UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

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MEMORANDUM

Subject: EPA Response to answer SAP Comments provided in "SAP Minutes No 2011-06, A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: Scientific Conclusions Supporting EPA's FIFRA Section 6(b) Notice of Intent to Cancel Twenty Homeowner Rodenticide Bait Products."

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EPA has received comments from the Scientific Advisory Panel (SAP) regarding the "Scientific Conclusions Supporting EPA's FIFRA Section 6(b) Notice of Intent to Cancel Twenty Homeowner Rodenticide Bait Products" (hereafter referred to as the NOIC). EPA provided the SAP with 11 Charge Questions for their consideration. The SAP has submitted minutes from their review (SAP Minutes No. 2011-06), which included comments related to the analysis EPA conducted on the potential risks that rodenticides used for commensal rodent control pose to children, pets and non-target animals as well as efficacy and cost analyses. This response to the SAP comments was compiled based on the considerations and analyses of Office of Pesticide Program staff and focuses on the issues raised by the SAP.

The proposed cancellation is discussed in more detail in the NOIC and the Statement of Reasons and Factual Basis for Notice Intent to Cancel and Notice of Denial of Certain Rodenticide Bait Product Registrations and Applications.

1. Response to Comments within Charge Question 1:

1.1. **SAP Comment (page 6):** *[T]he vast majority of exposures to first and second generation anticoagulant rodenticide products by young children will not result in a clinically significant coagulopathy or bleeding. However, if the toxic threshold is exceeded, there is a widely available laboratory test and an antidote (vitamin K_1) with which clinicians are familiar because of the therapeutic use of warfarin.*

EPA Response: Fortunately, rodenticide exposures generally result in no clinical harm to children. EPA recognizes this, and is aware that a laboratory test and treatment (vitamin K1) for exposure to anticoagulant rodenticides are available. Nonetheless, continuing children's status quo exposure to non-conforming rodenticide products is unacceptable.

Rodenticides are potent mammalian poisons and the quantity in a typical placement is sufficient to cause adverse health effects to children. The Poison Control Center data show that around one percent of the rodenticide exposures to children result in such effects. This single percent corresponds to a significant number of children owing to the high number of children exposed. Furthermore, some rodenticide exposure incidents involving children do result in severe coagulopathy and bleeding.

EPA also notes that even initially asymptomatic children may experience a period of increased risk of excessive bleeding following exposure to anticoagulant rodenticides. Accidental ingestion of anticoagulants can lead to coagulopathy (impairment of the body's ability to stop bleeding) in a child; although the child is initially asymptomatic they have the potential to bleed excessively (internally or externally) if they experience bodily trauma while their ability to stop bleeding is impaired. This potential is not limited to easily recognized locations such as the elbow. Bleeding can take place within a less easily recognized location, such as the brain.

Even in the case of anticoagulant exposures where the dose is too low to produce observable symptoms and where no subsequent trauma presents bleeding risks, such fortunate outcomes are not initially obvious, and there are social costs associated with evaluating and treating children whose exposures are uncertain. While the availability of a laboratory test and a treatment

protocol may facilitate such evaluation and treatment, the availability of these tools does not negate the social cost of needing to undertake the evaluation and treatment in the first place. EPA's risk mitigation strategy is based on preventing exposures to children through the use of bait stations with solid bait that is reasonably expected to remain in the bait station and is less likely for mice to cache and for children to access.

1.2. **SAP Comment (page 6 and 19):** *[S]evere bromethalin poisonings are very concerning for clinicians because of less human experience with them and, unlike the anticoagulants, there is no specific diagnostic test or antidote . . . Given that bromethalin targets the CNS [central nervous system] and interferes with mitochondrial function, there is concern that the developing brain of young children may be particularly susceptible to the neurotoxic effects of bromethalin.*

EPA Response: The Agency anticipates that enclosing rodenticide baits in protective bait stations will greatly reduce the frequency of child incidents involving all types of rodenticides. Whether a particular exposure is to an anticoagulant or a bromethalin rodenticide is of significantly less importance to human health than whether the exposure occurs in the first place.

Nonetheless, EPA notes that the effects of severe bromethalin poisoning are the same as other uncouplers of oxidative phosphorylation such as aspirin, indomethacin and ibuprofen, and that clinicians are experienced in treating the effects of those types of chemicals.

Although a toxic dose of an anticoagulant causes somewhat more distinctive bruising and bleeding symptoms (including blood in urine, bleeding from the nose and gums, coughing blood and, depending on the amount consumed, bleeding into the joints and brain), those symptoms do not appear until several days after ingestion. Thus, neither type of rodenticide (i.e., either anticoagulant or bromethalin) is more likely than the other to produce symptoms that would alert parents or health care workers of a rodenticide poisoning within the critical first hours when gastric decontamination could be an effective treatment.

The SAP expressed concern that the developing brain of young children might be particularly susceptible to the effects of bromethalin. The concern appears to be that cerebral edema might occur more readily in young children and its effects on the developing brain might be more severe. Cerebral edema, and signs of cerebral edema such as tremors, could possibly occur in moderate or major bromethalin incidents, but incidents of such severity have rarely occurred. Uncoupling of electron transport is a reversible effect, Once the uncoupler is removed from the system, normal mitochondrial respiration resumes. Transient swelling of the brain and spinal cord is not associated with long term neurological damage.

EPA concludes that bromethalin and anticoagulant exposure present comparable human health concerns, and that both sets of concerns are appropriately mitigated through the RMD requirement for tamper-resistant bait stations. Sufficiently high exposures to either bromethalin or the anticoagulants (particularly the SGARs) have the potential to result in patients being admitted to intensive care units at considerable harm and expense to the patient. EPA is concerned about *all* types of rodenticide poisonings, and believes that they are all best prevented

by increasing the availability and use of bait stations that are not easily opened by children and are reasonably anticipated not to release rodenticide bait.

2. Response to Comments within Charge Question 2:

2.1. **SAP Comment (page 7):** *[T]he NOIC does not establish a quantitative level of risk for severe outcomes and hence, it is difficult to concur with EPA's "degree of risks" posed to humans.*

EPA Response: The Panel appears to have interpreted the charge question ("Does the SAP concur with the EPA's conclusions regarding the . . . degree of risks posed to humans?") as alluding to a quantitative risk determination and asking the Panel whether they concurred that risk had been properly quantitatively characterized. The Panel responded that EPA had not actually prepared a quantitative assessment of human risks.

EPA agrees with the SAP that it has not quantitatively characterized the risk to human health from the non-conforming pesticide products. The Agency did not expect that the SAP would be able to offer quantitative confirmation of the Agency's qualitative risk characterization. Rather, EPA had *qualitatively* characterized the risk to human, health, with sufficient clarity to support the proposed cancellations. FIFRA does not require a quantitative characterization of risk. Given that all of the rodenticide products at issue are capable of providing satisfactory rodent control, a qualitative comparison of their respective risks is sufficient to establish whether the risks of some of those products are unreasonable in comparison to available, registered alternative products.

2.2. **SAP Comment (pages 6-7):** *[T]he incident data come from several sources, all of which have strengths and limitations.*

EPA Response: The Agency generally agrees that individual sources of incident data differ from each other in terms of their respective strengths and limitations. Incident information can, however, provide important feedback to the Agency, assisting in determining real-world exposures and risks posed by pesticide products.

3. Response to Comments within Charge Question 3:

3.1 **SAP Comment (page 22):** *[S]upporting data presented are not sufficient to draw conclusions regarding how RMD compliance would provide a benefit related to societal costs. Any effect on utilization of emergency medical resources . . . is uncertain.*

EPA Response: EPA values the scientific advice that members of the Panel offer within their respective areas of expertise. However, determining whether compliance with particular regulatory requirements would provide benefits to society, or the extent of those benefits, does

not appear to fall within the mandate of the SAP which is to provide advice on the science EPA uses to make decisions.

EPA's review of available exposure information suggests that children commonly gain access to baits placed in homes even in cases where users may believe they are complying with label instructions aimed at preventing child, pet, and non-target wildlife exposure. EPA expects rodenticide exposures to children will substantially decrease if all consumer rodenticide products conform to the RMD (i.e., packaged with or in bait stations that are tamper-resistant; produced in block forms that are expected to remain in bait station). If post-cancellation experience demonstrates that the RMD requirements are still insufficient to lower children's exposure to rodenticides, then EPA will evaluate the need for further follow-up action on the basis of such experience.

3.2 **SAP Comment (page 22):** *It is also important to note that since 2007, U.S. poison centers have adopted a treatment guideline for anticoagulant rodenticides that discourages routine referral to health care facilities and laboratory studies for typical exposures in young children (Caravati, 2007).*

EPA Response: This comment raises two separate issues, one regarding the reliability of incident reporting databases, and another regarding the costs to society of the products EPA proposes to cancel.

In regard to the first issue, EPA agrees that it is important to recognize that incident reporting rates can be affected by events unrelated to the actual risks posed by rodenticides. The 2007 treatment guidelines may have exerted a downward influence on the number of rodenticide exposure incidents reported as significant, as a fraction of the number of rodenticide exposure incidents that *actually were* significant.

In regard to the second issue, EPA acknowledges that decreasing the frequency with which rodenticide-exposed children are referred for medical care or observation could mitigate some of the costs of such exposures, by improving discrimination between circumstances in which medical referrals is a necessary response and circumstances in which it is not a necessary response. However, EPA does not agree that these guidelines (intended simply to reduce the frequency of an unnecessary medical response) can justify maintaining children's exposure to rodenticides at status quo levels. The 2007 guidelines do not alter the frequency with which children actually come into contact with rodenticides. Nor do they alter the percentage of those children who will consume a quantity of rodenticide that can result in adverse effects.

3.3 **SAP Comment (page 21):** *Health outcomes associated with rodenticides exposures are better than those associated with numerous other pesticides and common household products.*

EPA Response: The Agency acknowledges that there are other pesticides and household products that may be associated with health outcomes worse than those of the rodenticides. The fact remains, though, that rodenticides are potent mammalian poisons. The status quo of continuing widespread, unnecessary exposure of children to rodenticides remains unacceptable.

3.4 **SAP Comment (page 7):** *The Panel urged EPA to make certain that rodent control can be adequately maintained for protection of human health following the proposed cancellations. The Panel urged EPA to make certain that a thorough and well-researched assessment of the public health issues associated with a potential reduction in rodent control (e.g., the potential for increases in rodentborne diseases, bites) is provided by the Department of Health and Human Services (DHHS), and that this assessment be used in the overall risk assessment of the rodenticide products under consideration in this NOIC.*

EPA Response: Especially in light of input from the Centers for Disease Control (CDC), the Agency believes the Panel's concerns about potential impacts to public health are misplaced.

In 2012, CDC reaffirmed its support for EPA's risk mitigation requirements via written comments on the "Draft Notice of Intent to Cancel and Notice of Denial of Registration to Certain Rodenticide Products" (hereafter "Draft NOIC") (Buchanan, 2012). This reaffirmation encompassed the CDC's earlier conclusion, in 2007, that the cancellation is "in the interest of public health." The CDC noted in 2007 that it "rarely recommends rodenticides for plague control." Rather, "host-targeted flea control" would be the typical pesticidal intervention. Even in the unlikely event that conditions "seemed to warrant rodenticide use," the CDC "would almost undoubtedly recommend" that such applications "be done by professionals rather than by the general public."

The cancellations at issue will only affect the type of rodenticide products available to *consumers*. EPA notes Panel members' own recognition that consumers' "individual efforts will seldom result in even the localized elimination of rodents." This assessment is consistent with the CDC's recommendation that rodenticide applications intended to achieve a public health benefit be undertaken by professionals. This cancellation action will not limit the range of products available to professional applicators.

4. Response to Comments within Charge Question 4:

4.1 **SAP Comment (page 8)***: The Panel concurred that the results from the database searches and literature provided by EPA and others support the conclusion that exposure to, and adverse effects from, rodenticides, including anticoagulant rodenticides, have occurred in pets in the United States from 1999 to 2010. However, the Panel's response provides only the risk perspective, and does not include the benefit perspective of the analysis. The database results and literature review were interpreted as observational data, not an assessment of risk, per se; consequently, they do not support use of the terms "risk" or "high frequency" in the NOIC, at least to the extent that those terms imply that a risk assessment was conducted.*

EPA Response: EPA values the advice that members of the Panel offer within their respective areas of expertise. However, specifying the particular risk and benefits assessments that should inform a risk management decision under FIFRA is a question of regulatory policy; it does not appear to fall within the mandate of the SAP which is to provide advice on the science EPA uses

to make decisions. EPA acknowledges that the available information on rodenticide exposure and toxicity are insufficient to prepare an ideal risk assessment. However, EPA has conducted a risk assessment that is adequate to support the proposed cancellations.

The term "high frequency" was used to describe the number of pet incidents involving rodenticides compared to other substances. Relative to other pet poisoning incidents, there is a high frequency of incidents involving rodenticides. In fact, rodenticide pet poisonings are among the most frequent type of pet incident reported across databases. The term "risk" was used to explain that among the reported rodenticide pet incidents, a sizable fraction of exposed animals died or suffered severe effects requiring veterinary treatment.

4.2. **SAP Comment (page 8)***: Recent evidence for numerous incidents involving pets and nonconforming rodenticides appears to be adequate and brodifacoum use in and around the home has been involved in the majority of reports. Decreasing over-the-counter availability of brodifacoum is likely to reduce adverse pet events associated with it, if properly applied. The potential consequences of increased use of the non-anticoagulant rodenticide bromethalin are unknown and worrisome due to the lack of diagnostic tests and effective treatment options for bromethalin intoxication.*

EPA Response: EPA's strategy for reducing rodenticide risks to pets focuses on the requirement for bait stations, which is expected to greatly reduce the frequency of pet exposure incidents, irrespective of the types of rodenticide. Whether a particular exposure is to an anticoagulant or a bromethalin rodenticide is of significantly less importance to human health than whether the exposure occurs in the first place.

EPA notes that for those pets that do consume enough bromethalin to cause adverse effects, the course of treatment for bromethalin pet poisonings includes common veterinary treatments. Costs and prognoses associated with rodenticide pet incidents (whether SGAR or bromethalin) vary widely depending on amount consumed and amount of time between consumption and treatment.

SAP Comment (page 8)*: The Panel noted additional risk concerns not mentioned in the NOIC, such as the increased risks associated with a choking hazard from bait blocks, exposure to a 1 ounce bait block and gastrointestinal trauma from bait station ingestion, particularly for dogs.*

EPA Response: The Panel is contemplating an unlikely scenario. If the proposed cancellations become effective, the only rodenticide products that would be registered for general consumer use where they could be accessible to dogs would have to include Tier 1 bait stations. Tier 1 bait stations have been demonstrated to meet the criteria for tamper-resistant bait stations that are set forth in Pesticide Registration (PR) Notice 94-7, and have successfully isolated bait from children and dogs in laboratory testing according to EPA protocols. There are no reports of pets choking on rodenticide bait blocks or bait stations in the pet incident data that EPA has reviewed. This remains true in recent years despite the increased use of single-use bait stations recently in response to EPA's 2008 risk mitigation decision. The incident data do show, however, that pets

have experienced major trauma (*i.e.*, life threatening symptoms and/or residual disability) and death as a result of consuming unprotected rodenticide bait.

5. Response to Comments within Charge Question 5:

5.1. **SAP Comment (page 8):** *The Panel agreed that, to the extent that the mechanisms of action (inhibition of "recycling" of vitamin K1, uncoupling oxidative phosphorylation, and increased circulating 25- hydroxy cholecalciferol causing hypercalcemia) are the same in pet and other non-target mammals, it is reasonable to conclude that hazards to pets and other non-target mammals are similar, but not the same. The literature supports the notion that the "toxic dose" on a mg/kg body weight basis varies among mammals, so the term comparable must account for this dose difference to arrive at comparable risk. For the rodenticides under review, published experimental studies provide information on dose levels that produce adverse outcomes in dogs, cats, and, in some instances, other pets. Use of this pet-specific data may be more appropriate than extrapolation of risk from non-target mammalian wildlife. Based on the available wildlife data there is sufficient evidence that significant risks also exist for larger pets, as risk quotients (RQs) were found to increase with the body weight of the assessed generic/wild animal, though the potential risks to pets could be better evaluated by reviewing the available data that are specific for companion animal species. Pet-specific information would also better address potential differences in sensitivity among species and between different rodenticides. The Panel stated that it is generally reasonable to conclude that risks to pets are similar to risks to non-target mammalian wildlife of comparable body sizes; however, the mammalian body weight groups of 15, 35, and 1,000 grams used to assess primary exposure risk are not practical for pets except in the case of the very smallest pets. The 1,000 and 3,000-gram size mammalian classes included in the secondary exposure risk assessment provide a better approximation of small dogs and cats, but not for larger pets.*

EPA Response: The Agency acknowledges that the Panel generally agrees with the methodology used in EPA's pet assessment, but believes refinements could be made by considering larger body weight groups, as well as pet-specific toxicological information from experimental studies. EPA agrees that more species-specific and breed-specific toxicological information would refine the Agency's risk assessment. However, that information is not currently available, and the analytical refinements the information would enable are not prerequisites to an adequate risk assessment.

6. **Response to Comments within Charge Question 6:**

6.1. **SAP Comment (page 9)***: The Panel did not agree with EPA that limiting consumer use to conforming rodenticide products will generally reduce the opportunity for exposure of pets to commensal rodenticide products. They concluded that the pet incident reports demonstrate that residential consumers in general do not read and/or follow label directions for current rodenticides and hence, would not be any more likely to do this for*

rodenticide products formulated in block form. To the extent that conforming rodenticide products are provided outside of bait stations, the pet incident report does not support the conclusion that the opportunity for exposure of pets to commensal rodenticide products is likely to be reduced. To the extent that conforming rodenticides are provided solely in tamper-proof bait stations that actually reduce exposure to dogs and other pets, the above conclusion may change. Use of rodenticides in bait stations will decrease the ease of accessibility and likely decrease the number of exposures involving pets, but use of them will not completely eliminate exposures, especially with dogs.

EPA Response: EPA agrees with the Panel's statement that the "[u]se of rodenticides in bait stations will decrease the ease of accessibility and likely decrease the number of exposures involving pets, but will not completely eliminate exposures, especially with dogs." EPA also agrees with the Panel's observation that the human and pet incident data suggest that many residential consumers are not following current label directions to place bait out of reach of children or pets or in a tamper-resistant bait station. EPA's RMD was intended to reduce the opportunity for misuse and greatly reduce the frequency of pet exposure to these products by making it easier for residential consumers to comply with label requirements. The Agency will continue to monitor incident data to evaluate if the mitigation produces the desired decrease in incidents, and will consider additional restrictions if necessary.

Unless data show misuse is resulting in significant adverse effects, EPA will presume that residential consumers will generally comply with reasonable, practicable label requirements. EPA expects that most consumers will purchase single-use bait stations, and that products containing multiple bait block refills and a refillable bait station will be a niche market for persons with recurring rodent problems. If further incident data associate significant adverse effects with rodenticides sold as multiple bait block refills with a single, refillable bait station, EPA will take appropriate action.

6.2. **SAP Comment (page 51)***: A societal cost not sufficiently included in the data and information provided is the increased cost of diagnosis and treatment of pets, and perhaps other non-target species, exposed to non-anticoagulant rodenticides. Generally speaking the cost of treatment is higher, and the prognosis is lower, for the non-anticoagulant rodenticides compared to the anticoagulant rodenticides.*

EPA Response: EPA's strategy for reducing rodenticide risks to pets (and associated costs) focuses on the requirement for bait stations, which is expected to greatly reduce the frequency of pet exposure incidents, irrespective of the types of rodenticide. Whether a particular exposure is to an anticoagulant or a bromethalin rodenticide is of significantly less importance to human health than whether the exposure occurs in the first place.

EPA notes that for those pets that do consume enough bromethalin to cause adverse effects, the course of treatment for bromethalin pet poisonings includes common veterinary treatments. Costs and prognoses associated with rodenticide pet incidents (whether SGAR or bromethalin) vary widely depending on amount consumed and amount of time between consumption and treatment.

7. Response to Comments within Charge Question 7:

7.1. **SAP Comment (page 9):** *In contrast to the Agency's selection of uniform species, a better approach would be to conduct chemical-specific assessments with conceptual models that identify receptors of interest for a refined risk assessment. . . . A species sensitivity distribution provides a more quantitative approach which, in turn, would provide a quantitative estimate of uncertainty.*

EPA Response: In response to the SAP suggestion, EPA conducted a limited probabilistic risk assessment to better address differences in species sensitivity by utilizing the distributions of toxicity data and liver or blood plasma half-life data. This analysis was conducted to address concerns regarding the risk assessment for the secondary exposure pathway. The results of the limited probabilistic assessment for secondary exposures help quantify some uncertainties through the use of exposure distributions, but did not change any of the general conclusions reached in the deterministic assessment. For example, brodifacoum and difethialone present secondary exposure risks exceeding EPA level of concern for some bird species under all accumulation scenarios, and the "probability to exceed" was greatest for both brodifacoum and difethialone compared to the other evaluated rodenticides. Because the results of this secondary exposure probabilistic assessment are consistent with the deterministic assessment and do not support conclusions different from those drawn from the deterministic assessment, EPA concluded that limited additional information would be gained by conducting an additional probabilistic assessment for primary exposure. Accordingly, EPA did not conduct a probabilistic risk assessment to further evaluate primary exposure risks.

7.2. **SAP Comment (page 10):** *A problem in the analysis of the first generation anticoagulant rodenticides (FGARs) (i.e., chlorophacinone, diphacinone) is the exposure scheme used in the avian and mammalian acute oral toxicity tests where a single oral dose or multiple doses are administered in a 24-hour period. As noted by EPA, the toxicity of FGARs increases by nearly two orders of magnitude when the dose is administered for 5 days. Therefore, acute oral toxicity tests for FGARs may greatly underestimate toxicity.*

EPA Response: EPA acknowledges that there are two studies (Ashton *et al*. (1986); Shirazi et al (1994)) indicating that anticoagulant rodenticides show increased toxicity when the dose is delivered over multiple days rather than a single day. However, the extent of the increase appears to vary between chemicals and is likely to vary between species. Owing to the limitations of those studies, the single dose toxicity data remain the most meaningful and reliable basis for comparing the relative toxicity of rodenticides.

EPA remains confident that the analyses conducted in the SAP Background Paper provide a meaningful representation of the risks of the rodenticides subject to the NOIC. Given the lack of definitive information on the effects of exposure duration and post-exposure duration on the toxicity of both first and second generation anticoagulants, EPA believes it is appropriate for it to continue to base its quantitative risk estimation on single-dose toxicity values from the dose-based and the dietary-based toxicity and exposure studies.

7.3. **SAP Comment (pages 11, 31**): *The relative contribution to dietary exposure from consumption of invertebrates that bioaccumulate rodenticides is uncertain. . . . The EPA White Paper, and the conceptual model shown on page 29, discuss invertebrates as a possible source of exposure to compounds. The relative contribution to dietary exposure is uncertain, but given the incident report of the Philadelphia Zoo, invertebrate trophic transfer to insectivorous species may be significant, especially in rural and agricultural applications. Fisher et al. (2010) discuss the consumption of rodenticide bait and the accumulation of brodifacoum and diphacinone in terrestrial invertebrates. The calculation of bioaccumulation factors (BAFs) within invertebrates and other prey items for each compound should reduce uncertainties of exposure to wildlife.*

EPA Response: EPA presumes that residential consumers will apply rodenticides where rodents are active, and that in those situations target rodents will out-compete insects to consume the overwhelming majority of the bait. However, the Agency concurs that invertebrate consumption of bait is a potential rodenticide exposure pathway for organisms consuming invertebrates, and this pathway should be further evaluated. Accordingly, EPA has conducted a further literature review to quantify the level of exposure to invertivores and to document evidence of this exposure pathway to invertivores.

From its review, EPA concludes that invertebrates are exposed to and will consume bait (placed inside or outside bait boxes) with resulting body burdens no greater than the empirical or theoretical body burdens utilized in the small mammal prey for the secondary exposure analysis in the SAP Background Document. EPA also concludes that animals that are strict or primarily invertivores will consume invertebrates contaminated with rodenticides. Finally, EPA notes that the risk assessment conducted in the SAP Background Document for secondary consumers exposed to rodenticides through consumption of contaminated small mammals would also be protective of invertivores as the secondary consumer.

8. Response to Comments within Charge Question 8:

8.1 **SAP Comment (pages 13, 30, 27):** *Reliance on standardized avian toxicity endpoints using less sensitive species is likely to underestimate the risk to birds of prey from both FGARs and SGARs making it difficult to determine if FGARs present less risk than SGARs to birds of prey. . . . [I]t was unclear to the Panel why a probabilistic approach was not used to quantify liver concentrations of individual compounds. . . . [T]here are clearly enough data for a species sensitivity distribution for several compounds.*

EPA Response: As suggested by the SAP, EPA conducted a limited probabilistic analysis to inform the level of confidence and explore uncertainty in the likelihood that a randomly selected secondary consumer may achieve a lethal rodenticide dose. This was accomplished using a Monte Carlo simulation with a distribution of possible outcomes that were analyzed to allow for more thorough understanding of the uncertainties associated with the available data. The modeling exercise was performed by varying selected parameters for liver or blood-plasma half-life and the LD_{50} or LC_{50}. For each chemical, results from the probabilistic assessment support the overall conclusions the EPA has drawn from the other lines of evidence (*i.e.,* RQ estimates,

quantity of contaminated mice or rats in diet required to consume the equivalent of an LD_{50}, and results of the secondary feeding studies).

8.2 **SAP Comment (page 13):** *The conclusion that bromethalin presents lesser risk to non-target wildlife may be flawed due to limited information on tissue persistence of bromethalin.*

EPA Response: EPA acknowledges that there is some uncertainty associated with the analysis of the relative ecological risks of bromethalin and SGARs, because of limited data on tissue persistence. However, this uncertainty is not such as would call into question the Agency's overall conclusions about the relative risks of bromethalin and second generation anticoagulants.

The data that are available suggest bromethalin is unlikely to be highly persistent in tissue—it is rapidly eliminated from blood plasma. Moreover, persistence in tissue is simply a less important factor in assessing secondary exposure risks of bromethalin than it is for anticoagulants, because of the rapid mortality and cessation of eating associated with bromethalin poisoning. Together, these two considerations make it unlikely that target rodents will accumulate bromethalin body burdens significantly greater than a dose lethal to the target rodent.

8.3 **SAP Comment (page 13):** *"[I]t is not clear that brodifacoum and difethialone should be considered together since their overall risks are not similar."*

EPA Response: EPA disagrees that the "overall risks" of brodifacoum and difethialone are "not similar." Difethialone and brodifacoum are similar, both with respect to hazard and with respect to risk profile.

While the Agency agrees that the available evidence of secondary risks from brodifacoum is more conclusive than the corresponding evidence of secondary risks from difethialone, the analyses (*i.e.*, RQ estimates, quantity of contaminated mice or rats in diet required to consume the equivalent of an LD_{50}, and results of the probabilistic analysis) identified risks for both chemicals more frequently than for the other evaluated rodenticides. The two chemicals are similar in that respect. Furthermore, brodifacoum and difethialone have similar physical-chemical properties and similar acute toxicological properties.

Response to Comments within Charge Question 9:

9.1 **SAP Comment (page 37):** *However, rodenticides are also deployed by professionals representing commercial and institutional entities in urban and suburban areas and it is not clear how one would separate domestic from commercial/institutional usage as sources in urban and suburban land use areas.*

EPA Response: The Agency agrees that the available incident location data are not a basis to quantify the fraction of overall exposure in urban/suburban locations that results from use by residential consumers (as compared to the fraction that results from use by professional users at commercial and industrial sites). EPA did not propose to draw such quantitative inferences from

the spatial analysis of incident data. Indeed, it is rare that a wildlife pesticide exposure incident is tied definitively to a particular user or product and this will likely remain an intractable uncertainty.

However, a quantitative allocation of rodenticide product use between professional/commercial users and residential consumer use is not an analytical prerequisite to the cancellation action. In the absence of additional contrary information, EPA believes it is reasonable to infer that a significant fraction of the large number of incidents that take place in residential areas are a consequence of residential consumer use. EPA's spatial analysis of rodenticide incidents demonstrates that many non-target species are present in urban/suburban environments, and are succumbing in those environments to poisoning by rodenticides used by residential consumers.

9.2 **SAP Comment (p. 39):** *[A] further source of error or bias in the land use component of this analysis may come from changes in land use with time, particularly increased urbanization. . . . [S]ome incidents which were classified as urban or suburban based on current land use, occurred when the land was still in rural use at the time of the incident.*

EPA Response: The Agency agrees that some amount of urbanization does occur and could have occurred during the time span of the reported incidents. However the majority of the incidents were categorized based on information recorded in the "Habitat" field of the incident report, which records the land use at the site at the time of the incident. Additionally, many of the reported brodifacoum incidents characterized as occurring in urban/suburban habitats occurred in major cities, including New York, Albany, Buffalo, and Los Angeles. These areas have been urban for several decades, including the time period when the rodenticide incidents were reported. Therefore, the Agency believes that the impact of urbanization on the accuracy of the original classifications of incidents is minor, and that urbanization does not impact the Agency's conclusion that the available incident reports for rodenticides demonstrate that one or more exposure pathways are complete and that incidents occur in urban/suburban and rural areas.

9.3 **SAP Comment (p. 39-40):** *Of further relevance to this assessment are data on diet and habitat use of three owl species inhabiting urbanized environments in south western British Columbia, the barn owl (Tyto alba) and of diet of two other species, the barred owl (Strix varia) and the great horned owl (Bubo virginianus). Although these data are unpublished, they were recently presented and abstracted by Hindmarch and Elliott (2011a, 2011b) and the Panel was informed of the results for these deliberations.*

EPA Response: The Agency agrees that this new unpublished data as well as other data cited in the minutes of the SAP response further support EPA's position that nontarget wildlife, particularly raptorial species, are susceptible to secondary poisoning from rodenticides.

9.4 **SAP Comment (p. 42):** *Wild canids, such as foxes and coyotes, fall within the omnivore category and could conceivably be exposed through consumption of contaminated insects, treated grains, pellets or bait blocks as well as being potentially exposed via predation or scavenging.*

EPA Response: The Agency agrees that in some cases it may have miscategorized (as secondary poisoning incidents) wildlife mortality incidents that actually involved primary poisoning of the red, grey, and San Joaquin Kit fox. Available literature and life histories show an occasional use of corn and other grain based food items, and thus these species may also be primary consumers of rodenticide bait. However, the Agency does not believe this issue extends to coyote incidents. The literature indicates that when coyotes do seek out vegetative food items, they usually seek fruit and berries. Thus, coyotes would not likely recognize rodenticide bait as a potential food. Furthermore rodenticide bait is expected to be used in areas of a high rodent population and therefore the rodent prey (dead and alive) would likely be more available than rodenticide bait. Thus, even for the fox species, the Agency believes that the majority of mortality incidents would likely be the result of consumption of poisoned rodents rather than from direct consumption of bait. Moreover, the prevalence of rodenticide poisoning among exclusive carnivores suggests that secondary poisoning is likely to be the major exposure pathway among species such as fox and coyote that are primarily carnivores. The possibility that some predators may additionally face a primary exposure pathway does not reduce the risk they face through secondary exposure.

9.5 **SAP Comment (page 43):** *For omnivorous and/or scavenging species, due to the delayed onset of signs caused by anticoagulant rodenticides, analysis of stomach contents that are present at the time of the animal's death will not necessarily determine primary or secondary exposure. That is, absence of bait granules in the gastrointestinal tract at time of death does not rule out primary poisoning as the animal could have ingested the lethal dose 3 to 5 days earlier. Likewise, bait present in the gastrointestinal tract at the time of death may not have caused the animal's death, although it does show that the animal had access to bait and would ingest the bait. In this case, the presence of granules upon death can suggest that the animal may also have consumed a lethal feeding of bait several days prior to death, but it is not absolute proof of primary poisoning. In summary, the Panel concluded that this approach of separating primary and secondary poisonings by diet is basically sound, but post-mortem evidence from gut contents must be interpreted with caution.*

EPA Response: The Agency agrees that the delayed toxicity of anticoagulant rodenticides could cause mortality several days after the ingested item that caused the initial poisoning (be it bait or by ingesting another animal that consumed bait). The gut/crop contents were used to make determinations of likely exposure pathways in 12 total incidents, all of which were associated with brodifacoum. If these incidents were re-categorized as unknown exposures, the total counts would change little. Such changes would have no impact on the overall conclusions previously made about the incident reports. The incident data would still provide evidence that the primary and secondary exposure pathways are complete for the use of these chemicals.

10. Response to Comments within Charge Question 10:

10.1 **SAP Comment (page 44):** *The Panel did not believe that efficacy data alone can be used to conclude that conforming rodenticide products are an effective option for the control of commensal rodents by nonprofessional users. The effectiveness of*

products vary greatly across species, populations, and time (Tobin et al., 1993; Witmer, 2007a and 2007b; Pitt et al., 2011). This variation has been demonstrated repeatedly with several of the conforming products. Prior rodenticide exposure and rodenticide resistance (via either genetic or behavioral changes) may account for some, but not all, of the variation in control effectiveness. Environmental realities, including but not limited to, access to areas where rodents are normally found, structural condition of the home or building, availability of alternate food sources, learned foraging behaviors, variation in wild strains and neophobia, all play a part in the effectiveness of a rodent control effort (Clapperton, 2006).

EPA Response: The performance of rodenticide products under conditions of actual use is influenced by various factors, including those noted by the Panel. Consideration of these factors, however, leads EPA to conclude that the influence of most of these factors apply to all rodenticide products and, in many cases, non-chemical lethal control methods in a similar manner. As a variety of active ingredients encompassing at least two distinct modes of actions would remain available to consumers, as would non-chemical control methods, the cancellation of noncompliant products is not expected to decrease the level of control obtained by residential consumers or to affect the time to achieve that level of control.

10.2 SAP **Comment (page 44):** *Limiting use to bait stations can greatly reduce the ability of users to establish the bait in some locations where the rodents are more likely to encounter and consume it and practical field efficacy of the available rodenticides will be likely reduced. Placing bait into small spaces such as inside of walls, under foundations, or in attic crawl spaces will be impractical with bait stations and/or larger bait blocks.*

EPA Response: EPA recognizes that it may be impractical to insert bait stations into certain cramped spaces such as wall voids, floor voids, and burrows. However, locations that are insufficiently accessible to accommodate the insertion of a bait station are also very likely insufficiently accessible to accommodate the application of the non-conforming loose bait products, consistent with labeling requirements to collect and dispose of leftover bait properly at the end of the treatment period. To the extent that application in a particular location is *already* inconsistent with product labeling, EPA does not recognize, as a loss of social benefit, the loss of the practical ability to persist in such illegal application.

10.3 **SAP Comment (page 44):** *[P]lacing baits in bait stations may decrease or delay uptake of bait by rodents, further reducing effectiveness, thereby allowing commensal rodents to continue to be a significant risk to human health (Buckle and Prescott, 2011). Especially with rats, time to acclimate to the stations and to begin consuming adequate bait to induce mortality will be delayed. Rodents may also avoid established bait stations that have been disturbed by predators.*

EPA Response: Based on data from the American Housing Survey (Census Bureau, 2011), over 90 percent of rodent problems in residential units involve the house mouse, a species which has been reported to enter bait stations readily (e.g., Palmateer, 1982; Morris and Kaukeinen, 1988). Consequently, latency to enter bait stations is not expected to be a serious problem when house mice are being targeted. Commensal rats tend to be initially reluctant to enter bait stations newly

placed in their environment (e.g., Barnett, 1946), but they also tend to be reluctant to sample new potential food sources such as loose bait blocks and pelleted bait packets. Although there may be some delay and variation in the time for individual rats to find and consume new baits and succumb to their effects, the time-course for controlling infestations is likely to be similar once bait consumption begins, regardless of whether the bait is in a bait station or not.

10.4 **SAP Comment (page 45):** *Limiting the bait formulation reduces the opportunity to select the formulation that is best suited for the environment in which control efforts are taking place. In some cases, pellets will have greater acceptance than a novel bait block. In some situations the bait blocks are more appropriate because of moisture or other factors.*

EPA Response: Most residential consumers will be dealing with sporadic infestations (e.g., in the fall as rodents seeks shelter from colder weather). Even in cases of frequent infestations, the consumer will be facing new rodents each time. In such circumstances, where all elements of the rodents' environment are relatively new, bait stations are less likely to regarded as a new feature. The bait-block formulations available for consumer use via the RMD have been demonstrated to be palatable and lethal to targeted rodents.

Lublinkhof (2012) made the points that it is possible to produce bait blocks that are as well accepted as pellets (although in cage trials with laboratory strains) and that Bell's trials with wild-type house mice with mouse-sized bait stations which contained bait blocks indicated entry by mice and 100% mortality in the test group. Lublinkhof (2011) also noted that bait blocks are not novel pest management tools and that they are the preferred bait form by professional applicators in residential settings. Kaukeinen and Marsh (2009) reviewed the approximately 50-year history of rodenticide bait blocks in the U.S. and noted that improvements to formulation processes and bait palatability have occurred over that time period. Bait blocks have been on the residential consumer markets as far back as the late 1980s.

10.5 **SAP Comment (page 45)** *EPA may have underestimated the complexity of effective rodent control in the home and assumed that a one-size fits all approach will provide homeowners with satisfactory results.*

EPA Response: The RMD does not leave consumers with a "one-size fits all approach." For the sometimes complex problem of controlling commensal rodents in the home environment, consumers have the options of a variety of rodenticide products – containing either first-generation anticoagulants or bromethalin, in a variety of distinct bait-block formulations, in tamper-resistant bait stations – and various types of traps, including glue and mechanical, covered or uncovered. It is important to note that snap traps are the only method of rodent control that the CDC recommends for consumers and that traps are generally less expensive than rodenticide baits. Furthermore, traps are currently the leading choice of consumers for controlling rodents, as shown by IRI sales register data (traps account for almost 70% of rodent control sales, whereas rodenticides account for about 30% of rodent control sales) (IRI data via Bell Laboratories, 2012).

10.6 **SAP Comment (page 16 and 45):** *The requirement that rodenticides sold to residential consumers not contain the active ingredients brodifacoum, difethialone, bromadiolone, or difenacoum has the potential for increasing rodenticide resistance and limiting effective options. EPA has not adequately considered the risks and costs from increased rodenticide resistance and the potential costs associated with limiting chemicals that can be used in future products.*

EPA Response: EPA considered the risks of increased resistance to anticoagulant rodenticide products due to the proposed cancellation of SGARs and concluded that the risks are minimal. Resistance refers to genetic changes in a rodent population as a result of tolerant individuals being more likely to reproduce and pass that trait on to subsequent generations, as a result of rodenticides removing large portions of susceptible individuals. EPA recognizes that there is the potential for the development of resistance to anticoagulants given the way they work and the genetic and reproductive characteristics of rodents. However, residential consumer use of the conforming anticoagulant rodenticides will not be so widespread, frequent, and repetitive that enough anticoagulant tolerant individuals will be selected to result in a resistant population.

The Agency retains discretion to register new rodenticides if those registrations meet the standard of no unreasonable risk to human health or the environment, considering the risks and benefits of the rodenticides. Furthermore, in the event that a significant rodent resistance problem were to emerge, EPA retains the discretion to reconsider this cancellation, taking any substantial new evidence into account.

Regarding SAP's potential cost concerns, EPA acknowledges that there are likely local populations which include anticoagulant-resistant house mice and rats within the United States. However, the estimated incremental cost to residential users of cancelling SGARs is not based solely on their use of FGARs. As noted above, most of the currently available RMD-conforming products found on retail store shelves contain bromethalin rather than **F**GARs. Resistance to bromethalin has not been reported. Therefore**,** the estimated cost is not affected by the presence of resistance to anticoagulants.

11. Response to Comments within Charge Question 11:

11.1 **SAP Comment (page 46):** *For the near term, the Panel believed effective control is possible with a combination of both an effective product and non-chemical methods. However, for the long term, limiting chemical control options to only two classes of rodenticides will likely lead to an increase in the number of commensal rodent populations that exhibit anticoagulant resistance and that will limit control options. The distribution of current anticoagulant resistant populations in the United States is not known.*

EPA Response: The cancellation of particular pesticide products containing second-generation anticoagulants does not forever limit consumers' chemical control options to only first-generation anticoagulants and acute rodenticides. The Agency retains discretion to register new rodenticides if that registration meets the standard of no unreasonable risk to human health or the

environment, considering the risks and benefits of the rodenticides. Furthermore, in the event that a significant rodenticide- resistance problem were to emerge, EPA retains the discretion to reconsider this cancellation, taking any substantial new evidence into account.

11.2 **SAP Comment (page 46):** *The NOIC assumes that homeowners should rely more on non-chemical means of rodent control. The Panel is concerned that in the NOIC, EPA has failed to recognize the difficulty associated with non-chemical control, especially in those communities where rodent populations are at high levels. The complexity of the physical environment, coupled with food availability and the lack of what many would consider basic sanitation makes it impossible to effectively reduce harborage, eliminate food sources, manage adjacent land areas, limit access to buildings, or trap enough animals to impact the population. Dependence on non-chemical controls would be least effective for those neighborhoods that have the most significant problems. Further, many mechanical control products are not as effective as chemical rodenticides and mechanical tools are not subject to any efficacy requirements.*

EPA Response: EPA is not assuming that significant numbers of residential users of rodenticides will switch to non-chemical means of rodent control as a result of this action. To the contrary, EPA concludes that few residential users of rodenticides will switch to non-chemical controls as a result of this action. However, EPA is aware that a high proportion of general consumers already prefer non-chemical controls (70% per IRI 2012), and expects that a high proportion will continue to prefer such controls.

EPA has concluded that RMD-compliant rodenticides, considered as a whole, are likely to perform as well as noncompliant rodenticides in the same situations, even where rodent control is challenging due to limitations to sanitation and rodent-proofing. See EPA's Response to Comment 10.1.

In the case of house mice, EPA's analysis and additional market data submitted after the SAP met show that RMD-compliant products are also approximately the same price as noncompliant products. Thus, EPA concludes that most residential users who would typically purchase a noncompliant rodenticide product for mouse control will simply purchase a compliant rodenticide and experience no difference in performance.

In the case of commensal rats, EPA recognizes that currently available RMD-compliant rodenticides are more expensive than noncompliant products. Thus, some residential users who would typically purchase a noncompliant rodenticide may be prompted to shift to a lower-cost nonchemical control method such as snap traps. However, snap traps can effectively control rodents, including commensal rats, even where rodent populations are at high levels (Quy, et al., 1995). In fact, because snap traps can be deployed with different food items or other attractive objects, they may be more effective than rodenticide baits in situations where other available food sources cannot be eliminated.

11.3 **SAP Comment (page 46-7)** *The Panel concluded that the estimated added costs associated with the use of conforming rodenticide products along with non-chemical control are underestimated in the NOIC. … [T]he costs of traps or rodenticides cannot*

be considered on a 'per infestation basis' but have to be considered as an ongoing cost since individual efforts will seldom result in even localized elimination of rodents. This should be considered a social equity issue.

EPA Response: EPA disagrees that it has underestimated the added cost of using conforming rodenticide products instead of nonconforming products. The SAP conclusion is based on the Panel's assumptions about potential reduced performance of conforming rodenticide products, which EPA has addressed in its previous responses above. EPA evaluated the incremental cost of switching from a non-compliant rodenticide product to a compliant rodenticide product or a non-chemical control method regardless of environmental conditions. Thus, EPA concludes that residential consumers will obtain similar levels of rodent control without expending additional efforts to improve sanitation or exclusion.

Finally, regarding the unit of analysis, EPA disagrees that evaluating costs on a per-infestation is inappropriate. Even in communities where rodent populations are at high levels, the individual residential consumer may face repeated infestations but is likely to achieve the temporary elimination of rodents from his or her living unit. However, given local environmental conditions and access by rodents to the building, new rodents may soon enter the household space. It is precisely for that reason that EPA placed the increase in costs in the context of the monthly income of a household at the poverty level.

11.4 **SAP Comment (page 47):** *Noncompliance with product labeling is likely . . . and inappropriate use will continue, even with RMD compliant products.*

EPA Response: EPA recognizes that it is likely that there will be *some* degree of inappropriate use of any pesticide product that is widely marketed to consumers. However, this truism does not undermine EPA's conclusion that the RMD-conforming rodenticide products dramatically improve consumers' capability to comply with label requirements regarding placement where children, pets, or non-target wildlife might have access. Nor does it establish that cancellation of the rodenticide products subject to the NOIC (which do not at all augment consumers' capability to make compliant placements) is futile. Prior to the issuance of the RMD and the subsequent registrations of RMD-conforming consumer-oriented products, it was difficult for residential consumers to locate and purchase the tamper-resistant bait stations that they were directed to use when bait placements otherwise would have been within reach of children under six years-of-age, pets, domestic animals, and/or non-target wildlife. The registrants who have introduced products that conform to the RMD have provided such persons with bait products that include protective bait stations, thereby, for the first time, making appropriate use of bait in accessible areas a realistic possibility for residential consumers.

12. Response to Additional Panel Comments:

12.1 **SAP Comment (page 50)**: *Under "**Pest Resistance and Use of FGARs**" The role of increased pest resistance from use of FGARs was not addressed in the background document. … If increased usage of an FGAR alternative leads to development of*

widespread pest resistance, … there appears to be a potential risk of needing to re-introduce SGARs, or other alternative products, back into the domestic market in 10 years or so.

EPA Response: EPA recognizes the general potential for a currently unreasonable risk to become a reasonable risk at some later date, due to a potential future relative increase in benefits. But specifically with respect to the possibility that consumer use of non-conforming rodenticide products might become necessary in ten years' time, EPA does not agree that this potential is a reasonable basis to forego action to eliminate currently unacceptable risks. Regarding resistance more generally, see EPA's response to SAP Comment 10.6.

12.2 **SAP Comment (page 50-51)** *Under "**Rodenticide Use Awareness Programs**", the SAP recommends that: "More proactive training and education as currently being carried out in the United Kingdom and Europe should also be considered. Helping homeowners more easily understand how their actions impact children, pets, and wildlife has the potential of reducing the off label uses that increase risk for non-target impacts. It would be worth taking a closer look at the Campaign for Responsible Rodenticide Use to understand how that has impacted use of rodenticides in the United Kingdom. If there is evidence that programs such as the Campaign for Responsible Rodenticide Use can reduce non-target impacts there may be value in considering a similar program in the United States."*

EPA Response: EPA agrees that proactive training and education are important and should be encouraged. According to their website, The Campaign for Responsible Rodenticide Use appears to be an organization that promotes responsible rodenticide bait use among professional applicators and agricultural professionals in the United Kingdom. Based on the website, it is not clear that this organization has any outreach to "homeowners" although it would be possible for residential consumers to access the website and read the materials.

In the U.S., EPA has conducted outreach and published educational materials through its Field and External Affairs Division (FEAD) aimed at the residential consumer who is attempting to control household pests. In addition, the CDC has published manuals on commensal rodent control for about 60 years. Various other agencies and non-governmental organizations also have developed and circulated relevant educational materials, sometimes as part of specific campaigns to control one or more species of commensal rodents. Still, misuse, rodenticide exposure incidents, and rodent control problems persist. While public educational efforts are useful and should be encouraged, it is clear that those efforts alone are insufficient to solve the exposure and risk issues that are addressed with the RMD.

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