

PMSS/ISS



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

DEC 7 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. No. 45639-128. DCNA

Request for Time Extensions for the Submission of
Certain Studies Required by the DCNA Registration
Standard.

DEB#: 4450 HED#: 8-1293 MRID#: None

FROM: Maxie Jo Nelson, Chemist
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mjn

THRU: Robert S. Quick, Section Head
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TO: Lois A. Rossi, PM Team 21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

and

Toxicology Branch - HFA Support
Health Effects Division (TS-769C)

BACKGROUND

By letter dated August 10, 1988, NOR-AM Chemical Company, reg-
istrant of products (Botran®) containing 2,6-dichloro-4-nitro-
aniline (DCNA) as active ingredient, has requested time exten-
sions for the submission of certain studies required under the
DCNA Registration Standard.

The three studies involved and the new dates requested are:

- Analytical Methodology for Animal Tissues, Eggs and Milk: June 1, 1989
- Storage Stability in Meat and Eggs: January 30, 1989
- Storage Stability of Metabolites: December, 1989

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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 is: "Allowance will be made for sequential [tiered] 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:

Residue Analytical Methodology In Animal Commodities

NOR-AM: The poultry metabolism study submitted (6/88) in response to the Standard indicates two significant metabolites of DCNA in the hen: 4-amino-3,5-dichloroacetanilide and 2,6-dichloro-4-nitrophenol. Available methodology is for DCNA only. Analytical methodology for these metabolites in animal tissues, eggs, and milk is now under development. A time extension until 6/1/89 is requested for completion of this work.

DEB: No objection; sequential data.

Storage Stability in Meat and Eggs

NOR-AM: The analysis of these frozen materials is dependent upon the completion of poultry and swine metabolism studies, the latter of which will not be completed and available for submission until late September, 1988. To allow adequate time for analysis of the storage study samples, reporting, and quality assurance evaluation of the storage stability report and data, a time extension until 1/30/89 is requested for submission of the report.

DEB: We find NOR-AM's reasoning to be puzzling since they also indicate (see Storage Stability of Metabolites, below) this storage stability study was designed for parent DCNA only. That being so, analysis of stored samples for residues of DCNA would not be dependent upon the outcome of the metabolism studies. DEB does not consider NOR-AM's explanation supports the granting of this time extension. However, we also note this is almost a moot point since 1/30/89 is fast approaching.

Storage Stability of Metabolites

NOR-AM: The aforementioned storage stability study was designed for parent DCNA only. Since we now know there are metabolites of significance, we are planning an additional storage stability study to evaluate them. Assuming this additional study is set up to run for at least 12 months, we anticipate a reporting date of December 1989; at that time a determination will be made whether to continue the study.

DEB: No objection; tiered data.

CONCLUSIONS

1. DEB does not object to the requested time extensions of:
 - Analytical Methodology in Animal Tissues, Eggs and Milk - June 1, 1989
 - Storage Stability of Metabolites - December, 1989
2. DEB does not consider NOR-AM's explanation supports the granting of the requested time extension of:
 - Storage Stability in Meat and Eggs - January 30, 1989However, we also note this is almost a moot point since 1/30/89 is fast approaching.
3. DEB recognizes that the granting of time extension requests is a Registration Division administrative decision.

cc: M. Nelson (DEB), DCNA Registration Standard File, Reading File, Circulation (7), E. Eldredge (ISB/PMSD).

TS-769C:DEB:Reviewer(MJN):CM#2:Rm804:557-7324:typist(mjn):12/7/88.
RDI:SectionHead:RSQuick:12/7/88:DeputyChief:RDSchmitt(ByRALoranger):
12/7/88.