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Atrazine / Review # 50 / 1-21-83 / 4 pages

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

Releasable

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TO: Anne Barton, Deputy Director
Hazard Evaluation Division (TS-769)

THRU: Laurence D. Chitlik, Section Head
Review Section #5
Toxicology Branch/HED (TS-769)
and
Orville E. Paynter, Ph.D.
Chief, Toxicology Branch
Hazard Evaluation Division (TS-769)

LDC 1/21/83

SUBJECT: Memo of January 4, 1983 Regarding the Validation of Two Additional IBT Studies of Atrazine

My memo of January 4, 1983 (attached), regarding the validation of two additional IBT studies (mouse oncogenicity and rat chronic feeding studies of Atrazine) appears to have not clearly communicated the reasons for the late addition of these studies into the IBT validation program. For this reason, additional background information is being submitted for the record.

Toxicology Branch has been aware of the need for validation of these studies since October 8, 1983, when Dr. Spencer discovered their existence after review of SPRD data call-in files for the Atrazine Registration Standard. SPRD was informed of this issue immediately and Arty Williams of SPRD notified Toxicology Branch that Atrazine studies were assigned to Canada for validation. We were also informed that SPRD would check with Canada as to their validation status. Soon afterwards it was learned that these studies had not been sent to Canada for validation. Arty Williams indicated that she would ascertain when these studies would be validated and she would get back with us when she knew more. A number of weeks went by and SPRD did not get back to us. Dr. Spencer called Canada and was immediately informed that they had completed their review of Atrazine and would not validate these additional studies. At this point the available data was immediately forwarded to SPRD to be entered into the U.S. validation program.

Although the events described above occurred in September, October and November, as of December 17, 1982 (when this reviewer discussed Atrazine validation status with Ms. Williams) the studies had not yet entered the validation process. Further delay in their validation has occurred due to the failure of the registrant to submit all of the supporting raw data until January 7, 1983, subsequent to a request by this reviewer.

As noted in my previous memo, the late addition of these studies into the validation program preclude their use in February 1983 for the Atrazine Registration Standard or completion of the validations before the February 28, 1983 deadline for completion of all IBT validations.

Footnote: We have recently learned from the registrant that 4 studies on CGA-12223 submitted by Ciba-Geigy to SPRD months ago have not yet been submitted to HED for validation. If this is indeed the case, these studies may not be completed until several months after the February deadline. Ferial Bishop of the Process Coordination Branch has been informed of this development.

Gary J. Burin, Toxicologist
Toxicology Branch
Hazard Evaluation Division (TS-769)

Attachment

CC: Arlene } info
SIS }
M1170 - please note in Status report

Bill Burns } Can't we improve Communication within TOX to avoid these problems?
Orv. Paynter }

Arne

LC see what you can do about this
OEP

MEMORANDUM

TO: John W. Melone, Director
Hazard Evaluation Division (TS-769)

THRU: Laurence D. Chitlik, Section Head
Review Section #5
Toxicology Branch
Hazard Evaluation Division (TS-769)

THRU: Orville E. Paynter, Ph.D.
Chief, Toxicology Branch
Hazard Evaluation Division (TS-769)

SUBJECT: Validation of Additional IBT Studies: Atrazine Mouse Oncogenicity and Rat Chronic Oral Toxicity

On December 17, 1982, this reviewer discussed the validation status of Atrazine with Arty Williams of SPRD. During the discussion it was found that two IBT studies on Atrazine (a mouse oncogenicity study, IBT#3580-8906 and a rat chronic feeding study, IBT#622-6769) have been submitted by the registrant for validation. These studies have not yet entered the validation process despite the fact that Dr. Henry Spencer of Toxicology Branch noted that they required validation during the review of studies for the registration standard in September of this year.

The two studies were promptly obtained from SPRD and sent to our contractor for validation.

It is noted that the Registration Standard for Atrazine is scheduled to be completed in February of 1983 and that, given the amount of time required to properly validate and if necessary evaluate long-term studies such as these, the findings of these

studies are not likely to be available for incorporation into the Registration Standard. It is also noted that they are not likely to be completed before the February 28, 1983 deadline for completion of all IBT validations.

Gary J. Burin, Toxicologist
Toxicology Branch
Hazard Evaluation Division (TS-769)

cc: Kevin Keaney
Henry Spencer

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