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DRAFT Policy 013

Science Advisory Council for Exposure

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Regarding: Postapplication Exposure Assessment For Children From Pet Treatments
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ISSUE:

Many types of chemicals can be used to control pests on companion animals such as dogs and cats. These pests can include fleas, ticks, and other disease carrying insects or parasites. The Agency has addressed these exposures since the advent of the Food Quality Protection Act and the issuance of the first version of its *Standard Operating Procedures For Residential Exposure Assessment* in 1997. Since 1997, little more has become known about how these exposures might take place. Even so, it is important to make incremental changes in the approaches used and to consider new data as it becomes available so that assessments reflect the most current information. The products that are used to control pests on animals are varied and can include dusts, dips and shampoos, collars, spot-ons, and feed-throughs. The Agency is interested in the use of any of these that results in exposure to children although the Agency generally is not concerned about feed-throughs and spot-ons based on how they are used. It is believed that small children (e.g., toddlers) potentially have the highest exposures associated with the use of these types of products compared to adults or older children because of the time spent with animals and the nature of the contact they have with animals. For example, a small child might be more prone to put their hands in their mouth after petting a dog without washing their hands. This policy illustrates how the Agency addresses exposures from different types of animal treatment products.

BACKGROUND:

The Agency began considering exposures from pet treatment products routinely based on the 1997 version of the *SOPs For Residential Exposure Assessment* after the passage of the Food Quality Protection Act. Dermal exposures at this point in time were calculated based on a percentage of the total amount of active ingredient applied. Hand-to-mouth exposures were calculated using the older SOP approaches. In September of 1999, the Agency proposed a number of modifications to the manner in which it calculated residential exposures to the FIFRA Science Advisory Panel for review. Among the proposals were a number of changes that impacts how the Agency calculated exposures from treated pets. The major changes included the use of a hug approach for calculating dermal

exposures and modifications to the manner in which hand-to-mouth exposures were calculated (e.g., addition of a saliva extraction factor, modification to the frequency and surface area factors used for hand-to-mouth exposures). More detailed information concerning these changes can be found in the document *Overview of Issues Related to the Standard Operating Procedures For Residential Exposure Assessment* available at www.EPA.Gov (link to SAP Archives). The approaches outlined in this document were adopted at that point by the Agency for calculating exposures from treated pets.

The scientific data in this area are very limited but the Agency has attempted to use the available information to formulate policies that are protective without being unreasonable. Much of the scientific research related to this topic is being completed or has been done at the Center For Environmental Health Sciences, College of Veterinary Medicine, Mississippi State University with funding through Agency STAR grants (Science to Achieve Results) by researchers such as Boone and Chambers. In one of their recent publications (Boone, 2001), they put the potential for exposure in the general population in perspective:

> "A demographic survey of companion animals by the American Veterinary Medical Association indicated that in 1991 approximately 34.6 million households (36.5%) in the United States owned a dog or dogs, a number essentially unchanged from 1987. More households had dogs as pets than other types of animals. There was a mean of 1.52 dogs per dog-owning household, yielding an estimated national population of 52.5 million dogs. Fifty percent of pet-owning households were parental households with children; in comparison, 40% of total households have children. The authors of that study projected that there would be 53.6 million dogs in the United States in 1998. These dogs would be a source of exposure to millions of children who live in the same environment and come into direct contact with dogs treated with flea control products."

This current policy summarizes the changes that were made to the *SOPs For Residential Exposure Assessment* based on the 1999 presentation at the FIFRA SAP. Additionally, since that time, there have been proposed refinements over and above those presented. Many of these have been discussed and approved at routine Exposure SAC meetings. These changes are also included below.

POLICY:

Exposures from treated pets are thought to occur as a result of dermal contact with their fur and from young children (i.e., toddlers) putting contaminated hands in their mouth. Because children are believed to have the highest exposures because of their behaviors, the Agency completes its risk assessments using toddlers as the model or sentinel population for exposure. The approach that is used in the calculations can be summarized very concisely in that it involves 1) defining residue deposition on the animal from treatment; 2) defining how much can be removed by touching the animal (i.e., transferability to the skin); 3) defining how long it takes residues to dissipate from the animal; 4) defining how much contact toddlers may have with treated animals; and 5) defining human dose related to contact with treated animals. The approaches for each step in the calculations

are presented below as well as the recommended input values.

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Step 1: Defining Residue Deposition On Treated Animal

The first step required for defining how much residues are deposited on the surface (fur/coat) of the animal is to identify the label application rate on a per animal basis if possible for dusts and liquids. For collars, the active lifetime of the collar is usually included on labels. This is needed to define daily emission rates from the collar. If these values are not available, the value from Exposure SAC Policy 12 (½ container of end-use product per animal) is to be used to define how much material is deposited on the animal for each treatment. Labels which have specific directions on the amount to be used should also be considered in the assessment. For example, a label might say a can of material is good for five treatments.

Dusts and Liquids: The next step in the process is to equally spread the residues over the surfaces of the treated animals. Dusts and liquid treatments are handled differently than the use of collars. This is done by dividing the amount of active ingredient used to treat the animal by the surface area of a dog which has been selected by the Agency to represent companion animal uses. Cat only treatments will have to be defined separately on a case-by-case basis. The surface area for a dog is based on a 30 pound animal and an algorithm described in the 1999 presentation to the SAP ((12.3*((BW (lb)*454)^0.65)) resulting in a surface area for the standard treated dog of 5986 cm^2.

For illustrative purposes, if an animal was treated with 1 gram of active ingredient the deposited total residues would be 167 $\mu g/cm^2$ (i.e., [1 g * 1000 mg/g * 1000 $\mu g/mg$]/5986 cm^2).

Collars: The intent of a collar is significantly different from the use of dusts or liquid treatments where the entire dog is to be coated as a course of treatment. For collars, residues are not spread evenly over an entire animal because residues from collars are expected to be localized. This position is supported by ongoing research at Mississippi State University where transferable residues from collar use have been measured and they appear to be localized around the collar region with residues diminishing as distance from the collar increases. The Agency has used these data to define a region covered by a single dermal hug around the collar for risk assessment purposes (see Step 2 below for further information).

Step 2: Defining residue removal while touching the animal (i.e., transferability to the skin)

The next step in the process is to define how much can rub from the treated animal's skin and fur when toddlers contact the animal. Dusts and liquid treatments such as shampoos are again considered differently from collars in this step of the process.

Dusts and Liquids: The Agency proposed at the 1999 FIFRA SAP that a value of 20 percent transferability be used for liquids and dusts. This value should be used by exposure assessors unless another value can be justified such as through the use of chemical-specific data.

Collars: As indicated above, the intent of a collar is significantly different from the use of dusts or liquid treatments where the entire dog is to be coated as a course of treatment. For collars,

residues are not spread evenly over an entire animal because residues from collars are expected to be localized. In the recent monitoring efforts (Boone et al at ISEA, 2001) at Mississippi State University, residues were collected on the neck with the collar on, on the neck with the collar off, and on the back of the dog. The Agency took the average of these three areas to define the transferable residues from a collar. The Agency also normalized the results to calculate a factor on a per gram active ingredient in the collar basis. The factor that should be used by assessors when considering the use of collars is 0.00027 mg/cm^2/gram ai in collar. The specific data and approach used to define this factor was discussed at several SAC meetings. The notes and discussions are summarized in SAC meeting minutes. [Question to SAC - should we use different factors for short- and inter-term??]

Step 3: Defining how long it takes residues to dissipate from the animal

The next step in the process is to define how long residues are present on the animal. Dusts and liquid treatments are handled differently than the use of collars.

Dusts and Liquids: Dusts and liquid treatments are expected to dissipate from the animal after treatment. As such the Agency treats this like any other residue dissipation situation in a risk assessment (e.g., DFRs or TTRs). In cases, where no chemical-specific dissipation data are available, the Agency uses a generic factor of 5 percent of the total dissipates per day. This is half that used for DFRs and TTRs because the limited pet fur data indicate lower dissipation rates (based on unpublished phosmet data conducted concurrently with Boone, 2001).

Collars: The intent of a collar is significantly different from the use of dusts or liquid treatments where a collar is intended to provide constant control over a long period of time. This means that a collar should have a slow, constant emission of residues over its useful lifetime (i.e., there is no real dissipation). As such, the Agency calculates a daily constant emission rate over the life of the collar that is used (i.e., how much emits per day from the collar over the life of the collar). The emission term described in Step 2 above is based on longitudinal sampling so the Agency is confident that this value represents an appropriate factor for calculating long-term emissions from collars.

Step 4: Defining how much contact toddlers may have with treated animal

At the September 1999 FIFRA SAP meeting, the Agency proposed a number of new or revised methods for calculating residential exposures including from dermal contact with treated pets and for hand-to-mouth behaviors. The newly proposed approach for dermal contact with treated pets used a single hug technique for a child wearing short pants and a short-sleeved shirt. Using a clothing penetration factor of 50 percent and accounting for bareskin, the total surface area of a child that contacts a treated pet is 1875 cm^2/hug. In this approach, once a hug has occurred, a residue equilibrium is thought to be established on the child. Therefore, a single hug/loading of the skin is the basis for this approach.

Revisions to the inputs used to calculate hand-to-mouth exposures were also presented at the 1999 FIFRA SAP. The basic methodology remains the same. There were three major input changes including: 1) hand surface area per contact was changed to 20 cm^2 per event to represent the palmar surfaces of the three middle fingers; 2) the frequency of events was increased from 1.56 events/hour to 20 events/hour; and 3) a saliva extraction factor of 50 percent was added to account for the likelihood that residues are not quantitatively removed every time the hand goes in the mouth.

Step 5: Defining human dose related to contact with treated animal

The algorithms which can be used to calculate dermal and hand-to-mouth exposures are presented below. They incorporate each of the steps described above.

Dermal Dose:

Install Equation Editor and double-click here to view equation.

where:

D	=	dose from dermal pet contact (mg/day);
AR	=	application rate or amount applied to animal in a single treatment (mg ai/animal);
F_{AR}	=	fraction of the application rate available for dermal contact as transferable residue (20%/100);
SA_{pet}	=	surface area of a treated dog (5986cm^2/animal);
t	=	time after application (days);
DR	=	fractional dissipation rate per day (5% per day/100); and
SA_{hug}	=	surface area of a child hug (1875cm^2 contact/hug).

[Note: For collars, the $((AR*F_{AR})/SA_{Pet})$ term is replaced by the generic factor for determining transferable residue levels described above in Step 2 (0.00027 mg/cm^2/gram ai in collar). An adjustment to the proper amount of active ingredient is also required.]

Install Equation Editor and double-click here to view equation.

Hand-to-mouth dose:

where:

D	=	nondietary ingestion dose from with treated pets (mg/day);
AR	=	application rate or amount applied to animal in a single treatment (mg ai/animal);
F_{AR}	=	fraction of the application rate available as transferable residue (20%/100);
SA_{pet}	=	surface area of a treated dog (5986cm^2/animal);
t	=	time after application (days);
DR	=	fractional dissipation rate per day (5% per day/100);
SAL	=	saliva extraction factor (50% extractability);
SA_{hands}	=	surface area of the hands (20cm^2);
Freq	=	frequency of hand-to-mouth events (20events/hour); and
Hr	=	exposure duration (2 hours).

[Note: For collars, the $((AR*F_{AR})/SA_{Pet})$ term is replaced by the generic factor for determining

transferable residue levels described above in Step 2 (0.00027 mg/cm^2/gram ai in collar). An adjustment to the proper amount of active ingredient is also required.]

ISSUES FOR CONSIDERATION:

There are several other issues that should be generically considered in the calculation of postapplication residential risk values such as whether or not to average transferable residue levels over specific timeframes. Please refer to other appropriate Agency policy documents for guidance on these issues such as the *SOPs For Residential Exposure Assessment*, Health Effects Division Hotsheets, or policies developed by the Exposure Science Advisory Council.

The pet collar study (Boone et al at ISEA, 2001) also included a biological monitoring component. Although the pet collar study is a good start into researching the potential exposures children may receive from treated pet collars, the design of the biological monitoring portion of the study was insufficient for regulatory purposes. The study design did not include a "play routine" to determine exposure to children that have intensive contact with the dog. The monitoring of children without a specific activity to mimic those who play with their dogs (i.e., study did not record contact of children with the dog) would require a larger sample size than 24 to be able to draw regulatory conclusions from the biological monitoring portion of the study.

The scope of this policy should also be carefully considered. This policy is not intended to address issues of aggregation. This policy is only intended to focus on children's postapplication exposures from treated animals.

REFERENCES:

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U.S. EPA (1997) *Standard Operating Procedures For Residential Exposure Assessment*, Health Effects Division of the Office of Pesticide Programs.

U.S. EPA (1999) *Overview of Issues Related To The Standard Operating Procedures For Residential Exposure Assessment*, Health Effects Division of the Office of Pesticide Programs. [Presented to the FIFRA SAP in September, 1999.]