

Bayer HealthCare  
Animal Health



June 27, 2016

**Submitted electronically through Regulations.gov**

**Office of Pesticide Programs (7508P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potmac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501**

Re: Chemical Common Name: **Coumaphos**; PC Code 036501  
Docket EPA-HQ-OPP-2008-0023

Submission of benefit, general sales and application use  
information in response to the Agency's Registration Review  
Draft Risk Assessments

Bayer HealthCare LLC  
Animal Health  
P.O. Box 390  
Shawnee Mission, KS 66201-0390

Attn: Mr. Brian Kettl, Chemical Review Manager  
Risk Management and Implementation, Branch I  
Pesticide Re-evaluation Division (7508P)

Dear Mr. Kettl:

Bayer is the sole registrant of Coumaphos Technical (EPA Reg. No. 11556-11) and does not sell technical to formulators nor authorizes any Supplemental Distributor Registrations of coumaphos-containing products, except for *Checkmite+ Bee Hive Pest Control Strip* (EPA Reg. No. 11556-138-61671.) For risk assessment purposes, the Agency should not consider the use patterns or sales of any other end-use coumaphos-containing products except those registered to Bayer HealthCare LLC, Animal Health Division (EPA Company Number 11556).

The attached additional information is being submitted to provide continued support of the subject active ingredient pursuant to the Agency's Registration Review Draft Risk Assessments.

Please find attached the document titled:

*"Benefit, General Sales and Application Use Information for Coumaphos-containing Products," dated June 27, 2016, Bayer HealthCare LLC, 12pp.*

**Please ensure that a copy of the attached document, as well as the document titled "*General and Specific Sales Information*," dated June**

**27, 2016, and submitted separately as Confidential Business Information (CBI), is made available to all scientific risk assessors for their use in understanding the actual use patterns and sales of all coumaphos-containing products.**

If there are any questions concerning this response, please contact me by telephone (913-268-2751) or e-mail ([doug.spilker@bayer.com](mailto:doug.spilker@bayer.com)).

Sincerely,

A handwritten signature in black ink, appearing to read "Douglas A. Spilker", followed by a long horizontal line extending to the right.

Douglas A. Spilker. Ph. D.  
Manager, EPA Regulatory Affairs



**Benefit, General Sales and Application Use Information for  
Coumaphos-containing Products**

**Bayer HealthCare LLC, Animal Health Division**

**POB 390, Shawnee Mission, KS 66201**

**June 27, 2016**

## Benefit, General Sales and Application Use Information for Coumaphos-containing products

Bayer is the sole registrant of **Coumaphos Technical** (11556-11) and we currently market five coumaphos-containing end-use products. Based on Bayer sales of all coumaphos-containing products for 2015, the total use volume of coumaphos active ingredient was 25,816 lb., significantly lower than the 71,000 lb. A.I. presented in the “2008 EFED problem formulation.” Bayer concurs that the largest use is on cattle, followed by bee hives, with only a small amount going for other livestock such as swine and horses. Our calculations estimate that only 2.2% of cattle treated would potentially contribute to any residues in the food supply, and only an estimated 4% of the bee hives being treated with a coumaphos-containing product.

### 1. Coumaphos-containing Product Registrations

For risk assessment purposes, the Agency should not consider the use patterns or sales of any other end-use coumaphos-containing products (especially other dusts) except those registered to Bayer Animal Health (EPA Company Number 11556; see Table below).

EPA Registration Number	Product Name	% Active Ingredient
11556-14	Co-Ral® Animal Insecticide 1% Bulk Dust	1.0%
11556-98	Co-Ral Flowable Insecticide	42.0%
11556-115	Co-Ral Fly and Tick Spray	6.15%
11556-138	Checkmite + Bee Hive Pest Control Strip	10%
11556-148	Corathon Insecticide Cattle Ear Tag	15.0%

There are three coumaphos-containing products registered by Bayer with the U.S. EPA, which although federally registered, are not currently produced or marketed and are being discontinued (state licenses are requested for cancellation). Therefore, these products are not listed in the sales 2015 figures, nor should they be used in any risk assessments. Those include:

EPA Registration Number	Product Name	% Active Ingredient
11556-4	Co-Ral Shaker Can (1% Dust)	1.0%
11556-23	Co-Ral (Coumaphos) Emulsifiable Livestock Insecticide	11.6%
11556-123	Co-Ral Plus Insecticide Cattle Ear Tag	20%

Bayer is the sole registrant of **Coumaphos Technical** (11556-11) and no longer sells technical to formulators nor authorizes any Supplemental Distributor Registrations of coumaphos-

containing end-use products, except for **Checkmite+ Bee Hive Pest Control Strip** (EPA Reg. No. 11556-138-61671.) Although there may be such products in the channels of trade, the supply of these products is disappearing, and therefore they should not be included in any risk assessment for the future evaluation of coumaphos.

## 2. Value and Benefit Information

### Resistance Management

Nuisance and blood-feeding flies (Insecta: Diptera) cause enormous economic losses to the U.S. livestock industry. For example, using cattle inventories and average prices for 2005 – 2009, losses due to the stable fly (*Stomoxys calcitrans*) alone are estimated to be: \$360 million for dairy cattle; \$358 million for cow-calf herds; \$1,268 million for pastured cattle; and \$226 million for cattle on feed, for a total impact of \$2.221 billion per year (Taylor et al. 2012). Byford et al. (1992) estimated annual losses in cattle production due to horn flies (*Haematobia irritans*) and face flies (*Musca autumnalis*) at \$730 million and \$53 million, respectively. Corrected for inflation ([http://www.bls.gov/data/inflation\\_calculator.htm](http://www.bls.gov/data/inflation_calculator.htm)) these numbers become \$1.245 billion and \$90 million, respectively. Furthermore, these figures do not include losses due to the most widespread fly species in livestock operations, the house fly (*Musca domestica*).

Scott et al. (2013) examined the resistance levels in house flies collected from nine states (CA, NM, KS, NE, MT, MN, FL, NC and NY) to the six most commonly used insecticides for house fly control.

Insecticide	IRAC Mode of Action (MoA) Group
methomyl	1A
tetrachlorvinphos	1B
pyrethrins (with the addition of piperonyl butoxide)	3A
permethrin	3A
cyfluthrin	3A
permethrin	3A
imidacloprid	4A

These authors determined that the effectiveness of insecticides available for house fly control varies between states. However, resistance in some states is relatively high to all compounds they tested, suggesting that resistance is reducing effectiveness of the remaining insecticides available for house fly control.

A similar situation exists for horn flies. Organophosphate insecticide cattle ear tags became available in the late 1970's. Pyrethroid ear tags were launched in 1981, and pyrethroid resistance in horn flies was first detected in the U.S. in 1984. Since the late 1980's rotation

using an organophosphate tag (such as coumaphos-containing **Corathon Cattle Ear Tag**) for three years followed by one year with a pyrethroid tag has been recommended. In the 30+ years since pyrethroid tags were introduced, an abamectin (plus piperonyl butoxide) ear tag is the only new rotational compound/mode of action (MoA) currently on the market for horn fly control.

In a recent draft Pesticide Registration Notice (PRN 2016-X, "Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling") the EPA considers the development of pesticide resistance to be an adverse event, and acknowledges that managing resistance development is an important part of sustainable pest management. An important proactive resistance-management strategy is pesticide rotation with different MoA's to control target pests in any given location. Rotation may delay resistance development, without resorting to increased rates and frequency of application, and may prolong the useful life of pesticides.

Clearly the number of insecticide MoA's available for rotation to control some of the most economically important livestock pests is very limited. Without effective compounds, economic losses of cattle producers will be even greater than those noted above. This is why for certain product reviews, such as this one for coumaphos (one of the few remaining organophosphate rotational options with multiple application uses), EPA's risk-benefit determination and registration evaluation need to be influenced by factors linked to pest resistance and its management.

### **Quarantine Pest Control**

USDA-APHIS uses **Co-Ral Flowable** (42% coumaphos, EPA Reg. No. 11556-98) in their Cattle Fever Tick Eradication Program (CFTEP). Coumaphos has been the most effective chemical at treating the southern cattle tick, *Boophilus microplus*, and the cattle fever tick, *B. annulatus*. These ticks carry and transmit the two species of blood parasites, *Babesia bovis* and *B. bigemina*, which cause the cattle diseases collectively known as "Texas fever," "cattle fever," or "bovine babesiosis." The use of coumaphos has allowed APHIS to ensure the eradication of exotic introductions of these ticks. Without the program's current use of coumaphos, APHIS expects widespread reintroduction of cattle fever ticks within 1 year, ending the effectiveness of the CFTEP in Texas and severely threatening the cattle industry in the United States.

### **3. General Sales Information**

Based on Bayer sales of all coumaphos-containing products, the total use volume of coumaphos active ingredient for 2015 was 25,816 lb., significantly lower than the 71,000 lb. A.I. presented in the "2008 EFED problem formulation." Bayer concurs that the largest use is on cattle (~90%), followed by bee hives, with only a small amount going for other livestock (~5%.) About 50% of the active ingredient was sold as cattle ear tags, for which the Agency has found occupational

exposure to be “negligible” when applying. Furthermore, the Agency should not consider the ear tags as a significant pathway of potential exposure for environmental, drinking water or ecological effects, since these impregnated plastic products are designed for slow release of very low amounts of active ingredient at any one time over a 5-month performance period.

**Co-Ral Flowable** (EPA Reg. No. 11556-98; 9% of total coumaphos A.I.) is restricted for use in Texas to employees of the USDA-APHIS under the “Cattle Fever Tick Eradication Program,” with a unique application method (dip vat). The Agency has decided to evaluate the potential exposure pathway of the dip vat use independent of all other coumaphos uses. After combining the ear tag and dip vat uses (57%), the remaining 43% of the total coumaphos active ingredient is spread across spray, dust, back rubber and bee hive uses.

Based on sales of the various coumaphos-containing products and their known use patterns (e.g. number of applications per animal, etc.), Bayer has calculated the number of animals treated with all coumaphos-containing products for 2015. Since the majority of the use is on cattle, the treatment incidence rate was calculated using the USDA inventory of cattle in the U.S. Accordingly, approximately 3,146,242 animals were treated with coumaphos, out of the 2015 U.S. cattle inventory of 92,000,000 (~3.4% treated.) Further breakdown of sales by product and estimates of animals treated per product will be available to the Agency, but will be submitted as Confidential Business Information.

#### **4. Application Use Information**

Please find below, additional application use information gleaned from various sources, including USDA, Cooperative Extension Service, and Bayer’s Marketing and Field Veterinarian staff.

##### **Cattle Ear Tags**

The application of active ingredients to cattle through ear tags is a convenient way to minimize the labor necessary for insect control by applying very small amounts of the active ingredient(s) over the desired seasonal interval for pest (fly/tick) control on pastured cattle (ear tags are not used on confined-feedlot cattle), lasting generally from late spring through summer and into early fall. The mechanism to achieve the release of insecticide is through the use of active ingredient(s) formulated into a plastic matrix, and the plastic tag attached to the ear(s) of the animal. The active ingredient(s) slowly and continually migrates from the interior of the plastic tags to the surface where the active ingredient(s) spreads on the animal surface and can act on the pests. In terms of labor, this is a convenient mode of application, and popular because tags can be applied when cattle are worked (e.g. vaccinated, etc.) in the spring and early summer, before being turned out to pasture. The tags remain on the animals to provide pest control throughout the following 3-5 months of fly season. Cattlemen using ear tags will only apply

them once per year. The label allows for flexibility in the number of tags applied per animal based on anticipated fly pressure, with some users applying 1 tag per animal and some applying 2 per animal; we encourage the Agency to use an average of 1.5 tags per animal, since actual use figures are not available. Furthermore, it is very uncommon for cattle treated with an ear tag to be also treated with another ear tag, dust, spray or have access to a dust bag or back rubber containing coumaphos.

### **Dust Applications**

Less than 3 percent of coumaphos dust treatments will occur in confined animals; nearly all dust applications are for horn fly control on pasture cattle using dust bags. Confined animals typically are not treated for horn flies. Environmental pests such as house flies and stable flies, which are the most common pests of confined animals, are not effectively controlled by on-animal applications of pesticides.

### **Spray and Back Rubber Applications**

About 95 percent of **Co-Ral Fly and Tick Spray** is applied as a spray on beef cattle, with about 4 percent of product sprayed on other species such as pigs. Co-Ral Fly and Tick Spray is not a preferred product for use with back rubber applications, and therefore very little is used this way. It is more expensive to use and more difficult to mix than alternate pyrethroid products currently available to producers.

### **Bedding Treatments**

Very few treatments, dust or spray, are applied to livestock bedding. The few ranchers treating bedding only make one application per year, since it is costly.

### **General Information on Feedlot Pest Control**

According to the United States Department of Agriculture, APHIS (2011), only approximately 0.6% of all U.S. feedlots use any organophosphate product for pest control. Furthermore, of those feedlots using an organophosphate, only about 0.3% of the cattle in these feedlots were treated with these products.

## **5. Use Rates and Application Frequency for Registered Uses of Coumaphos**

Please find below (Table 1), a summary of the use rates and application frequency for registered uses of coumaphos. The Agency has included various versions of a similar use table in each of the risk assessments (Ecological Risk Assessment, DP Barcode D409355, dated 6/11/2014; Occupational Exposure Assessment, DP Barcode D410244, dated 3/20/2016; Human Health Risk Assessment, DP Barcode D409347, dated 3/22/2016; Drinking Water



Assessment, DP Barcode 420394, dated 6/2/2014) for the active ingredient. This table provides additional clarifying use information and corrections regarding these use patterns. Bayer's responses to these draft risk assessments will use these refined/corrected values. Therefore, Bayer encourages the Agency to use these "real world" values in refining their draft risk assessments.

Table 1. Application Information for Registered Uses of Coumaphos:

[Items in red differ from those presented by EPA in aforementioned Risk Assessments; Bayer calculation comments follow table.]

Application Timing, Type & Equipment	Formulation (% A.I.) [EPA Reg. No.]	Maximum Application Rate		Max. (Avg.) No. Applications per Year	Minimum Treatment Interval	Max. Ann. App. Rate (lb. A.I./animal)	Bayer Comments
		lb. IA/animal	lb. A.I./gallon				
<b>Cattle/Horses</b>							
Swim Dip Vat Cattle Only	Co-Ral FC (42%) [11556-98]	0.015 (summer)	0.021*	2	Do not make applications less than 10 days apart	0.0315 (based on avg. lb A.I. / animal)	*EPA original value of 0.025 lb. A.I./gallon is incorrect.
Hydraulic Dip Vats Cattle Only		0.021 (winter)					
Manual & Mechanical Spray Cattle & Horses		0.01575 (avg.)					
Manual & Mechanical Spray Cattle & Horses	Co-Ral Fly & Tick Spray (6.15%) [11556-115]	0.015-0.021	0.021	6 (3)	Do not make applications less than 10 days apart	0.0225	
Manual & Mechanical Spray Cattle & Horses	0.01 (tick)	0.01 (tick)	6 (3)				
Manual & Mechanical Spray Cattle & Horses	0.005 (fly)	0.005 (fly)					
Back Rubbers Oil Cattle	Co-Ral Fly & Tick Spray (6.15%) [11556-115]	0.0075 (avg.)	0.0075 (avg.)		Re-treatment only necessary when insects reappear and constitute a problem	0.0077 (30 animals) 0.0058 (40 animals)	*EPA original value of 0.076 lb. A.I./gallon is incorrect. This was based on the Co-Ral ELI (11.6% A.I.) label, which been discontinued
Back Rubbers Oil Cattle	0.00128 (30 animals)	0.0385 lb.*	6				
Back Rubbers Oil Cattle	0.000963 (40 animals)						

Dust Bags & Shaker Can Cattle, Horses, Swine, Swine Bedding	Co-Ral Animal Insecticide (1%) Bulk Dust [11556-14]	0.00125 lb. A.I./animal	0.125 lb. IA/ dust bag	12 (3)	Do not make applications less than 10 days apart		Horses are not on the 1556-14 label
Ear Tags Beef & Non-Lactating Dairy Cattle	Corathon (15%) [11556-148]	0.00703 lb A.I./head (1.5 tags/head)			Replace as necessary (In practice applied 1X/year) and lasts up to 5 months control		per day rates from: 0.00007812 lb. A.I. (over 3 mos.) to 0.00004687 lb. A.I. (over 5 months)
<b>SWINE</b>							
Shaker Can	Co-Ral Animal Insecticide (1%) Bulk Dust [11556-14]	0.000625 lb. A.I./pig		6 (3)	Do not make applications less than 10 days apart		
Manual & Mechanical Spray	Co-Ral Fly & Tick Spray (6.15%) [11556-115]		0.005 lb. A.I. /gallon of diluted spray	6 (3)	Do not make applications less than 10 days apart		
<b>Swine Bedding</b>							
Shaker Can	Co-Ral Animal Insecticide (1%) Bulk Dust [11556-14]	0.000042 lb A.I./ft <sup>2</sup> of bedding		6 (3)	Do not make applications less than 10 days apart		EPA original value of 0.00045 lb. A.I./ft <sup>2</sup> is incorrect
<b>Bee Hives</b>							
Bee Hive Strips	Checkmite + Bee Hive Pest Control Strip (10%) [11556-138]	10 % A.I. by weight		2X per year for <i>Varroa</i> mites & no more than 4X per year for small hive beetle			

Bayer Calculation Comments:

**Co-Ral Flowable Insecticide (11556-98) – USDA Use Only**

Dip Vat rate (for ticks): ½ - 1 gallon FC / 200 gallons water

1 gallon FC / 200 gallons = 4.2 lb. A.I. / 200 gallons = 0.021 lb. A.I./gallon

Per USDA (personal communication), a typical animal retains ½ gallon of dip with a summer coat and 1 gallon of dip with a winter coat. Therefore, it seems more appropriate in the risk assessment to use a yearly volume average of ¾ gallon of dip / Animal  $\times$  0.021 lb. A.I. / gallon = 0.01575 lb. A.I. / Animal

Spray rate (for ticks): ½ - 1 gallon FC / 200 gallons water =

1 gallon FC / 200 gallons = 4.2 lb. A.I. / 200 gallons = 0.021 lb A.I./gallon

Using an average of ¾ gallon of spray / animal  $\times$  0.021 lb. A.I. / gallon = 0.01575 lb. A.I. / animal

**Co-Ral Fly and Tick Spray (6.15% EC) - 0.5 lb. A.I. / gallon (11556-115)**

***Spray Applications:***

Beef/non-lactating dairy cattle rate (1 gallon diluted spray/animal<sup>1</sup>):

Flies: 2 quarts / 50 gallons = 0.25 lb. A.I. / 50 gallons = 0.005 b A.I. / gallon = **0.005 lb. A.I. / animal**

Ticks: 4 quarts / 50 gallons = 0. 5 lb. A.I. / 50 gallons = 0.01 b A.I. / gallon = **0.01 lb. A.I. / animal**

Average: 3 quarts / 50 gallons = 0. 375 lb. A.I. / 50 gallons = 0.01 b A.I. / gallon = **0.0075 lb. A.I. / animal**

Table 2-1 assumes the “tick rate”: the third line from the bottom of shows a “Maximum Single Application Rate (lb. A.I./animal)” of 0.01 lb. Most applications of this product are for fly control, rather than tick control, and therefore we encourage the Agency to use the average dose of 0.0075 lb. A.I./Animal in the risk assessment.

Lactating dairy cattle rate (1 gallon diluted spray/animal<sup>2</sup>):

1 quart / 50 gallons = 0.125 lb. A.I. / 50 gallons = 0.0025 b A.I. / gallon = **0.0025 lb. A.I. / animal**

***Back Rubber application:***

Use Rate: 1 gallon product / 13 gallons = 0.5 lb. A.I. / 13 gallons = 0.0385 lb. A.I. / gallon

Recent literature (Townsend 2016; <http://pest.ca.uky.edu/EXT/Recs/ENT11-Beef.pdf>) indicates that 1 gallon of oil solution in a back rubber will treat 30-40 head.

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<sup>1</sup> Other similar livestock spray products (e.g., RaVap EC) labels indicate ½ - 1 gallon / animal for beef and non-lactating dairy cattle and ½ gallon / animal for lactating dairy cattle.

<sup>2</sup> Since the concentration of the diluted spray for lactating dairy cattle is ½ that of non-lactating animals, an application volume of 1 gallon / animal was used for the calculation.

Calculated rates:

0.0385 lb. A.I. / gallon X 1 gallon / 30 head = 0.00128 lb. A.I. / head - (max 0.0077 lb. A.I./Animal)

0.0385 lb. A.I. / gallon X 1 gallon / 40 head = 0.000963 lb. A.I. / head - (max 0.0058 lb. A.I./Animal)

**Co-Ral Animal Insecticide (1%) Bulk Dust (11556-14)**

Cattle Dust Rate: 2 oz. / head                      1 lb. dust = 0.01 lb. A.I.                      2 oz. dust = 0.00125 lb. A.I. / animal

Swine Dust Rates

Animal Treatment: 1 oz. / head                      1 lb. dust = 0.01 lb A.I.                      1 oz. dust = 0.000625 lb. A.I.

Area treatment rate: 2 oz. / 30 ft<sup>2</sup>                      0.00125 lb. A.I. / 30 ft<sup>2</sup>                      0.00042 lb. A.I. / ft<sup>2</sup>

**Corathon Ear Tag (15%) (11556-148)**

The Agency lists 3 applications/year; only 1 application per year is made to cattle in the spring. The label allows for flexibility in the number of tags applied per animal based on anticipated fly pressure. Some users apply 1 tag per animal and some apply 2/animal; we encourage the Agency to use an average of 1.5 tags/animal, since actual use figures are not available.

See below for calculations:

0.5 oz wt./ tag = 0.03125 lb. wt./tag

0.03125 lb. /tag X 15% A.I. = 0.004688 lb. A.I./tag X 1.5 tags/head (avg.)/year= 0.007031 lb. A.I./animal/year

As the cattle ear tag provides control for 3 to 5 months, if one assumes the coumaphos is released from the plastic matrix at the same rate over the 3 to 5 month period the tags are used, then the “application” of coumaphos **per day** would range from:

0.00007812 lb. A.I. (0.007031 lb. A.I./ 90 days)

to

0.00004687 lb. A.I. (0.007031 lb. A.I./150 days)

Therefore, the cattle ear tag would result in very low potential daily exposures regarding dietary and environmental exposures.

## References

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- USDA-APHIS, Veterinary Services. 2011. Feedlot 2011 - Part IV: Health and Health Management on U.S. Feedlots with a Capacity of 1,000 or More Head.
- USDA . 2016. United States and Canadian Cattle and Sheep. National Agricultural Statistics Service, Agricultural Statistics Board (Released 8 March, 2016).