

November 29, 1972

PP #2F1230. Daconil on various crops. Amendments of 10/16/72 and evaluation of method tryout.

Coordination Branch
and Toxicology Branch
Registration Division

The subject amendment is in reply to the PCB (L. E. TerBush) letter of 6/22/72 and as a follow-up to the conference of 7/18/72 (see L. E. TerBush memo of conference). The amendment includes amended Sections B and F.

The CB deficiencies, the petitioner's responses and our comments on the responses are listed below in the same order used in the reject letter.

Deficiency 1: A more appropriate tolerance or a longer PHI for the vines of lima beans and snap beans.

Response: The petitioner has amended the label to prohibit the feed uses of the bean vines (lima and snap) and has amended Sec. F by deleting the proposed tolerance of 50 ppm for the vines of lima beans and snap beans.

In addition, the petitioner presents statements from four (4) authoritative sources which support a conclusion that a feeding restriction for the vines of lima beans is practical since the vines will remain under the control of the grower.

Our Comment: The proposed restriction against the feeding of vines of lima beans and snap beans is probably not "practical" in the sense that there will be isolated or occasional instances where individual farmers will feed the vines to livestock. However, with respect to Daconil, we can inform TB that (1) the vines and vine hay of lima beans and snap beans are not considered to be prime feed items (Morrison, "Feed and Feeding"); (2) that there is little likelihood that residues at the time of ingestion would approach the 100 ppm

level necessary to cover foraging or feeding on "zero-day" since it is unlikely that spraying and harvesting would occur on the same day and (3) that residues of Daconil dissipate rather rapidly. Considering all these factors, we consider it unlikely that residues of Daconil on bean vines will be transferred to milk at a higher level than those present on the major feed item, sweet corn forage (see below under Deficiency 3) and (4) if the unlikely event did occur, the higher level in the milk from such a situation would last only a day or so. Thus, unless TB is concerned over an occasional incident wherein Daconil levels would slightly exceed 0.14 ppm for a day or two, we consider this deficiency is resolved.

Deficiency 2: A more appropriate tolerance for snap beans. (A common tolerance of 15 ppm for snap beans and lima beans would be satisfactory.)

Response: The petitioner has amended Section F to propose an increase from the established tolerance of 5 ppm for snap beans to one of 15 ppm.

Our Comment: This deficiency has been resolved.

Deficiency 3: A more appropriate tolerance for meat and milk.

Response: The petitioner is now proposing (in the amended Section F) a tolerance of 0.14 ppm for residues of Daconil and its 4-hydroxy metabolite in milk and in the fat, meat and meat byproducts of cattle. (The above suggested level for milk was agreed on in the conference as being appropriate providing the petitioner imposes a feeding restriction for the vines of lima beans and snap beans.)

Our Comment: As discussed in the conference of 7/15/72, the transfer of 4-OH Daconil to milk and meat is a direct function of the residue level on the feed item. We had concluded in our review of 5/23/72 that a tolerance of 100 ppm would be needed for the vines of lima beans, which could comprise 100% of the cow's diet. Of this 100 ppm, it was calculated that 1 ppm (1%) would be 4-hydroxy Daconil. Based on the available feeding studies, a tolerance of 0.7 ppm for milk (whole milk basis) was necessary. With the amended use pattern, (and as discussed under Deficiency 1 above), the highest tolerance for feed items is 20 ppm peanut vine hay, sweet corn forage and sugar beet tops. Thus, on an adjusted basis, the required tolerance for milk is now 0.14 ppm.

As to meat, we had originally suggested a 1 ppm tolerance as being appropriate, assuming a 100 ppm diet level. On an adjusted basis, this would result in a calculated appropriate tolerance of 0.2 ppm. The fact that the 0.2 ppm is based on the ~~minimal~~ residue level found in an individual cow plus the fact that tolerances for the feed items are based on levels necessary to cover residues on the first day that they could be fed (with levels declining rapidly), we believe it more reasonable to set the tolerance level for meat at the same as that for milk. The proposed tolerance of 0.14 ppm for meat and milk is rather awkward and implies a precision in residue methodology and toxicology which is probably not justified. CB would not object to establishing the proposed tolerances at 0.15 ppm providing that TB concurs.

Deficiency 4: A tolerance of 0.3 ppm for peanut hulls should be proposed.

Response: The petitioner has amended Section F to propose a tolerance of 0.3 ppm for peanut hulls.

Our Comment: This deficiency has been resolved.

Evaluation of Method Trial

AMS, CB has completed the method tryout for residues of 4-hydroxy Daconil in meat and milk (memo of K. T. Zee, 6/27/72). The results are as follows:

Fortification level (ppm)	0.2	0.4
Recoveries, (milk) (%)	65,70	61,76
Recoveries, (beef kidney) (%)	70,65	70,72
Blanks (controls), ppm; for both substrates	<0.01	<0.01

The tryout was at a level slightly above the newly proposed tolerance level. However, the lower tryout level is so close that we do not question the method's ability to recover residues at the lower (tolerance) level.

Mr. Zee reported that no major modifications were made in the petitioner's GLC method. ECGC was used by AMS rather than MCGC.

As indicated in our review of 5/23/72, an alternate non-polar column may be used for confirmatory purposes.

With the exception of the appropriateness of the tolerance for sugar beets, the petitioner has resolved all the CB deficiencies and the method tryout is successful.

Consequently, if TB concurs (see Deficiency 1 above) we recommend for the establishment of the following proposed tolerances:

peanut vine hay, sugar beet tops	
and sweet corn forage	20 ppm
lima beans and snap beans	15 ppm
peanut hulls	0.3 ppm
sugar beets	0.2 ppm
meat, fat and meat byproducts	
of cattle, goats, hogs, horses,	
and sheep and in milk	0.15 ppm

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PP #2F1230

WSCox:mae
11/29/72
RD/init:JGCummings and RSQuick
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