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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: Aldicarb: Review of Results of the Reanalysis of Components of the Aldicarb National Food Survey Submitted in Response to Data Call-In Notice.

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

THRU: Richard D. Schmitt, PHD., Chief
Dietary Exposure Branch
Health Effects Division (H7509C)

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

Rhone-Poulenc as the registrant of aldicarb has submitted the results of its reanalysis of components of the Aldicarb National Food Survey (ANFS) as required by the aldicarb data call-in of 6/3/89.

The purpose of this particular data request was to determine whether all individual components of a composite sample have similar residue levels. This is of importance in dealing with an acutely toxic pesticide. 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, it may be more appropriate to use the highest values associated with the individual components for risk assessment.

The company was requested to analyze individual components of the composited samples of ANFS that showed detectable residues greater than 10 ppb. The commodities that the DCI requested to be

reexamined were potatoes, sweet potatoes, bananas, oranges, and grapefruit.

One half of each individual commodity of the sample as purchased had been kept at -15°C since the original analyses in 1987. The remaining halves were individually analyzed for total toxic residue using the method originally employed for the composited samples of the ANFS.

Storage stability studies submitted with petition data had shown stability for aldicarb under these conditions for at least 2 years.

Results

The results of the ANFS showed that of the composited samples, 17 white potato samples, 5 sweet potato samples, 10 grapefruit samples, and 29 banana samples had residues equal to or greater 10 ppb. (Detectable residues were not found in orange samples.) Consequently, 183 individual white potatoes, 44 sweet potatoes, 45 grapefruit, and 337 bananas were examined for aldicarb residues. The results are given in the tables appended to this review. Below we present and discuss the results of the analyses of the specific commodities.

Potatoes

ANFS Potato Samples - Individual Analyses

Sample ID	N*	Range (PPM)	Original Mean	New Mean	Std. D
RG563	13	<0.01 - 0.05	0.02	0.02	0.01
RG770		LOST			
RG815	14	<0.01 - 0.05	0.01	0.02	0.01
RG1013	9	<0.01 - 0.12	0.03	0.04	0.04
RG1103	16	<0.01 - 0.10	0.01	0.02	0.03
RG1247	8	<0.01 - 0.04	0.01	0.01	0.01
RG1292		LOST			
RG1672	12	<0.01 - 0.07	0.02	0.03	0.02
RG1680	18	<0.01 - 2.1**	0.14	0.16	0.49
RG1682	14	<0.01 - 0.50	0.11	0.10	0.13
RG1686	13	<0.01 - 0.25	0.06	0.06	0.02
RG1691	6	<0.01 - 0.05	0.01	0.02	0.02
RG1692	15	<0.01 - 0.17	0.06	0.06	0.04
RG1704	14	<0.01 - 0.24	0.04	0.05	0.08
RG1708	15	0.08 - 0.49	0.18	0.23	0.14
RG1722	9	0.01 - 0.06	0.03	0.03	0.02
RG1723	7	0.02 - 0.16	0.09	0.07	0.04

* = Number of components in sample
** = Includes residue value(s) greater than tolerance

Although there is a good correspondence between the average of values of the reanalyzed commodities of any sample and the value originally obtained for that composite sample, there is considerable variation in the range of individual values in a given sample. The ratios of the lowest residue value in any sample to the highest range from 4 fold to greater than 200 fold, including one potato at twice the tolerance level. (None of the composited samples exceeded the white potato tolerance of 1.0 ppm.)
Roughly half of the reanalyzed samples have residue levels in the individual commodities that are close to each other, while the remainder have widely varying individual levels.

Accepting the premise that all the potatoes in the purchased sample were from the same field casts doubt on the assumption that all potatoes in a uniformly treated field would contain roughly the same residue levels. The aldicarb data call-in requests that experiments be conducted to answer the question of the uniformity of residue levels in individual potatoes harvested from uniformly treated fields. The registrant has submitted a protocol designed to obtain this information.

Sweet Potatoes

ANFS Sweet Potato Samples - Individual Analyses

Sample ID	N*	Range (PPM)	Original Mean	New Mean	Std. D
RG1580	7	0.02 - 0.14	0.03	0.06	0.04
RG1605	18	<0.01 - 0.24**	0.06	0.07	0.06
RG1619	7	<0.01 - 0.11**	0.02	0.04	0.04
RG1625	9	0.03 - 0.29**	0.06	0.10	0.09
RG1636	3	0.01 - 0.05	0.02	0.03	0.02

* N = Number of individual commodities in sample
** Greater than the tolerance of 0.1 ppm

Of the 44 individual sweet potatoes comprising the 5 composited samples, 10 have residue levels of aldicarb equal to or greater than the tolerance for sweet potatoes of 0.10 ppm. However, the mean residue values of the composited samples did not exceed the 0.01 ppm tolerance. As with white potatoes, considerable variation was found in individual components of a given sample. As with white potatoes, there is no satisfactory explanation for this finding. If all the sweet potatoes in the 5 lb. purchased sample came from the same treated field there had to be wide variation in the residue levels of commodities in one field. If the samples were a mixture of commodities from various growing sites, these results would indicate that RAC's from some sites were over tolerance.

These sweet potato samples were purchased in Whitstone, NY; Kansas City, MO; Wilson, NC; Louisville, KY; and Chandler, OK,

respectively. The data for the points of purchase do not indicate where the sweet potatoes were grown and thus no area can be identified as the site or sites of the over-tolerance commodities.

Grapefruit

ANFS Grapefruit - Individual Analyses

Sample ID	N*	Range (PPM)	Original Mean	New Mean	Std. D
RG786	6	<0.01 - 0.04	0.01	0.02	0.01
RG858	6	0.02 - 0.08	0.04	0.05	0.02
RG867			L O S T		
RG894	5	0.01 - 0.04	0.02	0.03	0.01
RG912	4	0.01 - 0.03	0.02	0.02	0.01
RG930	5	<0.01 - 0.10	0.03	0.04	0.03
RG966	5	<0.01 - 0.05	0.01	0.02	0.02
RG975	6	<0.01 - 0.03	0.02	0.02	0.01
RG993	4	0.01 - 0.04	0.02	0.02	0.01
RG1110	4	<0.01 - 0.05	0.03	0.033	0.02

* N = Number of individual commodities in sample

Only the edible pulp was analyzed. The peel was discarded. Reanalyses of the individual components of the grapefruit composite samples with detectable residues did not show a wide variation in residue levels in the components of the sample. None of the individual values exceeded the citrus tolerance of 0.3 ppm.

Bananas

ANFS Banana Samples - Individual Analyses

Sample ID	N*	Range (PPM)	Original Mean	New Mean	Std. D
RG64	10	<0.01 - 0.03	0.01	0.02	0.01
RG307	12	<0.01 - 0.05	0.02	0.02	0.02
RG577	13	0.01 - 0.10	0.04	0.05	0.03
RG649	10	<0.01 - 0.11	0.05	0.05	0.05
RG694	8	0.01 - 0.04	0.02	0.03	0.01
RG712	13	<0.01 - 0.06	0.03	0.03	0.01
RG721	12	0.02 - 0.07	0.03	0.04	0.02
RG757	12	<0.01 - 0.15	0.11	0.08	0.05
RG775	9	0.03 - 0.08	0.06	0.06	0.02
RG784	13	0.04 - 0.08	0.06	0.06	0.01
RG811	9	0.06 - 0.31**	0.22	0.22	0.10
RG928	14	0.02 - 0.05	0.04	0.04	0.01
RG1108	11	0.05 - 0.13	0.07	0.08	0.04
RG1171	14	0.02 - 0.24	0.12	0.11	0.08
RG1189	13	<0.01 - 0.06	0.04	0.03	0.02
RG1355	7	0.04 - 0.11	0.05	0.07	0.02
RG1356	12	0.02 - 0.06	0.03	0.04	0.01

(Continued)

Sample ID	N*	Range (PPM)	Original Mean	New Mean	Std. D
RG1358	10	<0.01 - 0.62**	0.23	0.49	0.18
RG1360	14	<0.01 - 0.19	0.07	0.08	0.01
RG1362	11	0.02 - 0.04	0.02	0.02	0.01
RG1363	12	0.02 - 0.08	0.02	0.04	0.01
RG1383	13	0.03 - 0.35**	0.11	0.13	0.10
RG1384	14	<0.01 - 0.09	0.02	0.03	0.02
RG1399	13	0.06 - 0.14	0.03	0.07	0.02
RG1408	10	<0.01 - 0.04	0.01	0.02	0.01
RG1411	7	0.03 - 0.03	0.03	0.03	---
RG1412	16	0.02 - 0.05	0.02	0.03	0.01
RG1415	11	<0.01 - 0.01	0.01	0.01	---
RG1423	15	<0.01 - 0.08	0.04	0.05	0.10

* = Number of components in sample
** = Includes residue value(s) greater than tolerance of 0.30 ppm.

Only the edible pulp was analyzed. The peel was discarded.
Of the 29 samples of bananas that were examined, the analyses of the individual components led to average results that were close to that of the original composited value in 27 instances. In the remaining 2 samples (RG1358 and RG1399) the averaged reanalyzed values were twice that of the original composite value. The reasons for this are unexplained.

For 16 of the samples the values found for each of the individual bananas was in close agreement with the value found for the composited sample. For the remaining samples (RG's 577, 649, 757-, 811, 1108, 1171, 1189, 1355, 1358, 1360, 1383, 1384, and 1423) there appears to be 2 clusters of values in each sample.
In these instances, the results of the individual analyses are understandable if we assume that the samples consisted of bananas from 2 distinct hands.

We do not have data that shows that all of the individual bananas in a hand treated with a systemic pesticide have a narrow range of residue levels. However, accepting this assumption and the proviso that all bananas in a sample come from the same hand, we can conclude that the composite values for bananas reflect the residue level of the individual components of the sample.

Of concern is the finding of a considerable number of over-tolerance individual bananas in composite samples that, in themselves, did not exceed the tolerance of 0.3 ppm. Of the 332 individual bananas examined, 12 (3.6%) contained residues ranging from 0.3 ppm to 0.62 ppm, residue levels greater or equal to the tolerance. If the total number of bananas sampled in the ANFS was about 2600, then about 0.5% of the bananas were over tolerance.

The over-tolerance bananas were found in samples RG811, RG1358, and RG1383 purchased in Cleveland in May of 1987, and in Butler, PA, and Osage City, KS, in September of 1987, respectively. All these samples bore the producer's identity code of "D".

In its cover letter accompanying the data, the registrant indicates that it is aware of the problem of over-tolerance residues in aldicarb treated bananas. The registrants states that it became aware of the problem in 1985 when over-tolerance bananas were detected on a site in Costa Rico. This instance was brought to the attention of the Agency in a letter dated July 8, 1986. At the time that it became aware of the problem, the registrant states that it instituted a "stewardship" program in conjunction with growers to insure that bananas would not have excess aldicarb residues. The program consisted of reducing aldicarb application per season, the use of specific metering application equipment, the introduction of a special formulation of aldicarb for this equipment.

According to the registrant, this stewardship program went into effect in 1985 or 1986. However, the bananas with the over-tolerance residues were purchased in the US in May and September of 1987. This means that either the program was not fully in place or was not fully effective at that time.

At present the Agency has no way of knowing if individual bananas currently being purchased and consumed in the US have excess residues of aldicarb. The registrant writes that it has reasons to believe that this is not now the case. This belief is based on "extensive monitoring by Rhone-Poulenc, major international banana production companies, and the Federal Food and Drug Administration. . . .." Rhone-Poulenc "is working with the major production companies to identify the proper mechanism for this data to be made available to the EPA."

The company proposes to do the following:

1. Formally amend the directions for use on bananas by reducing the amount applied per year to 30 grams from the present 90 grams and require the use of specific precision applicators.

2. Require that aldicarb be sold only to growers who could demonstrate that they possessed the technical expertise to apply the pesticide in the recommended manner. (We note that no enforcement procedures are described.)

3. Provide a special formulation for use on bananas only.

4. Recommend that aldicarb be used in alternating rotation with other insecticides/nematocides.

5. Implement a banana sampling program to demonstrate the effectiveness of the above measure.

If this program is implemented for bananas, additional residue data should be generated to determine whether the existing banana tolerance is still adequate.

Comments

The request for the analysis of the individual components of the samples of the ANFS was prompted by the need for potential aldicarb residue values to use in dietary risk assessment. Aldicarb is an acute toxicant. The commodities on which it is used most are generally consumed or can be consumed as single entities, that is a banana or an orange or grapefruit or as a baked potato, either white or sweet. Therefore it was important to know whether the values of the composited samples of the ANFS were reflective of the residue levels on the individual commodities.

If the components of the composited sample were all subjected to the same treatment and remained together from field to point of purchase it appeared reasonable to assume that the composited value and individual residue levels would be similar. If, how- ever, there were significant variations in residue levels in commodities from a treated field, if commodities were intermixed at point of purchase, or both, there would significant differences when the results of analyzing individual components were compared with the residue level of the composite sample.

Such differences were found with white potatoes, sweet potatoes, and bananas. We therefore recommend that the residue values for the dietary risk assessment of aldicarb be based upon the residue values of the individual components of the ANFS samples.

The Agency should be concerned that over-tolerance residue levels were detected in individual white potatoes, sweet potatoes, and bananas.

We must bear in mind that the tolerances for these commodities were based upon results obtained from composited samples and that analytic methods for enforcement are also based upon composited samples. As a result, these over-tolerance commodities would not be detected in conventional residue trials and monitoring programs. The problem of residue levels in individual commodities exceeding tolerances needs to be addressed by the Agency.

cc: P. Errico, E. Zager, R. Schmitt, B. Kapner, Aldicarb Subject File, RF., Circ., Reviewer, PMSD/ISB
RDI: PE:2/28/90:RAL:2/28/90:EZ:3/2/90
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