Benomyl PP# 1F1033

October 29, 1971

PP #1F1033. Benomyl on apples, pears. Comments on amendment of 7/14/71 with changes in Sections B and F, and additional residue data.

Petitions Control Branch
and Toxicology Branch

E. I. duPont de Nemours and Company proposes a tolerance for residues of methyl-1-(butylcarbamoyl)-2-benzimidazole carbamate (common name benomyl, trade name Benlate) of 7 ppm on apples, crabapples, and pears from preharvest or postharvest use on combination of such uses. Originally the proposal included also quinces; however, on 11/23/70, the petitioner withdrew this crop from the tolerance request.

In our original evaluation of this petition of 4/9/71, we recommended against the establishment of the proposed tolerances because: (1) no residue data reflecting aerial applications were submitted, (2) the submitted residue data did not indicate the contribution to the total final residue from postharvest dip or spray applications (3) no residue data for crabapples were submitted, and (4) no data were submitted reflecting the level of residues in apple pomace resulting from the proposed use.

On 7/14/71, the petitioner submitted amended labeling. The petitioner deletes all references to airplane applications and consequently limits the proposed use to ground applications only. The petitioner wishes to withdrew the request for the tolerance of 7 ppm on crabapples and now, proposes a tolerance for residues of benomyl of 7 ppm on apples and pears only.

The petitioner submitted additional residue data reflecting postharvest dip applications. The apples were washed in detergent solution prior to treatment to simulate commercial practice. The apples were immersed for 10 seconds, 1 minute, and 5 minutes in 300 ppm 2-C^{14} benomyl. The proposed use is ca. 240 ppm. The residue data indicate that residues calculated as benomyl range from 0.35-0.40 ppm when the apples are dipped for 10 seconds. When the dip time is 1 minute, residues range from 0.50-0.90 ppm. When the apples are immersed for 5 minutes, residues range from 1.00-1.36 ppm.

In another experiment, apples were immersed in 300 ppm of 2-C^{14} benomyl for 10 seconds, 1 minute, and 5 minutes; however, the dip suspension contained surfactant and the apples were not pre-washed. Residues on the apples that were dipped for 10 seconds, 1 minute, and 5 minutes ranged respectively from 0.05-0.08 ppm, from 0.21-0.29 ppm, and from 0.49-0.75 ppm. One apple of each time interval was peeled and the

residues in the peel and interior of the apple determined. Residues in the peel of the 10 second, 1 minute, and 5 minute dips were respectively 1.6 ppm, 1.6 ppm, and 3.1 ppm. Residues in the interior of the apple were respectively 0.01 ppm, 0.04 ppm, and 0.13 ppm.

No data for other postharvest applications such as sprays or flooding procedures were submitted. From the review of other petitions, we know about the various equipment and procedures used in postharvest spray, flood and dip techniques. Although the petitioner states that the 5 minute dip represents an exaggerated time interval, under commercial processing, we know of postharvest applications which subject fruit to a 5 minute treatment. Therefore, we will use the data from the 5 minute immersion test. Consequently, we note that up to 1.36 ppm in or on Winesap apples can be contributed by postharvest applications from a slightly exaggerated dosage. The petitioner does not indicate what the variation in the extent of the residue is when the size of the apples become smaller. Usually, the residues will increase when the size of the apples decreases, sometimes as much as 2 times. However, residues submitted for various sizes of apples concerning residues of Thiabendazole show that the increase in concentration of residues as a function of smaller size is practically nil. Therefore, it is our estimation that on an overall basis the contribution to the total residues from the maximum proposed use for postharvest applications will be ca. 1.5 ppm.

In our previous evaluation of PP #1F1033, of 14/9/71, we estimated the maximum residue contributed from preharvest use to be ca. 5 ppm. Consequently, the total maximum residue (6.5 ppm) will not exceed the proposed tolerance of 7 ppm for apples and pears.

Residue data for apple juice shows that no concentration of residues takes place as compared with those on the whole fruit. We anticipate residues in apple juice not to exceed the proposed 7 ppm for apples and therefore no food additive tolerance for apple juice is needed.

Concerning the residues in apple pomace, residue data indicate a concentration of residues from the whole apple to dry pomace af as much as 10 times. Residues in the wet pomace are ca. 1.4 times those present in the whole fruit or 9.0 ppm. Because the dry pomace is the product which is introduced in inter-state commerce, we must concern ourselves with this commodity. Legally, apples may contain as much

as 7 ppm benomyl. Dried apple pomace could have up to 7 x 10 = 70 ppm of benomyl when shipped inter-state. We therefore advise the petitioner to propose a food additive tolerance which will cover these residues.

Wet apple pomace as well as dried apple pomace can be used as feed items for cows. We contacted the American Apple Institute in Washington, D. C. (see memo of conference re: PP #1F1031 of 8/17/71 by L. E. TerBush) which indicated that wet apple pomace may be fed to cows up to 50% of the diet. It is our understanding that dried apple pomace, which usually is fed from 20-5% of the diet, can be fed up to 30% of the diet (see aforementioned memo of conference). Accordingly, if a cow were fed dried apple pomace containing 70 ppm of benomyl at 30% of her diet, the total diet would contain 70 x .30 = 21 ppm of benomyl.

In PP #1F1010, the petitioner proposed afor a tolerance of 0.05 ppm in meat, fat and meat byproducts of cattle, goats, hogs, horses, and sheep and a tolerance of 0.05 ppm in milk for residues of benomyl which occurred in or on feed items from snap beans, peanuts, and sugar beets. The petitioner withdrew this proposal for meat and milk tolerances because of deficiencies in the liquid chromatographic method to be used for enforcement purposes. Feeding studies submitted with PP #1F1010 and which are partially submitted with this amendment indicate that, at a dosage of 21 ppm, metabolites of benomyl would definitely transfer to milk (i.e., Category 1, Section 420.6).

The question whether or not residues would transfer to meat (muscle, fat, liver and kidney) was never answered in PP #1F1010 because liquid/liquid chromatograms by which the feeding study results had been calculated were, at the time the petitioner filed for withdrawal of the meat and milk tolerances, still under evaluation. The petitioner agreed to send us additional chromatograms but has not done so. Consequently, we cannot give an opinion whether or not residues of benomyl will transfer to meat (muscle, fat, kidney, and liver). It is our opinion that the petitioner should resubmit his proposal for suitable tolerances for residues of benomyl in meat and milk with the appropriate data and chromatograms.

Conclusions

1. The petitioner deleted all references to airplane applications on the revised labeling; therefore, no additional data reflecting these applications are required.

2. Additional residue data from postharvest dip applications indicate the contribution to the total final residue on apples from postharvest applications to be ca. 1.5 ppm. The total final residue is estimated to be ca. 6.5 ppm. The proposed 7 ppm tolerance will be adequate to cover these residues and also those which may be present in the juice.

3. Residues in or on dried apple pomace may be as much as 70 ppm. Wet apple pomace may contain an estimated 7 ppm x 1.4 = 9.8 ppm. An appropriate food additive tolerance for either one is indicated.

4. The feeding of dried apple pomace will transfer residues of benomyl (hydroxy metabolite) to milk (Category 1, Section 420.6(a)). No adequate data have been submitted indicating whether or not residues of benomyl will transfer to meat (muscle, fat, kidney, and liver) at a daily diet of 21 ppm fed to cows.

Recommendations

For a favorable recommendation, the petitioner should be informed:

1. An adequate food additive tolerance for dried apple pomace is needed.

2. That we also need an adequate tolerance for residues of benomyl in milk and adequate data and chromatograms indicating whether or not a tolerance for meat is also necessary.

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