



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

DEC 23 1980

Memorandum

SUBJECT: PP#9F2270. Chlorpyrifos in or on Soybeans.
Amendment of 10/14/80

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TO: J. S. Ellenberger, PM #12, RD (TS-767)
and TOX (TS-769)

THRU: Robert S. Quick, Section Head *RM*
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This amendment is in response to the reject letter of June 10, 1980, in which the following deficiencies are listed:

1. A minimum time period between applications of Lorsban 4E should be indicated on the label.
2. A number of the metabolites in the plant metabolism study were not identified. Further identification of the residues in the plant metabolism studies are needed. If any additional metabolites are found to be significant and should be included in the tolerance regulation, appropriate processing studies and residue data determined by a validated analytical method (which may have to undergo a method trial) will be needed.
3. The metabolism of chlorpyrifos in animals is not adequately characterized. A new metabolite [0,0-diethyl-0-(3,6-dichloro-2-pyridyl)phosphorothioate] has been detected in cattle liver and a major metabolite similar to chlorpyrifos (methythio group substituted for a chlorine on the pyridinol ring) has been identified in human liver. Since new metabolites have been identified and you have requested to raise the present tolerance for residues in goats and sheep, a goat lactating study using radiolabelled chlorpyrifos is needed to further clarify the metabolism of chlorpyrifos in animals.

If additional metabolites from further plant metabolism studies are judged significant and in need of regulation, animal metabolism studies on these compounds may be required.

4. The apparent residues on untreated samples are exceptionally high, especially on soybean straw. Therefore, adequate analytical methods are not available to enforce the proposed tolerance for residues of chlorpyrifos and TCP. To resolve this deficiency, submit either additional data to assure that the reported control residue levels are outliers, an explanation as to why these levels are high or an improved method (the improved method may have to undergo a method trial).
5. Additional residue data on soybeans, forage and straw are needed from the major soybean producing states. This data should cover the maximum proposed use, aerial application (or delete this use from the proposed Section B), the granular formulation and all regulated residues including significant metabolites found in the plant metabolism studies.
6. The submitted processing study showed residues in or on meal equal to that of soybeans. However, we are not assured that the meal residues will not exceed those in the bean and that a food additive tolerance is not needed for meal. Therefore, a processing study is needed using soybeans fortified with the regulated components of the residue at the tolerance level. We are withholding judgement on whether a food additive tolerance is needed for the other processed fractions until the plant metabolism question is resolved.
7. We are withholding judgment on the proposed increases in tolerance for meat, fat and meat by-products of goats and sheep until the above deficiencies have been resolved.
8. Submit a revised Section F expressing the tolerance proposal for soybean straw as soybean hay.

Response to 1:

The petitioner does not see a need to indicate the minimum time period because it would severely handicap the uses in certain adverse situations.

Residue data reflects 4 or 5 applications which are spread 17 to 39 days apart except for one two-day spacing shortly after emergence. No data was submitted with short-spaced applications at the PHI which would reflect maximum possible residues under the proposed use. This deficiency is not resolved.

Response to 2 and 3:

The petitioner has studies underway to resolve the plant and animal metabolite questions. A revised Section F has been submitted. The tolerance proposals for soybean forage and hay and the fat, meat and meat by-products of goats and

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sheep have been deleted. Only a tolerance for 1 ppm in or on soybeans is now proposed. In conjunction with this revision, Section B has also been revised and now includes a restriction against feeding treated soybean forage or hay to meat or dairy animals. The deletion of tolerances for forage and hay will not eliminate the need for plant metabolism data and we cannot make an animal metabolism conclusion until the plant metabolism question is resolved.

This deficiency is not resolved.

Response to 4:

The petitioner has reanalyzed some forage, straw and soybean samples which had high control values. Little difference was seen in the apparent residue upon reanalysis. The presence of chlorpyrifos in untreated samples 139009, 139011, 141326 and 147945 was then confirmed by GC/MS analysis by monitoring m/e 352 and 350. We can conclude that these controls were contaminated and eliminate them from consideration. Apparent residues on the remaining controls (5) ranged from 0.001 to 0.024 chlorpyrifos and 0.008 to 0.06 ppm TCP or 0.009 to 0.074 ppm for total residues in soybeans.

Additional recovery data were also submitted. It ranged from 74 to 102%, 74-110% and 70-110% for green forage, straw and soybeans at fortification levels ranging from 0.01-50 ppm chlorpyrifos.

We can conclude that an adequate method is available to determine chlorpyrifos and TCP in soybeans.

We were also concerned with the high apparent residues on untreated straw samples. These samples were reanalyzed. Out of seven samples, apparent residues increased upon reanalysis in five samples. Controls were fortified with 0.01 to 5 ppm chlorpyrifos. Recoveries ranged from 74-110%. All seven controls analyzed contained chlorpyrifos as determined by GC/MS. These samples were contaminated. Apparent residues after the elimination of these samples ranged from 0.001 to 0.019 ppm chlorpyrifos and 0.004 to 0.12 ppm TCP. This deficiency is resolved.

Response to 5:

The petitioner feels that, since the states where soybean residue data were collected represent 40% of the soybean acreage, no further residue studies are needed. Of the seven residue studies submitted, only one had a PHI close to the 28 days specified on the label. Considering the difficulty the petitioner had with contaminated controls, this is too small a sampling to adequately judge whether residues would exceed the proposed tolerance. Additional residue data are needed.

The petitioner also requested that we reconsider our request to delete the use of aerial applications in spite of the lack of residue data reflecting this type of application. To support this request, the petitioner has submitted,

tabular summaries of residue data for alfalfa, (PP#6F2281), sorghum (PP#6F1830) and cotton (PP#6F1673) which compare residues from ground and aerial applications. No consistent trend can be observed between residues in or on cottonseed, sorghum forage and alfalfa when matched sets, i.e., the same application rate and PHI, are compared. However, with these data and the label foraging restriction imposed, we conclude that residue data reflecting aerial applications are not needed.

This deficiency is not resolved due to the need for additional residues data for soybeans reflecting the maximum proposed rate and a 28-day PHI. The question concerning granular formulation data was not addressed.

Response to 6:

The petitioner sees no need for an additional processing study. He recognizes that the combined residues of chlorpyrifos and its metabolite TCP for the bean sample used in his processing study was low in view of the 1 ppm tolerance level. However, he believes that the data presented in this study are adequate to show that residues from the raw agricultural commodity do not concentrate in process functions, and additional processing studies are consequently not needed. The issue is that the residues observed in meal (0.13 ppm) were approximately the same as in soybeans (0.14 ppm), while in other fractions residues were apparently lower: hulls, 0.1 ppm; crude soybean oil, 0.01 ppm; refined soybean oil, 0.02 ppm; refined bleached soybean oil, 0.02 ppm; and soapstock, less than 0.05 ppm.

Considering the sensitivity of the methods, 0.01 ppm chlorpyrifos and 0.05 ppm TCP and that only one sample bearing a residue of 0.14 ppm was studied, we cannot adequately judge whether residues in meal will exceed those in soybeans. Therefore, additional data are needed, preferably in the form of a processing study where the residues in soybeans are at the tolerance level. Sufficient residues would then be present in soybeans to observe whether residues in fact concentrate in meal.

In addition, if additional metabolites are judged in need of regulation as a result of the resolution of the plant metabolism question, processing studies will be needed for these components.

This deficiency is not resolved.

Response to 7:

Since 2, 3, 5 and 6 remain to be resolved, this deficiency is not resolved.

Response to 8:

Tolerances for soybean hay and forage have been deleted from Section F and Section B has been revised to contain a feeding restriction.

This deficiency is resolved.

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Recommendation:

We recommend against the proposed tolerance. The deficiencies in 1, 2, 3, 4, 5, 6 and 7 still need to be resolved for the reasons discussed above.