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Subject: Ecological Risk Assessment for Fipronil Uses (Addendum)
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The following is an addendum ecological risk assessment for fipronil to support registration decisions, conditional registrations decisions as well as decisions on pending label changes and new uses. This addendum is in response to the finding that dry bulb onion seed use refers to treatment of actual onion seeds and not onion sets, as was assumed for the wildlife risk assessment in the February 6, 2007 risk assessment for fipronil. In that risk assessment, EFED concluded that onion set treatment would not be a complete exposure route for terrestrial vertebrates and no quantitative dietary risk assessment for its direct ingestion was conducted. However, a finding that this proposed use is for seed treatment requires EFED to reevaluate the wildlife exposure and risks associated with potential direct consumption of the treated seed.

The treatment rates for fipronil on onion seed are assumed as follows:

- 2 lbs seeding rate/A @ 25 g ai/A=12.5 g ai/ lb seed (5.67 g/kg)
- 4 to 5 lb seeding rate/A @ 60 g ai/A= 15 to 12 g ai/lb seed (6.80 to 5.44 g/kg)

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Substituting this treatment rate for the T-Rex fipronil residues concentrations in seeds allows for an estimation of risk quotients for granivorous birds and mammals. This risk quotient calculation method is described in the February 6, 2007 risk assessment. The resulting risk quotients for the lowest and highest rates on onion seed are as follows:

Terrestrial Vertebrate Acute and Chronic Risk Quotients for Fipronil Use Based on Residues In/On Treated Seeds and Baits						
Chemical	Animal Type	Body Weight g	Food Item	Acute RQ (Bird:Dose/Diet) (Mammal: Dose)	Chronic RQ (Bird: Diet) (Mammal:Dose/Diet)	LOC Exceeded
Onion Seed Treatment 5440 mg/kg-seed						
Fipronil	Bird	20	Treated seed (5440 mg/kg)	760/113	544	A,RU,LS,C
		100		340/113	544	A,RU,LS,C
		1000		1076/113	544	A,RU,LS,C
	Mammal (granivore)	15		5.38	199/180	A,RU,LS,C
		35		4.61	169/180	A,RU,LS,C
		1000		2.49	96/180	A,RU,LS,C
Onion Seed Treatment 6800 mg/kg-seed						
Fipronil	Bird	20	Treated seed (6800 mg/kg)	951/141	680	A,RU,LS,C
		100		425/141	680	A,RU,LS,C
		1000		1345/141	680	A,RU,LS,C
	Mammal (granivore)	15		6.72	248/225	A,RU,LS,C
		35		5.77	211/225	A,RU,LS,C
		1000		3.12	120/225	A,RU,LS,C

A= Acute LOC, RU= Restricted Use LOC, LS = Listed LOC, Chronic LOC, -- no LOC exceeded

In all cases Agency levels of concern for acute and chronic risk are exceeded. Assuming 102,000 onion seeds per pound¹, the mass of fipronil on a seed would be as low as (12 g a.i./lb)/102,000 = 1.176 X10⁻⁴ g or 0.1176 mg. The following shows the number of seeds needed to be consumed to achieve a dose commensurate with a 50% chance of mortality.

<u>Animal Mass (kg)</u>	<u>Mass fipronil /animal at LD50*</u>	<u>Number of seeds required to reach 50% chance of mortality**</u>
0.02 (bird)	0.1628 mg	1.4
0.1 (bird)	1.036 mg	9
1.0 (bird)	14.64 mg	124
0.015 (mammal)	3.20 mg	27
0.035 (mammal)	6.04 mg	51
1.0 (mammal)	74.61 mg	634

* adjusted LD50 from T-REX multiplied by bw in kg

** mass fipronil/animal at LD50 level/ 0.1176 fipronil/seed

¹ www.mainstreetseedandsupply.com/vsonion.htm

These results suggest that it is within the realm of possibility that birds of all sizes and mammals less than a kg in weight could consume enough treated seed associated with the labeled use of fipronil on onion seed to achieve a dose with a 50 percent probability of mortality. Chronic concerns for seed consumption involve an uncertainty as to how long seed will remain available to wildlife and whether fipronil will remain associated with the seed for these periods. Short durations of availability or contamination would serve to reduce concerns for chronic risks. However, given that the RQs are so high (96 to 680) it is unclear how much impact additional information on these areas of uncertainty would serve to alter risk assessment conclusions of chronic risk