Toxicity data considered in setting the tolerance for the Pesticide Petition:

- Oral LD₅₀: 1,000 - 2,850 ppm/kg
- Oral LD₅₀: 2,300 - 5,300 ppm/kg
- 47-day Human Feeding Study - MRL = 0.2 mg/kg/day
- 2-Year Rat Feeding Study #1 - MRL = 100 ppm
- 2-Year Rat Feeding Study #2 - MRL = <100 ppm
- Rat-Assay Mutagenicity - negative
- Revision Assay Mutagenicity Study - negative
- Delayed Neurotoxicity Study - negative
- 1-Generation Reproduction Study - reproductive effects observed at 4,900 ppm
- Single Dose Intraperitoneal Teratogenic Study - negative

2. The following studies and data are considered desirable but currently lacking:
   a. Teratogenic Studies - 2 species
   b. 3-Generation Reproduction Study
   c. Teratogenicity (Feeding) Study

7. All the above studies were previously requested on 1/27/76 in review of PP 17-4110 and on 12/25/76 in review of PP 7E1881. It is expected that these studies will be required at the time of reregistration.
4. The following tolerances have been granted for the pesticide Malathion:
   a. PP# 13
   b. PP# 90
   c. PP# 156
   d. PP# 187
   e. PP# 752001
   f. PP# 015140
   g. PP# 7E1381

5. Approval of the requested will not affect the ADI for the following reason:

   a. Tolerances are presently in existence for residues of Malathion in meat, milk, and meat by-products extending from tolerances on other forage crops.

6. The ADI was determined from a 47-Day Human Feeding Study in which the no observable effect level (NOEL) was 0.2 mg/kg/day. A ten fold safety factor was employed in calculation of the ADI.

   \[
   \text{NOEL} = 0.2 \text{ mg/kg/day} \\
   \text{ADI} = 0.02 \text{ mg/kg/day}
   \]

7. No regulatory actions are pending against registration.

8. One consideration in recommending that the tolerance be established is that the latest Total Dietary Survey indicates that residues of Malathion in the U.S. food supply do not exceed the WHO ADI of 0.02 mg/kg/day.