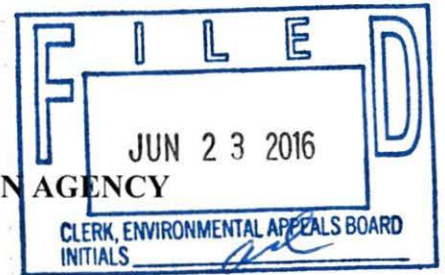


ENVIRONMENTAL APPEALS BOARD
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C.



In re:)
)
Bayer CropScience LP, and Nichino) FIFRA Appeal No 16-01
America, Inc.)
)
Docket No. FIFRA-HQ-2016-0001)
)

ORDER ON POST-ARGUMENT BRIEFING

On June 22, 2016, the Board held oral argument in this proceeding. At the argument, the panel requested a single post-argument brief from each party. These briefs must be submitted by 12:00 pm EDT on Friday, July 1, 2016, and the section of the brief consisting of the argument must not exceed 25 pages. The purpose of such briefs shall be to respond to questions raised by the Board at the oral argument. The parties may not raise new arguments, nor may they introduce new affidavits or declarations not contained in the record. In addition to any other issues the parties wish to address, the Board requests the briefs to focus specifically on the following issues:

1. (a) What authority does the Board have in a FIFRA section 6(e) proceeding to consider the lawfulness of a condition of registration, given that section 6(e) proceedings are statutorily limited to two issues: (1) whether a condition of registration has been violated, and (2) whether EPA's determination with respect to disposition of existing stocks is consistent with FIFRA?

(b) If the Board does possess the authority in a section 6(e) proceeding to consider the lawfulness of a condition of registration, may a third party also challenge the lawfulness of either that condition or any other aspect of the registration?

(c) Finally, if the Board were to conclude that the voluntary cancellation condition in the flubendiamide registrations is unlawful, what effect would such a holding have on the registration itself?

2. FIFRA section 6(e) provides that any hearing on a notice of intent to cancel issued under section 6(e) shall be conducted under FIFRA section 6(d). An order issued after a section 6(d) hearing “shall be based only on substantial evidence of record of such hearing.” 7 U.S.C. § 136d(d). What standard of proof does this provision require? In answering this question, take into account that FIFRA section 16 requires that a substantial evidence standard be applied by a court in reviewing EPA decisions following a hearing, and the Supreme Court’s decision in *Steadman v. SEC*, 450 U.S. 91 (1981).
3. What “conclusions” are covered by the requirement in the flubendiamide conditional registration that EPA “shall engage in dialogue about the data and the Agency’s conclusions?” Does EPA’s determination on the toxic endpoint level constitute a “conclusion” within the meaning of the registration?
4. Appellants argue on appeal that EPA presented “new * * * conclusions * * * in the January 29, 2016 Decision and supporting documents that were not discussed with Registrants.” Appeal Brief of Bayer CropScience LP and Nichino America, Inc. at 22. If there were new conclusions presented in these documents, what were they, and where in the record are these conclusions detailed?

5. EPA relied upon a toxic endpoint level from the Des-iodo – Spiked Water 28-Day Study (MRID 46817023), among other evidence, in its January 29, 2016 unreasonable adverse effects determination for flubendiamide. What does the record show as to whether Appellants were notified of EPA’s intent to use this toxic endpoint level prior to January 29, 2016?
6. FIFRA section 6(f) mandates that voluntary cancellation requests may not be acted upon by EPA until a notice-and-comment procedure has been completed. If Appellants had requested voluntary cancellation of the flubendiamide registrations under section 6(f), could they have challenged EPA’s unreasonable adverse effects determination during the notice-and-comment period?
7. Is the doctrine of laches legally applicable to this proceeding? If so, explain how the record supports this conclusion.

Appellants Bayer and Nichino are also reminded to provide the Board with specific citations to the record showing where they raised their legal objections to the adequacy of the scientific dialogue in their Request for Hearing and Statement of Objections. Appellee EPA is reminded to provide the Board with recent federal court case law in support of their argument on the applicability of the doctrine of laches.

So ordered.

ENVIRONMENTAL APPEALS BOARD

Dated: June 23, 2016

By: Kathie A. Stein
Kathie A. Stein
Environmental Appeals Judge

CERTIFICATE OF SERVICE

I certify that copies of the foregoing Order on Post-Argument Briefing in the matter of *Bayer CropScience LP, and Nichino America, Inc.*, FIFRA Appeal No. 16-01, were sent to the following persons on June 23, 2016, in the manner indicated:

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Dated: JUN 23 2016


Annette Duncan
Secretary
Environmental Appeals Board