7/12/90

BEFORE THE ADMINISTRATOR
U.S. ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C.

In the Matter of:	
Ciba-Geigy Corporation, et al.,	FIFRA Docket Nos. 562, et al.
Petitioners	

REMAND DECISION

On March 29, 1988, the Agency cancelled registrations for the pesticide diazinon unless amended to prohibit use on golf courses and sod farms. [1] Applying Section 6(b) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §136d(b), the Agency determined that diazinon use on golf courses and sod farms poses an unreasonable risk to birds. On petition for review, the United States Court of Appeals for the Fifth Circuit set aside that order and remanded the case to the Agency for a determination of whether these uses cause an unreasonable risk "commonly" or "with considerable frequency." [2] Today's decision responds to that remand. For the reasons set forth below, diazinon use on golf courses and sod farms causes an unreasonable risk to birds commonly and with considerable frequency. Moreover, the record fails to show that regulatory alternatives short of cancellation would reduce risk to reasonable levels.

See In re Ciba-Geigy Corp., 53 Fed. Reg. 11119 (April 5, 1988) 988 Decision").

-Geigy Corp. v. EPA, 874 F.2d 277, 279 (5th Cir. 1989).

I. BACKGROUND

This case is the first proceeding in which Respondent, the Agency's Assistant Administrator for Pesticides and Toxic Substances, [3/] has advocated the cancellation of pesticide registrations based on risks posed solely to birds. Ciba-Geigy Corporation, diazinon's major producer, is the lead party advocating continued registration. The procedural history is set forth in the Agency's 1988 Decision and need not be repeated here. That decision analyzes the avian risks posed by diazinon as historically used, as well as the risks that would be posed if diazinon were used under the so-called "2+2" label previously proposed by Ciba-Geigy. This 2+2 proposal specified a maximum application rate of two pounds of active ingredient per acre (ai/A), to be followed in seven days by a second two-pound treatment for certain pests. The 2+2 label also required, among other things, that diazinon be applied by a certified applicator (as the ALJ had recommended in his Initial Decision), that most applications be followed by irrigation, and that certain seasonal and geographic restrictions be observed to protect Atlantic brant

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[3/] Consistent with the ALJ's Initial Decision and the parties' post-trial briefs, the 1988 Decision refers to Respondent as "the Agency" or "EPA." Under the rules that govern this proceeding, Respondent is actually the Agency's Assistant Administrator for Pesticides and Toxic Substances. For the sake of clarity, the terms "EPA" and "Agency" will be used herein for reference to the Administrator or EPA as a whole. The record will be cited as described in the 1988 Decision. See 53 Fed. Reg. at 11120 n.1; Initial Decision at 4-5. Unless otherwise noted, citations to the parties' briefs refer to their briefs on remand. Citations to the record are intended to be illustrative, not comprehensive.

and wigeon. After analyzing the massive record generated at the hearing, the Agency concluded that Respondent had presented a prima facie case that diazinon use on golf courses and sod farms poses a "widespread and continuous hazard," that the benefits of continued use at these sites would be "negligible," and that "Ciba-Geigy has failed to meet its burden of showing that the benefits of continued use under its proposed [2+2] label justify the avian risk involved." 53 Fed. Reg. at 11130 (col. 1).

In discussing the legal standard for cancellation under FIFRA, the 1988 Decision briefly analyzed the meaning of FIFRA §6(b), which provides for cancellation if the pesticide, "when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment * * *." 7 U.S.C. §136d(b). Ciba-Geigy had argued in its post-trial briefs that the word "generally" in this provision means "most of the time," and that the Agency may cancel diazinon registrations only if diazinon results in bird kills more often than not. [4/] The Agency, however, interpreted the word "generally" as meaning "with regard to the overall picture," an alternative reading that Ciba-Geigy itself had proposed, and one that the Agency viewed as consistent with its obligation to

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[4/] See 53 Fed. Reg. at 11122 (col. 1); CG Post-Tr. Bf. at 16-17.

consider a broad range of factors when determining whether a risk is unreasonable. [5/]

On petition for review, the Fifth Circuit rejected the Agency's interpretation, stating that EPA "improperly read the word 'generally' out of FIFRA §6(b)." 874 F.2d at 280. It held that "generally" means "commonly" or "with considerable frequency," though not necessarily 51 percent of the time. Id. at 279. Because FIFRA §2(bb) defines "unreasonable adverse effects" to include not only harmful consequences but also "unreasonable risk," the Court recognized that diazinon use on golf courses and sod farms need not generally cause actual bird kills to warrant cancellation. Id. at 279-80. Instead, prohibiting diazinon use at these sites is justified if it generally causes an unreasonable risk of bird kills:

> [A] significant risk of bird kills, even if birds are actually killed infrequently, may justify the Administrator's decision to ban or restrict diazinon use. [Id.]

The Court noted that in applying the proper standard, the Agency should pay particular attention to whether any cancellation is sufficiently tailored to reflect distinctions in risk frequency among different kinds of uses. Id. at 280. By way of illustration, the Court stated:

> If the use of diazinon creates an unreasonable risk of killing birds on only

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[5/] 53 Fed. Reg. at 11122 (col. 1). In arguments before the Fifth Circuit, Ciba-Geigy evidently modified its interpretation of "generally" from "more often than not" to "for the most part." See Motion for Setting a Briefing Schedule, at 2 n.1 (July 7, 1989).

> 10% of the golf courses on which it is used, for example, the Administrator should define the class of golf courses on which its use is to be prohibited more narrowly.

Id. The Court also rejected Ciba-Geigy's argument that a risk is unreasonable only if it endangers bird populations, stating:

> FIFRA gives the Administrator sufficient discretion to determine that recurring bird kills, even if they do not significantly reduce bird population, are themselves an unreasonable environmental effect.

Id. The Court remanded the proceeding to the Agency "for application of the correct legal standard" and to consider whether the prohibited application has been defined "sufficiently narrowly." Id. [6/]

Shortly after the Fifth Circuit's decision, Ciba-Geigy proposed a series of additional label amendments further restricting diazinon use on golf courses and sod farms. These new proposals include a seasonal restriction intended to protect migratory waterfowl; a ban on use within 100 yards of any body of water; a ban on use within 100 yards of any turf area used by waterfowl for feeding or loafing; and a ban on the use of diazinon's granular formulation, intended primarily to protect songbirds. [7/] Ciba-Geigy no longer defends the 2+2 label

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[6/] Ciba-Geigy represents that even though the Fifth Circuit vacated the 1988 cancellation order, it has not subsequently sold diazinon for use on golf courses and sod farms.

[7/] See CG Reply (Appendix). Ciba-Geigy states that it would agree to minor wording changes to its proposals where necessary to clarify ambiguities. Today's decision does not turn on any deficiencies that could be readily cured through such changes.

standing alone, and its current proposals are intended to supplement (not replace) the restrictions in the 2+2 label. See CG Bf. at 11. For the first time in its Reply Brief (p.14), Ciba-Geigy also suggests that, if necessary, diazinon could be banned on golf courses and sod farms having resident waterfowl.

Before filing their substantive briefs on remand, the parties submitted numerous procedural motions, including a request by Ciba-Geigy that the case be referred to an ALJ for further hearings. These motions were addressed by orders of the Chief Judicial Officer and Acting Chief Judicial Officer dated August 1 and 31, 1989, respectively. The orders reiterate the Agency's responsibility to consider label refinements proposed by Ciba-Geigy as an alternative to cancellation, but they hold that such proposals must be considered based on the existing record. For the reasons stated in those orders, they are hereby adopted and incorporated herein. [8/]

[8/] The Agency's rules require that a motion to reopen a hearing set forth "good reason" for why any newly proffered evidence was not previously adduced. 40 CFR §164.110(b). The intervening Fifth Circuit decision in this case does not alter this requirement. The court ordered a remand "to the Administrator for application of the correct legal standard" (874 F.2d at 280), nowhere suggesting that additional evidentiary hearings would be necessary or appropriate. Although the Fifth Circuit's remand has given Ciba-Geigy a unique opportunity to respond to the concerns set forth in the now-vacated 1988 Decision, Ciba-Geigy had ample prior notice of these concerns. It had every opportunity to defend any label restriction necessary to reduce risk to reasonable levels. Its litigation strategy to defend the 2+2 label does not constitute "good reason" for not previously adducing evidence regarding the feasibility of its most recent proposals.

II. DISCUSSION

Although the Fifth Circuit rejected the Agency's reading of "generally" in FIFRA §6(b), the guiding principles provided by the Court for consideration on remand are not foreign to those traditionally used by the Agency under FIFRA. The 1988 Decision expressly recognizes the Agency's obligation to consider Ciba-Geigy's proposed label amendments as an alternative to cancellation, as well as whether additional tailoring of those proposals might be a workable solution. [9/] Measures short of cancellation have been considered at virtually every stage of this proceeding. The limitation of this case to golf courses and sod farms -- which account for only eight percent of total diazinon use (RX 4 (p.I-3)) -- likewise reflects Respondent's recognition of the Agency's obligation to tailor its regulatory actions under FIFRA.

At the outset, the scope of this remand proceeding must be defined. As noted above, Ciba-Geigy no longer defends diazinon use under the 2+2 label as previously proposed, and it argues that the only issue on remand is the acceptability of its most recent label proposals. It asserts that all diazinon labels have been amended to prohibit use on golf courses and sod farms, that to its knowledge there is no existing diazinon stock without such labels, and that it would agree to a stop-use order for any such stocks. Because no party advocates diazinon use under prior

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[9/] See 53 Fed. Reg. at 11120-21, 11130 (cols. 2 and 3).

labels or under the previous 2+2 proposal, Ciba-Geigy argues that there is no case or controversy regarding such use and that issues relating thereto are moot. Respondent questions the factual basis for Ciba-Geigy's assertions about existing stocks, and notes that Ciba-Geigy's commitment to comply with a stop-use order does not bind other diazinon registrants or users. It also contends that the Agency has a duty to the public to decide the primary issues litigated at the hearing, namely whether diazinon use on golf courses and sod farms under historical labels and under the previous 2+2 proposal generally poses an unreasonable risk to birds.

Respondent's concerns about existing stocks are legitimate. A binding stop-use order for remaining stocks should be based on a determination that use of those stocks under their existing labels generally poses an unreasonable risk. Moreover, a brief analysis of diazinon as used historically and as proposed under the 2+2 label provides a logical point of departure for analyzing Ciba-Geigy's most recent proposals. This analysis will also help to ensure that the burdens of production and persuasion are properly allocated. The Agency must first determine whether Respondent has presented an affirmative case for cancellation under the standards enunciated by the Fifth Circuit (40 CFR §164.80(a)), and then whether Ciba-Geigy has either rebutted that prima facie case or demonstrated by a preponderance of the evidence that use under an alternative label would not generally

pose an unreasonable risk to birds. [10/] Ciba-Geigy retains the ultimate burden of proof, i.e., the risk of non-persuasion, on all issues. [11/]

Because no party defends diazinon as used historically or under the 2+2 label, an abbreviated analysis of these uses will suffice. [12/]

A. Diazinon as Used Historically and as Proposed Under the 2+2 Label

In its 1988 Decision, the Agency determined that Respondent had established a "prima facie case of a widespread and continuous hazard based on laboratory data and reported bird kills." 53 Fed. Reg. at 11130 (col. 1). Respondent's showing

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[10/] Although the Fifth Circuit emphasized the Agency's obligation to consider regulatory alternatives short of cancellation, it did not address issues relating to the burden of establishing the viability of such alternatives. As this case demonstrates, the number of potential label amendments short of outright prohibition is limited only by the imagination of those defending continued registration. It would be impossible for Respondent to anticipate and affirmatively disprove the viability of each potential alternative. Once Respondent presents a prima facie case that a pesticide, when used in accordance with widespread and commonly recognized practice, generally poses an unreasonable risk, the burden shifts to the registrant to prove that an alternative short of cancellation would reduce risk to reasonable levels.

[11/] See 40 CFR §164.80(b); Environmental Defense Fund, Inc. (EDF) v. EPA, 548 F.2d 998, 1015-16 (D.C. Cir. 1976), cert. denied, 431 U.S. 925 (1977); EDF v. EPA, 510 F.2d 1292, 1297 (D.C. Cir. 1975).

[12/] The issues on remand have been fully briefed. Oral argument would not aid in the disposition of these issues, and Ciba-Geigy's request for oral argument is therefore denied. To the extent consistent with today's decision and the Fifth Circuit's remand order, the findings and conclusions set forth in the Agency's 1988 Decision are adopted and incorporated herein.

includes data regarding diazinon's comparative toxicity; data on diazinon turf residues under various application rates; testimony regarding avian feeding ecology and avian exposure to diazinon residues on golf courses and sod farms; a risk assessment model showing waterfowl exposure to lethal diazinon residues; and evidence of the extensive history of reported bird kills associated with diazinon. [13/]

Essentially, Respondent established that diazinon is extremely toxic to a wide variety of bird species. Diazinon, like other organophosphates, disrupts the normal transmission of signals by the central nervous system, and can result in lack of motor control, ataxia, coma, and death (usually by asphyxiation). [14/] Based on LD_{50} values, the single dose that causes mortality in 50 percent of adult birds, diazinon is classified by Respondent as "very highly toxic," the most toxic of Respondent's five classifications. [15/] Diazinon residues from a one-pound ai/A application is estimated to be 53 ppm (a lowest worst case value). [16/] Using published LD_{50} values and the 53-ppm residue estimate, Respondent presented a risk-assessment model showing

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[13/] The benefits portion of Respondent's affirmative case for cancellation is discussed at page 15 below.

[14/] See EPA W-2 (pp.15-16); EPA W-20 (pp.6-7).

[15/] A substance's LD_{50} is expressed as a ratio of milligrams of substance per kilogram of bird body weight (mg/kg). Most published LD_{50} values for diazinon are below 10 mg/kg, levels which are categorized as "very highly toxic." 53 Fed. Reg. at 11122 (col. 3).

[16/] See 53 Fed. Reg. at 11123 (Section III.C); EPA W-4.

that mallards and Canada geese grazing on diazinon-treated turf would reach their respective LD_{50}s in a relatively short period of time. [17/] Testimony regarding avian feeding ecology shows that both migrating and non-migrating waterfowl are directly exposed to diazinon residues on golf courses and sod farms. [18/] Waterfowl use of these sites can be expected to increase in the future as wetlands and other natural feeding habitats diminish. [19/] Songbirds are also exposed to diazinon on invertebrates, puddles, and seeds, and by the direct ingestion of diazinon granules. [20/]

The extensive history of more than fifty reported bird kills associated with diazinon use verifies the avian hazard reflected

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[17/] For a four-pound application rate, time to LD_{50} for mallards ranges from 15 to 24 minutes, and for Canada geese from 25 to 40 minutes. At a two-pound rate, time to LD_{50} for mallards ranges from 30 to 47 minutes, and for Canada geese from 50 to 80 minutes. 53 Fed. Reg. at 11123 (col. 3). Despite certain criticisms leveled by witnesses for Ciba-Geigy, the risk assessment model was favorably peer-reviewed by scientists inside and outside EPA, and both the ALJ and the Agency found the model to be a reliable and valid indicator of the risk posed by diazinon to grazing waterfowl. Id. at 11123-24.

[18/] 53 Fed. Reg. at 11122-23; Initial Decision at 25-26; EPA W-3 (pp.7-9). The term "waterfowl" generally refers to all species of ducks, geese, and swans, and sometimes to coots. See EPA W-3 (p.2). Geese, swans, and dabbling ducks are known to use golf courses, sod farms, parks, and similar grassland environments for feeding. Id. at 3.

[19/] See, e.g., 53 Fed. Reg. at 11123; EPA W-3 (pp.7-9, 13); RX 244; TR 289-90, 3391.

[20/] 53 Fed. Reg. at 11123 (col. 1); Initial Decision at 17, 24-25; EPA W-3 (p.4); EPA W-13 (p.25); EPA W-22 (p.14). Songbirds exposed to diazinon include bluejays, robins, common grackles, red-winged blackbirds, brown-headed cowbirds, house sparrows, and magpies. See EPA W-3 (p.4). These and other songbird species feed on seeds, invertebrates, and insects found on golf courses and sod farms.

in the lab data and risk-assessment model. Kills have occurred in every area of the country and during every month of the year, and have ranged from one to more than 800 birds per incident. [21/] Reported kills occurred at both high and low application rates, and involved many different waterfowl and non-waterfowl species. [22/] Due to the widespread failure to observe, report, investigate, and diagnose bird kills, reported kills represent only "the tip of the iceberg" of total actual kills. [23/] The number and frequency of actual kills that have occurred cannot be precisely quantified. [24/]

Taken together, the lab toxicity data, exposure evidence, risk-assessment model, and reported bird kills demonstrate that diazinon, when used in accordance with widespread and commonly recognized practice, generally poses a very serious risk to birds. Ciba-Geigy attempted to rebut this showing through five field studies focusing on diazinon use under its then-recently

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[21/] 53 Fed. Reg. at 11124 (Section III.E).

[22/] See EPA W-5 (pp.5-6, 15-17).

[23/] 53 Fed. Reg. at 11124 (col. 2) (citing TR 1514); see also EPA W-5 (pp.13-14); TR 677.

[24/] Due to the nature of the factors that affect the relationship between actual and reported kills, this relationship is subject to only adjectival characterization (e.g., "tip of the iceberg"). Ciba-Geigy expert Dr. Klem applied a factor of 100 to the 1000 reported bird mortalities in 1972 to provide an "extreme," worst-case estimate that diazinon as historically used resulted in 100,000 bird mortalities annually. CG Ex. 104 (pp.8-10); TR 3785-86. Although this figure was derived for purposes of comparison to other causes of avian mortality and should be viewed as such, it provides a reasonable, worst-case upper bound on the number of annual diazinon-related bird kills.

proposed 2+2 label. [25/] Due to a variety of defects, however, these studies are insufficient to rebut Respondent's prima facie case on risk. The two primary flaws are (1) the failure to account adequately for off-site mortality; [26/] and (2) the small number of studies, which undermines any conclusion that use under the 2+2 label would materially reduce adverse effects. [27/] These two overarching deficiencies were exacerbated by additional problems associated with each of the field studies individually. [28/]

[25/] All five field studies were "level-one" studies, i.e., screening studies to determine whether adverse effects would occur under the 2+2 label. Four were conducted on golf courses and focused on waterfowl. The fifth study was conducted on home and commercial lawn sites and focused on non-waterfowl species. 53 Fed. Reg. at 11124 (col. 3).

[26/] 53 Fed. Reg. at 11125 (col. 1). In a recently conducted study using radiotelemetry, birds exposed to organophosphates like diazinon left the exposure site to die elsewhere. Id. (citing EPA W-20 (p.9)); cf. CG Ex. 125 (p.46).

[27/] To show the absence of an adverse effect to twenty percent of an exposed population, at least fourteen studies are recommended to obtain a reasonable level of statistical confidence. EPA W-19 (pp.14-15). Where the studies involve worst-case scenarios, as few as eight might be sufficient. Id. These figures are set forth in a 1986 draft Guidance Document (CG Ex. 1B (pp.13-16)), which was reviewed by EPA's FIFRA Science Advisory Panel (CG Ex. 1A). Here, there were only four studies that focused on waterfowl and only a single study that focused on non-waterfowl species. As noted in the 1988 decision, it might have been difficult to complete an adequate number of studies relating to the 2+2 label prior to trial, but Ciba-Geigy bears the ultimate burden of persuasion, and the lack of field experience under its 2+2 label cuts against its efforts to vindicate that proposal.

[28/] See 53 Fed. Reg. at 11125 n.35; EPA W-12; EPA W-20 (pp.10-12). Ciba-Geigy's own expert, Dr. Louis Best, testified that "some" of the limitations of the studies included inadequate search efficiency trials, incomplete carcass removal experiments, lack of contemporary untreated controls, and "unreplicated

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In addition to its field studies, Ciba-Geigy offered supporting testimony from several avian experts. Their collective opinion shows that diazinon use under the 2+2 label would probably not adversely affect overall bird populations, but it does not rebut Respondent's prima facie case of a general risk of regularly repeated bird kills. [29/]

[28/](...continued)
treatments thus limiting the statistical inferences that can be drawn from the study." CG Ex. 125 (pp.37-38). Due to these and other defects in the field studies, Dr. Best could make only a single definitive finding supporting Ciba-Geigy's case, namely that "in general" mortality to Canada geese and mallards would be "minor" under the 2+2 label. Id. (p.38). Even this narrow conclusion of "minor" mortality -- limited to only two of the 200 bird species that feed on golf courses (TR 1102) -- appears to refer not to individual mallards and Canada geese, but instead to their populations, which was his primary concern. CG Ex. 125 (pp.34, 47); TR 4359-60, 4424, 4466-67, 4470. Dr. Best's only other definitive finding was that diazinon poses an unacceptable risk to exposed wigeon at any effective application rate. Id. at 38. His other findings were less than definitive and of marginal significance. CG Ex. 125 (pp.38-39). Respondent's experts were considerably less generous in their evaluation of the field studies. See, e.g., EPA W-12; EPA W-20 (pp.10-12).

[29/] See 53 Fed. Reg. at 11125-26. For several reasons, little weight can be give to the policy judgment offered by Ciba-Geigy's experts that the avian risk under the 2+2 label would be reasonable or acceptable. First, the primary focus of Ciba-Geigy's experts was on risk to bird populations, not individual birds. See 53 Fed. Reg. at 11125 n.38. Second, Ciba-Geigy's experts were evidently unfamiliar with the respective burdens of production and persuasion under FIFRA, and some of them proposed that diazinon be used under the 2+2 label until sufficient testing could be conducted to determine whether it is a viable alternative. See, e.g., CG Ex. 125 (pp.33-34, 47). Because the program established a prima facie case for cancellation, however, it is Ciba-Geigy's burden to demonstrate the viability of any alternative proposal before it will be accepted. Third, their conclusion that the avian risk posed by the 2+2 label is "reasonable" fails to reflect a balancing of the risks against any benefits of continued diazinon use as required by FIFRA.

On the benefits side of the equation, there are effective, less toxic alternatives to diazinon, and cancellation would result in only a negligible cost increase for golf courses and sod farms. [30/] The record does not support Ciba-Geigy's contention that other benefits of continued diazinon use would include continued enhancement of price competition, avoidance of significant turf damage or pest resistance, or significant comparative safety to humans or wildlife. [31/]

This brief review of the record thus reveals that: (1) Respondent presented a strong prima facie case of a widespread and continuous risk to a wide variety of bird species; (2) Ciba-Geigy failed to rebut this case or to show that avian risk under the 2+2 label would be low; and (3) the benefits of continued use would be minimal. As noted above, the number and frequency of actual bird kills that have occurred, or that could be expected in the future, cannot be precisely quantified. Nonetheless, continued diazinon use under historical labels and the 2+2 proposal would generally pose a serious risk of regularly repeated bird kills, a risk that the Agency unquestionably views as unreasonable in light of the safer alternatives to diazinon for effective turf pest control, the negligible benefits of

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[30/] 53 Fed. Reg. at 11126 (col. 3); Initial Decision at 71-74; EPA W-16 (p.17 & Table 20); EPA W-17 (p.17).

[31/] 53 Fed. Reg. at 11126-30.

continued diazinon use, and the absence of any economic dislocations that would attend cancellation.

B. Ciba-Geigy's Most Recently Proposed Label Amendments

As discussed above, diazinon as historically used has resulted in a disturbing, and sometimes shocking, record of bird mortalities, and generally poses a very serious, widespread avian risk, a risk that the Agency views as unreasonable in light of diazinon's limited benefits. While the Agency must consider regulatory alternatives to cancellation in such situations, a party defending the pesticide has the burden of showing that any proposed alternative will in fact satisfy the statutory standard for continued registration. This burden may be satisfied through expert testimony, field studies, and the like, but with the recognition that the burden might be particularly difficult to meet where the alternative proposal involves a wholesale label revision under which there is little (if any) application experience. The Agency will draw upon its expertise in evaluating any alternative proposal, but it will not accept regulatory alternatives based on speculation, or supported only by indirect evidentiary shreds, or where critical questions remain unanswered regarding compliance and enforcement.

With respect to Ciba-Geigy's previously proposed alternative to cancellation (the 2+2 label), the record shows that use thereunder would not pose a long-term, adverse effect on overall bird populations. Ciba-Geigy failed, however, to show by a preponderance of the evidence that the avian risk under the 2+2

label would be reduced to reasonable levels. As discussed in more detail below, its most recent proposals suffer from a similar, and perhaps even more pervasive and debilitating, failure of proof.

In contrast to earlier proposals to reduce application rates and require irrigation -- which attempted to reduce diazinon's toxicity -- Ciba-Geigy's most recent proposals are aimed at reducing exposure. In analyzing the new proposals, it must be kept in mind that Ciba-Geigy has made no specific showing of the economic benefits of continued diazinon use under these restrictions. Instead, it argues that its newest proposals would reduce avian risk to de minimis levels, and that therefore the benefits should be presumed to outweigh the risks. CG Bf. at 16. Each of the most recent proposals is analyzed separately in Sections II.B.1 through B.4 below, and then their cumulative impact is discussed in Section II.B.5.

1. The Seasonal Restriction

To protect migrating waterfowl, Ciba-Geigy proposes that diazinon use on golf courses and sod farms be allowed only during the late spring and summer months. Specifically, Ciba-Geigy proposes that diazinon be banned on golf courses and sod farms from September 1 to May 15 in specified northern states, and from October 1 to April 30 in southern states. This proposal is based on the principal migratory seasons for four kinds of waterfowl

reported in a 1976 treatise entitled "Ducks, Geese and Swans in North America" by Frank C. Bellrose. [32/]

Although limiting diazinon use to a four or five-month period might appear to be a rather significant restriction, this proposal would not dramatically alter historical use patterns. About 80 percent of diazinon applications have traditionally occurred from May through September. CG Ex. 125 (p.46); TR 3657. Although Ciba-Geigy contends (Bf. at 8) that this proposal would provide "almost complete protection for migratory waterfowl," the record does not support this assertion. The Bellrose treatise indicates that in August up to 15 percent of certain migratory waterfowl populations are in several broad geographic areas of the United States, [33/] and that large numbers of migratory waterfowl remain in certain areas in May. [34/]

[32/] See CG Bf. at 7; RXs 110, 112, 114, 115. Ciba-Geigy proposes (Reply at 8 n.4) to retain additional seasonal restrictions in certain locations to provide a few extra days of protection for migrating wigeon and Atlantic brant.

[33/] For example, the Bellrose charts show that on September 1, the first day of the proposed ban in northern states, significant portions of the wigeon population are in the Upper Mississippi, the Northern Plains, and the Northwest Basin (RX 110), and significant portions of the mallard population are in the Great Lakes area, the Northern Plains, and the Western Plains (RX 112). These populations continue to decline through the autumn and winter months and thus presumably consist, at least in part, of waterfowl that subsequently migrate further south. Elsewhere, Bellrose states that wigeons begin to move south into adjacent states from their major Canadian breeding areas as early as mid-August. RX 110 (p.202).

[34/] As of April 30, significant portions of the wigeon, Canada goose, and mallard populations exist in several broad regions listed on the Bellrose Charts. See RX 110, 112, 114. The cited portions of the record do not give population figures for these

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The record also shows that migratory seasons can fluctuate significantly from year to year due to changes in temperature, food availability, and other factors. [35/] Although additional protection could be provided by manipulating the specific dates of the seasonal restriction, diazinon residues can remain lethal long after application, with one reported kill occurring a full month after application at a relatively low rate. [36/] Thus, diazinon applications within the proposed use period might well continue to pose lethal risk to waterfowl that subsequently migrate down from Canada. Moreover, the cited portions of the Bellrose treatise cover only four waterfowl species and thus provide little up-to-date guidance as to whether other migrating waterfowl would be substantially protected. Perhaps most importantly, the seasonal restriction would provide no protection to non-migrating or sedentary waterfowl. As Ciba-Geigy recognizes (Bf. at 8), sedentary waterfowl constitute a substantial portion of the waterfowl that forage on golf courses

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[34/](...continued)
areas as of May 15, the last day of the proposed seasonal restriction in northern states. Bellrose indicates, however, that in the summer about 400,000 wigeons (13 percent of the population) remain in the contiguous United States to breed. RX 110 (p.199). The mallard breeding range includes the northern one-third of the U.S. (RX 112 (p.231), and certain Canada geese populations also remain in the continental U.S. during the summer to breed. See RX 114 (p.152). Summertime waterfowl populations in the U.S. include many species. TR 282-85.

[35/] Compare EPA W-13 (pp.62-68) (migratory seasons can vary by "many months") with CG Ex. 125 (p.31) ("bird migration may vary 2-3 weeks from year to year").

[36/] See Initial Decision at 42 n.106.

and sod farms. [37] Ciba-Geigy has identified no geographic area without significant numbers of waterfowl that would remain at risk during the summer months. [38]

2. The Water Restriction

To provide additional protection to both migratory and non-migrating waterfowl present during its proposed use season, Ciba-Geigy proposes to prohibit diazinon use within 100 yards of any body of water. It argues that waterfowl "generally focus their feeding activity near ponds or other water sources." CG Bf. at 11. To support this contention, Ciba-Geigy quotes the following

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[37] Non-migrating mallards and Canada geese are found across the country. TR 283-85. Of the 768 golf courses interviewed in a telephone survey conducted for Ciba-Geigy, 75 percent responded that they have waterfowl present at some time during the year (CG Ex. 95 (Table 003)), a figure that might underestimate the actual percentage due to the manner in which the survey was conducted. Of the golf courses with waterfowl, 58 percent (44 percent of the total) reported that waterfowl are "always" or "usually" present. Id. (Table 018).

[38] Many of the reported bird kills reflected in the record, including several large-scale kills, occurred during Ciba-Geigy's proposed use period. See, e.g., EPA W-5 (Appendix: No.3 (4 Canada geese, Ore. 8/86); No.5 (3 mallards, upstate N.Y. 5/19/86); No.9 (4 Canada geese, N.Y. 6/7/85); No.10 (3 Canada geese, Cal. 6/5/85); No.13 (68-70 mallards, Tex. 9/12/84); No.15 (2 mallards, Mich. 8/28/84); No.16 (12 mallards, Minn. 7/84-8/84); No.17 (6 Canada geese, Mich. 5/19/84); No.24 (28 Canada geese, Colo. 8/83); No.26 (11 mallards, Ky. 8/82); No.27 (4 Canada geese, 5 mallards, and 3 blackbirds, Mich. 7/82); No.28 (Canada goose, Va. 8/81); No.31 (81 Canada geese, N.Y. 8/27/80); No.33 (10 Canada geese, N.Y. 8/79); No.34 (25 Canada geese, Mich. 6/79); No.37 (4 mallards, Ky. 9/77); No.38 (Canada geese, N.J. 7/77); No.49 (35 Canada geese, N.Y. 6/74); No.50 (31 Canada geese, Conn. 8/73)). Although Ciba-Geigy might argue that some of these kills would have been prevented by other portions of its proposed label, they all bear upon the efficacy of its proposed seasonal restriction in reducing exposure.

assertion from the testimony of Dr. Kenneth Abraham, a wildlife biologist called as a witness by Respondent:

> The presence of water areas is a key element, because waterfowl need open expanses of sheltered water for night roosts safe from predators and many grazers feed in close proximity to water.

EPA W-3 (p.9).

The quoted testimony, however, serves merely to support Dr. Abraham's more general conclusion that golf courses and sod farms are attractive feeding habitats for waterfowl within their respective flyways. Id. at 8-9. Nothing in this discussion shows that waterfowl feed only in those portions of a golf course or sod farm near water. Without reference to surface water location, Dr. Abraham testified elsewhere that grazing waterfowl are attracted to areas that are highly cultivated through mowing, fertilizing, and irrigation. Id. at 9-10. He nowhere suggests that his use of the phrase "in close proximity to water" can be reasonably quantified and translated into a 100-yard buffer zone. Elsewhere he describes certain feeding areas for brant as "in close proximity" to their historical habitats (EPA W-3 (p.8)), a use that reflects the obvious fact that for birds, "in close proximity" can refer to a considerable distance. In fact, Dr. Abraham submitted exhibits indicating that certain waterfowl regularly make daily flights of up to 15 kilometers, and occasionally up to 30 kilometers, from roost to feeding area. RX 118 (p.90). The minimum distance noted from roost to feeding areas for geese is "a few kilometers." Id. Certain mallards

frequently fly 25 miles one way to cultivated feeding areas and at times up to 40 miles when the occasion demands. RX 112 (p.243). Even urban mallards can make significant flights for a variety of reasons, including a desire to feed. RX 113 (p.13-14). Read in this context, Dr. Abraham's assertion that waterfowl feed "in close proximity" to water cannot be used to show that a 100-yard buffer zone around water would provide any appreciable protection.

In its reply brief (p.12), Ciba-Geigy relies on the testimony of Mark Jaber as additional support for its water restriction. The cited page, however, demonstrates only that on a single golf course in Connecticut, the "principal areas" of geese activity were near two ponds. TR 2508. Jaber's report also shows that portions of these "principal" activity areas were further than 100 yards away from either pond. See CG Ex. 45 (Figure 3). Indeed, another Ciba-Geigy expert, Dr. Klem, stated that waterfowl move toward water at night for protection from predators, but that during daytime feeding "they can skip around on the golf course throughout the day." TR 3778. [39/] Jaber's

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[39/] Ciba-Geigy argues (Reply Bf. at 13) that the size of the buffer zone need not be based on record evidence, but may instead reflect a common sense judgment. In this regard, it refers to a 100-foot buffer zone around a golf course pond proposed by a representative of the U.S. Fish and Wildlife Service to protect the San Francisco garter snake, an endangered species potentially threatened by diazinon. This analogy is strained, if not absurd. Garter snakes occupy and feed in the fringe area around the edge of the pond. TR 1656. The 100-foot buffer zone reflects the Service's professional judgment as to the protection necessary for this relatively immobile creature (id.), a judgment that coincides with common sense. The record regarding waterfowl

(continued...)

testimony is inadequate to show that a 100-yard buffer zone around surface water would reduce avian risk on a general basis.

Ciba-Geigy evidently recognizes the deficiencies in its proposed water restriction, stating that it "is not intended to stand by itself." CG Reply at 12. It also acknowledges that its seasonal ban would not protect non-migratory waterfowl or migratory waterfowl present outside the period of the ban. In view of these limitations, the seasonal ban and the water restriction together would not reduce avian risk to de minimis or reasonable levels. Diazinon use under the 2+2 proposal, even with these two restrictions, would generally pose an unreasonable risk to waterfowl. It is thus fair to say that the key label revision suggested by Ciba-Geigy to protect waterfowl is its proposed feeding-area restriction.

3. The Feeding-Area Restriction

Ciba-Geigy proposes that diazinon not be applied "within 100 yards of any turf area (including any golf course fairway, rough, tee, or green) where waterfowl feed or loaf." This critical proposal rests upon two assumptions: (1) that waterfowl do not use all areas of a golf course or sod farm, but instead establish feeding patterns in particular locations on these sites; and (2) that turf managers are familiar enough with such established patterns that they could and would avoid treating turf areas that

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[39/](...continued)
mobility and feeding ecology undercuts any suggestion that a similar 100-yard buffer zone for birds would provide any significant protection.

might be used by waterfowl for feeding. Neither proposition withstands scrutiny.

Waterfowl feeding ecology: Ciba-Geigy again relies on testimony from Respondent's witness, Dr. Abraham, to argue that waterfowl develop patterns of feeding locations within a season. CG Bf. at 9 (citing EPA W-3 (pp.11-12)). Although some waterfowl do establish feeding patterns, Dr. Abraham made clear that any such patterns are subject to shifts and modifications depending on food abundance, weather, tidal rhythms, time of day, and other factors. See EPA W-3 (pp.9-10); see also EPA W-12 (p.5) ("Birds can be quite variable in where they fly and feed."). Fertilization and other turf cultivation activities common to golf courses and sod farms also effect feeding patterns by drawing waterfowl to recently cultivated areas. [40/] The central thrust of Dr. Abraham's testimony is that the unique characteristics of avian feeding ecology "make it difficult to dissuade [waterfowl] from using areas of chemical application." EPA W-3 (p.11). Nowhere does he suggest that specific portions of a golf course or sod farm are unlikely to be used by waterfowl and thus may be safely treated with diazinon.

Ciba-Geigy relies on testimony by Mark Jaber, discussed above, that certain fairways observed during the Connecticut study were the "principal" areas of goose activity on that

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[40/] See TR 1233-34 (fertilization of certain turf areas had the "very remarkable effect" of drawing birds for feeding); EPA W-3 (pp.9-10) (turf cultivation attracts waterfowl for feeding).

course. TR 2508-09. As noted by Respondent, however, this field study undercuts the argument that there are "safe" areas for diazinon treatment. The average number of geese in the "principal" activity area dropped dramatically from more than 220 during the site-selection period (TR 2509), to a daily average of 23 during the study period. CG Ex. 45 (p.20). On five of the 21 study days, the daily number of geese in this "principal" activity area was zero. Id. It is unknown why these numbers fluctuated so widely, but it shows that the geese might well have been using other portions of the course for feeding. Ciba-Geigy insists (Reply at 5) that there is no record evidence of waterfowl feeding outside the treated areas, but Jaber's investigation made no systematic observations of untreated portions of the golf course. TR 2502. Because geese are known to spend a large proportion of each day feeding, [41/] it is fair to assume that the geese were feeding somewhere on the days they were absent from the "principal" activity area. A crucial component of Ciba-Geigy's reliance on this study is thus missing, namely evidence that geese were not feeding on other portions of the course. Jaber had no reason to compile such data because the purpose of his study was to observe geese feeding on treated turf. TR 2502. The absence of evidence regarding whether there

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[41/] Dr. Abraham testified that waterfowl have simple digestive systems and quickly process large quantities of food. EPA W-3 (pp.9-10). Some consume more than 40 percent of their body weight in fresh grass every day. Id. The proportion of time spent feeding during daylight hours for certain waterfowl ranges from 74 to 90 percent. Id.

was feeding on untreated areas -- now of critical relevance to Ciba-Geigy's most recent proposals -- underscores the difficulties in litigating the merits of one proposal and then defending a very different set of restrictions after trial.

Ciba-Geigy also relies on testimony by Lindsey Taliaferro, who conducted a field study on a golf course in Virginia to examine goose exposure under the 2+2 label. CG Bf. at 9 (citing TR 2833, 2903-06). Based on discussions with golf course personnel, he specified certain areas where geese "historically" congregate. TR 2833. Again, however, his primary aim was to observe goose exposure to treated turf, not to identify "safe" areas for diazinon application. He made only one reference to areas where geese might not go: "heavily wooded areas that are narrow," which might reduce their ability to escape from predators. TR 2905. His testimony, if credited, might theoretically support a label restricting diazinon use to "narrow, heavily wooded areas" (which would be fraught with compliance- and enforcement-related deficiencies), but it does not show that waterfowl feed exclusively within identifiable areas. [42/]

[42/] Ironically, at trial the parties' respective positions on this issue of waterfowl feeding ecology appear to be almost the reverse of where they now stand. To establish the possibility of repeated exposure to a treated area, Respondent attempted to establish through Ciba-Geigy expert Dr. Dickson that waterfowl tend to feed in certain areas on a regular basis. TR 4066-68. Although Dr. Dickson agreed with this as a general proposition, he made the obvious point that "birds in the wild are not penned into a particular area," and he testified that the probability that birds "would not browse around the course * * * is pretty

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Turf manager compliance: Assuming arguendo that waterfowl limit their feeding to specific portions of golf courses and sod farms, the second key assumption that underlies the feeding-area restriction -- that turf managers can identify and avoid treating such feeding areas -- is even more tenuous. Ciba-Geigy recognizes that "there is only limited evidence" in the record supporting this proposition, and that additional evidence would be "essential" to the Agency's ability to determine the sufficiency of the feeding-area restriction. [43/] It is Ciba-Geigy, however, that bears the risk of non-persuasion regarding the feasibility of its proposals. Ciba-Geigy had every opportunity to defend any label it chose to propose at trial, and its failure to submit evidence "essential" to its current proposal plainly undercuts its case. Its reliance on evidence that birds sometimes leave indications of their presence, e.g.,

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[42/](...continued)
low." TR 4066. Although waterfowl tend to return to a particular area on a course, and although they tend to use bodies of water as activity centers, Dr. Dickson made clear that birds do roam and "will not tend to stay in one particular area constantly." TR 4068. This testimony suggests that while the chances of repeated exposure to a particular treated area might be low, at the same time there appears to be no "safe" area on the course that could be treated with diazinon without potential for exposure. Because Ciba-Geigy chose not to propose its feeding-area restriction prior to trial, no witness directly testified as to whether such a restriction would significantly reduce exposure due to waterfowl feeding patterns. Given the limited and somewhat confused state of the record on this issue, there is insufficient evidence to conclude that the feeding-area restriction would sufficiently protect waterfowl that use golf courses and sod farms for feeding.

[43/] Motion for Reconsideration of Order Denying Referral to ALJ to Take Further Evidence, at 4 (Aug. 21, 1989).

feathers and droppings (TR 2509), is wholly inadequate to establish that turf managers can identify and avoid areas that might be used by waterfowl. Although turf on golf courses and sod farms is regularly maintained and cultivated, [44/] and although turf managers undoubtedly observe waterfowl on occasion during such operations, the record fails to show that turf managers are capable of identifying and avoiding, with any degree of confidence or reliability, areas used by waterfowl. [45/]

[44/] EPA W-14 (pp.15-16).

[45/] The feeding-area restriction might well be meaningless at a new golf course or sod farm, or new portions of existing sites. In certain situations, turf managers would also lack economic incentive to adhere to the feeding-area restriction, particularly where an area in need of treatment becomes subject to waterfowl feeding after diazinon is purchased, or after the first of the two treatments under the 2+2 label. The record also demonstrates that waterfowl can sometimes be a nuisance to turf managers (see CG Ex. 63 (p.232)), a factor that further undercuts the Agency's ability to rely on turf managers to make largely discretionary determinations regarding waterfowl feeding patterns.

To strengthen its proposed feeding-area restriction, Ciba-Geigy suggests (Bf. at 10) that diazinon use be prohibited where the applicator is uncertain whether an area is used by waterfowl for feeding or loafing. Essentially, this proposal would allow for use only where the applicator is certain that the area to be treated has not been used by waterfowl. This approach raises serious enforcement concerns, however, such as the difficulty in establishing lack of subjective certitude by an alleged violator. Moreover, as discussed above the record fails to show that there are any turf areas at golf courses and sod farms for which an applicator could be certain that they are not subject to waterfowl use.

In its reply brief (p.14), Ciba-Geigy proposes for the first time that diazinon be prohibited on golf courses and sod farms having resident waterfowl. It is not clear whether "resident waterfowl" refers only to non-migrating waterfowl, or whether it would include migrating waterfowl that spend the summer breeding period in the United States. It is also unclear whether it includes only waterfowl that actually roost or nest at the site,

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4. The Ban of Granular Diazinon

To reduce risk to songbirds, Ciba-Geigy proposes that the Agency prohibit the use of diazinon's granular formulation on golf courses and sod farms. Ciba-Geigy recognizes that songbirds are exposed to diazinon residues through invertebrates, insects, puddles, and seeds, but suggests (Bf. at 3, 12) that the only serious risk to songbirds identified by the Agency's 1988 Decision is from direct ingestion of diazinon granules.

Ciba-Geigy misreads the 1988 Decision. In the ultimate risk findings in that Decision, the Agency stressed the risk posed to songbirds by diazinon granules, but this discussion assumed arguendo that Ciba-Geigy's field studies were "perfectly sound" and "flawless." 53 Fed. Reg. at 11126 (cols. 1 and 2). In other words, assuming for the sake of argument that the field studies demonstrate that the 2+2 proposal would reduce the overall avian risk, the Agency concluded that a serious risk of songbird kills

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[45/](...continued)
or extends to waterfowl that roost elsewhere but use the site for feeding. Apart from these ambiguities, and apart from concerns regarding surprise and lack of notice to Respondent, Ciba-Geigy fails altogether to cite record evidence or to otherwise show that applicators could adhere to the proposal, or that it could be adequately enforced, or that it would effectively reduce avian risk to reasonable levels. Although the Agency's expertise, as well as common sense, may be employed to supplement the record in analyzing regulatory alternatives, the "resident-waterfowl" restriction presents too many issues regarding compliance, enforcement, and efficacy to allow for confident reliance on this proposal in the absence of record support.

from granule ingestion would still remain. [46/] The field studies, however, were far from flawless. Due to their deficiencies, the Agency found that the risk to individual birds under the 2+2 label would still be widespread and continuous. [47/] This determination was made without regard to specific diazinon formulations and essentially reaffirmed the vast bulk of Respondent's prima facie case of risk to both waterfowl and non-waterfowl species from all formulations. A re-examination of the record bears out this determination with respect to songbird risk from liquid diazinon.

The Agency previously found, and it is virtually undisputed, that songbirds would continue to be exposed to non-granular formulations of diazinon through residues on seeds, invertebrates such as earthworms, and in puddles. Id. at 11123 (col. 1). The question then becomes whether such exposure could be lethal. As for residues on seeds, Ciba-Geigy correctly notes (Bf. at 13) that Respondent itself has determined such residues would be at non-lethal levels. [48/] The record shows, however, that other

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[46/] Specifically, the Agency determined that "[b]ecause only a few granules might cause mortality, the proposed 2+2 application rate would not significantly reduce this risk." 53 Fed. Reg. at 11126 (col. 2).

[47/] At one point, the Agency stated that avian risk "might well" remain widespread and continuous under the 2+2 label (53 Fed. Reg. at 11126 (col. 1)), but it concluded its ultimate risk findings by stating "that Ciba-Geigy has failed to show that the avian risk would be anything other than widespread and continuous due to the defects in its field studies." Id. (col. 2).

[48/] See CG Ex. 119 (pp. II-5 to II-8) (Diazinon Support Document).

diazinon residues from the liquid formulation can be lethal to non-waterfowl species. For example, a field study commissioned by Ciba-Geigy resulted in earthworm residues of 15.8 ppm. Dr. Margaret Rostker, an EPA wildlife biologist, testified unequivocally that these levels would pose a lethal risk to small birds such as robins. EPA W-13 (p.24). Pierre Mineau, a pesticide evaluator with the Canadian Wildlife Service, supported this conclusion, stating that residues of 15.8 ppm in earthworms are "high enough to be of concern." EPA W-4 (p.27). Ciba-Geigy argues (Bf. at 14) that Dr. Rostker offered no exposure model for songbirds (as she did with waterfowl), but she was not required to do so. As an expert witness, she was entitled simply to state her opinion on the matter. It was Ciba-Geigy's responsibility to question her as to the data underlying this opinion, but it evidently failed to do so.

Reported kills of non-waterfowl species associated with spray diazinon bear out these concerns. See EPA W-5 (Appendix: Nos. 14, 27, 43). Although Ciba-Geigy describes these incidents as "questionable and essentially unconfirmed" (Bf. at 15), the record supports the ALJ's finding that for these, and most other reported incidents, diazinon "was the most likely cause" of death. [49/] Ciba-Geigy (Bf. at 15-16) also relies on its field

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[49/] Initial Decision at 41. The ALJ gave no credit to three other reported kills for which diagnoses and cholinesterase results were missing. Id. at 41 n.103. Without deciding the propriety of discrediting these incidents, it is abundantly clear that the ALJ properly credited the three incidents of songbird kills by non-granular diazinon. Incident 14, a kill of 24

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studies as evidence that non-granular diazinon poses no significant risk to songbirds, but only one of its five studies focused on songbirds, and this was so flawed as to have "very little to contribute to the assessment of the risks of diazinon." EPA W-12 (p.24); see also id (pp.25-26). Some songbird exposure occurred in the other studies, [50/] but even Ciba-Geigy's experts could draw only tentative conclusions relating to songbird

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[49/](...continued)
cowbirds after diazinon application, was confirmed by residues in the birds' gizzards, intestines, livers, and hearts. Samples were tested for residues of other pesticides, but only diazinon residues were reported. EPA W-5 (Appendix: No.14). Although the diazinon residues were relatively low, there is no evidence that the carcasses were discovered and frozen soon after the kill, and the reduced diazinon levels can thus be explained by continued dissipation after the kill. See EPA W-5 (Appendix: No.35).

Incident 27 involved a kill of four Canada geese, 5 mallards, and 3 red-winged blackbirds found "shortly" after diazinon treatment. EPA W-5 (Appendix: No.27). Ciba-Geigy argues (Bf. at 14) that no residues or cholinesterase inhibition were reported for the blackbirds. It fails to note, however, that diazinon residues were reported in the esophagus contents of the geese and mallards. The presence of nine dead waterfowl whose deaths were confirmed as diazinon-related, together with the timing of the application, establishes by a preponderance that the blackbirds were also killed by diazinon.

In Incident 43, 15 sparrows were found on a lawn just hours after diazinon application. EPA W-5 (Appendix: No.43). Some distressed sparrows were euthanized, and the incident was reported to the Agency as a diazinon-related mortality. Again, the preponderance of the evidence points to diazinon as the cause of mortality.

[50/] One or two dead passerines were found in four of the five field studies conducted by Ciba-Geigy. See EPA W-12; CG Ex. 125 (Appendix). Although none of these mortalities was confirmed as diazinon-related, diazinon could not be ruled out conclusively as the cause of death. Id. In the fifth field study, abnormal behavior, possibly caused by diazinon intoxication, was noted in two robins. Id.

populations. [51/] Dr. Best, a Professor of Avian Ecology, testified:

> With the exception of one field study and one survey, little attention has been paid to the effects of diazinon use on songbirds and other non-waterfowl species. Most studies, and their protocols, have focused on waterfowl species. Nongame birds also use golf courses regularly, and the extent of diazinon-related mortality that these smaller, less conspicuous birds have suffered has not been adequately assessed.

CG Ex. 125 at 44. Although Dr. Best addressed the specific risk to songbirds posed by granular diazinon, his concern was not limited to this formulation. Given the limitations that undermine Ciba-Geigy's field studies, Dr. Best could conclude only that "mortality of non-waterfowl birds may be low" under the 2+2 label (id. at 38 (emphasis added)), a speculative assertion at best. It is unnecessary in this case to decide whether the risk posed to non-waterfowl by liquid diazinon standing alone is

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[51/] For example, Dr. Ronald Kendall predicted that there might be "some" but not "widespread" mortality among passerines (TR 1072-74), a conclusion not specifically limited to the granular formulation. When pressed on cross-examination, Dr. Kendall stated that it is inappropriate to draw conclusions regarding any bird species which were not observed during his studies to be feeding on treated turf. TR 1136-37; see also TR 1184 (small number of robins observed in field study was "getting to a point where you might have too few observations to make any kind of useful conclusion."); TR 1078 ("We didn't focus the study on [passerines]. Therefore, I can't say that we wouldn't have any mortality."). Mr. Jaber stated that the carcass searches in the Connecticut field study were sufficient to detect only "an extreme number" of songbird kills -- i.e., one with a population effect -- but he was much less confident that they would have detected a smaller number of passerine deaths. TR 2557. He recommended additional research regarding diazinon's risk to songbirds. TR 2472.

unreasonable, but that risk is certainly cognizable and should be considered in determining whether the overall avian risk under the newly proposed restrictions would be de minimis.

5. Conclusions Regarding the Most Recent Proposals

As noted above (see pp.8-9 & n.10), Ciba-Geigy has the burden of establishing the viability of its most recent label proposals. The record does not support Ciba-Geigy's contention that its most recent proposals would reduce avian risk to de minimis or otherwise reasonable levels. In a case based upon ecological hazard, the risk analysis necessarily differs dramatically from cases involving human health risks. On the other hand, the Agency's concern for wildlife is not limited to long-term adverse effects on populations. Absent some countervailing benefit of continued use, as a matter of policy an unnecessary risk of regularly repeated bird kills will not be tolerated.

The number of bird mortalities resulting from continued diazinon use at golf courses and sod farms cannot be precisely predicted, just as the exact number of past kills is unknown (see note 24, above). It is not, however, reasonable to conclude that continued use would result in only a few bird kills per year. Although the most recent label proposals would undoubtedly reduce avian risk below that posed by diazinon as historically used, both waterfowl and songbirds would continue to be generally exposed to lethal levels of diazinon residues, and individual kills would likely be repeated on a fairly consistent basis.

Indeed, the serious risk of even large-scale waterfowl kills would continue to loom large. The avian risk in this case, even under the most recent label proposals, is far from de minimis, and it cannot be presumed that the benefits of continued diazinon use would outweigh that risk as Ciba-Geigy contends.

Ciba-Geigy's evidentiary failure should not be surprising. From its opening statement, [52/] to its expert testimony, [53/] through its Fifth Circuit appeal, [54/] the central thesis of Ciba-Geigy's case has been that cancellation is warranted only if diazinon poses an unreasonable effect on bird populations, a position inconsistent with this Agency's commitment to eliminate unreasonable risks generally posed to individual birds, regardless of the effect on bird populations. [55/] Although the

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[52/] See TR 19 ("The question presented is whether, under the normal conditions of use of diazinon on golf courses and sod farms, it will have a significant effect on bird populations."); TR 20; (same); TR 22 (same).

[53/] See 53 Fed. Reg. at 11125 n.38.

[54/] See 874 F.2d at 280 ("Ciba-Geigy asserts that the Administrator cannot find that the risk of adverse effects of diazinon on birds is unreasonable unless use of the chemical not only kills birds but also endangers overall population.").

[55/] Although our society tolerates the hunting of waterfowl, hunters have been largely responsible for federal and state programs to restore and preserve wetlands for waterfowl (RX 109 (p.44)), one of the most important factors in waterfowl conservation. Id. at 42. In contrast, diazinon use plays no similarly beneficial role. (Any turf damage prevented by diazinon can be prevented by using less toxic, equally effective alternatives.) Hunting, together with other significant human sources of avian mortality -- window and vehicle collisions (CG Ex. 104 (p.8)) -- involve a risk-benefit balance so different from that at issue here as to provide no meaningful comparison.

proposed seasonal restriction and granular ban are fairly straightforward, the water and feeding-area restrictions are far removed from the issues litigated at the hearing. Not a single witness was called to defend these proposals, and the trial transcript (5700+ pages) contains no testimony directly and specifically discussing their feasibility. Simply put, Ciba-Geigy never made any serious effort at trial to demonstrate that unreasonable risks to individual birds could be eliminated by reducing exposure. Although alternatives to cancellation must be considered under FIFRA, where (as here) the Agency has determined that historical, registered use patterns commonly pose an unreasonable risk, caution must be exercised to ensure that use under a proposed alternative label would not also commonly pose an unreasonable risk. It would not be responsible stewardship of our natural resources to adopt and rely on restrictions, such as those proposed here, that are based on unfocused, fragmentary scraps of evidence, much of it from witnesses who, based on the overall thrust of their testimony, would have probably opposed such proposals had they been given an opportunity to do so. [56/]

[56/] Ciba-Geigy suggests that it could not have anticipated the specific concerns discussed in the Agency's 1988 Decision, and that the Fifth Circuit's remand provided its first chance to do so. Although that remand has given Ciba-Geigy a unique opportunity to propose additional label refinements, it does not excuse any failure at trial to offer evidentiary support for such refinements. The basic concerns addressed by the water and feeding-area restrictions -- risk to waterfowl exposed to treated turf -- have been at the core of this proceeding since its inception. Ciba-Geigy could have readily advocated and defended its current proposals at the hearing, but it chose instead to defend the less restrictive 2+2 label. This strategic choice

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In its opening statement at trial, Respondent described Ciba-Geigy's various label proposals as "an everchanging kaleidoscope of regulatory fixes." TR 15. This kaleidoscopic label has since undergone several additional transformations. [57/] Ciba-Geigy would undoubtedly argue that these many restrictions simply exhibit its willingness to reduce risk, but they are also a function of three basic facts: that diazinon, even at the 2+2 rate, kills birds; that many birds at risk are present across the country at all times of the year; and that birds are highly mobile creatures, rendering futile any effort to eliminate exposure. Indeed, it is no exaggeration to say that virtually every time diazinon is used on golf courses and sod farms, there is a risk of avian exposure to toxic residues. Given the mobility and virtual ubiquity of waterfowl and non-waterfowl species, as well as the absence of sufficient record evidence to support the efficacy of the new proposals, the only way to

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[56/](...continued)
its current proposals at the hearing, but it chose instead to defend the less restrictive 2+2 label. This strategic choice does not require the Agency to reopen the hearing for evidence on Ciba-Geigy's most recent proposals simply because their efficacy is not supported by the record. See note 8, supra.

[57/] Ciba-Geigy itself has at times been confused as to which restrictions protect which birds. In its brief (p.8), Ciba-Geigy asserts that its seasonal restriction is adequate, despite variations in migration seasons, because migratory waterfowl that are present during diazinon use will be protected by the feeding-area ban. In its reply brief (p.6), however, it argues that the feeding-area ban is adequate, despite unpredictability in feeding patterns, because such unpredictability relates solely to migratory birds. One is left to wonder exactly how migratory birds present during the proposed use season would be protected.

preclude diazinon from generally posing an unreasonable avian risk is to prohibit its use on golf courses and sod farms altogether. [58/]

For the reasons set forth above and in Respondent's submissions on remand, diazinon use on golf courses and sod farms poses an unreasonable risk with considerable frequency, and Ciba-Geigy has failed to establish the adequacy of any proposal short of a complete prohibition of diazinon use at these sites.

[58/] It is unnecessary in this case to determine the exact point at which an avian risk posed by a pesticide becomes de minimis, or so negligible that any benefits of continued use should be presumed to outweigh the risk. Here, the record shows that diazinon use on golf courses and sod farms generally poses an unreasonable risk, and this risk will undoubtedly increase in magnitude, scope, and frequency as natural feeding habitats continue to dwindle and waterfowl use of golf courses and sod farms thereby increases. Ciba-Geigy's most recent proposals, aimed at reducing exposure, are based on assumptions that are either unsupported or contradicted by the record. If in the future Ciba-Geigy develops substantial new evidence to support its proposals that meets the requirements of 40 CFR Part 164, Subpart D, it may seek modification of today's Order.

FINAL ORDER

1. The registrations at issue in this proceeding are hereby cancelled, unless they are already amended as described below or unless the registrant submits a timely application to amend the registration to prohibit use on golf courses and sod farms. To be timely, an application must be submitted within 30 days of receipt of this Order or its publication in the Federal Register, whichever is later. The application shall propose to amend the registration of the product to include the following statement on top of the front panel of the label (or on supplemental labeling):

This product must not be used on golf courses and sod farms.

2. The Assistant Administrator for Pesticides and Toxic Substances may require or disallow such other language as she considers appropriate. She is directed to monitor efforts to comply with this Order and, if appropriate, to suggest modifications relating to the treatment of existing stocks.

3. Distribution and sale of any diazinon product at issue in this proceeding is prohibited unless the product bears a new label (or supplemental labeling) approved by the Assistant Administrator for Pesticides and Toxic Substances.

4. Use of diazinon products on golf courses or sod farms is prohibited.

5. Any pending applications for diazinon products for use on golf courses and sod farms are hereby denied.

6. This Order applies to all diazinon products covered by the Notice of Intent to Cancel, 51 Fed. Reg. 35034 (October 1, 1986), as amended by 52 Fed. Reg. 5656 (February 25, 1987).

7. This Order shall become effective at the date and time it is filed with the Hearing Clerk.

Dated: JUL 12 1990

William K. Reilly
Administrator