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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT Chlorpyrifos registration standard. Dow's response to residue chemistry data gaps. Accession Number 256045. [RCB No. 501]

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In response to the document "Guidance for the Reregistration of Pesticide Products Containing Chlorpyrifos as the Active Ingredient" (issued 9/28/84) Dow Chemical USA has submitted a package containing metabolism and residue data as well as arguments as to why some of the requested studies should not be required.

Chlorpyrifos is the common name for the insecticide O,O-diethyl-O-(3,5,6-trichloro-2-pyridyl)phosphorothioate. Tolerances for this pesticide are regulated in terms of the parent compound and its metabolite 3,5,6-trichloro-2-pyridinol (often referred to as TCP).

Those data gaps which the registrant has addressed in the current submission are listed below (usually in abbreviated form; including the footnote numbers from the Residue Chemistry section of the Generic Data Requirements Table) followed by Dow's response and our conclusion.

171-4 Nature of Residue (Metabolism)

DATA GAP:

Plants (Footnote 3)-Studies must be submitted concerning the metabolism of ring-labeled [^{14}C]-chlorpyrifos and metabolites, especially TCP, by corn and a representative legume and root crop. Radioactive residues must be characterized by a method such as GC or HPLC and verified by MS.

DOW'S RESPONSE We will conduct a corn and root crop metabolism study as required. However, the request for another legume study is not justified since an earlier study on soybeans (PP#'s 9F2270 and 0F2281) adequately identified the nature of the residue. This study identified chlorpyrifos and TCP in forage, beans, and field trash. The remainder of the activity (40% forage, 88% bean, 40% field trash) consisted of naturally incorporated ^{14}C , a multiple of minor polar products, and insoluble activity. These ill-defined products should not detract from the evidence that TCP is the only metabolite of chlorpyrifos.

RCB'S CONCLUSION

As noted in our chapter for this Standard, we are concerned with some of the metabolism studies wherein identification was based upon paper chromatography employing one solvent system. Such data is not sufficiently specific. Also, high levels of unidentified residues were present in various plant samples. At this time we conclude that the legume study will not be required provided that the corn and root crop metabolism studies identify most of the residue using GC or HPLC in conjunction with mass spectral confirmation. Both grain and foliage must be analyzed in corn. The foliage of the root crop should also be examined. We suggest sugar beets be used due to the significant residues (8 ppm tolerance) found in the tops.

This data gap (plant metabolism) remains outstanding until adequate corn and root crop metabolism studies have been conducted.

DATA GAP:

Animals (Footnote 4)-Metabolism studies must be submitted for ruminants (dermal study on cattle using dip treatment) and for poultry (3 days of oral dosing).

DOW'S RESPONSE: We will conduct a poultry feeding study and a ruminant dermal application study. The latter will be based on pour-on use since we have no interest in supporting the dipping vat use. We also have four reports to be added to the chlorpyrifos data base-two concerning the oral administration of the sodium salt of TCP to pigs and two concerning the nature of the residue in goat milk.

DISCUSSION OF ADDITIONAL DATA: The swine studies are not required and have limited value since they involved feeding a metabolite of chlorpyrifos, not the active ingredient. A quick review of the studies indicates that TCP is rapidly eliminated following withdrawal from the diet. Residues in tissues and urine consisted mostly of TCP and its glucuronide.

Although the registrant was not informed of the necessity for milk data, our chapter of the Standard states that available ruminant studies did not identify residues in milk. The studies in the current package include a continuation of earlier goat work by Dow and data from Egypt (Isotope & Radiation Res., 14, 63-9 [1982]).

The Dow study (R D. Glas, 1981, Report GH-C 1470) entailed dosing of two goats for 10 days at levels of 16 & 21 ppm based on the, feed consumption. Each goat received 32 mg chlorpyrifos per day divided into two doses in gelatin capsules. Milk was collected on days 3, 7 & 10 for identification of residues. Four extraction procedures were utilized for examination of the milk samples. The solutions were made basic (pH>12) and extracted with benzene to determine non-polar residues. The second procedure involved basic hydrolysis followed by acidification and benzene extraction to measure total residues convertible to TCP. The third method was a neutral hexane extraction aimed at measuring chlorpyrifos, while the fourth entailed acidification followed by benzene extraction. Radioactivities of the various extracts were counted and analyses performed using reverse phase HPLC. Total radioactivity in milk ranged from 0.010 to 0.046 ppm after day 1. Percentages of total activity removed by the four procedures were 65-72, 96-97, 55-63, and 83-89, respectively. Sample histograms demonstrate that >90% of extracts 1 and 3 consist of chlorpyrifos. As expected, >90% of extract 2 consisted of TCP. The fourth extract contained about 85% chlorpyrifos and 15% TCP. Combining extraction efficiencies with the % composition data, Dow claims the following distribution of residues in goat's milk: 66-74% chlorpyrifos, 13-20% TCP, and 11-17% non-extractables (that is, not extractable by procedure 4 above) but hydrolyzable to TCP. We concur with their basic conclusion-about 2/3 of the milk residue consists of the parent compound and >90% of the total residue is hydrolyzable to TCP.

The Egyptian study has a major difference from the Dow study in that it utilized a ¹⁴C label in the ethyl groups of the phosphate moiety. Therefore, this experiment would not detect TCP. The goats received 5 consecutive daily doses of either 20 or 40 mg chlorpyrifos (versus 32 mg in the Dow study). Milk was collected twice daily and found to contain 0.12-0.52 and 0.3-0.65 ppm total activity from the low and high doses, respectively. Thin layer chromatographic analysis revealed the following distribution of the residue: 28% monoethyl phosphate, 17% diethyl phosphate, 36% diethyl thiophosphate, and 18% chlorpyrifos. The first three components were not found in the Dow study since the phenyl label would prohibit their detection. The 18% chlorpyrifos translates to about 0.1 ppm maximum in the milk versus about 0.03 ppm in the Dow study. We do not consider this difference serious enough to question the results of the two studies.

RCB'S CONCLUSION

The submitted data are adequate to determine the nature of the residue in milk. Chlorpyrifos and its metabolite 3,5,6-trichloro-2-pyridinol (TCP) are the components of concern.

This data gap (animal metabolism) remains outstanding until adequate dermal (pour-on) cattle and poultry (3 oral doses) metabolism studies have been conducted.

171-4 Magnitude of the Residue (Residue Studies)

DATA GAP

Sweet potatoes (Footnote 7)-Additional data are required with a 90 day PHI or the registrant should revise the labels to include a 125 day PHI.

DOW'S RESPONSE: Product labels will be amended to show 125 day PHI's for sweet potatoes.

RCB'S CONCLUSION

The practicality of such a PHI for sweet potatoes is questionable since the grower will harvest the potatoes when they have reached a marketable stage, which could be less than 125 days. However, the presence of only trace residues (up to 0.05 ppm) in potatoes following exaggerated rates (PHI's of 136-182 days) alleviates our concern over the possibility of earlier potatoes containing chlorpyrifos residues above the 0.1 ppm tolerance. Therefore, when revised labels have been submitted, we will consider this data gap to be filled.

This data gap for sweet potatoes remains outstanding until revised labels having the 125 day PHI have been submitted for the 15G and 4E formulations.

DATA GAP:

Turnips (roots) (Footnote 8)-Additional residue data are required from TX and GA for at-plant and transplanting applications.

DOW'S RESPONSE: These data should not be required since they were deemed adequate at the time the tolerances were established thru the IR-4 petition. Requesting more data than are absolutely necessary is contrary to EPA's minor use policy. Alternatively, a label restriction against use in southern states would be acceptable since the pest does not occur there.

RCB'S CONCLUSION

Reexamining the data for turnip roots from MI, NH, NY & WA wherein the maximum combined residues of chlorpyrifos and TCP were about 2 ppm, we conclude that these data provide adequate geographic representation for this minor use tolerance (3 ppm).

This data gap for turnip roots has been filled.

DATA GAP:

Turnip greens (Footnote 9)-As with turnip roots, additional data are needed from TX and GA for the planting and transplanting (directed spray to plant bases) uses of chlorpyrifos.

DOW'S RESPONSE: Same as above for turnip roots.

RCB'S CONCLUSION

As with turnip roots. we consider the data from MI, NH, WA & NY adequate for the minor use tolerance on turnip greens.

This data gap for turnip greens has been filled.

DATA GAP:

Broccoli and Brussels sprouts (Footnote 12)-Additional residue data are required from California for soil applications at planting and at transplanting.

DOW'S RESPONSE: As with turnips, requiring additional data is contrary to EPA's Minor Use Policy.

RCB'S CONCLUSION

Since California produces over 90% of the Brussels sprouts and broccoli in the U.S., we do not concur with the registrant that additional data from that state are not necessary. The data in the petitions represented MI, NY, WA and WI.

This data gap has not been filled. Residue trials from CA are required for both broccoli and Brussels sprouts as described in the Chlorpyrifos Guidance Document.

DATA GAP:

Cabbage (Footnote 13)-Additional data are required for planting and transplanting uses of chlorpyrifos in NY, FL, TX, CA & WI.

DOW'S RESPONSE: Same minor use argument as presented for turnips- additional data would be against EPA policy.

RCB'S CONCLUSION

Data submitted for cole crops in PP#7E2010 represented the states of NY, MI, WA & WI. As noted in our chapter of the Standard, the acreage for cabbage in 1978 was distributed as follows: NY-15%, FL-17%, TX-18%, CA-9%, WI-7%. Therefore, we feel that data are still needed for FL and TX.

The data gap for cabbage has not been filled. Residue trials employing the planting and transplanting treatments are required from the states of Florida and Texas.

DATA GAP:

Chinese cabbage (Footnote 14)-Additional residue data are required for the planting and transplanting applications in CA, FL, HI & NJ.

DOW'S RESPONSE: Again, requiring such data is contrary to the Minor Use Policy.

RCB'S CONCLUSION

In PP#0E2412 data were provided for Chinese cabbage in WA and NH. We concluded this number of studies was inadequate, but approved the 2 ppm tolerance by translating data from the other cole crops. Since Chinese cabbage does belong to the Brassica leafy vegetable group, we will not require additional data for this minor crop provided the studies requested for the other cole crops are carried out.

The data gap for Chinese cabbage remains outstanding. However, additional data for this crop are not necessary if the studies requested for broccoli, Brussels sprouts, cabbage and cauliflower are conducted.

DATA GAP:

Cauliflower (Footnote 15)-Additional residue data reflecting the at-planting soil treatment (15% G formulation) are required in CA and MI or NY and OR. Also tests must be conducted in the same sites for the transplanting use of the 4 EC formulation.

DOW'S RESPONSE: As with the other cole crops, requiring additional data is contrary to EPA's minor use policy.

RCB'S CONCLUSION

The data in PP#7E2010 represent analyses of treated cauliflower from the states of MI, NY, WA, and WI. Therefore, since CA produces over 70% of the cauliflower in the U.S., we require studies in that state reflecting the planting and transplanting uses of chlorpyrifos.

The data gap for cauliflower has not been filled. Studies are needed from California for the planting and transplanting uses of chlorpyrifos. We will not require the additional trials requested in MI, NY and OR.

DATA GAP:

Cowpeas/lentils (Footnote 17)-Separate tolerances of 0.1 ppm should be established on these commodities since the seed and pod vegetable group is now obsolete.

DOW'S RESPONSE: We do not intend to support seed treatment uses on these minor crops. These uses will be deleted from the labels.

RCB'S CONCLUSION

This data gap remains outstanding until the revised labels which do not have uses on cowpeas and lentils are submitted or until tolerances for these commodities are established (see Note to the P.M. on page 15 concerning administrative establishment of these tolerances).

DATA GAP:

Dry beans/peas (Footnote 17)-Separate tolerances of 0.1 ppm should be established on these commodities since the seed and pod vegetable group is now obsolete.

DOW'S RESPONSE: Petitions will be submitted for 0.1 ppm tolerances for peas and beans (dry and succulent). Soybeans will be excluded from the latter tolerance expression due to different use patterns.

RCB'S CONCLUSION

This data gap remains outstanding until the tolerances for peas and beans are established. The registrant is urged to submit these tolerance petitions as soon as possible.

DATA GAP:

Lima beans (Footnote 18)-The tolerance is not supported due to the absence of data for lima bean cannery waste. However, similar data requested for snap beans can be used to satisfy this requirement.

DOW'S RESPONSE: Our comments regarding this subject are presented in the section for snap beans.

RCB'S CONCLUSION

This data gap for lima beans has been filled. See our conclusion below under snap beans for discussion of this topic.

DATA GAP:

Snap beans (Footnote 19)-The following data are required:

- (A) Residue data from snap beans taken at maturity from plants raised from treated seeds in Oregon.
- (B) Residue data for cannery waste from processing of snap beans having detectable weathered residues as a result of being grown from treated seed.

DOW'S RESPONSE: (A) A residue study will be conducted in a West Coast state using seed treated at 1 oz ai/100 lb seed. We prefer doing the study in Calif. instead of Oregon. Is this acceptable? (B) Data in PP#4F1445 show no detectable residues in beans grown from seeds treated at three times the label rate. Therefore, we believe there will be no concentration of residues in the cannery process fraction beyond that of the existing tolerance. This data should translate to lima beans and satisfy the data requirement for both snap and lima beans.

RCB'S CONCLUSIONS

(A) Considering that seven studies have been conducted in 5 states (WI, NY, MS, FL, IL) and all these experiments showed no residues in beans raised from treated seeds, we do not see the need for any more trials. The geographic representation is adequate for seed treatments with a pesticide that is only slightly systemic.

(B) We concur with the registrant that cannery waste data should not be required. In addition to the absence of residues in beans, only traces (<0.1 ppm) were found in bean plants at the time of normal harvest (Section D.1.0.0 of PP#4F1445) following seed treatment at the registered rate. Therefore, residues in cannery waste will be well below the 1 ppm tolerance for bean forage.

This data gap (snap beans) has been filled. The registrant should be informed that the seed treatment study on the West coast will not be needed.

DATA GAP:

Soybeans (Footnote 20)-Data are required for beans which have been harvested 28 and 40 days after the last of six foliar applications (aerial and ground) which were preceded by at-planting or early postemergence treatment with the 15G formulation at 1.3 lb ai/A.

DOW'S RESPONSE: Data on other crops (alfalfa, cotton, sorghum, sugarbeets, sunflowers, wheat) show residues from aerial applications are no greater than those from ground treatments (see the attached summary table). These results should be translated to soybeans so that data from aerial applications are not necessary. Regarding the absence of data for the combination of soil and foliar treatments, we refer to data in PP#9F2270. In these studies the first treatment was a soil broadcast application of the 4E formulation (2-4 lb ai/A) 0-11 days following emergence. Although this does not represent the early season uses of the 15G product, the rate used is well above that of 15G (1.3 lb ai/A) and should satisfy the concern over use of this formulation.

RCB'S CONCLUSION

An examination of the summary tables reveals that aerial residues for sorghum (forage/fodder/grain), sugar beet tops, sunflower seeds, wheat (grain/straw), alfalfa forage and cottonseed are in most cases either comparable or less than those from ground applications. We concur that additional aerial data for soybeans are unnecessary. In addition, our 12/23/80 review (E. Leovey) of PP#9F2270 stated that aerial data for soybeans would not be needed if foraging were restricted. As noted under the data gap for soybean forage and straw below, Dow intends to place such a restriction on the labels. This reinforces the argument against the requirement of soybean aerial data as the beans are shielded from the pesticidal spray by the pods.

Concerning the need for data reflecting the granular soil use plus foliar applications, we also concur with the registrant that such studies are not necessary. With an early season application we often translate data from one formulation to another. In addition, in this case the data in PP#9F2270 for the 4E formulation included soil applications at rates of 2-4 lb ai/A, well above the granular rate, and therefore would certainly cover a worst case situation for use of the 15G.

The data gap for soybeans has been filled.

DATA GAP:

Bean and pea forage and hay (Footnotes 22 & 25)-Residue data are required from dried hay, harvested at its normal time of maturity, from plants grown from treated seed in NY,OR,CA,WI,MI, and ND.

DOW'S RESPONSE: A feeding restriction for bean and pea hay will be added to the seed treatment labels. Thus, residue studies will not be conducted for dried hay.

RCB'S CONCLUSION

This data gap remains outstanding until revised labels containing the bean and pea hay feeding restrictions have been provided.

DATA GAP:

Cowpea and lentils forage and hay (Footnote 23)-Tolerances must be proposed for these commodities or a crop group tolerance established for the Foliage of Legume Vegetables Group.

DOW'S RESPONSE: Since we are not supporting the seed treatment use on these minor crops, a tolerance petition will not be submitted for these commodities.

RCB'S CONCLUSION

This data gap remains outstanding until labels deleting use on lentils and cowpeas have been submitted. If tolerances were to be established for lentils/cowpeas and their forages (cowpea forage already covered by bean forage tolerance) and the hays restricted, we would have no objection to retaining these uses (see page 15).

DATA GAP:

Soybean forage, hay, and straw (Footnote 26)-Residue data must be obtained for these commodities following foliar applications with the 4EC formulation and at-planting use of the 15G product.

DOW'S RESPONSE: Instead of conducting such studies with soybeans, we will add feeding and grazing restrictions to the LORSBAN labels.

RCB'S CONCLUSION

The data gap for soybean forage, hay and straw remains outstanding until labels restricting the feeding/grazing of these plant parts have been provided.

DATA GAP:

Peppers (Footnote 27)-Residue data are required involving use of the 4 lb/gal EC formulation on peppers at 0.85 lb ai/A from field tests conducted in Israel using a PHI of 5 days and as normally grown for export to the U.S.

DOW'S RESPONSE: Because the tolerance on peppers was established at the request of an Israeli based pesticide formulator not affiliated with The Dow Chemical Company, we are unable to provide the additional data.

RCB'S CONCLUSION

The data provided for peppers in PP#1E2523 represented market-basket surveys and not controlled field studies. The tolerance was established by translating data from tomatoes. Therefore, we still need data from Israel reflecting the registered use.

This data gap remains outstanding until the requested data for peppers grown in Israel has been provided.

DATA GAP:

Cranberries (Footnote 32)-Studies must be conducted in OR and WA reflecting two aerial applications of the 4EC product (1.5 lb ai/A).

DOW'S RESPONSE: Additional data should not be required for this minor use tolerance requested by the IR-4 project. In addition, data on other crops comparing aerial and ground applications show that the former do not result in higher residues. These results should be translated to cranberries.

RCB'S CONCLUSION

We concur with the registrant that the comparative studies show aerial applications do not result in higher residues. Therefore, we will not require additional data on cranberries.

This data gap (cranberries) has been filled.

DATA GAP:

Strawberries (Footnote 33)-Residue data are required from CA (73% of U.S. production) for strawberries which have been treated foliarly when buds first appear and again 10-14 days later. Data are also needed from OR or WA and ID for strawberries from plants which received preplant soil treatment the previous year. In the same studies some plants should receive foliar treatments to show the effect of combination of uses on first year fruit production.

DOW'S RESPONSE: A study conducted by the IR-4 project in CA is attached for Agency review (discussed below under RCB'S CONCLUSION). This should satisfy the concern for data from that state. The requested studies in the NW will be conducted in the summers of 1985 and 1986. We will require an extension of the requested data submission date of March 1986 to December 1986.

RCB'S CONCLUSION

The additional study in this submission was conducted in Santa Ana, CA (1981). One application of 1 lb and 2 lb ai/A took place on 6/5 with berries harvested on 6/18, 6/25, and 7/2. Therefore, preharvest intervals were 13, 20 and 27 days (tables list 14, 21 and 28 days?). Total residues were determined as TCP following basic hydrolysis (i.e., chlorpyrifos not measured separately). Control samples contained less than 0.05 ppm TCP and recoveries were 91-100% for three spiked samples (0.4 ppm of apparently TCP).

A total of 24 treated berries were analyzed (4 per PHI per rate). Following the registered 1 lb rate residues of TCP were 0.11-0.13, 0.06-0.24, and 0.07-0.08 ppm for the 13, 20 and 27 day PHI's, respectively. For the 2 lb rate TCP values were 0.05-0.06, 0.05-0.10, and 0.06-0.08 ppm for the same three intervals. Unfortunately, the plots didn't receive the two applications allowed on registered labels. However, we can combine residues from the 20 and 27 day samples to approximate the effects of the two treatments. In that case a maximum of $0.24 + 0.08 = 0.32$ ppm TCP would be found. Converting to terms of chlorpyrifos, which weighs 1.77 times TCP, the total residue would be 0.57 ppm chlorpyrifos. This is slightly over the tolerance of 0.5 ppm. Although the actual level of chlorpyrifos + TCP is less than this calculation (since the latter assumes all the residue is parent and none is the metabolite), the results of this study indicate the 0.5 ppm tolerance may be exceeded in CA. We believe that a controlled study is still needed in that state reflecting the use of two applications. Preferably, residues of chlorpyrifos and TCP should be measured separately.

The data gap for strawberries remains outstanding. The requested studies from OR/WA, ID and CA are still necessary. The studies must reflect the registered use: two foliar sprays of 1 lb ai/A, 21 day PHI, no applications after berries start to form. RCB concurs with the registrant that an extension beyond March 1986 will be needed to conduct the studies in the NW.

DATA GAP:

Sorghum grain (Footnote 36)-The following data are required:
(A) Data in KS reflecting three foliar treatments at three day intervals, starting at 50% bloom; both aerial and ground data.
(B) Florida data for at-planting granular use followed by the three foliar uses noted in (A).
(C) Data from TX for successive treatments (i) seed use, (ii) at-planting granular and (iii) foliar as in (A).

DOW'S RESPONSE: Regarding the additional data for grain in KS, we submit data from a milling study. Sorghum in KS & MS was sprayed three times starting at 30% bloom with 0.25 lb ai/A. At harvest the grain from MS (49 days) contained 0.05 ppm chlorpyrifos and 0.22 ppm TCP. Six samples of Kansas grain (62 days) had <0.01 and ≤ 0.05 ppm of those two components.

Concerning the need for aerial and ground data we again refer to the summary of data for various crops including sorghum. Addition aerial data should not be necessary.

Regarding the data request for multiple treatments (seed, at-plant, foliar) we refer to residue studies conducted in the closely related crop corn. No detectable residues were found in grain, forage and fodder of field corn following at-plant applications of 1-3 lb ai/A (PP#3F1306). For sweet corn, seed treatment use was found to produce no residues in the whole green plant, kernels, and kernels + cobs. These data should translate to sorghum negating the need for grain data for the seed and at-plant uses as only negligible residues are expected.

RCB'S CONCLUSION

We concur that additional grain data from KS are unnecessary. The milling study was reviewed in the preparation of the Standard but was apparently overlooked as a source of residue data for the r.a.c. grain. Concerning aerial data we also agree that more data are not required since the available sorghum studies in MS & TX show aerial residues of chlorpyrifos + TCP to be either less than or comparable to those from ground uses in most cases. Finally, in connection with the data request for multiple uses we do not see the need for such information on sorghum grain. The registrant has submitted a reasonable argument: studies on the closely related crop corn indeed showed no residues in the grain portions of field and sweet corn. Seed treatment studies with beans also revealed no detectable residues in snap and lima beans at harvest.

The data gap for sorghum grain has been filled.

DATA GAP:

Sorghum forage and fodder (Footnote 38)-The same three sets of data requested for sorghum grain in KS, FL and TX are required for these crop parts. Forage should be cut and analyzed 14 days after the final foliar treatment. Some forage should be dried to fodder and some ensiled prior to analysis.

DOW'S RESPONSE: We will conduct a study in Kansas reflecting three foliar ground applications at three day intervals. Using the same arguments presented under grain sorghum we feel that additional data for aerial applications and multiple treatments (seed/at-plant/foliar) are not necessary.

RCB'S CONCLUSION

We again concur that aerial data are not needed. For multiple uses we note that although corn studies showed no residues from at-plant and seed treatments, bean forage contained measurable residues at various times up through normal harvest time for the beans. Therefore, we would like to see at least one trial reflecting at-planting plus foliar uses on sorghum. We suggest that the KS study planned for forage and fodder analysis be modified to include an at-planting application. If the Kansas study is so conducted, additional data from Florida and Texas will not be required providing the existing tolerances are shown to be adequate.

The data gap for sorghum forage and fodder has not been filled. At a minimum, the registrant needs to conduct one trial using both at-planting and foliar applications of chlorpyrifos as noted in the previous paragraph.

DATA GAP:

Alfalfa forage and hay (Footnote 40)-Additional data are required as follows: (A) Combined residues of chlorpyrifos and TCP 14 days after the fourth aerial application of 0.5 lb ai/A and 21 days after the fourth aerial application of 1.0 lb ai/A. Data should also include the residues from maximum use within the individual cuttings. (B) A processing study to determine residues in meal processed from hay containing detectable weathered residues.

DOW'S RESPONSE: Regarding the need for aerial data, we refer to PP#0F2281 with aerial data from KS and CA reflecting three 1 lb ai/A applications. Although the 0.5 lb rate and a fourth treatment were not examined, the data should be sufficient to conclude that aerial applications will not result in residues exceeding the established tolerances. We will provide the necessary data for alfalfa meal.

RCB'S CONCLUSION

As with other crops discussed above, we agree there is no need for additional aerial data. Also, the available data for three applications (and three cuttings) indicate there is no increase in residues as the number of sprays increases. In most cases residues after the third cutting were the same or less than those after the first cutting. Therefore, we will not require data for four consecutive cuttings. However, in reexamining the data in PP#0F2281 we have concluded that more data are needed reflecting the 14 day PHI/0.5 lb use (residues were as high as 4 ppm, the existing tolerance) and from the 21 day/1.0 lb use (no data available for this use pattern). Furthermore, there is no information for residues in alfalfa seed, a source of the human food item alfalfa sprouts.

The data gap for alfalfa is still outstanding. Studies are required from at least two states reflecting three applications (ground or aerial as convenient) over three consecutive cuttings. Both the 0.5 lb/14 day PHI and 1.0 lb/21 day PHI use patterns must be examined for both forage and hay. We are also concerned with use of chlorpyrifos on alfalfa grown for seed. Therefore, data should be supplied for seeds harvested 14 and 21 days after treatment with 0.5 and 1.0 lb ai/A, respectively. The seed data may be from one application to one cutting (i.e., the registrant does not have to spray two or three cuttings before allowing the alfalfa to go to seed).

DATA GAP:

Bananas (Footnote 43)-Information for regulatory purposes (rep. labels, English translations, etc.) must be collected and submitted on chlorpyrifos usage on bananas in countries which export bananas to the U.S.

DOW'S RESPONSE: Copies of product labels are attached for EPA's consideration.

RCB'S CONCLUSION

Copies of labels for Lorsban 1-PE and Polyethylene D are provided. These are polyethylene products containing chlorpyrifos for manufacture of banana fruit bags. Instructions are present in both English and Spanish. However, labels were not provided for the 5% G formulation which is registered for banded soil applications. These labels are still required.

The data gap for bananas remains outstanding until foreign labels are submitted which describe use of the 5% G product for banded soil applications.

DATA GAP:

Cottonseed (Footnote 44)-Data must be supplied reflecting five applications (both aerial and ground) in CA.

DOW'S RESPONSE: We will conduct a study in CA employing five ground applications. Aerial data should not be required based on similar residues in ground and aerially treated cottonseed in PP#6F1673.

RCB'S CONCLUSION

We concur that aerial studies on cottonseed gave similar results to those employing ground applications. Only the latter need to be tested in CA.

The cottonseed data gap remains outstanding until data have been obtained in California. We emphasize that this trial should be conducted on irrigated cotton.

DATA GAP:

Figs (Footnote 45)-Data must be submitted for fresh figs 7 months following soil application of 2 lb ai/A. Data must also be provided for dried figs prepared from fresh figs treated at that rate.

DOW'S RESPONSE: The use on figs involves treatment when fruit are not present. The available data show no detectable residues in dried figs, a worst case situation as far as residue concentration is concerned. Therefore, a tolerance based on such data should cover both fresh and dried figs.

RCB'S CONCLUSION

We concur with the registrant that additional data are not needed. Taking into account the results for field corn soil treatments with chlorpyrifos, the use on figs before fruit are present (ca 7 months before harvest) is not expected to result in detectable residues.

The data gap for figs has been filled.

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Notes to the Product Manager. The registrant should be informed of all our conclusions, especially since some result in a change (in most cases a reduction) in the data requirements. We particularly wish to emphasize that the following data gaps have been filled due to our acceptance of Dow's arguments that existing data are adequate (Footnote # in Generic Data Requirements Table): turnip roots (#8), turnip greens (#9), lima beans-cannery waste (#18), snap beans-cannery waste (#19), soybeans (#20), cranberries (#32), sorghum grain (#36), and figs (#45).

It should be noted that Dow intends to remove use on lentils and cowpeas from their seed treatment labels. Tolerances of 0.1 ppm are needed for these minor crops in connection with label restrictions against feeding lentil forage and cowpea/lentil hays (cowpea forage is covered by existing bean forage tolerance). Instead of imposing a lentil forage restriction, a 1 ppm tolerance could be established for that commodity based on existing data for bean and pea forages. We suggest the Minor Use Officer of EPA be contacted to see if these tolerances could be established administratively to retain use on these crops. (Another alternative to the 0.1 ppm tolerances for cowpeas and lentils is a crop group tolerance of 0.1 ppm for the Legume Vegetables excluding soybeans.)

This submission does not address Product Chemistry data gaps for chlorpyrifos. These all remain outstanding at this time.

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