PP# 451450

PP# 4F1452 and FAP# 5H5D62. Benomyl on tomatoes. Comments on amendment of 8/16/74.

11/4/14

Coordination Branch and Toxicology Branch, RD

The petitioner has responded to the two deficiencies in a COB reject letter from C.M. Young (5/16/74). The response consists of a food additive tolerance proposal for benomyl residues on concentrated tomato products and a reference to manufacturing information submitted on 7/9/74 to satisfy the same CB requirement in PP/ 4F1456.

The first deficiency in the reject letter requests benomy? residue data for concentrated tomato processed food items, namely, ketchup and/or tomato paste. The petitioner submitted residue data which show that the benomy! residues concentrate to the same degree as do the solids in the concentration process. Consequently, a food additive tolerance proposal of 50 ppm is included for the combined residues of benomy!, and its metabolites containing the benzimidazole molety, in or on concentrated tomato products when present as a result of the application of benomy! to field and greenhouse tomatoes.

Field treated tomatoes, containing 1.2 and 3.2 ppm benomyl, were ground, concentrated by cooking to approximately 50% of their original weight, and then screened to make a puree. A control tomato sample fortified with 3.0 ppm benomyl was carried through the same process on a laboratory scale.

The tomatoes and puree were analyzed for benomyl residues using the same liquid chromatographic method as that used to obtain the residue data for tomatoes. The residue levels of the concentrated products (adjusted to a 50% weight loss) were found to be 2.2 ppm, 6.9 ppm and 6.6 ppm for the two field treated and fortified tomato samples, respectively. These results indicate concentration factors of 2.2, 1.9, and 2.1 for the benomyl residues (cf. solids concentration of 2.0). Also included in the present amendment is information from Food Industries Manual, 20th Ed., Chemical Publishing Co., N.Y., which states that the solids content in concentrated tomato products may range from a 4-fold to 8-fold increase over the starting material. Considering these facts and our previous conclusion that residues of benomyl will not exceed 5 ppm from the proposed use (see memo of R. Beyak, PP# 4F1452, 5/10/74), we conclude that the residue level in concentrated tomato products may reach 40 ppm.

PP# 4F1452-Page 2

A food additive tolerance of 50 ppm has been established for raisins (CFR 121.1254); therefore, it is proposed that this level be extended to include concentrated tomato products. We conclude that the proposed food additive tolerance of 50 ppm is adequate to cover the residues of benomyl, and it's metabolites containing the benzimidazole moiety, in or on concentrated tomato products resulting from the proposed use on field and greenhouse tomatoes. This action along with the supporting data resolves the first deficiency in the reject letter.

The description of the manufacturing process for benomyl submitted in connection with PP# 4F1466 satisfies the second deficiency in the reject letter of 5/16/74 (see memo of R.S. Quick, PP# 4F1466, 7/24/74).

We recommend for the establishment of the proposed tolerances for benomyl in or on tomatoes at 5 ppm and processed tomato products at 50 ppm. We note that favorable recommendations were reported by TB (R.D. Coberly, PP# 4F1452, 2/28/74 and FAP# 5H5062, 9/25/74) and EEEB (R.E. Ney, Jr. and F.J. Schenck, PP# 4F1452, 7/29/74).

Richard Beyak Chemistry Branch Registration Division

cc: Tox. Br. RO-130(FDA) P. Critchlow EEEB CB(4)

RBeyak: yp: 11/5/74

RD/I-ELGunderson: 11/5/74 RSQuick: 11/1/74