



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

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SUBJECT: Safety Factors for Teratogens: Carbaryl

FROM: Kyle R. Barbehenn *KRB*
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TO: George E. Whitmore, DVM
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THRU: Ronald E. Dreer *R. E. Dreer*
Director, Office of Special Pesticide Reviews

Douglas Camp
Acting Director, Registration Division *D. Camp*

Your statement of May 20, 1977 regarding the position of the Toxicology Branch on the teratogenicity of carbaryl is certainly of historical interest and I do not seek to find fault with past RD actions based on the best available evidence and a reasonable interpretation thereof. The situation, however, does involve complex scientific issues that have not necessarily been satisfactorily resolved. Additional comment or input from RD on the following points would be welcome.

1. The conclusion that the metabolism of man and dog differ in relevant ways is based on a single, brief paper on the dog published in 1967. Dr. Wyman Durrough has characterized this work as very poor by current standards. In any event, who can say what the teratogenic mechanism of action is and what compound is responsible? We are dealing here with educated guesses and not a precise, scientific determination.
2. A reanalysis of the guinea pig studies by Dr. Dianne Courtney of RTP certainly suggests that carbaryl may be teratogenic in this species. Thus, we are left with more uncertainties in selecting a defensible "no-effect" level.
3. The ultimate relevance of the monkey studies is debatable.
4. Your statement that exposure from house and garden uses is less than that to be expected from food crops is disconcerting. We are concerned with an effect that may be generated by a single acute exposure during a critical period of gestation. We have been struggling to obtain a valid way to estimate possible exposure to the home gardener who may be treating sweet corn, pole beans, or ornamentals above waist height. If you have made any actual calculations of such potential exposure, we would be very happy to have

the results. If not, we would appreciate any practical suggestions for estimating any of the several factors that enter the equation.

5. The opinion of the Toxicology Branch is respected by OSPR. However, we are required to undertake an independent, rigorous reassessment of all compounds on the RPAR list. The outcome of our review on teratogenic risk is still uncertain.

cc: Patton
Rogoff
Paynter