This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical, and it is presented here exactly as submitted.

via Federal Express

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Ms. Monica Alvarez
Chemical Review Manager
Special Review and Reregistration Division (H7508W)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
192l Jefferson Davis Highway
Arlington, VA 22202

Subject: Reregistration of Coumaphos

Dear Ms. Alvarez:

This submission is in response to Robert McNally's July 9, 1999 letter on this subject requesting comments within 30 days. We received the letter on July 15, 1999.

Before getting into specific matters there are some general comments which should be made. Coumaphos is a relatively old active ingredient with a very narrow market focus, almost solely for application directly to cattle. Coumaphos products have been safely used in American agriculture for more than 40 years, and although some uses have been phased out by the introduction of newer chemicals (this is the natural progression of our scientific advances and agriculture), there are still certain uses of coumaphos which are very important to American agriculture. For example, Coumaphos is used to control cattle fever ticks, and USDA has estimated that the cattle industry would sustain annual losses of $1-5 billion dollars if cattle fever ticks and the associated disease babesiosis were to become re-established in the U.S. (source, EPA's RED document).

The reregistration process for coumaphos began in 1981 and has continued through the present. Bayer has faithfully provided the data requested by the Agency in the initial guidance document (1981), the second round review document (1989), the Reregistration Eligibility Document (RED, issued in 1996) and a number of other Data Call-In Notices. Bayer has worked with numerous personnel in the Agency over the course of this time period to ensure that appropriate studies are designed and conducted to provide the data necessary to answer all the Agency's questions. Often these specifically designed studies have been necessary because most of the Agency's study guidelines are designed for products which are directly applied to land – such as crop and or turf areas – as opposed

to products directly applied to animals, and the somewhat unusual application techniques such as dip vats and backrubbers.

Bayer is pleased the reregistration process is nearing completion for coumaphos. However, we are very dismayed at some aspects of the recent HED risk assessment. The occupational use risk assessment is particularly problematic. In explanation, over the last 4 – 5 years, Bayer has met with various Agency personnel to address this issue, explained the unusual application techniques, made a video to demonstrate the application techniques, generated data specifically to address this issue, and with the submission of the special short-term dermal exposure study (Agency personnel were very helpful in working with Bayer's toxicologists to design this special study specifically to address short-term dermal occupational exposure issue) documented that the dip vat and spray uses of coumaphos are safe. These two uses are the "worst case" exposure scenarios for coumaphos and as they are safe, the other minor, lower exposure application scenarios are safe. This approach to focus on the highest exposure scenarios has been discussed and agreed upon throughout the process. Considerable Bayer and Agency resources were spent to address this matter. However, the recent occupational risk assessment either ignores or disregards nearly all of the previous efforts. To go back and "reinvent the wheel" is a terrible waste of both Bayer and Agency resources.

The following comments are in some instances very specific and in others very general. A 30-day comment period is inadequate to provide detailed comments, particularly in those instances where previous work is ignored or dismissed, and entire assessments have to be repeated. In addition, Bayer's relatively recent cancellation of Co-Ral® 25% Wettable Powder, EPA Reg. No. 11556-21, on June 3, 1999 will require both the Agency and Bayer to revise risk assessments to reflect this. We assume the Agency is interested in using the most accurate information in making their decisions and is not being driven any arbitrary time deadlines.

Consequently, although the previous uses of Co-Ral 25% Wettable Powder, as also with the other coumaphos products, are safe, nevertheless, Bayer will be providing more detailed comments reflecting only the most current labeling and use information in the future.

Since the RED was issued, Bayer has voluntarily cancelled Co-Ral (Coumaphos) Insecticide Pour-on, EPA Reg. No. 11556-25, K.R.S. With Co-Ral (Coumaphos) Spray Foam Insecticide, EPA Reg. No. 11556-40, and Co-Ral (Coumaphos) Animal Insecticide 25% Wettable Powder, EPA Reg. No. 1156-21. In addition, every coumaphos label has been revised in accordance with the RED and agreements with the Agency's reregistation personnel. In general, these cancellations and changes in the use patterns are not reflected in the Agency's risk assessments.

As examples, based on these cancellations, there are no longer any registered uses for sheep or goats. Moreover, Bayer has previously proposed and the Agency accepted revised labeling from Bayer removing the use of our 1% dust formulation in mechanical dusters. However, these uses are still discussed in the HED risk assessments.

Bayer proposed deleting the mechanical duster use and the voluntary cancellations for two primary reasons. First, there is no longer a market need, or only a minimal market need, for these uses or formulations (i.e., no one uses mechanical dusters anymore), and second because Bayer is sensitive to not wasting the Agency's resources evaluating uses or formulations that are not needed by agriculture.

The use rates in many of the risk assessments are incorrect. The correct label application rates range from 0.0025 to 0.029 pounds active ingredient per gallon of spray or dip, 0.000625 to 0.00125 pounds active ingredient per animal for dust applications and 0.042 pounds active ingredient per 1,000 square feet of swine bedding.

A specific correction that should be made in the documents is that coumaphos technical is a solid material with a purity of 96%; it is not a liquid with a purity of 93% as stated in some of the risk assessments.

With regard to the occupational risk assessments, as previously stated, Bayer has worked with the Agency to provide information (including preparing and providing a videotape to visually demonstrate how coumaphos products are used), to provide data, to develop and reach agreements which are not reflected in the current HED document. For example, following the last joint meeting with the Agency on this issue, Bayer agreed to limit the number of cattle which can be sprayed to no more than 100 head per day at the full use rate and limit spraying to 200 head of cattle per day when half the full use rate is used. These label restrictions were to be maintained until the short-term dermal exposure study was completed. Bayer's labels currently contain this "100 head per day" limitation (we will be proposing to remove this limitation in the future based on the data cited in our February 2, 1999 letter). However, the HED document does not cite the current 100 head per day limitation and uses 1,000 head in the risk assessment.

With regard to dip vat uses, the HED occupational risk assessment assumes one person would mix and load a dip vat and recharge the dip vat on the same day. This is an incorrect assumption. As previously related to the Agency, dip vats are only very infrequently filled, possibly once or twice a year, or even more infrequently, depending upon the number of animals dipped in the vat. We are not certain at this time if one person alone could mix and load a 5,000 gallon vat in one day, and we will seek more information on this. Nevertheless, no one will fill an entire vat and then have to recharge it in the same day. With regard to recharging dip vats, for the large 4,000 gallon vats, one worker can mix and load up to 1,000 gallons (25% of vat size) in a day; for the smaller vats, a recharge would be up to 450 gallons in a day.

With regard to the evaluation of short-term dermal exposure for the spray uses, the incorrect toxicological end point was used. As the Agency documents state, there are definitive NOAEL's established for 2-day dermal exposures, 5-day dermal exposures and 21-day dermal exposures. The HED documents relate that the survey of spray uses demonstrate that for some short-term exposure scenarios, the spraying operations typically took less than 21 days. In fact, the survey demonstrated the spray operations are less than 2 days (detailed later). HED uses the 5-day NOAEL because among other reasons, "the toxicity endpoint (NOAEL) from the 2-day study will underestimate the worker risk because short-term exposure is defined as exposure to a pesticide from one to seven days." The Agency can define short-term exposure in any manner they wish, and exposure from 1 to 7 days is a fine general definition, but in this particular situation, the length of spray uses is very well-defined (see below), and these exposures are infrequent and less than 2 days in length. To use a 5-day value when a 2-day value is available is incorrect in the risk assessment for spray uses of coumaphos.

The spray uses are documented in the survey cited by the Agency and the most pertinent information relating to lengths of exposure are detailed below.

In response to "How many times per year does your operation spray cattle?," there were 71 definite numerical responses. The average was 3.2 times per year; 66 of 71 responses (93%) were $\leq$ 6 times per year. The maximum values were 1 response at 20 times per year, 1 response at 15 times per year and 2 responses at 10 times per year with all the remaining responses $\leq$ 7 times per year.

In response to "How many days per year does each individual spray?," there were 69 definitive, numerical responses. The average was 3.4 days per year; 63 of 69 responses (91%) were $\leq$ 6 days per year. The maximum values were 1 response at 20 days per year, 1 response at 15 days per year and 1 response at 10 days per year with all the remaining responses $\leq$ 9 days per year.

Note how the responses are nearly identical between the number of times per year spraying occurs and the number of days per year reported for spraying.

Moreover, with regard to how much spraying a person does on a "spray" day, there were 68 definitive, numerical responses to the question "How man hours per workday does an individual spray cattle with insecticide?". The average response was 2.2 hours per work day; 49 out of 68 responses (72%) were $\leq$ 2 hours per day; 61 out of 68 response (90%) were $\leq$ 4 hours. The maximum values were 2 responses at 8 hours, 4 responses at 6 hours and 1 response at 5 hours; all other 61 responses were $\leq$ 4 hours.

In summary with regard to occupational uses of coumaphos, the two uses with the most exposure are the dip vat and spray uses. The MOE's for dip vat uses of coumaphos along with additional weight-of-the evidence data are summarized in Bayer Report No. 74852,

(EPA MRID No. 44296901). In addition, Bayer provided additional data from dip vat studies conducted in the UK. In these studies, although the workers were exposed, no cholinesterase inhibition below normal human values were observed in any of the workers. Even more convincing, the USDA monitors cholinesterase depression in its dip vat workers, and the USDA has not found the use of coumaphos to cause cholinesterase depression. Abnormal cholinesterase measurements have been obtained only very infrequently, but when these were investigated, the causes responsible have been something other than coumaphos.

With regard to spray uses, the MOE's for the spray uses of coumaphos liquid formulations are 3,571 for mixing/loading and spraying 100 head per day and 488 for 1,000 head per day as reported in Bayer's February 2, 1999 letter.

With regard to dietary risks, there are some minor errors in the HED DEEMS analysis, and the analysis should reflect the deletion of sheep and goat uses. Bayer is in the process of preparing a revised analysis and will submit this in the future. Bayer's preliminary results indicate coumaphos residues represent only 0.2% of the acute PAD and 0.4% of the chronic PAD.

With regard to the drinking water risk assessment and the subsequent aggregate (dietary plus drinking water) assessment, there is a very significant error. In Bayer's preliminary recalculation of the drinking water assessment, it appears the Agency used a K_{OC} value of 7,700 for the parent compound coumaphos; however it appears the Agency used a K_{OC} value of 0.1 for the oxygen analog of coumaphos. This erroneous K_{OC} value for the oxygen analog results in an erroneously high ground water value, subsequent drinking water and subsequent aggregate risk values. The oxygen analog of coumaphos is slightly more polar than the parent compound, but the K_{OC} value for the oxygen analog will not be 77,000 times lower than the K_{OC} for coumaphos. Bayer will examine the existing environmental fate data to determine the ability to provide a more reliable K_{OC} value for the oxygen analog to provide a more meaningful drinking water exposure assessment.

The above comments are the result of Bayer's brief review of the HED risk assessment. A more detailed review was not possible within the 30-day timeframe imposed by EPA. Bayer will continue its evaluation of the assessments and will provide these in the future.

If you have any questions on these comments, please do not hesitate to call me at (913) 268-2588.

Sincerely,

F. Terry McNamara

Manager, Preclinical Development

FTM/lt