**MEMORANDUM**

**April 20, 2000**

SUBJECT: Response to Public Comments on the Preliminary Risk Assessment for the Organophosphate **Coumaphos**

FROM: Monica B. Alvarez, Chemical Review Manager
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TO: OPP Public Docket for Coumaphos

## Introduction

This document addresses public comments that were received in response to EPA's Notice of Availability (64 FR 48164-48165; September 2, 1999) of preliminary risk assessment for two organophosphate chemicals: coumaphos and fenitrothion. Each preliminary risk assessment may contain individual dietary (including drinking water), occupational, residential, and ecological assessments.

To better organize the comments in this document, EPA has divided this document into two parts. Part I of this document addresses comments specific to coumaphos. Comments specific to the coumaphos dietary (food and water) and occupational risk assessments were made by the registrant (Bayer Corporation). The Texas and Southwestern Cattle Raisers Association, the Texas Cattle Feeders Association and the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA APHIS) commented on the benefits of coumaphos. USDA APHIS also submitted specific information on the use of coumaphos in its Tick Eradication Program and provided a summary of cholinesterase monitoring information from its Cholinesterase Testing Program.

Part II focuses on comments submitted to the OPP Public Dockets that generally apply to regulatory or science policy issues that are not unique to any one of the risk assessments.

Full responses to some of the comments are outlined in a December 17, 1999 memorandum from Christina Jarvis to Monica Alvarez. This memorandum is available in the OPP Public Docket for Coumaphos designated for Phase 5 of the TRAC process.

**Note:** Since the closing of the public docket in November 1999, refinements have been made to both the dietary and occupational risk assessments for coumaphos. For further details on how these studies and refinements impacted the risk assessments, refer to the Revised Dietary and Occupational Risk Assessment and related documents, which are now available in the Public Docket and on the Agency's website: www.epa.gov/pesticides/op/coumaphos.htm.

## Part I: Coumaphos-Specific Comments and Responses

The Agency received coumaphos-specific comments from Bayer Corporation (Bayer or the registrant), the Texas and Southwestern Cattle Raisers Association, the Texas Cattle Feeders Association and the U.S. Department of Agriculture, Animal and Plant Health, the Washington State Department of Agriculture's Animal and Plant Health Inspection Service (USDA APHIS).

### A. Response to Comments on the Preliminary Dietary and Occupational Risk Assessments

#### 1. Comments from Bayer Corporation

**Comment:** Bayer stated that the preliminary risk assessment did not reflect Bayer's current labels or requests for voluntary cancellation of several products.

**Response:** The Agency has updated the assessments to reflect the voluntary cancellation of the wettable powder (EPA Reg. No. 11556-21) along with sheep and goat uses and the spray foam insecticide (EPA Reg. No. 11556-40), which were officially canceled by the Agency on January 31, 2000 and July 29, 1999, respectively. Although Bayer has removed the mechanical duster use from its labels, this method of application still remains on other dust labels and was not removed from the risk assessments.

**Comment:** Bayer disagrees with the toxicological endpoint from the 5-day study used by the Agency in its evaluation of the short-term dermal exposure for spray use.

**Response:** The Agency determined that the 5-day dermal toxicity study better characterizes the shape of the dose response for plasma, RBC, and brain cholinesterase inhibition than the 2-day dermal toxicity study. Therefore, the NOAEL of 5.0 mg/kg from the 5-day dermal toxicity study was used in the risk assessments.

**Comment:** Bayer provided the Agency with a dietary risk assessment, which concluded that acute and chronic dietary exposures for the U.S. population are less than 1 percent of the population adjusted dose (PAD) and 1.3 percent of the PAD for chronic, children 1-6, which is the highest dietary exposure.

**Response:** The Agency has reviewed Bayer's dietary assessment and found it to be unacceptable at this time. Bayer used assumptions that are inconsistent with the ones used by the Agency regarding percent livestock treated and did not include the use of Residue Data Files (RDFs) or milk as a commodity. The complete dietary risk assessment conducted by Bayer and the Agency's review can be found in the OPP docket for coumaphos..

**Comment:** Bayer disagrees with the Agency's chronic aggregate risk estimates, which show a risk concern due to the contribution of estimated coumaphos concentrations in ground water based on modeling. The registrant believes that the chronic aggregate assessment is unrealistic and uses ultraconservative assumptions, mainly because of limitations of the water model and an incorrect $K_{oc}$ value for coumaphoxon.

**Response:** The Agency uses the Concentrations in Ground Water (SCI-GROW) model as a Tier I screening-level model in the FQPA drinking water assessment process. SCI-GROW was designed to estimate pesticide concentrations for vulnerable sites (sandy soils with shallow groundwater), which are expected to be upper-bound concentrations in ground water. It serves, therefore, to provide a reliable detection of pesticides that are not expected to exceed human health endpoints. In the absence of data for coumaphoxon, conservative assumptions were used to estimate the potential impact of coumaphoxon movement into surface and ground water. Aerobic soil metabolism and batch equilibrium data for coumaphoxon are clearly stated as data gaps in the Tier I water assessment document, which is available in the OPP docket for coumaphos. Data for coumaphoxon, including its $K_{oc}$ value and half-life, could help the Agency in refining the drinking water assessment.

**Comment:** Bayer states that the most efficient use of Bayer and EPA resources is to focus on the assessments for the dip vat and spray uses of coumaphos, because these are the two major uses with the greatest potential for exposure.

**Response:** The Agency agrees with Bayer that the liquid formulations are used more than the dust formulations; however, exposure to every formulation should be assessed. Presently, the Agency does not have adequate data to determine whether the use of liquids would result in a higher exposure than that from the use of dusts. Liquids and dusts have different exposure routes of concern. Therefore, without adequate data on dusts, exposure resulting from the use of dust formulations cannot be assumed to be acceptable if the spray and dip vat liquid exposures are acceptable. The registrant intends to submit worker exposure studies for the dust formulation of another chemical, which could help the Agency refine the occupational risk assessment.

**Comment:** Bayer disagrees with the several assumptions used by the Agency in its occupational risk assessment, specifically with regard to dip vat and spray uses.

**Response:** The Agency appreciates Bayer's comments and has made some changes to the revised occupational risk assessment to reflect the new information provided by the registrant during the public comment period. For more details on these changes, please refer to the "HED's Response to Comments Submitted During Phase 3 (Public Comment Period)" available in the OPP public docket for coumaphos.

## B. Response to Comments on Benefits and Testimonials

The following comments are testimonials to the benefits of coumaphos and are not related to the preliminary dietary or occupational risk assessments.

### 1. Comments from the Texas and Southwestern Cattle Raisers Association (TSCRA)

**Comment:** TSCRA stated the importance of coumaphos in the cattle industry, particularly to control fever ticks along the Texas/Mexico border.

**Response:** The Agency notes this comment and appreciates TSCRA's participation in the TRAC Public Participation Process.

### 2. Comments from the Texas Cattle Feeders Association (TCFA)

**Comment:** TCFA stated the importance of the continued use of products containing coumaphos to control ticks, flies, and lice in beef cattle. They also commented that coumaphos products are safe to the environment, efficacious, and cost-effective.

**Response:** The Agency notes this comment and appreciates TCFA's participation in the TRAC Public Participation Process.

### 3. Comments from the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA APHIS)

**Comment:** USDA APHIS provided information on the benefits and the use of coumaphos (formulation, volume and personal protective equipment used, etc.) in its Tick Eradication Program. In addition, USDA APHIS submitted a section of its "Safety and Health Manual" on occupational health and summary of cholinesterase monitoring information from its Cholinesterase Testing Program.

**Response:** The information provided by USDA APHIS has helped the Agency to better understand the frequency of use and procedures followed by APHIS staff during the handling of coumaphos in dip vats and in spray applications, as well as the disposal practices of coumaphos spent solutions.

## Part II: Non-Chemical-Specific Comments and Responses

There were no non-chemical-specific comments received in response to this public docket. Some of the chemical-specific comments received relate to Agency policy, and were addressed, as appropriate, in Part I of this document.