

**UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY**

BEFORE THE ADMINISTRATOR

IN THE MATTER OF:)
)
SYNGENTA CROP PROTECTION, INC.) **FIFRA Docket No. 660**
)
Petitioner)

ORDER DENYING REQUEST FOR HEARING

Background

Syngenta Crop Protection, Inc. (Syngenta) asserts that, under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), it was the principal data submitter for the registration of the pesticide abamectin. In November 2001, Nations Ag II applied for registration of a product containing abamectin, as a follow-on, or “me-too,” registration, citing to data (scientific studies) that had been submitted by Syngenta. Section 3(c)(1)(F)(iii) of FIFRA provides that EPA may consider data in support of an application for pesticide registration if the applicant has made an offer to compensate the original data submitter. Therefore, when Nations Ag II submitted to EPA its application for “me-too” registration, on November 13, 2001, Nations Ag II submitted a letter to Syngenta advising of its application, advising that it had cited certain studies that Syngenta had submitted to EPA in support of abamectin’s registration, and including an offer to commence negotiations to pay Syngenta compensation for studies cited to the extent required by Section 3(c)(1)(F) of FIFRA.

On March 22, 2002, Syngenta filed a petition to deny Nations Ag II’s application, for two reasons. The first reason Syngenta alleges is that Nations Ag II failed to comply with Section 3(c)(1)(F)(iii) of FIFRA by not including citations to all of the studies necessary to support Nations Ag II’s registration, and not offering to pay Syngenta for the additional necessary studies. Syngenta requested that the application for registration be denied unless Nations Ag II offers to pay Syngenta for approximately 52 additional studies. The other reason is that Nations Ag II offered to pay compensation for selected studies, but only as to “each compensable Syngenta study required by and relied upon by EPA in issuing our registration.” Syngenta asserts that an offer to pay for selected studies cannot be conditional.

On April 6, 2004, Syngenta sent a letter to Philip J. Ross, Esq., of EPA’s Office of General Counsel (OGC), Pesticides and Toxic Substances Law Office. In the letter, Syngenta referred to its March 22, 2002 petition, and to another petition, which claimed that additional testing is needed before EPA can determine whether Nations Ag II’s abamectin products are toxicologically substantially similar to Syngenta’s. The letter stated that after two years, Syngenta had not yet received a response from EPA to the two petitions, and that Nations Ag II

has not offered to compensate Syngenta for the studies. The letter requested notice of EPA's decisions on the petitions and an opportunity to seek judicial review and injunctive relief before EPA approves Nations Ag II's applications for registration.

The letter also advised OGC that Syngenta is requesting a hearing on the issues of fact raised in its first petition. Syngenta states in the letter (at 3) that it "now believes that these factual issues should be decided in a hearing presided over by an Administrative Law Judge, so that both parties can be assured of receiving the procedural protections and fairness provided by the Agency's hearing regulations, and so that this petition process is placed on a procedural track that will result in a decisional endpoint." The letter requested EPA to advise it within ten days whether EPA agrees to commence the requested hearing, and whether EPA agrees to provide notice to Syngenta prior to approving Nations Ag II's registration.

Also on April 6, 2004, Syngenta submitted to the U.S. EPA Hearing Clerk a Request for Hearing (Request), along with copies of the first petition and supporting documents, and the letter to Mr. Ross. Syngenta requested the Hearing Clerk to docket the Request, assign a FIFRA docket number and refer the request to the Chief Administrative Law Judge for assignment.

On April 7, 2004, the EPA Hearing Clerk assigned a FIFRA docket number to the Request and sent a copy of it along with a cover letter to OGC, to EPA's Office of Administrative Law Judges. On May 11, 2004, the undersigned issued an Order designating herself as the presiding judge.

By letter dated April 22, 2004, OGC (Mr. Ross) submitted a letter to the Hearing Clerk requesting her to immediately deny the hearing request on the basis that it is inappropriate and without basis in statute, regulation or delegation.

On April 27, 2004, Nations Ag II sent a letter to OGC, with a copy to the Hearing Clerk, concurring in the EPA's views expressed in the April 22 letter.

Discussion

EPA has set forth regulatory procedures at 40 C.F.R. part 152 subpart E, in regard to pesticide registration applications, to ensure protection of data submitters' rights in accordance with Section 3(c)(1)(D) of FIFRA. Procedures for data submitters to petition to deny or cancel product registrations of applicants which fail to comply with data compensation requirements are set forth in Section 152.99. The regulations provide that the petition is filed with the "Agency," which either denies the petition, or takes steps which may result in denial or cancellation of the registration. 40 C.F.R. § 152.99(c). The Agency's denial of a petition or of a registration is final Agency action under the regulations. *Id.* If the Agency determines that the registration applicant acted in a way that deprived an original data submitter of rights to compensation under FIFRA § 3(c)(1)(F)(iii), then the Agency issues a notice of intent to deny or cancel the registration or notice of intent to hold a hearing for determination of whether registration should be denied or

canceled, under procedures of Section 6(b) of FIFRA. 40 C.F.R. § 152.99(c)(3). The regulations provide at 40 C.F.R. § 152.99(d) that any hearing will be conducted in accordance with 40 C.F.R. part 164, which are rules of practice for hearings initiated under Section 6 of FIFRA, and which require an administrative law judge to preside.

Syngenta asserts that the regulations specify that hearings arising from petitions to deny or cancel registrations are conducted under 40 C.F.R. part 164. Syngenta may be impressed by the requirement of 40 C.F.R. Section 164.90 for an initial decision to be filed 25 days after the post hearing reply briefs are filed, which is a maximum of 85 days after hearing, and which would provide a “decisional endpoint” within a short time frame. However, Syngenta neglects to consider that the regulations do not authorize the initiation of a hearing while its petition is still under consideration in another office within EPA

In short, Syngenta’s Request for Hearing is not consistent with the procedures set forth in FIFRA and the implementing regulations. Petitions under Section 152.99 are determined by the “Agency.” EPA’s Delegations Manual sets forth the delegations from the EPA Administrator, which authorize the offices within the Agency to perform the various duties set forth by statute and regulation. Delegation 5-7 of the Delegations Manual sets forth the delegation for performing responsibilities relative to administrative review, suspension and cancellation of registration under Sections 3, 4 and 6 of FIFRA to the Assistant Administrators for Prevention, Pesticides and Toxic Substances and for Enforcement and Compliance Assurance. A limitation set forth in that Delegation is that the authority to preside at hearings pursuant to Section 6 of FIFRA, is retained by the Administrative Law Judges. Viewing together the regulations and the Delegations Manual, there is no authority for an administrative law judge to act as the “Agency” in making determinations on petitions under 40 C.F.R. § 152.99(c).

If the Agency denies the petition to cancel registration or denies registration for reasons set forth in Section 152.99(a)(1), such disposition is “final Agency action,” which is not subject to review by an administrative law judge. 40 C.F.R. § 152.99(c)(1) and (2).

The authority to request a hearing as to cancellation of registration is provided in Section 6(b) of FIFRA, as referenced in 40 C.F.R. Section 152.99(c)(3), which provides that only “*if the Agency determines* that an applicant for registration of a product has acted in any way that deprives an original data submitter of rights under FIFRA”, then the procedures of Section 6(b) of FIFRA are triggered, which include hearings. 40 C.F.R. § 152.99(c)(3)(emphasis added). No such Agency determination has yet been made. Section 152.99(d) does not grant any other authority for requesting a hearing, but merely specifies the issue to be addressed at the hearing and that the procedural rules of part 164 apply. Section 6(b) of FIFRA and 40 C.F.R. § 164.20 indicate that *after* EPA issues a notice of intent to cancel registration or change classification of a pesticide, then any person adversely affected by the notice may request a hearing.¹ Neither the

¹ A hearing may also be commenced when EPA decides to call a hearing to determine whether registration should be canceled.

statute nor any implementing regulatory provisions provide any authority for Syngenta's Request for Hearing.

Syngenta is apparently frustrated with EPA's two year delay in resolving its petitions. Indeed, there is no time frame or deadline set forth in either the statute or regulations as to disposition of petitions. Syngenta cannot, however, circumvent the statutory and regulatory procedures in order to accelerate the process or to pursue an alternate venue within EPA to make a determination on its petition.

Accordingly, Syngenta's Request for Hearing is **DENIED**. This proceeding is hereby **DISMISSED** for lack of jurisdiction.

Susan L. Biro
Chief Administrative Law Judge

Dated: June 1, 2004
Washington, D.C.