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

PMSD/ISB
2249

APR 6 1988

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: EPA Reg. No. 45639-110. Botran® (DCNA).

Time Extension Requests for Certain Studies
Required by the DCNA Registration Standard.

RCB Nos.: 3609, 3613. MRID No.: None.

FROM: Maxie Jo Nelson, Chemist
Tolerance Petition Section I
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C) *mjn*

THRU: Robert S. Quick, Section Head
Tolerance Petition Section I
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C) *RN*

TO: Lois A. Rossi, P. M. 21
Herbicide-Fungicide Branch
Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

BACKGROUND

By letter dated February 8, 1988, NOR-AM Chemical Company, registrant of products (Botran®) containing 2,6-dichloro-4-nitroaniline (DCNA) as active ingredient, reiterated its requests of November 1987 (to which NOR-AM states it has not yet received any reply) for time extensions for the submission of certain studies (eight) required by the DCNA Registration Standard.

The studies (four) germane to RCB considerations are:

- Peach Metabolism
- Swine Metabolism
- Poultry Metabolism
- Method for Poultry Tissue

NOR-AM is also now requesting time extension requests for additional studies (seven) required by the Registration Standard, only one of which is of relevance to RCB:

- Frozen Storage Stability for Meat and Eggs

A six-month time extension (from 1/30/88 to 6/30/88) is sought for submission of these frozen storage stability data. The reason given is:

" This study has been designed to continue for a full 2-year storage period. However, analysis of the frozen tissue is dependent upon results of the poultry and swine metabolism studies that are still in progress. The additional time requested accounts for the completion of these studies."

Finally, NOR-AM reminds the Agency that it will not be supplying the required residue data to support registered uses on cotton, blackberries, boysenberries, and raspberries for Botran[®] 75W, and on cotton, blackberries, boysenberries, raspberries, nectarines, sweet cherries, and peaches for the Botran[®] Dust products. NOR-AM states the dropping of these uses from the above labeling was approved by the Agency on 10/28/87.

DISCUSSION

The registrant's requests for time extensions for the submission of the studies on:

- Peach Metabolism
- Swine Metabolism
- Poultry Metabolism
- Method for Poultry Tissue

have already been addressed by RCB (memo of M. Nelson, 3/9/88), and no further comment on them by RCB is required at this time.

A copy of that review is attached hereto for the PM's convenience.

The request for the time extension for the submission of the frozen storage stability data for meat and eggs is covered by PR Notice 85-5, which provides guidance on the Agency's policy for granting time extensions for submitting data required to support existing registrations. That Notice indicates that allowances will be made for sequential data requirements, such as are involved in this instance.

CONCLUSIONS

RCB agrees the frozen storage stability study in meat and eggs is a tiered data requirement, dependent upon the outcome of the animal metabolism studies (swine, poultry) currently in progress.

RCB would have no objection to the granting of the requested time extension of 6 months (until 6/30/88) for submitting the frozen storage stability study on meat and eggs. However, the granting of time extension requests is a Registration Division administrative decision.

RCB's comments re the requested time extension requests for the submission of the studies on peach metabolism, swine metabolism, poultry metabolism, and a method for poultry tissues are given in our (M. Nelson) 3/9/88 review on this subject (see Attachment).

Since NOR-AM will not be supplying the residue data required by the DCNA Registration Standard to support registered uses on cotton, blackberries, boysenberries, and raspberries for Botran® 75W, and on cotton, blackberries, boysenberries, raspberries, nectarines, sweet cherries, and peaches for the Botran® Dust products, the PM should notify the other registrants (if any) of products containing DCNA as active ingredient who have uses on these crops of the need to supply the required residue data if registration is to be maintained on these commodities.

Attachment: Memo of 3/9/88, M. Nelson, RCB
EPA Reg. No. 45639-110. Botran® (DCNA)
"Time Extension Requests for Certain Studies"
RCB No. 3176. MRID No.: None.

cc (without Attachment): RF, Circ, Reviewer (M. Nelson), DCNA
Registration Standard File, PMSD/ISB (Eldredge).

TS-769C:RCB:Reviewer(MJN):CM#2:Rm804:557-7324:typist(mjn):4/6/88.

RDI:SectionHead:RSQuick:4/6/88:DeputyChief:RDSchmitt:4/6/88.



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MEMORANDUM

SUBJECT: EPA Reg. No. 45639-110. Botran® (DCNA).
Time Extension Requests for Certain Studies.
RCB No.: 3176. MRID No.: None.

FROM: Marie Jo Nelson, Chemist
Tolerance Petition Section I
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C) *mjn*

THRU: Robert S. Quick, Section Head
Tolerance Petition Section I
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C) *RM*

TO: Lois A. Rossi, P. M. 21
Herbicide-Fungicide Branch
Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

BACKGROUND

By letter dated November 13, 1987, NOR-AM Chemical Company, registrant of products (Botran®) containing 2,6-dichloro-4-nitroaniline (DCNA) as active ingredient, has indicated:

"In the course of performing studies required by EPA under the DCNA Registration Standard [issue date: December 1983], we have determined that problems encountered during some of the studies make it necessary for us to request extensions of time to complete the studies. Enclosed with this letter is an attachment containing reports on the progress of the studies concerned and our estimates of additional time required."

NOR-AM requests time extensions for the following studies which are germane to certain of the residue chemistry data gaps cited in the DCNA Registration Standard:

- Peach Metabolism
- Swine Metabolism
- Poultry Metabolism
- Method for Poultry Tissue

* * *

PR Notice 85-5, dated 8/22/85, provides guidance to registrants regarding the Agency's policy on granting time extensions for submitting data requested to support existing registrations.

Among the reasons cited in that Notice which are acceptable for consideration in the granting of time extensions are:

- "...on a case-by-case basis, consideration will be given to extension requests due to unavoidable analytical problem(s).... However, registrants will be required to demonstrate the validity of the problem(s) and show good faith effort towards resolution."
- "Also, allowance will be made for sequential data requirements in cases where studies cannot be initiated until other studies have been completed."

DISCUSSION

The registrant provides the following explanations for the requested time extensions:

Peach Metabolism

Only 55% of the total residue is extractable, and so far only 55% of that has been identified; the remainder is of a very polar nature and appears to comprise at least 10 minor metabolites. 45% of the total residue remains associated with the fiber and all attempts at characterizing this residue have as yet proved unsuccessful.

Time Extension Needed: 6 months (until July 31, 1988).

RCB Comment: No objection.

Swine Metabolism

Difficulties are being encountered in the identification phase of this study. Progress is slow because of the large percentage of unidentified polar metabolites in the pig liver. There are at least 3 metabolites which are more polar than DCNA and are as yet unidentified.

The metabolite pattern appears at this stage to be more complex than in poultry, or at least different from that in poultry.

Time Extension Needed: 5 months (until June 30, 1988).

RCB Comment: No objection.

Poultry Metabolism

In poultry liver, 3 metabolites which are more polar than DCNA are yet to be identified; these account for 27%, 22%, and 17% of the total radioactivity, respectively.

In egg white, two main TLC bands were seen in acidic solvent; one (40%) remained at the origin and the other (60%) moved from the origin. The component(s) in these bands are as yet unidentified.

Time Extension Needed: 2 months (until March 31, 1988).

RCB Comment: No objection.

Poultry Tissue Residue Method

Development of an adequate residue method is dependent on the results of the poultry metabolism study.

It is anticipated that adequate metabolite identification will not be available before the end of March 1988, so a time extension will be necessary in order to develop residue methodology for poultry tissue.

Time Extension Needed: 2 months past the completion of the poultry metabolism study (until May 31, 1988).

RCB Comment: No objection.

CONCLUSIONS

RCB considers that the registrant is putting forth a good faith effort to complete the peach, swine, and poultry metabolism studies, and that the requested time extensions are reasonable on scientific grounds and within the scope of PR Notice 85-5.

RCB agrees the development of poultry tissue residue methodology is a tiered data requirement, dependent upon the outcome of the poultry metabolism study.

RCB would have no objection to the granting of the requested time extensions; however, the granting of these time extension requests is a Registration Division administrative decision.

cc: RF, Circ, Reviewer (M. Nelson), DCNA Registration Standard File, PMSD/ISB (Eldredge).

TS-769C:RCB:Reviewer(MJN):CM#2:Rm804:557-7324:typist(mjn):3/8/88.

RDI:SectionHead:RSQuick:3/8/88:DeputyChief:RDSchmitt(byKHArne):3/9/88.