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August 5, 2011

OPP Regulatory Public Docket (7502P)
Environmental Protection Agency
Rm. S-4400 One Potomac Yard (South Bldg.)
2777 S. Crystal Dr.
Arlington, VA 22202

Re: Comment on the *Fipronil Summary Document for Registration Review: Initial Docket June 2011*
Case No. 7423; Docket No. EPA-HQ-OPP-2011-0448

To Whom It May Concern:

toXcel, LLC appreciates the opportunity to offer the following comment regarding the Agency's "*Fipronil Summary Document for Registration Review: Initial Docket June 2011*". Our response is focused on the potential impact of the stated decision on spot-on pesticide products that are used monthly for control of fleas, ticks, and other external parasites and pests found on companion animals. In the referenced registration summary document, it is stated that:

"The Agency anticipates requiring data for use in conducting a comprehensive ecological risk assessment, including an endangered species risk assessment, for all uses of fipronil. The Agency also anticipates requiring additional data for use in conducting human exposure risk assessments."

*We are concerned that the Agency has stated... "for **all** uses of fipronil" and does not differentiate between spot-on use on companion animals and the use of fipronil on crops, lawns, and other outdoor use pesticide products that have the potential for run-off and other exposure pathways to water bodies. Spot-on fipronil products simply do not have the environmental release or human exposure potential associated with the outdoor uses of fipronil.*

With regard to the assessment of risk associated with spot-on products the Agency did not identify any additional data needs and confined additional toxicity data needs to **occupational** exposure situations. The Agency's May 24, 2011 document, "*Fipronil; Human Health Assessment Scoping Document for Registration Review*" states:

“Residential application and post-application exposures from the uses of fipronil on pets and from residential uses of fipronil to control fire ants and other outdoor nuisance pests for children and adults, have been previously assessed and are below HED’s level of concern. No additional data gaps were identified in the residential exposure assessment during the registration review scoping process.”

“A 28/90-day inhalation toxicity and 90-day dermal study in the rat have been requested to further characterize the occupational inhalation and dermal risks of fipronil.”

It is fully understood that the data requirements identified in the above referenced fipronil summary document are focused on the technical grade active ingredient (TGAi) as the test material. In general, TGAIs are supplied as manufacturing use products (MUPs) that are broadly used to formulate the entire spectrum of end use products containing that active ingredient. However, that is not the uniform case for fipronil. The Agency appears to have overlooked the fact that there are fipronil MUPs that are strictly confined to the formulation of pesticide products for use on companion animals. For some TGAi registrants, fipronil use as a spot-on product is the limit of their market niche and network.

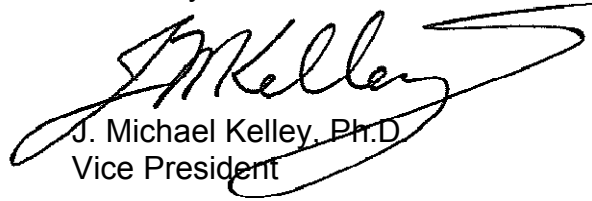
The conceptual model of ecological risk for fipronil from pages 24 and 25 of the Agency’s May 4, 2011 problem formulation memorandum¹ indicates that the sources of release of fipronil to aquatic habitats include spray drift, runoff, leaching to groundwater, and atmospheric transport. Sources of terrestrial exposure to fipronil include direct application to soil, spray drift, runoff, and atmospheric transport. For spot-on products containing fipronil, not one of the aforementioned exposure pathways is relevant. Thus, there are no significant or routine releases of fipronil to the environment from spot-on products.

Accordingly, we respectfully request that the Agency consider the need to separate the data requirements for fipronil use in crop, lawn, and outdoor ant control products from an appropriately reduced set of data requirements for spot-on animal care products containing fipronil. The requirement for extensive ecological testing, crop field trials, and subchronic toxicity data for “all” uses of fipronil is inappropriate for TGAIs (MUPs) that are confined to use in formulating spot-on products. Such excessive data requirements may force the voluntary withdrawal of the limited-use MUPs, which would certainly be an unnecessary economic hardship for those primary registrants.

¹ May 4, 2011 memorandum from Edward Odenkirchen and Stephen Wente (EFED) to Susan Bartow and Eric Olson (Risk Management and Implementation Branch IV) through Nancy Andrews and Sujatha Sankula (EFED) entitled “*Regulation review – Preliminary problem formulation for ecological risk and environmental fate, endangered species, and drinking water assessments for fipronil (PC Code 129121; DP 387319)*”.

Since residential uses of fipronil lack significant exposure to the environment and are “below HED’s level of concern,” we request greater clarification and restriction with regard to the additional data that will likely be required on fipronil. The proposed additional ecological testing, crop field trials, and sub-chronic toxicity data identified in the registration review summary are not warranted for fipronil TGA1 (MUPs) limited to the formulation of spot-on pesticide product use on companion animals.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Michael Kelley". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

J. Michael Kelley, Ph.D.
Vice President