, under the current restriction, growers have no flexibility to use EBDCs different from those with which they begin the season, and suppliers must order products to address all possible situations. (Stipulation No. 19; Sandberg Testimony at p. 22, line 19- p. 23, line 5; Sprague Declaration at pp. 2-3; Sprague Supplemental Declaration at p. 2.)

19. Forecasting problems are compounded by the fact that all technical EBDCs are manufactured overseas and many manufacturers require orders well ahead of the season. (Stipulation No. 20; Loar Testimony at p. 61, line 20-p. 62, line 8; Hazen Supplemental Declaration at p. 7; Sprague Declaration at p. 3.)

20. In the past, before the label change, EBDC shortages were not a problem because growers could use whatever EBDC a supplier had in stock until the new supplies were delivered. (Michael Supplemental Declaration at ¶ 4; Sprague Supplemental Declaration at p. 1.)

21. Growers using other fungicide or pesticide products may face similar supply problems, however, they can more easily deal with a shortage as they are not precluded from switching to the next logical treatment alternative. (Stipulation No. 21; Ollinger Testimony at p. 85, lines 10-15; Sprague Supplemental Declaration at p. 1.)

22. Because the current EBDC label language locks a grower

into using only one EBDC active ingredient during a growing season, growers' costs to treat a particular disease often increase either because they use additional pre-mixed fungicides, which are more expensive and, in addition, may contain fungicides that are not needed, or they must use more of a less effective fungicide product. (Stipulation No. 22; Lamey Declaration at pp. 4-5; Olson Declaration at ¶ 9; Jaeger Declaration at ¶ 3; Mueller Declaration at ¶ 7.)

23. The current EBDC label language may also increase pesticide use as growers may have to make more applications of a less-effective non-EBDC product to achieve the same results as they would with an EBDC product or must continue to use an EBDC product because of a treatment decision made earlier in the season. (Stipulation No. 23; Loar Testimony at p. 68, lines 14-20; Jaeger Declaration at ¶ 6; Matthews Declaration at ¶¶ 9 and 10; Mueller Declaration at ¶ 7; Hazen Declaration at p. 4; Olson Declaration at ¶ 9.)

24. There are other disincentives to growers that should dissuade them from exceeding EBDC crop usage limits, such as the risk of having treated crops with over-tolerance residues which could make treated crops subject to seizure. (Stipulation No. 24; Dumas Declaration at ¶ 18; 59 Fed. Reg. at 22108.)

25. The current label language may restrict a grower's ability to address effectively the fungal problems associated with a particular crop by using the most effective EBDC product

to treat a particular problem. (Stipulation No. 25; Loar Testimony at p. 68, lines 14-20; Hazen Supplemental Declaraton at p. 4; Mueller Declaration at ¶¶ 7, 10; Jaeger Declaration at ¶ 3; Michael Declaration at ¶ 10.)

26. The current label language can be inconsistent with certain IPM approaches. IPM seeks to selectively use different classes of fungicides to maximize the effects of beneficial organisms, increase the spectrum of pest control at key times during the season, and prevent pest resistance. Because the current label language locks a grower into using the EBDC active ingredient the grower selects early in the growing season, the grower may lack some of the flexibility later in the season to use another EBDC active ingredient that might be required to manage crops in accordance with an IPM approach. (Stipulation No. 26; Loar Testimony at p. 69, lines 3-14, p. 70, line 20-p. 71, line 6; Matthews Supplemental Declaration at ¶ 5; Jaeger Declaration at ¶ 5; Sandberg Declaration at ¶ 12; Mellinger Declaration at ¶¶ 7 and 9; Mueller Declaration at ¶ 10.)

27. There also has been confusion about the application of the prohibition to seed treatment. (Stipulation No. 27; Compare Ollinger Declaration at ¶ 11 and attachment <u>with</u> Michael Declaration at ¶ 12, Mueller Declaration at ¶ 11 and Michael Supplement Declaration at ¶ 3.)

28. Changing the label to permit a single application for seed treatment in addition to the maximum number of foliar

applications would be desirable to growers because, among other things, it would give growers the flexibility to use dry powder formulations EBDCs. Growers report that such dry formulations are particularly effective seed treatments. (Stipulation No. 28; Ollinger testimony at p. 89, lines 11-14; Michael Declaration at ¶¶ 5, 12; Michael Supplemental Declaration at ¶¶ 2-3.)

29. An additional benefit of making the requested label change would be elimination of confusion, which, although reduced, still exists with respect to the label restriction. (Sandberg Testimony at p. 31, lines 1-18; Sandberg Declaration at ¶ 13; Lamey Declaration at p. 5; Michael Declaration at ¶ 11; Ollinger Declaration at ¶ 10; Matthews Declaration at ¶ 8; Michael Supplement Declarationat ¶ 5.)

30. The label language required by the NOITC has created post-cancellation order confusion and implementation problems in the marketplace and at the grower level. (Stipulation No. 31; Dumas Declaration at ¶ 31.)

31. The Agency's goal of limiting the potential exceeding of EBDC usage limits by growers can be addressed in a better way by adopting the proposed language. (Stipulation No. 31; Dumas Declaration at ¶ 31; 59 Fed. Reg. at 22108.)

32. There will be no impact on the potential dietary risk associated with apples, bananas, grapes, cranberries, papayas, tomatoes, potatoes, sweet corn, dry bulb onions, and sugar beets because the maximum seasonal EBDC poundage for these crops is the

same for all EBDCs. (Stipulation No. 32; Arce Declaration at ¶ 8; Dumas Declaration at ¶ 16.)

33. The maximum seasonal poundage is measured by multiplying the maximum number of applications allowed per season by the maximum poundage allowed per acre per application. (Stipulation No. 33.)

34. With respect to cucumbers, the five types of melons, and summer squash, which have different seasonal maximums, the potential dietary risk may be reduced slightly because the proposed label requires that the total poundae of all EBDC products used on a crop within a season must not exceed the lowest specified individucal EBDC product maximum seasonal poundage. (Stipulation No. 34; Arce Declaration at ¶ 9.)

35. With regard to mixer-handler exposure, the proposed label language changes might also mitigate some potential worker risk. With current EBDC use restrictions, the EBDC used initially on a crop must be used for the rest of the season. Using pre-packaged mixes is not always possible as the mixes may contain another EBDC. The use of pre-packaged products eliminates tank mixing and thus can reduce potential exposure when mixing pesticides and in disposing of containers. (Stipulation No. 35; Arce Declaration at ¶ 10; Ollinger Declaration at ¶ 9; Dumas Declaration at ¶ 23.)

36. EPA's intention in requiring the current label language prohibiting sequential applications of two or more EBDCs to one

crop during a growing season was to avoid potential overuse of EBDCs caused by active ingredient switching. (Stipulation No. 36; Dumas Declaraton at ¶ 17; Sandberg Declaration at ¶ 7.)

37. The March 2, 1992 NOITC, which contained the label prohibitions at issue, did not provide a specific risk/benefit rationale for the specific application prohibitions at issue in this proceeding. The Agency's thinking at that time was that the provision would help assure that growers would not exceed EBDC usage limits per crop. The language was designed to address this need. (Stipulation No. 37; Dumas Declaration at ¶ 17; 59 Fed. Reg. at 22108.)

38. The proposed label language will not permit an increase in the maximum amount of EBDC that can be applied to any crop during a growing season. (Stipulation No. 38; Arce Declaration at ¶¶ 8, 9; Ollinger Declaration at ¶ 6; Dumas Declaration at ¶¶ 31 and 32.)

39. Based on available information, allowing the requested label changes for foliar use and seed treatment should not result in any increased EBDC dietary exposure. The new label language should provide the same level of dietary exposure control that the Agency originally sought with the current label prohibitions. (Stipulation No. 39; Dumas Declaration at ¶ 16; Arce Declaration at ¶ 11.)

40. The adoption of the proposed label language will not increase the total risk associated with EBDC use, as calculated

by EPA in connection with the NOITC. (Stipulation No. 40; Dumas Declaration at ¶ 16; 59 Fed. Reg. at 22109; Arce Declaration at ¶ 4.)

41. Substantial new evidence, available only since EPA issued the NOITC, has been presented pertaining to benefits resulting from the use of more than one EBDC active ingredient per crop per season.

42. Substantial new evidence, available only since EPA issued the NOITC, has also been presented pertaining to the benefits resulting from the allowance in certain cases for a single seed treatment application per crop per season, in addition to foliar applications.

43. In addition, substantial new evidence, available only since EPA issued the NOITC, has been presented pertaining to the negative impact of the current restriction, which restricts a grower to using one EBDC active ingredient per crop per growing season.

44. There was no evidence of any increased toxicological risk associated with permitting the use of more than one EBDC active ingredient per crop per season or of allowing, in certain cases, a single seed treatment application in addition to foliar applications.

45. The evidence presented demonstrates that the benefits of allowing the use of more than one EBDC active ingredient per crop per season and allowing in certain cases a single seed

treatment application in addition to foliar applications (i.e., the requested label change) outweigh the risks of such use.

RECOMMENDED ORDER

Accordingly, the final cancellation order for pesticide products containing EBDCs shall be and it is hereby modified to permit the use of more than one EBDC active ingredient per crop per season, and to allow a single seed treatment in addition to foliar uses where there is a registered seed treatment use, so long as the current allowable maximum amount of EBDCs is not exceeded. Accordingly, the labels of seven EBDC pesticide products which were subject to the Cancellation Order and which contain the active ingredients of mancozeb or maneb (Manex™, Maneb 75DF, Maneb 80, Maneb Plus Zinc F4, Penncozeb, Penncozeb DF and Pro-Tex) shall be amended to add the following language:

Foliar Applications

Where EBDC Products Used Allow the Same Maximum Poundage of Active Ingredient Per Acre Per Season

If more than one product containing an EBDC active ingredient (maneb, mancozeb or metiram) is used on a crop during the same growing season and the EBDC products used allow the same maximum poundage of active ingredient per acre per season, then the total poundage of all such EBDC products used must not exceed any one of the specified individual EBDC product maximum seasonal poundage of active ingredient allowed per acre.

Where EBDC Proudcts Used Allow Different Maximum Poundage of Active Ingredient Per Acre Per Season

If more than one product containing an EBDC active ingredient is used on a crop during the same growing season and the EBDC products used allow different maximum poundage of active ingredient per acre per season, then the total poundage of all such EBDC products used must not exceed the lowest specified individual EBDC product maximum seasonal poundage of active ingredient allowed per acre.

Seed Treatment

In addition to the maximum number of foliar applications permitted by the formula stated above, a single application for seed treatment may be made on crops which have registered seed treatment uses.

And it is further ordered that all EBDC registrants shall be permitted to modify their end use product label(s) in the same manner.

J. F. Greene
Administrative Law Judge

Washington, D. C.
July 8, 1994

APPENDIX

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

In the Matter of: Notice of Hearing Concerning Application To Modify The Final Cancellation Order for Pesticide Products Containing EBDCs, Petitioner	FIFRA Docket No. 657 STIPULATIONS

For purposes of the above-referenced action only, Elf Atochem, N.A. and Griffin Corporation (the "Petitioners") and the United States Environmental Protection Agency (the "Agency") agree to the Stipulations set forth below:

BACKGROUND

1. On March 2, 1992, the Administrator issued a Notice of Intent to Cancel ("NOITC") and Conclusion of the EBDC Special Review, which announced EPA's intent to cancel registrations and deny applications for registration for all EBDC products unless the registrants/applicants complied with certain terms, including limiting seasonal maximums for EBDC use.

2. One requirement of the cancellation order was that, to avoid cancellation, all EBDC product labels and registrations bearing agricultural uses be amended to include the following label statement: "If this product is used on a crop, no other product containing a different EBDC active ingredient may be used on the same crop during the same growing season."

SUBSTANTIAL NEW EVIDENCE

3. The current label language was not included in any prior decision document before the PD4 regarding EBDCs and the registrants and the grower community did not have any notice prior to issuance of the NOITC that such a restriction was to be mandated.

4. Evidence of actual impacts resulting from implementation of the label restrictions was necessarily unavailable prior to the effective date of the cancellation order, which put the label restriction into effect.

ECONOMIC IMPACTS FROM LABEL

5. If the present restriction on using multiple EBDC active ingredients on the same crop during the same growing season continues and growers are forced to switch to non-EBDC fungicides because of unanticipated disease pressure, or inability to obtain adequate supplies of EBDCs, available information suggests that they may experience lower yields due to reduced disease control, higher costs, and lower revenues.

6. According to Petitioners' economist's projections, the total revenue loss to growers that use the most-widely used non-EBDC because the EBDC they initially select is not available or they are precluded from using the preferred EBDC by earlier use of another EBDC could total as much as $227.2 million on a nationwide basis for the following crops: apples, tomatoes, grapes, potatoes, onions, cucumbers, and sweet corn. Petitioners state that the estimated impact on growers was prepared based on

National Agricultural Pesticide Impact Assessment Program ("NAPIAP") estimates of percent of acres treated by crop, disease, fungicide alternatives, and NAPIAP yield loss estimates for all crops except onions and cucumbers. Yield loss estimates for onions were obtained from the PD2 and PD3 and for cucumbers from the Economic Benefits for Maneb prepared by John M. Urbanchuk for Atochem North America, Inc. in September 1990.

7. As a result of the potential production shortfall, it is further estimated by Petitioners that processor costs could increase by as much as $71.2 million for the same seven crops.

8. Petitioners also project that consumer expenditures could increase by as much as an estimated $46.8 million as a result of the current restriction.

9. The processor cost and consumer expenditure impacts for each crop were estimated based on demand elasticities prepared by economists of the USDA Economic Research Service as analyzed and projected by petitioners' economist.

USE PRACTICES PRIOR TO RESTRICTION

10. Prior to the current restriction, growers often rotated among EBDC products during a single growing season. This enabled growers to address specific disease conditions as they arose. Alternating among EBDC products also helped to avoid pest or disease resistance.

11. Prior to the current restriction, growers chose EBDC products based on price, availability, and particular conditions during the growing season, including but not limited to the

particular disease or pest pressure, efficacy, and timing of treatment.

EFFECT OF CURRENT RESTRICTIONS

12. The current label provision precludes growers from switching among EBDC active ingredients for any reason. This is true even if a particular product is not available or is higher priced due to its short supply.

13. Because growers can no longer alternate among EBDC active ingredients during a single growing season, there is a concern that increased pest or disease resistance may occur.

14. Early blight and late blight are two diseases that are of particular concern to potato and, to a lesser extent, tomato growers. Despite the names, either disease can occur at any time during the growing season. Early blight occurs during warm weather, while late blight is a cooler weather disease.

15. Essentially growers are forced to choose between a treatment regime that is effective against early blight -- for example, maneb plus zinc -- and a regime that is more effective against late blight -- such as Ridomil MZ 58 (mancozeb plus metalaxyl).

16. A grower that cannot use Ridomil MZ 58, the most cost-effective treatment for late blight, because of use of a different EBDC earlier in the season, faces the possibility of reduced yields and/or greater costs to control late blight.

17. Under the current restriction, in order to preserve the option of using Ridomil MZ 58 to control late blight, a grower

must use the more expensive mancozeb formulations throughout the season.

18. Where a supplier does not stock adequate inventory and runs out of a particular EBDC, a grower may have to pay additional costs to obtain the material or use a less-effective, non-EBDC product.

19. Suppliers of EBDC products face problems in forecasting inventory needs and increased costs, because growers have no flexibility to use EBDCs different from those with which they begin the season, and suppliers must order products to address all possible situations.

20. Forecasting problems are compounded by the fact that many manufacturers require orders well ahead of the season.

21. Growers using other fungicide or pesticide products may face similar supply problems, however, they can more easily deal with a shortage as they are not precluded from switching to the next logical treatment alternative.

22. Because the current EBDC label language locks a grower into using only one EBDC active ingredient during a growing season, growers' costs to treat a particular disease often increase either because they use additional pre-mixed fungicides, which are more expensive and, in addition, may contain fungicides that are not needed, or they must use more of a less effective fungicide product.

23. The current EBDC label language may also increase pesticide use as growers may have to make more applications of a

less-effective non-EBDC product to achieve the same results as they would with an EBDC product or must continue to use an EBDC product because of a treatment decision made earlier in the season.

24. There are other disincentives to growers that should dissuade them from exceeding EBDC crop usage limits, such as the risk of having treated crops with over-tolerance residues which could make treated crops subject to seizure.

25. The current label language may restrict a grower's ability to address effectively the fungal problems associated with a particular crop by using the most effective EBDC product to treat a particular problem.

26. The current label language can be inconsistent with certain IPM approaches. IPM seeks to selectively use different classes of fungicides to maximize the effects of beneficial organisms, increase the spectrum of pest control at key times during the season, and prevent pest resistance. Because the current label language locks a grower into using the EBDC active ingredient the grower selects early in the growing season, the grower may lack some of the flexibility later in the season to use another EBDC active ingredient that might be required to manage crops in accordance with an IPM approach.

27. There also has been confusion about the application of the prohibition to seed treatment.

28. Changing the label to permit a single application for seed treatment in addition to the maximum number of foliar

applications would be desirable to growers because, among other things, it would give growers the flexibility to use dry powder formulations EBDCs. Growers report that such dry formulations are particularly effective seed treatments.

29. There has been confusion among growers about whether a grower could switch between brands or formulations of a specific EBDC active ingredient on a single crop during a single growing season.

30. Some post-cancellation order incidents have been reported of registrant/marketplace/grower confusion over the meaning of the current label restriction. The Agency unsuccessfully attempted to remove the confusion arising from the current label provision by providing an interpretation of the label provision and responding to related questions.

31. The label language required by the NOITC has created post-cancellation order confusion and implementation problems in the marketplace and at the grower level. The Agency's goal of limiting the potential exceeding of EBDC usage limits by growers can be addressed in a better way by adopting the proposed language.

EFFECT OF PROPOSED LANGUAGE ON TOTAL RISK ASSOCIATED WITH EBDC USE

32. There will be no impact on the potential dietary risk associated with apples, bananas, grapes, cranberries, papayas, tomatoes, potatoes, sweet corn, dry bulb onions, and sugar beets because the maximum seasonal EBDC poundage for these crops is the same for all EBDCs.

33. The maximum seasonal poundage is measured by multiplying the maximum number of applications allowed per season by the maximum poundage allowed per acre per application.

34. With respect to cucumbers, melons, and summer squash, which have different seasonal maximums, the potential dietary risk may be reduced slightly because the proposed label requires that the total poundage of all EBDC products used on a crop within a season must not exceed the lowest specified individual EBDC product maximum seasonal poundage.

35. With regard to mixer-handler exposure, the proposed label language changes might also mitigate some potential worker risk. With current EBDC use restrictions, the EBDC used initially on a crop must be used for the rest of the season. Pre-packaged mixes are not always possible as they may contain another EBDC. The use of pre-packaged products eliminates tank mixing and thus can reduce potential exposure when mixing pesticides and in disposing of containers.

36. EPA's intention in requiring the current label language prohibiting sequential applications of two or more EBDCs to one crop during a growing season was to avoid potential overuse of EBDCs caused by active ingredient switching.

37. The March 2, 1992 NOITC, which contained the label prohibitions at issue, did not provide a specific risk/benefit rationale for the specific application prohibitions at issue in this proceeding. The Agency's thinking at that time was that the provision would help assure that growers would not exceed EBDC

usage limits per crop. The language was designed to address this need.

38. The proposed label language will not permit an increase in the maximum amount of EBDC that can be applied to any crop during a growing season.

39. Based on available information, allowing the requested label changes for foliar use and seed treatment should not result in any increased EBDC dietary exposure. The new label language should provide the same level of dietary exposure control that the Agency originally sought with the current label prohibitions.

40. The adoption of the proposed label language will not increase the total risk associated with EBDC use, as calculated by EPA in connection with the NOITC.

41. The previously filed witness statements and exhibits should be admitted as evidence in this proceeding.

Cynthia A. Lewis
Susan H. Ephron
Beveridge & Diamond, P.C.
1350 I Street, N.W., Suite 1300
Washington, D.C. 20005-3311
Counsel for Griffin Corporation

Philip J. Ross
Bret Williams
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460
Counsel for Respondent

Edward M. Ruckert
Christopher M. Lahiff
McDermott, Will & Emery
1850 K Street, N.W., Suite 500
Washington, D.C. 20006
Counsel for Elf Atochem North America, Inc. and the EBDC/ETU Task Force

q:\cli\12\20\2969\misc\2969she.10A

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing STIPULATIONS was filed in In the Matter of Notice of Hearing Concerning Application to Modify the Final Cancellation Order for Pesticide Products Containing EBDCs, FIFRA Docket No. 657 and was either sent by hand delivery or facsimile transmission to the following:

Ms. Bessie Hammiel
Hearing Clerk
U.S. Environmental Protection Agency
401 M Street, SW.
Washington, DC 20460

Edward M. Ruckert, Esq.
Counsel for Elf Atochem North America, Inc. and the EBDC/ETU Task Force
McDermott, Will and Emery
1850 K Street, N.W., Suite 500
Washington, D.C. 20006

Cynthia A. Lewis, Esq.
Beveridge and Diamond, P.C.
1350 Eye Street, N.W., Suite 700
Washington, D.C. 20005-3311

Philip J. Ross

DATED: June 17, 1994

CERTIFICATE OF SERVICE

I do hereby certify that the foregoing Initial Decision was filed in re Notice of Hearing Concerning Application To Modify the Final Cancellation Order For Pesticide Products Containing EBDCs; FIFRA Docket No. 657 and that exact copies of the same were mailed to the following:

Philip J. Ross, Esq., et al.
Office of General Counsel (2333R)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Edward M. Ruckert, Esq.,
McDermott, Will & Emery
1850 K Street, N.W., Suite 500
Washington, D.C. 20006

Cynthia A. Lewis, Esq.
Beveridge & Diamond, P.C.
1350 Eye Street, N.W., Suite 700
Washington, D.C. 20005-3311

Bessie L. Hammiel, Hearing Clerk
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Dated: July 8, 1994