COMMISSIONER OF FOOD AND DRUGS

Drew M. Baker, Jr. Petitions Control Branch, SCI-R

RRIKFING MEMORANDUM McLaughlin Gormley King Co. Minnespelis, Minn. (AF 8-176)

Food Additive Petition No. 6H1946 -- MCK 264

Petition No. 6H1946 is a request to allow certain combinations of MGK 264, piperonyl butoxide, and pyrethrins as an insecticide in areas used for processing and storing foods. MCK 264 is the tradename for the insecticidal synergist N-octvihicralshopteredia. synergist N-octylbicycloheptenedicarboximide. All of these pesticide chamicals are exempt from the requirement of a telerance when applied to o growing crops.

Various pesticide tolerances already established for posthervest use of piperonyl butoxide and pyrethrins on raw agricultural commodities allow o up to 20 and 3 ppm, respectively, on certain grains and up to 8 and 1 ppm respectively on some other commodities. Food additive telerances for piperonyl butoxide and pyrethrins allow up to 10 and 1 ppm, respectively, to cover specified uses on dried foods and on milled cereal grain fractions. Residues in the foods treated in accordance with the proposed directions in Petition No. 6H1946 are not to exceed 10 ppm MCK 264, 10 ppm piperonyl butoxide, and 1 ppm pyrethrins.

The Division of Food Standards and Additives finds that adequate analytical methods are available for enforcement. They find that residues in foods would not exceed the proposed tolerance levels under the proposed conditions of use. These conditions do not involve direct application to food since the label directions provide for the covering or removal of food before treatment. The proposed treatments in addition to those already permitted for piperonyl butoxide and pyrethrins will not result in residues in excess of the established tolerances of 20 and 3 ppm, respectively in grains and not in excess of the established tolerances of 10 and 1 ppm, respectively, in other specified foods.

The Division of Toxicological Evaluation finds that the proposed tolerances are safe. Adequate 3-generation reproduction studies and 2-year feeding studies have been submitted for MCK 264 and the present tolerance levels for piperonyl butoxide and pyrethrine are unchanged.

The Posticides Regulation Division of the U.S. Department of Agriculture has advised that the proposed labels are acceptable according to their requirements. Received

We recommend that the attached order be signed and published.

S APPROVED:

F. J. McFarland, Chief Petitions Control Branch Rureau of Science

L. L. Ramsey, Assistant Director for Regulatory Programs Bureau of Science 000377