UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: June 29, 1978

SUBJECT: Carbaryl - adjustment of ADI

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TO: Ed Gross
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and
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PP No: 6E1848, 7E1878, 7E1935 7E1974

Caswell No. 160

A rereview of the existing toxicity data summaries was necessary to eliminate the current fluctuations in the basis for calculation of the acceptable daily intake. The current variations in the establishment of the no effect level-hence a variation in the ADI-in both the two year rat feeding study and the one year dog feeding study are due totally to different individuals' classification of the same minor toxicological findings. In a split decision type arrangment these findings were considered as minor but never the less real effects by one reviewer and as minor and but transitory by another reviewer. Due to this condition, we have reexamined the rationale for prior decisions and have determined that the two year rat feeding study is superior to the one year dog study with respect to setting a NOEL and an ADI for Carbaryl.

Accordingly, we agree with Dr. Fitghugh and Dr. C.P. Carpenter of Mellon Institute that the no effect level for the two year rat feeding study is 200 ppm rather than 400 ppm. For the one year dog feeding study we disagree with Dr. Fitghugh that the NEL is 200 ppm and agree with Dr. C.P. Carpenter that the NEL is 400 ppm. We concur that the findings are transitory conditions and not early stages of toxic degeneration.

Using the rat as the most sensitive species, the following end points are made

1) Acceptable daily intake = 0.1 mg/kg/day.

200 ppm (rat NOEL) x 100 (safety factor)= 2.0 ppm

2.0 ppm x 0.05 (rat factor) = 0.1 mg/kg/day

2) Maximum permissible intake = 6.0 mg/day

3) The theoretical maximum residue concentration is 3.98 mg/day/1.5 kg

4) The TMRC represents 66.43% of the MPI

It should also be pointed out that the experimental results of the subchronic dog feeding would determine an identical ADI and MPI as calculated from the chronic rat feeding study.

RD inital G.E.W.6/28/78:lf

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