

10-21-91



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
THE ADMINISTRATIVE
LAW JUDGES

IN THE MATTER OF :
GRACE-SIERRA CROP PROTECTION : FIFRA DATA DOCKET NO. 176
COMPANY :
Petitioner :
:

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A0:

Federal Insecticide, Fungicide, and Rodenticide Act and regulations issued pursuant thereto, 7 U.S.C. §136 136a(c)(2)(B)(iv).

In this matter, the only issue which may be considered in a hearing conducted pursuant to this section is whether the registrant of a pesticide product has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required.

APPEARANCES

James P. Rathvon, Esquire, Piper & Marbury, 1200 Nineteenth Street, N.W., Washington, D.C., for petitioner.

Mary E. Gleaves, Esquire, U. S. Environmental Protection Agency, 401 M Street S.W., Washington, D.C., for respondent.

BEFORE: J. F. Greene
Administrative Law Judge

Decided: October 21, 1991

ORDER GRANTING MOTION FOR "ACCELERATED DECISION"

This matter arises under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §136-136y, and regulations promulgated pursuant to authority granted therein. The United States Environmental Protection Agency (EPA), respondent herein, moved for "accelerated decision" pursuant to 40 C.F.R. §164.91(a)(7) on the ground that there is no genuine issue of material fact to be decided and that respondent is entitled to judgment as a matter of law. For reasons set forth herein, respondent's motion for "accelerated decision" is granted.

Section 4 of FIFRA, 7 U.S.C. §136a-1, modified the process for re-registering pesticide products which contain active ingredients first registered before November 1, 1984 [7 U.S.C. §136a-1(a)], and placed upon the registrant the burden of identifying and providing data necessary to establish that the pesticide product will perform its intended function without unreasonable adverse effects upon the environment, 7 U.S.C. 136a(c)(5)(C), (D); 7 U.S.C. §136(j). Accordingly, on May 19, 1989, EPA sent to petitioner Grace Sierra Crop Protection Company (Grace Sierra), as registrant for the pesticide product having the trade name MILBAN¹, a notice which informed the company of certain re-registration requirements imposed by FIFRA. Petitioner responded by (1) indicating that it intended to seek re-registration of MILBAN; (2) identifying certain

¹ The EPA registration number for MILBAN is 58185-12.

data that it believed necessary to support re-registration, and (3) stating that the data would be supplied no later than August 24, 1990, in accordance with applicable regulations.

As of August 24, 1990, however, the data identified as necessary to support re-registration had not been supplied, and, on June 3, 1991, a notice of the EPA Administrator's intent to suspend the existing registration was issued to petitioner.

Section 3(c)(2)(B)(iv) of FIFRA, 7 U.S.C. 136a(c)(2)(B)(iv), provides that a registrant may seek a hearing to contest the notice of intent to suspend. Petitioner did so on June 11, 1991. Section 3(c)(2)(B)(iv) provides further, however, that the only issue which may be considered at such a hearing is whether "registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required," and certain other limited issues not raised here.²

² Subsection (iv), in its entirety, provides as follows:

Notwithstanding any other provision of this subchapter, if the Administrator determines that a registrant, within the time required by the Administrator, has failed to take appropriate steps to secure the data required under this subparagraph, to participate in a procedure for reaching agreement concerning a joint data development arrangement under this subparagraph or in an arbitration proceeding as required by this subparagraph, or to comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement under this subparagraph, the Administrator may issue a notice of intent to suspend such registrant's registration of the pesticide for which additional data is required. The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Any suspension proposed under this [Footnote continued on next page]

The less than elegant phraseology of the controlling portions of this provision nevertheless does not conceal its clear intent. The only issue which may be addressed in a hearing conducted in this proceeding is whether the necessary supporting data were supplied in a timely fashion. Petitioner does not argue that the data were in fact timely supplied. Rather, the request for hearing and other submissions raise the defense of impossibility based upon the refusal or inability of the supplier, BASF Germany, to provide quantities of the technical product for testing so as to permit

subparagraph shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person adversely affected by the notice or the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend. If a hearing is requested, a hearing shall be conducted under section 136d(d) of this titled. The only matters for resolution at that hearing shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this subchapter. If a hearing is held, a decision after completion of such hearing shall be final. Notwithstanding any other provision of this subchapter, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing. Any registration suspended under this subparagraph shall be reinstated by the Administrator if the Administrator determines that the registrant has complied fully with the requirements that served as a basis for the suspension of the registration. [Emphasis applied]

petitioner to go forward with its effort to obtain the necessary data in a timely manner.³ Unfortunately, the statute leaves no room for doubt as to its meaning. Petitioner's defense may not be considered in determining whether "accelerated decision" lies, i.e. whether there is a genuine issue of any material fact and whether respondent is entitled to judgment as a matter of law. Petitioner's defense might well prove persuasive if it could be considered.

Accordingly, because data requirements have not been met during the period provided,⁴ and since the only factual issue in this proceeding is whether data required for re-registration of MILBAN were submitted in a timely manner, respondent is entitled to judgment as a matter of law. Respondent's motion for "accelerated decision" must be, and is hereby, granted. As a consequence, petitioner's registration for MILBAN is suspended by operation of law, pursuant to section 3(c)(2)(B)(iv) of FIFRA, 7 U.S.C. §136a(c)(2)(B)(iv).

³ It is noted that Section 4(d)(4)(B) provides for applications for extensions of time to be granted by the EPA Administrator where "extraordinary circumstances beyond the control of the registrant" prevent compliance.

⁴ As of September 9, 1991, respondent had withdrawn certain data requirements, but certain other requirements are still outstanding. See September 9, 1991, letter from petitioner (attached).

ORDER

"Accelerated decision" having been granted, petitioner's request for hearing is dismissed. The suspension of registration proposed on June 3, 1991, shall become effective on the day following service of this Order. Thereafter, the pesticide product MILBAN may not be sold unless and until the registration is reinstated or the product is re-registered.



J. F. Greene
Administrative Law Judge

Dated: Oct 21, 1991
Washington, D.C.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 9 1991

OFFICE OF
GENERAL COUNSEL

Honorable J. F. Greene
Administrative Law Judge
Environmental Protection Agency
Room M3706, A-110
401 M Street, S.W.
Washington, D.C. 20460

Re: Grace-Sierra Crop Protection Co.,
FIFRA DATA Docket No. 176.

Dear Judge Greene:

This is to confirm that Respondent is withdrawing the following data requirements as bases for the Notice of Intent to Suspend Registration issued to Grace-Sierra Crop Protection Co. in the above-referenced case:

Toxicology

Primary dermal irritation (81-5)
Dermal sensitization (81-6)

Environmental Fate

Photodegradation-water (161-2)
Photodegradation-soil (161-3)

Residue Chemistry

Directions for use (171-3)

Although Respondent has withdrawn some data requirements, the following remain at issue in this proceeding:

Product Chemistry:

Chemical identity (61-1)
Beginning material and manufacturing process (61-2(a))
Discussion of impurities (61-2(b))
Preliminary analysis (62-1)
Certification of limits (62-2)

Analytical method (62-3)
Color (63-2)
Physical state (63-3)
Odor (63-4)
Melting point (63-5)
Density (63-7)
pH (63-12)
Stability (63-13)

Environmental Fate:

Chemical identity (160-5)

Residue Chemistry:

Chemical identity (171-2)

A copy of this letter has been served upon counsel for
Petitioner.

Respectfully,


Mary E. Gleaves
Attorney
Pesticides and Toxics Substances
Division (LE-132P)
(202) 260-7526

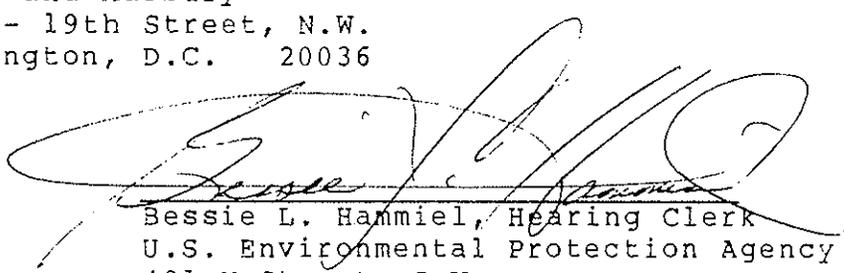
cc: Counsel of Record

CERTIFICATE OF SERVICE

I do hereby certify that the foregoing Order Granting Motion for "Accelerated Decision" was filed in re Grace-Sierra Crop Protection Company; FIFRA DATA Docket No. 176 and copies of the same were mailed to the parties indicated below:

(Interoffice) Mary E. Gleaves, Esquire
Office of General Counsel (LE-132P)
U.S. Environmental Protection Agency
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Washington, D.C. 20460

(Certified Mail) James P. Rathvon, Esq.
Counsel for Petitioner
Piper and Marbury
1200 - 19th Street, N.W.
Washington, D.C. 20036



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

Dated: October 22, 1991