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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Aldicarb: Review of the Aldicarb National Food Survey. Relevance of the Results to Dietary Exposure Assessment. Access. No. 405518-00; RCB No. 3527

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During 1987, Rhone-Poulenc, the successor to Union Carbide as the registrant of aldicarb, conducted a nationwide survey to determine the residue levels of aldicarb in food at the point of sale. Food items (citrus, bananas, and potatoes) representative of the major uses of aldicarb were purchased at 75 retail outlets throughout the nation. The location and size of the food markets had been selected as a stratified sample representative of 90% of American retail food purchases. In 1987, samples were obtained three times, in the winter, in the spring, and as a combined summer/fall sample. The samples were sent to Rhone-Poulenc's Research Triangle Park laboratories for analyses for aldicarb residues. The results were used by Technical Assessment Systems, Inc. to determine the dietary exposure associated with aldicarb use.

Technical Assessment Systems, Inc. also has calculated dietary exposure on the basis of tolerance levels, and 95th percentile values of residues found in all residue trials for all registered commodities. Dietary exposures based on these values considerably exceed the ADI.

Residue levels found in the food survey are lower than those used for the dietary exposure assessments of the PD2/3 which were anticipated residues derived from field trial results. RCB has been requested to update its dietary exposure assessment by including the results of the Aldicarb National Food Survey.

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Conclusions and Recommendations

1. The residue levels found for potatoes are lower than the results anticipated from field trial residue and monitoring data. Possible explanations for the difference may be a decline in aldicarb residues during storage of potatoes, lessened use of aldicarb by potato growers (a "market disruption") and differences in sampling and sample preparation.

2. The registrant should determine the stability of aldicarb in commodities stored under current market conditions to determine if storage can account for the lower level or absence of aldicarb residues in commodities as purchased.

3. The registrant should attempt to provide explanations for the discrepancy between previous residue levels of field trials and monitoring data and those actually found in the food survey.

4. The registrant should supply full information as to sample preparation including washing, peeling, etc.

5. The TAS calculations should be done using a range of all values equal to or greater than 0.01 ppm found in the Aldicarb National Food Survey including the 95th and 99th percentiles and the maximum value.

	Range	95th %tile	99th %tile	Max.
Bananas:	0.01-0.23	0.15 ppm	0.20 ppm	0.23 ppm
Infant Bananas	0.01-0.03	0.02 ppm	0.02 ppm	0.03 ppm
Oranges:	0.01-0.01	0.01 ppm	0.01 ppm	0.01 ppm (L.o.D.)
Grapefruit	0.01-0.05	0.04 ppm	0.05 ppm	0.05 ppm
Potatoes	0.01-0.19	0.15 ppm	0.19 ppm	0.19 ppm

6. The maximum values found in the food survey for citrus and potatoes, the results of current residue trials, monitoring data, and lessened usage suggests that tolerances and maximum allowable application rates be revised downward.

7. RCB will submit the protocol and results of the Aldicarb National Food Survey to statisticians in OPPE for their comment.

8. RCB recommends that the Aldicarb National Food Survey be continued so as to demonstrate that the present results do not reflect temporary "market disruptions". Prior to the initiation of a new survey, the experimental design should be reviewed by the Agency's Quality Assurance Management Staff.

Design of National Food Survey

The selection of the 75 sampling areas was done by the A.C. Nielson Co. Nielson used as a base its Nielson Food Index which is a survey of the food buying preferences of American consumers derived upon the analyses of purchases and inventory of a selected

group of 1050 food retailing establishments. Stores in the Index have minimum annual retail sales of $2,000,000. From this base Nielsen selected 75 stores as the sampling units to be employed for the aldicarb national food survey. It is noted that the 75 representative areas are not the same as those of the 72 Primary Sampling Units (PSU) as defined by the Bureau of Labor Statistics (BLS). According to Nielsen's survey design statisticians these 75 sampling units provide a more statistically valid representation of nationwide food buying habits.

The Nielsen statisticians calculated that the use of a sample of this size, i.e. 75, would result in a standard error of 11%. If there were no significant variation among the 3 seasonal samples, the sample size would be increased to 225 and the error reduced to 9.4%.

The actual purchasing of the selected commodities at the specfied sites was done by employees of Superior Product Pickup Services. A detailed protocol was devised to insure that the proper commodity was obtained and that a documented history could be established for each sample. At each site the following commodities were obtained:

Bananas	
Fresh	5 lbs
Infant food	4 jars
Potatoes	
Fresh (Idaho)	5 lbs
Sweet Potatoes	
Fresh	5 lbs
Infant food	4 jars
Oranges	
Fresh	5 lbs
Processed, Chilled	
Adult Juice	4 one quart cartons
Orange Juice	
Processed Strained	
Infant Juice	6 bottles
Grapefruit	5 lbs

Purchases of the adult foods were of the leading brands for each commodity. Infant foods were to be of the three major national brands, (presumably Gerber, Beechnut, or Heinz). Fresh produce was to be undamaged and in intact 5 lb bags if possible. Samples were refrigerated as needed and shipped to Union Carbide's analytical laboratories in Research Triangle Park within 2 or 3 days of purchase.

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Fruit and tubers were stored (3-4 days) at room temperatures

banana quarters were peeled, and the quartered segments from each sample chopped or blended together. The composited samples were stored in a freezer until analyzed. Juice samples were kept refrigerated until analyzed without further processing. Infant bananas and sweet potatoes were frozen as such until analyzed. Information as to whether all samples were washed, peeled, etc. was not included.

Aldicarb residues in each sample from every sampling unit were determined by minor modifications of the accepted PAM Method II for aldicarb. All analyses of samples were accompanied by the analyses of fortified commodities. The matrices for the fortified samples were demonstrated to be free of aldicarb residues.

Results of Aldicarb National Food Survey

Percentage of Samples with Detectable Residues*

Commodity	Season of Sampling			
	Winter/87 N Det/N (%)	Spring/87 N Det/N (%)	Summer/Fall/87 N Det/N (%)	Overall N Det/N (%)
Bananas				
Fresh	6/75 (8%)	14/75 (17%)	18/75 (24%)	38/225 (17%)
Infant food	42/72 (58%)	30/74 (41%)	2/69 (3%)	74/215 (34%)
Potatoes				
Fresh (Idaho)	7/75 (9%)	9/75 (12%)	11/75 (15%)	27/225 (12%)
Sweet Potatoes				
Fresh	0/57 (0%)	1/68 (1%)	7/72 (10%)	8/197 (4%)
Infant food	0/75 (0%)	0/75 (0%)	0/75 (0%)	0/225 (0%)
Oranges				
Fresh	0/75 (0%)	0/75 (0%)	0/75 (0%)	0/225 (0%)
Adult Juice	2/75 (3%)	11/75 (15%)	9/75 (12%)	22/225 (7%)
Infant Juice	4/75 (5%)	3/75 (4%)	12/75 (17%)	19/225 (8%)
Grapefruit Fresh	1/75 (1%)	13/75 (17%)	1/75 (1%)	15/225 (7%)

* Detectable residues include estimated levels less than the limit of detection 0.01 ppm.

Residue Levels (PPM's) of Aldicarb

Commodity	Winter/87		Spring/87		Summer/Fall/87	
	Range	95th % tile	Range	95th % tile	Range	95th % tile
Bananas						
Fresh	ND-0.05	0.02	ND-0.22	0.07	ND-0.23	0.07
Infant food	ND-0.03	0.02	ND-0.02	0.01	ND-Trace	0.01

Commodity	Winter/87		Spring/87		Summer/Fall/87	
	Range	95th % tile	Range	95th % tile	Range	95th % tile
Potatoes						
Fresh (Idaho)	ND-0.02	0.01	ND-0.05	0.02	ND-0.19	0.07
Sweet Potatoes						
Fresh	ND-ND	0.01	ND-0.01	0.01	ND-0.07	0.03
Infant food	ND-ND	0.01	ND-ND	0.01	ND-ND	0.01
Oranges						
Fresh	ND-ND	0.01	ND-ND	0.01	ND-ND	0.01
Adult Juice	ND-0.01	0.01	ND-0.01	0.01	ND-0.01	0.01
Infant Juice	ND-0.01	0.01	ND-0.01	0.01	ND-0.01	0.01
Grapefruit						
Fresh	ND-0.01	0.01	ND-0.05	0.02	ND-Trace	0.01

(All estimated levels <0.01 ppm are given as 0.01 ppm, the limit of detection. TAS, Inc. has calculated mean and percentile values to as many as 5 significant figures. RCB has rounded off values to 2 decimal places).

Comment

The protocol of the aldicarb national food survey followed the guidelines suggested by RCB for the monitoring program for residues of daminozide with the exception that the sampling areas were not the PSU's of the BLS. As such, RCB considered the protocol, in general, as satisfactory for providing additional and supplementary information to the data already at hand. Whether such a protocol is adequate to determine nationwide residue levels in/on commodities treated with an acutely toxic material is a matter of statistical concern. RCB will contact the Quality Assurance Management Staff of ORD for comment on the adequacy of such protocols for assessing acute exposures.

Rhone-Poulenc had used the preliminary results of the winter sampling to argue that residues were non-existent or close to the limit of detection on commodities as purchased and therefore the dietary exposure was minimal. At that time RCB commented upon the results for potatoes, the commodity for which there is the greatest use and largest amount of data. The levels reported as residues appeared to differ considerably from US and Canadian monitoring data and from results anticipated from residue trials corrected for current usage patterns.

Of note in the results is the absence of residues on whole fresh oranges and the presence of residues in adult and infant orange juices. Also of note are the high percentages of infant bananas with detectable residues (58% in the winter sample, 34%

overall) and the high levels of residue found in some fresh banana samples (as high as 80% of the tolerance value 0.3 ppm).

The overall results for bananas of the food survey appear to differ from the results of residue trials for bananas only by a factor of 2. The range of values is the same.

Aldicarb Residues on Fresh Bananas

Data from:	N	Mean (ppm)	Std. Dev. (ppm)	95th %tile (ppm)	Range (ppm)	Tol.
All Residue Trials	236	0.04	0.04	0.12	0.01-0.24	0.30
Food Survey	225	0.02	0.02	0.06	0.01-0.23	0.30

In the absence of data that demonstrate that aldicarb residues in fresh bananas decline during shipping and storage, the values found in the food survey are sufficiently close to those anticipated from residue data as to lend confidence to the predicated values. Further, a large number of infant bananas were found to contain detectable residues of aldicarb. Presumably a jar of infant food is an aliquot of large batch of homogenized and blended bananas that have been diluted with other ingredients and cooked and sterilized. The finding of detectable residues in a considerable portion (38%) of all samples implies that bananas entering the production process for infant bananas initially contained significant residues of aldicarb.

One consistent finding in all three samplings is the absence of residues of aldicarb in fresh oranges and orange juices and the relatively low level of residues in grapefruit. These results may reflect lower uses or the absence of use on citrus. We defer to BUD for the current usage rates on citrus. If there are declining rates of use or lack of use on citrus, ("market disruption"), the Agency should consider cancelling the use of aldicarb on citrus or imposing a continuous monitoring requirement.

In the next section of this review, the focus will be upon potatoes as this commodity represents a significant potential for exposure and is the commodity for which there is the largest amount of data.

Potatoes: Survey Results Compared with Residue Data and Monitoring Data

The table below gives the means and the anticipated 95%tile residue levels for aldicarb in or on the RAC potatoes as calculated by Rhone-Poulenc from its residue data, (all permissible rates at all pre-harvest intervals including data generated after 1974), RCB residue data taken from tolerance petitions for potatoes, (All rates allowable prior to 1974 with minimum PHI's), FDA surveillance

and compliance data for FY's 83 thru 85, (Surveillance samples are: "collected on an objective basis where there is no inspectional or other evidence of a problem with the product." Compliance samples are: "collected on a selective basis as the result of an inspection, complaint or other evidence that there may be a problem with the product."), and from recent Canadian monitoring data. (Earlier FDA data is not included. These data show higher residue values than those given in the table below. An explanation for the decrease in monitoring residue levels is a "market disruption" reflecting a decrease in the use of aldicarb by potato growers.) The data used to set the tolerance is included in the Rhone-Poulence data set.

Residue Levels of Aldicarb on Fresh, White Potatoes

STUDY	N	Range	% of Samples > 0.01 ppm	Mean (all)	Mean (+'s)	95th %tile all	95th %tile +-s
National Food Survey							
Winter	75		1.3	0.01		0.01	
Spring	75		6.7	0.01		0.02	
Summer/Fall	75		12	0.02		0.07	
Overall	225	ND-0.19	7.1	0.01	0.05	0.04	0.15
All Rhone-Poulenc Field Trial Residue Data 1964-1984	328	ND-0.97	92	0.14	0.16	0.43	
Residue Data on which Tolerance is Based 1964-1972	110	ND-0.97	94	0.28	0.30	0.78*	
FDA Data 83-85	180		40	0.08		0.47	
Canadian Data 1986	218	0.01-0.57 (detects)	26	-----	0.16 (detects)		
Canadian Data 1985	60		63	0.15		0.24	

* The 95th %tile values of petition residue data were used for the dietary exposure assessments of the current draft of PD 2/3.

The residue levels found in the food survey for potatoes are lower than the results anticipated from field trial residue and monitoring data. Possible explanations for the difference may be a

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decline in aldicarb residues during storage of potatoes, lessened use of aldicarb by potato growers, (a market disruption), and differences in sampling and sample preparation.

Value for Residues to be Used in Assessment of Dietary Exposure

The residue levels found in the food survey for bananas do not differ more than a factor of 2 from the results anticipated from banana cultural practices and residue trials. The values for citrus and citrus processed commodities are considerably lower than those anticipated from residue trials but are consistent with monitoring data and current citrus cultural practice.

The values for potatoes obtained in the food survey differ from those anticipated from residue trials and monitoring data. RCB's use of tolerance petition residue data to arrive at the 95%tile residue level results in the "worst case" analysis of dietary exposure. For potatoes, using values derived from all residues trials would decrease the exposure only by a factor of 2.

Several explanations can be proposed, any or all of which may be at work, to account for the difference between previous results and results of the food survey for potatoes.

1. Aldicarb residues may decline in potatoes in the interval between harvest and sale. If such a decline does occur it would be most evident in samples taken in the winter and spring as potatoes available for sale at these times are predominately from storage stocks. If this is the case residue values should be higher on summer/fall samples as these should be fresh harvest potatoes. This is what has been observed in the food survey.

Arguing against this explanation is the demonstrated stability of aldicarb in potato processing studies which show, that on the average, 50% of aldicarb residues in potatoes survive conventional boiling, baking, and frying.

2. Because of the widespread concern about aldicarb residues in ground water, the publicity given to outbreaks of aldicarb intoxication, and the subsequent potential for increased restrictions on aldicarb use, potato growers and their organization may be participating in a "market disruption". That is, the rates of use and the percentage of crop treated may be declining.

That this has occurred is confirmed by BUD who states that less potato acreage is being treated and that rates are lower. As examples, in 1984 Idaho growers treated 50-65% of their acres planted in potatoes with aldicarb; in 1986 the estimate is 10 to 15% of total acreage. Washington growers previously treated nearly all of their acres planted in russets with aldicarb. The current estimate is 50 to 70%. Many states are now allowing only biennial application at a lower rate. Continued monitoring of potatoes at the point of purchase would confirm the reduction in usage.

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In the Table below are listed the 11 states accounting for greater than 97% of US potato production together with their share of the total national production for 1985, our estimate of % of crop treated in each state and the % of total crop treated.

State	% of total U.S. production	% of state crop treated	% national crop treated
Idaho	29.2	12.5	3.7
Washington	17.8	60	10.7
Maine	7.8	*	1.5
Oregon	7.6	60	4.6
Wisconsin	6.9	**	--
N. Dak	6.7	**	--
Colorado	6.2	5	0.3
California	5.1	5	0.3
Michigan	4.2	20	0.8
Minnesota	4.0	**	--
New York	2.1	*	0.4
Total	97.6		22.3

* Biennnial treatment at 2 lbs/A lower rate.

* * Seed potatoes only

However, the current lower usage of aldicarb may be a temporary phenomenon and not predictive of what usages might be in the future. Aldicarb usage may be down because the pesticide is under scrutiny as a subject of the Agency's Special Review or economic factors may be at work. In any case, in a situation involving acute exposures, RCB believes it is not appropriate to to modify residue levels by percentage crop treated.

Residue studies have shown that 92-96% of all treated potatoes have residue levels greater than 0.02 ppm. If we assume that 20% of the potatoes currently grown are treated with aldicarb and if we assume that 90% of aldicarb treated potatoes have residue levels greater than 0.02 ppm, we would expect that 18% of potatoes would have aldicarb residue levels greater than 0.02 ppm. (0.02 ppm = 2 x the level of detection) Conversely, 82% of potatoes would have residue levels less than 0.02 ppm. Assuming that all potatoes

grown in the US for retail purchase are randomly and uniformly distributed, 18% of sampled potatoes should have residue levels of at least 0.02 ppm. Thus, presuming that the potatoes in the survey represented potatoes grown in the US under current potato cultural practices, the Aldicarb National Food Survey sample of 225 potato purchases should have had about 40 samples with aldicarb residues at this level or greater. Only 10 potato samples of the 225 in the survey had residue levels of this magnitude, i.e., 0.02 ppm.

3. An additional explanation that can be advanced is that the design and execution of the Aldicarb National Food Survey may be inappropriate for determining the potential for an acute exposure. Considering that the annual US production of potatoes is about 40 billion lbs, can purchasing 5 lbs of potatoes at 75 locations 3 times in a year determine the probability of encountering a single potato containing a residue level of aldicarb capable of inducing the symptoms of an acute toxic response? Also, the shoppers in the Aldicarb National Food Survey who were responsible for collecting the samples were instructed to purchase fresh Idaho or other white potatoes. If this were taken literally and the shoppers sought out potatoes grown in Idaho, only about 4% of the treated national crop could possibly be sampled.

4. The sampling methodology used by Rhone-Poulenc may not be appropriate to determine residue levels on individual potatoes. In dealing with an acutely toxic material such as aldicarb it is residue levels in or on discrete items of food which are of concern. An individual may consume a single baked or boiled potato with a significant residue level. If one or two such potatoes were part of a 5 lb bag of otherwise residue free potatoes and if all potatoes in the bag were to be composited together and an aliquot taken for analysis, it is unlikely that residues would be detected and the sample would be considered residue free. Yet this is the procedure used in the national food survey

5. Sampling preparation such as washing, peeling, and other procedures may affect residue levels.

Residue Values from Aldicarb National Food Survey to be Used for TAS

RCB considers that the residue values of the National Food Survey that were greater than the limit of detection are the values that should be used in its TAS analyses. Commodities bearing detectable residues are the commodities that pose a risk with acutely toxic pesticides. The percentage of such commodities found in the National Food Survey is given in the following table.

Percentage of Surveyed Commodities with Residues > 0.01 ppm

Commodity	Total N	N with Residues >or= to 0.01 ppm	%
Fresh Bananas	225	27	12
Infant Bananas	216	34	16

Commodity	Total N	N with Residues >or= to 0.01 ppm	%
Fresh Oranges	223	0	0.0
Adult Orange Juice	225	1	0.4
Infant Orange Juice	220	1	0.5
Grapefruit	223	10	4.5
Sweet Potatoes	197	5	2.5
Infant Sweet Potatoes	218	0	0.0
White Potatoes	225	16	7.1

RCB recommends that the TAS calculations be done using the values equal to or greater than 0.01 ppm found in the Aldicarb National Food Survey including the 95th and 99th percentiles and the maximum value.

	Range	95th %tile	99th %tile	Max.
Bananas:	0.01-0.23	0.15 ppm	0.20 ppm	0.23 ppm
Infant Bananas	0.01-0.03	0.02 ppm	0.02 ppm	0.03 ppm
Oranges:	0.01-0.01	0.01 ppm	0.01 ppm	0.01 ppm (L.o.D.
Grapefruit	0.01-0.05	0.04 ppm	0.05 ppm	0.05 ppm
Potatoes	0.01-0.19	0.15 ppm	0.19 ppm	0.19 ppm

cc: R.F., Aldicarb S.F., Circ., A.Rispin, J.Auerbach, A.Barton, BUD, Garbus, Arne, Schmitt, Errico, Tomerlin, PMSD/ISB

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