

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

16 SEP 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: DuPont Comments on the Draft Methomyl Final
Registration Standard and Tolerance Reassessment
(FRSTR) - announced 6/2/88, FR Vol. 53, No. 120, p.
23449 (RD Record No. 230398, DEB No. 4308).

FROM: Debra F. Edwards, Ph.D.
Dietary Exposure Branch
Health Effects Division (TS-769C)

THROUGH: Charles L. Trichilo, Ph.D., Chief
Dietary Exposure Branch
Health Effects Division (TS-769C)

TO: Dennis Edwards, PM-12
Insecticide/Rodenticide Branch
Registration Division (TS-767C)

Debra Edwards

Dupont Comments on Residue Chemistry Requirements in the Draft
Methomyl FRSTR

1. Poultry Metabolism: The Registrant's major concern pertained to the requirement for a poultry metabolism study. DuPont claims that no such study was required in the past in either the 1981 initial Standard or the 3/23/87 Data Call-In and that none should be needed now due to the availability of a poultry feeding study (unlabeled material) showing no measurable residues of methomyl per se (<0.02 ppm) in eggs or tissues of poultry fed a diet of 10 ppm methomyl (MRID 00009365). They propose that the requirement for a poultry metabolism study be held in reserve and triggered only if the metabolism in ruminants is found to differ significantly from that in rats or if residues of concern are found to occur in ruminant tissues or milk.

2. Bulb Onions: A second comment pertained to footnote 14 in the Residue Chemistry data requirement table. The footnote, which details the data requirements for bulb onions, requested data from CO (22%), NY (15%), and OR (26%) or ID (15%), states that accounted for 80% of 1985 U.S. onion production for storage (Agricultural Statistics, 1986, p. 161). The Registrant has inquired if CO should have been CA since, according to their records, "CO accounts for 9% of the total U.S. production of dry bulb onions, while CA accounts for 27%."

DEB Response

1. Poultry Metabolism: The initial 1981 Methomyl Registration Standard required data depicting "metabolism in food producing animals." Although the requirement did not specifically state that poultry data were required, the intent was to require data for both ruminants and poultry since these are both "food producing animals." The requirement for poultry metabolism data was not included in the 3/23/87 DCI because this document was intended solely to call in data to address the acetamide issue in cattle (personal communication with Dennis Edwards, RD, 9/15/88).

Methomyl is used on several crops which may be used as poultry feed items in either raw or processed form (e.g., beans, soybeans, corn, small grains, sorghum, cotton, peanuts). The submitted feeding study using unlabelled material cannot satisfy the requirement for a poultry metabolism study. Metabolism studies using labeled material are required to determine the qualitative nature of the residues in tissues and eggs. The feeding study indicates that methomyl is metabolized or excreted in poultry but does not provide information regarding the qualitative nature of any potential metabolites (e.g., degradates or conjugates), some of which may be of toxicological concern. It is not current DEB policy to reserve the requirement for poultry data, pending evaluation of ruminant data. Furthermore, Subdivision O of the Pesticide Assessment Guidelines clearly states that separate metabolism studies are required for ruminants and poultry. If the metabolism in poultry or ruminants is found to differ significantly from that in the rat, a swine metabolism study may also be required. The Registrant should be notified, therefore, that the poultry metabolism study is required at this time. The time frame for submission should be 18 months from the date of the final Guidance Document.

2. Bulb Onions: The dry bulb onion residue chemistry data requirement was originally written only to include storage onions, >20% of which are produced in CO. The Registrant is justified in questioning this requirement. All bulb onion production (storage, non-storage and processing) should have been considered in formulation of the data requirement. According to the 1986 edition of Agricultural Statistics, CA produces 28% of the U.S. commercial onion crop, primarily for processing, while CO produces 12% (storage). Therefore, if field trials are conducted in CA (28%), NY (9%), and ID (8%) or OR (15%), approximately 70% of the U.S. onion production area will be represented (NY may represent MI [6%] and OR or ID may represent WA [5%]). The Registrant should submit bulb onion field trials from CA instead of (or in addition to) CO.

TS-769C:D.Edwards:DEB:CM#2:Room 812D:557-4353
RDI:W.Boodee:9/88:R.Schmitt:9/88
cc:PMSD/ISB:SF:RF:FRSTR file for methomyl:Reviewer:Circu