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

OCT 5 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: Aldicarb: Comments on Rhone-Poulenc's Request for Time Extensions for Specific Items of the Aldicarb Data Call-In.

FROM: Joel Garbus, PhD., Chemist *Joel Garbus*
Dietary Exposure Branch
Health Effects Division (H7509C)

THRU: Philip Errico, Head *Philip Errico*
Tolerance Petition Section III
Dietary Exposure Branch
Health Effects Division (H7509C)

TO: Jack Housenger, Head
and
Bruce Kapner
Risk/Benefit Section I
Special Review Branch
Registration Division (H7505C)

Rhone-Poulenc has sent a letter to Bruce Kapner of Special Review Branch formally requesting time extensions to generate certain data requested in the Aldicarb data call-in of June 9, 1989. The registrant's proposals in this regard were informally presented at a meeting with Rick Tinsworth on August 17th. Joel Garbus represented DEB at that meeting.

Here we will restrict our comments to issues in which DEB has an interest.

Reanalyses of food survey samples with detectable residues greater than 10 ppb.

The company agrees to conduct the analyses of individual samples of those composite samples of the Aldicarb National Food Survey (ANFS) that showed detectable residues. The company estimates that this will require the analyses of some 800 samples and take 8

months at the rate of 5 samples a day. Therefore, they request an extension of 2 months until February 1990.

DEB's Comment

A time extension should not be necessary as the analyses of all samples in the ANFS with detectable residues is not needed.

The purpose of this data request was to determine whether or not all individual components of a composite sample have similar residue levels. This is of importance in dealing with an acutely toxic pesticide.

The company has argued vigorously that all individual components in a sample are considered to have been derived from the same growing site. Therefore, all were treated alike from planting through harvest to shipping and marketing; therefore, all individual components of a composited sample should have similar residue levels.

The DCI request was to test this assumption. If individual components of the sample had similar residue levels to that found for the composite we could be confident of using the composite values with its experimentally determined variance for the purposes of risk assessment. If the individual values were to differ widely from the composite values, we could, in those instances, use the highest values found for the individual components for risk assessment.

Furthermore, we are only interested in residue levels of potential toxicologic concern. Therefore the samples we wish to have additional information about are those with the highest level of residues of aldicarb. In the national food survey there were 28 composite samples with residue levels greater than 50 ppb and 8 with residue levels greater than 100 ppb (bananas: 6 samples at 50 to 100 ppb and six samples greater than 100 ppb; potatoes: four samples at 50 to 100 ppb and three samples greater than 100 ppb). We would suggest that Rhone-Poulenc analyze these samples first and submit an interim report. Based upon these results, which we estimate could be obtained within a few months, the Agency could determine whether or not all samples with detectable residues would need to be analyzed.

Degradation of residues in potatoes during normal storage

It was suggested in the DCI that Rhone-Poulenc immediately begin these studies by obtaining commercially grown, aldicarb-treated potatoes from the current (Fall of 1989) harvest.

Rhone-Poulenc instead proposes to conduct its tests by treating potatoes at exaggerated rates in the 1990 growing season beginning with Florida where potatoes may be planted late in the current year

or early next year. Allowing for the harvest of potatoes during the 1990 growing season, the storage required and the analyses, Rhone-Poulenc believes it can have the results of the studies submitted by April 1, 1991 or September 1 1991 or April 1 1992, depending upon the length of storage required.

Rhone-Poulenc is reluctant to obtain commercially grown potatoes known to have been treated with aldicarb for this study. It cites as reasons: a) the number of variables to be evaluated, b) the inability to assure the agency that the application of aldicarb to commercially grown potatoes met the requirements of good laboratory practice, and c) "with a significant fraction of treated crop normally showing no detectable residue, even in controlled field residue trials, and another large segment of crop likely to have inadequate residues to establish a decline curve during months of storage, it is problematical whether we could obtain adequate samples for testing."

DEB's Comments

DEB has no objection to this request for a time extension, provided that the company can document its objections to using potatoes from the current harvest and demonstrate that its proposed protocol is the only feasible means of obtaining the requested data.

DEB believes that the company can obtain adequate data using aldicarb treated potatoes from the current growing season. The purpose of the requested data is to determine the half-life of aldicarb residues in treated potatoes. Currently both the company and the agency are assuming a half-life of about six weeks for residues, based upon a poorly controlled study conducted in the early 70's. The data are needed to determine whether or not aldicarb residues do in fact decline in stored commodities, whether or not certain results of the ANFS are reasonable and to refine risk assessment.

The company makes several points in its request for a time extension. As to the objection that several variables need to be tested, (variety, soil, climate, etc.), DEB is willing to accept as an initial estimate of the half-life, results obtained using potatoes from the current harvest. [We note that in its proposed protocol for this study Rhone-Poulenc discounts these variables and proposes to do the study at one site with one variety of potato.] All protocols, whether for a study using current harvest or for those utilizing projected field trials, will have to be statistically acceptable.

As to the point that good laboratory practices could not be assured if commercially treated potatoes were to be used, in this instance DEB is willing to accept data regarding the application of the pesticide as long as all field application data are obtained from certified applicators of restricted use pesticides. The company

should indicate that this portion of the study was not conducted under GLP. We expect that the company would follow such practices once it obtained commercially grown samples and would continue to do so for the duration of the study.

DEB rejects the argument that it would be difficult or unlikely to obtain potatoes with significant residues of aldicarb in this harvest season. Field trial studies have shown that 90% of all potatoes treated at all rates of application at all PHI's have detectable residues of aldicarb. Fifty-five percent have residues greater than 100 ppb. Testimony of potato growers at the May SAP meeting on Aldicarb and information submitted by potato growing and marketing associations indicate that the current rate of application is about 2 lbs/A, at least in the Pacific Northwest. At this rate of application 62% of potatoes have been shown to have residues greater than 100 ppb. This is borne out by results submitted from processing facilities in Oregon showing substantial residue levels in aldicarb treated potatoes prior to processing.

It may be that the use of aldicarb on potatoes in the Northwest has substantially decreased. However, DEB believes that the company should be required to make a good faith effort to locate aldicarb treated potatoes and to begin the study in this harvest season. The company should document its efforts to locate growers who used aldicarb at sufficient rates to insure adequate residue levels and report its success or failure to the Agency in a timely manner.

As to the argument that exaggerated rates are needed, assuming a half-life of six weeks and a storage period of six months with residue levels continuously declining during that period, an initial residue of 16 ppb is required in order to obtain the required data. Such a residue level has been reported in 20% of field trials at the 2 lb rate. However a full study over the six month interval is not necessary for DEB's purposes.

Although DEB would welcome the results of the full detailed study, for its purposes the results of a study conducted with fall harvest potatoes would be adequate. DEB suggests that Rhone-Poulenc proceed along two tracks, attempting to obtain the required information from the current harvest and planning to conduct the studies with its own field trials. If the company makes a good-faith effort and conclusively finds that it cannot obtain the requested data, it could institute the full field studies.

If the company elects to begin immediately with commercially grown potatoes, the company should submit interim results as quickly as feasible. The Agency could then determine whether the results of the proposed field trial study would be needed.

Cooking studies

The company raises objections to conducting a cooking study with potatoes from the current harvest similar to those raised for the degradation studies and proposes a time extension .

DEB Comment

DEB would raise the same objections to the requested time extension as it raised in regard to the degradation study. DEB considers that adequate potato processing studies can be conducted with potatoes from the current harvest.

Additional Comments

DEB in conjunction with the statistical branch of OPPE is currently reviewing the submitted protocols for these studies. The Agency's response will be forwarded to the registrant as soon as it is available. One point that we would wish to stress at this time is the need for a complete statistical analysis as a component of the protocols required in the 3(c)2(b) letter of 6/9/89. According to OPPE the submitted protocols do not satisfy the required statistical analyses.

cc: I.Schulze, P. Errico, E. Zager, R. Schmitt, Aldicarb
Subject File, RF., Circ., Reviewer, PMSD/ISB
RDI: PE:10/3/89:RAL:10/3/89
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