

US EPA ARCHIVE DOCUMENT



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

OCT 27 1988

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. No. 10182-234. Phosmet.

Time Extension Request for Submission of the Nature  
of the Residue (Metabolism) - Livestock Studies  
Required by the Phosmet Registration Standard.

DEB#: 4487. HED#: 9-0150. MRID#: N/A.

FROM: Maxie Jo Nelson, Ph.D., Chemist  
Tolerance Petition Section I  
Dietary Exposure Branch  
Health Effects Division (TS-769C)

*mjn*

THRU: Robert S. Quick, Section Head  
Tolerance Petition Section I  
Dietary Exposure Branch  
Health Effects Division (TS-769C)

*rsq*

TO: G. LaRocca/A. Heyward, PM Team 15  
Insecticide-Rodenticide Branch  
Registration Division (TS-767C)

and

Toxicology Branch  
Health Effects Division (TS-769C)

BACKGROUND

ICI Americas Inc. has submitted a letter to the Agency dated  
9/29/88, which contains the following statements:

"The Guidance Document for the reregistration of  
Phosmet issued 10/14/86 established a requirement  
for ruminant and poultry oral as well as beef  
cattle and swine dermal <sup>14</sup>C-ring or carbonyl-  
labelled metabolism studies. Your letter [Office  
of Compliance Monitoring] of 8/3/87, after review  
of the programs, required the submission of each  
of these four studies by 12/88.

"ICI Americas Inc. contracted with a reputable lab, Analytical Development Corporation, to conduct all of these studies targeting for completion 10/1/88. Their letter of 8/11/88 describes the technical difficulties they have encountered with the studies. On the basis of these unforeseen technical problems, we hereby request an extension of one year."

#### DISCUSSION

The 8/11/88 letter submitted to ICI Americas Inc. by Analytical Development Corporation describes the technical difficulties they are encountering in conducting these metabolism studies, as follows:

"The metabolism of the compound [phosmet] is quite complex. We have experienced difficulty in extracting <sup>14</sup>C-activity from the tissues of the treated animals with the usual organic solvent extraction procedures. The compounds containing <sup>14</sup>C-activity are soluble in water, and therefore, difficult to isolate for identification. In addition, the greatest portion of <sup>14</sup>C-activity that has been examined has not yet been shown to match any of the Imidan [aka phosmet] parent or metabolite reference standards.

"For these reasons, we are requesting the extension of our deadline from 10/1/88 to 10/1/89."

PR Notice 85-5 provides guidance on the Agency's policy for the granting of time extensions for submitting requested data to support existing registrations. Normally, time extensions are only granted under the circumstances identified in that Notice.

PR Notice 85-5 does provide that, on a case-by-case basis, consideration will be given to extension requests due to unavoidable analytical problems(s).

The ICI Americas Inc. request falls within that category.

Moreover, considering that several metabolism studies are involved in this particular case, we do not consider the one year time extension being requested by ICI Americas Inc. to be unduly long.

CONCLUSIONS

1. DEB has no objection to the granting of the one year time extension request (until 12/89) for the submission of the Nature of the Residue (Metabolism) Livestock studies required by the Phosmet Registration Standard.
2. DEB recognizes the granting of a time extension request is an administrative decision of the Registration Division.

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

TS-769C:DEB:Reviewer(MJN):CM#2:Rm804:557-7324:typist(mjn):10/26/88.

RDI:SectionHead:RSQuick:10/26/88:DeputyChief:RDSchmitt:10/26/88.