October 4, 2013

Ms. Linda Irokawa-Otani  
Department of Pesticide Regulation  
1001 I Street, P.O. Box 4015  
Sacramento, CA  95812-4015

Re: Comments Concerning California DPR Regulation No. 13-002

Dear Ms. Irokawa-Otani:

I am pleased to submit the enclosed comments and exhibits on behalf of Reckitt Benckiser LLC, which distributes a full line of affordable and effective rodent control products under the d-CON® brand name. d-CON®’s rodenticide products include both snap and glue traps and bait products that are marketed only in small quantity packages for retail sales to consumers who primarily use our products to control house mice infestations in their residences and small businesses. d-CON® products are not sold for agricultural or professional uses. As such, when used as directed, d-CON® products are not anticipated to be a significant source of exposure to non-target wildlife.

We believe DPR should exempt rodenticide products that contain SGARs from the scope of any final restricted materials regulation when the products are packaged and sold in small volume containers and are clearly labeled exclusively for use indoors.

We look forward to working with you to implement a final rule that contains such an exemption. Please feel free to contact me directly if you have any questions concerning the enclosed comments.

Sincerely,

Hal Ambuter  
Director, Regulatory and Government Affairs  
North America

Enclosures: Public Comments and Exhibits
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>EXECUTIVE SUMMARY:</td>
<td>i</td>
</tr>
<tr>
<td>d-CON COMMENTS CONCERNING DPR PROPOSAL No. 13-002</td>
<td>1</td>
</tr>
<tr>
<td>I. DPR’S PROPOSAL WILL HAVE UNINTENDED PUBLIC HEALTH CONSEQUENCES</td>
<td>1</td>
</tr>
<tr>
<td>A. Commensal Rodents are a Persistent Threat to the Public Health and</td>
<td>2</td>
</tr>
<tr>
<td>the Economic Well-Being of the Citizens of California</td>
<td></td>
</tr>
<tr>
<td>B. DPR’s Proposal Will Have Significant Impacts on Minority and</td>
<td>4</td>
</tr>
<tr>
<td>Disadvantaged Populations</td>
<td></td>
</tr>
<tr>
<td>C. DPR’s Proposal Will Have Significant Impact on Small Businesses</td>
<td>6</td>
</tr>
<tr>
<td>II. DPR OVERSTATES THE RISK POSED BY SGARS TO NON-TARGET WILDLIFE</td>
<td>6</td>
</tr>
<tr>
<td>POPULATIONS</td>
<td></td>
</tr>
<tr>
<td>A. DPR Has Not Fully and Credibly Assessed the Risk to Wildlife</td>
<td>6</td>
</tr>
<tr>
<td>Posed by SGARs</td>
<td></td>
</tr>
<tr>
<td>B. DPR’s Analysis of Incident Data is Flawed and Unpersuasive</td>
<td>8</td>
</tr>
<tr>
<td>C. DPR Improperly Conflates Liver Residue Concentrations with Lethal</td>
<td>10</td>
</tr>
<tr>
<td>Concentration Values</td>
<td></td>
</tr>
<tr>
<td>D. DPR Does Not Demonstrate Impacts to Wildlife Populations</td>
<td>11</td>
</tr>
<tr>
<td>E. DPR Has Not Considered the Risk to Wildlife from SGAR Alternatives</td>
<td>12</td>
</tr>
<tr>
<td>III. DPR ERRONEOUSLY CONCLUDES THAT CONSUMER USE OF SGARS CONTRIBUTES</td>
<td>14</td>
</tr>
<tr>
<td>TO NON-TARGET WILDLIFE RISK</td>
<td></td>
</tr>
<tr>
<td>A. There is No Substantial Evidence that Consumer Uses Contribute to</td>
<td>15</td>
</tr>
<tr>
<td>Non-Target Wildlife Exposure</td>
<td></td>
</tr>
<tr>
<td>B. Locations of Incidents, Mill Assessment Data, and Registration</td>
<td>15</td>
</tr>
<tr>
<td>Records Do Not Constitute Substantial Evidence That Indoor Consumer</td>
<td></td>
</tr>
<tr>
<td>Uses of Small Quantity SGAR Products is the Source of Non-Target</td>
<td></td>
</tr>
<tr>
<td>Wildlife Incidents</td>
<td></td>
</tr>
<tr>
<td>C. Relative to Consumers, Rodenticide Use by PCOs is More Likely to</td>
<td>17</td>
</tr>
<tr>
<td>Result in Wildlife Exposure.</td>
<td></td>
</tr>
<tr>
<td>D. Rodents Targeted by Consumers Are an Unlikely Source of Secondary</td>
<td>19</td>
</tr>
<tr>
<td>Exposures</td>
<td></td>
</tr>
<tr>
<td>E. The Department Has Not Established the Comparative Contribution of</td>
<td>20</td>
</tr>
<tr>
<td>Non-Licensed and Licensed Users to Non-Target Wildlife Exposures</td>
<td></td>
</tr>
</tbody>
</table>
F. Published Studies Cited by DPR are Not Substantial Evidence of the Necessity to Restrict Consumer Use SGARs ................................................................. 22

G. Recent Information Gathered From California Rodenticide Users Shows That Outdoor Consumer Uses Can Be Easily Curtained Through New Labeling With Use Limitations. ... 25

H. Bulk Sales of SGARs to Non-Licensed Users Are Likely to Continue Via Internet and Interstate Purchases ................................................................................. 26

I. DPR Mis-states the Experience of the United Kingdom in Rodent Control.............. 27

IV. DPR HAS NOT ADEQUATELY CONSIDERED LESS IMPACTFUL ALTERNATIVES THAT WILL ACHIEVE AS MUCH OR GREATER WILDLIFE PROTECTION .............................................. 28

V. DPR HAS FAILED TO ASSESS THE RISKS TO CHILDREN AND PETS FROM EXPOSURE TO ALTERNATIVE RODENTICIDES LIKE BROMETHALIN.............................................. 30

VI. DPR HAS NOT EVALUATED THE EFFICACY OF ALTERNATIVE PRODUCTS OR THE IMPACTS ON PUBLIC HEALTH OF THE WIDESPREAD USE OF LESS EFFECTIVE RODENTICIDES THAT WILL RESULT FROM THIS PROPOSAL ............................................................................. 34

VII. DPR’S ECONOMIC ANALYSIS IS INADEQUATE AND UNDERSTATES THE COST IMPACT OF ITS PROPOSAL .............................................................................................................. 37

A. DPR Did Not Conduct a Sufficient Economic Analysis .............................................. 37

B. DPR’s Economic Analysis Documents Cited for Rulemaking Understate Economic Impacts to Consumers, Businesses, State & Local Governments and Registrants........... 38

VIII. ADDITIONAL CONSIDERATIONS .................................................................................. 42

A. DPR’s Proposal is Tantamount to a De Facto Cancellation, Which Requires an Adjudicatory Hearing .............................................................................................................. 43

B. DPR Must Comply With the California Environmental Quality Act (CEQA) .............. 43

C. The DPR Proposal Duplicates Existing Federal Regulatory Proposals......................... 44

D. DPR Has Not Complied with California’s Environmental Justice Mandates ................ 44

E. DPR Failed to Consult with CDFA as Required by Statute ........................................ 45

F. There is Ample Precedent in DPR Restricted Material Classifications for Excluding Consumer Uses .............................................................................................................. 46

G. DPR’s Proposal Does Not Address Internet Bulk Sales of SGARs or intra-state purchase of product outside of California ................................................................. 47

CONCLUSION .......................................................................................................................... 47
EXECUTIVE SUMMARY:

The regulation proposed by the California Department of Pesticide Regulation (DPR or the Department) to classify second-generation anticoagulant rodenticides (SGARs) as restricted materials should be modified to exempt certain consumer-use products. Specifically, DPR should permit sale of consumer-use SGAR products that are: 1) clearly labeled for indoor use only, and 2) sold in placement units of not greater than 3 ounces each, with multi-placement packages not to exceed one pound. Adoption of this alternative will ensure that Californians who can least afford the costs of professional pest control services will continue to have access to affordable and effective forms of rodent control for their homes and businesses, and will not be forced to rely instead on ineffective alternatives or potent non-anticoagulant toxins, including a neurotoxin. Moreover, DPR has not provided substantial evidence that designating these small-size consumer-use SGARs as restricted materials is necessary to achieve the goal of the proposed regulation. d-CON’s comments and the attached supporting materials collectively demonstrate that:

- The Department has failed to demonstrate with substantial evidence that the proposed regulation protects public health and provides for the proper, safe, and efficient use of rodenticides by consumers and small businesses, and the Department has ignored the potential negative consequences of prohibiting consumer uses of such SGAR products (see Section I, infra);

- The Department has overstated the risk to wildlife from consumer uses of SGARs and has failed to demonstrate that consumer use of SGARs contribute significantly to wildlife risk (see Sections II & III, infra);

- The Department only has documented evidence of a handful of wildlife fatalities per year that were definitely or likely attributable to SGAR exposure, and DPR has not attributed these exposures to indoor rodent control efforts by consumers, thus failing to demonstrate with substantial evidence the necessity for this proposed regulation insofar as it would designate small quantity indoor use only SGARs as restricted materials (see Sections II & III, infra);

- The Department has failed to demonstrate with substantial evidence that the proposed regulation protects wildlife from exposures to alternative rodenticides that are not proposed for restricted materials classification such as the potent neurotoxin bromethalin, and the first-generation anticoagulants (FGARs), which are likely to be used excessively in the environment due to their reduced effectiveness (see Section II, infra);

- The Department has not adequately considered less impactful and less costly alternatives that will achieve comparable or greater wildlife protection while continuing to provide effective and affordable rodenticides to Californians who cannot afford professional rodent control services (see Section IV, infra);

- The Department has failed to demonstrate with substantial evidence that this proposed regulation will protect public health in that DPR has not assessed the risks to children and pets that would result from exposures to alternative rodenticides that are not proposed for
classification as restricted materials, such as non-anticoagulant rodenticides which include potent toxins like bromethalin (*see Section V, infra*);

- The Department has failed to demonstrate with substantial evidence that this proposed regulation will protect public health in that DPR has not evaluated the efficacy of alternative products or the impacts on public health that are likely to result from the widespread use of less effective rodent control products that will remain as one of only two commercially-available options if SGARs are designated as restricted materials (*see Section VI, infra*);

- The Department’s economic analysis dramatically understates the costs of the proposal to Californian consumers, small businesses, state and local government and the registrants of consumer-use rodenticides (*see Section VII, infra*);

- The Department has failed to demonstrate with substantial evidence why DPR’s proposal does not exclude small-quantity, indoor use only SGAR products from the restricted materials designation, an exception that applies to all other restricted material designations for active ingredients which are used, in part, in the home by consumers, and which was the clear legislative intent underlying the law establishing the restricted material designation (*see Section IX, infra*);

- Absent an exemption for consumer-sized SGAR products, a final restricted materials designation would be tantamount to a de facto cancellation of d-CON®’s products in violation of California and federal law (*see Section VII, infra*);

- The Department has not complied in several material respects with the California Environmental Quality Act (*see Section VIII, infra*);

- The Department’s proposal unnecessarily duplicates federal rodenticide requirements and proposals (*see Section VIII, infra*);

- The Department has not adequately complied with state requirements to consider the environmental justice impacts of its proposal (*see Section VIII, infra*);

- The Department does not address the continuing impact on wildlife in California due to the unregulated access to SGARs through internet sales of such products in bulk-quantity containers, or from purchase of such products in neighboring states or from Mexico (*see Section VIII, infra*); and

- The Department has justified its proposal -- as documented in numerous instances described below -- either (i) without providing any substantive analysis or (ii) by uncritically accepting analyses and studies conducted by the U.S. Environmental Protection Agency (EPA) for a related but distinct proposal and without considering the critiques of EPA’s scientific analyses by that agency’s own Scientific Advisory Panel, which was comprised of select technical peer reviewers.
On the basis of the comments provided below and the numerous supporting materials attached, DPR must conclude that it lacks substantial evidence demonstrating that the consumer-use products we propose to exempt present a risk to non-target wildlife sufficient to justify classifying such products as restricted materials.
D-CON COMMENTS CONCERNING DPR PROPOSAL NO. 13-002

D-CON provides the following comments in support of its proposal that the Department modify its proposed regulation to exempt certain consumer-use products from the proposed restricted materials classification. Specifically, the Department should provide an exemption that permits the sale of consumer-use SGAR products that are: 1) clearly labeled for indoor use only, and 2) sold in placement units of not greater than 3 ounces each, with multi-placement packages not to exceed one pound (Indoor-Use Consumer SGARs).

I. DPR’S PROPOSAL WILL HAVE UNINTENDED PUBLIC HEALTH CONSEQUENCES

DPR is obligated by Food & Agriculture Code section 11501, a statute that this proposed regulation purports to implement, to provide for the proper, safe, and efficient use of pesticides essential for protection of the public health and safety. In addition, Food & Agriculture Code sections 403, and 11454 require DPR to prevent the introduction and spread of injurious animal pests. DPR is required by the California Administrative Procedures Act, Government Code sections 11340 and following, to demonstrate with substantial evidence that the proposed regulation is necessary to carry out the purposes of the regulation, that is, to implement the provisions of section 11501. Moreover, the regulation is required to be consistent with the provisions of sections 11501 and 403. (Government Code section 11342.2.) The truth of the matter is that DPR has not and cannot demonstrate that the regulation meets any of these standards. The record, as highlighted in these comments, is devoid of substantial evidence showing that the proposed regulation is necessary to effect its stated purposes or that it complies with DPR’s statutory obligations.

DPR has overlooked the substantial public health benefits of effective and affordable rodent control for consumers. These public health benefits justify an exemption from the proposed restricted materials regulation for Indoor-Use Consumer SGARs.

DPR’s Initial Statement of Reasons (ISOR),¹ its revised “White Paper,”² and the Economic Impact Assessment³ do not address the various impacts on public health that rodents present to society, and in particular to persons living in high density dwellings and in economically disadvantaged communities. Similarly, the Department does not consider the unintended public health consequences of its proposed regulation: that rodent control will be adversely affected, and the incidence and persistence of rodent infestation will increase. Consequently, DPR’s proposal, in an effort to mitigate risks of non-target wildlife exposures to SGARs, will render

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² DPR Memorandum from D. Daniels, Senior Environmental Scientist, to A. Prichard, Chief, Pesticide Registration Branch, Subject: Second Generation Anticoagulant Rodenticide Assessment (June 27, 2013), (“White Paper”) (Exhibit 2).
cost effective and affordable indoor-use rodent control products unavailable to consumers and small business persons, and leave these products accessible only to those who can afford professional pest control treatments.

d-CON® is submitting, as exhibits to these comments, documents that provide additional information the Department should consider when evaluating the exemption we propose. These materials provide demonstrate clearly the need for an exemption from the restricted materials designation for small quantity SGARs labeled for indoor use only. Such an exemption will achieve DPR’s goal of mitigating the risks of non-target wildlife exposure to SGARs, while still permitting consumers to have access to affordable and effective rodent control products for use inside their residences and small businesses.

A. Commensal Rodents are a Persistent Threat to the Public Health and the Economic Well-Being of the Citizens of California

Rodents invade millions of homes in the United States each year. Such infestations have marked social and economic consequences, including bites, exacerbation of asthma in children, the spread of rodent-borne diseases, and related health care concerns and costs. Because rodents’ front teeth grow rapidly throughout their lives, they must continuously gnaw at objects such as wood, wires, and other building materials to maintain and limit the length of their teeth. This continual gnawing action causes significant property damage, and increases the risk of fires, with consequent social and economic ramifications. Cost estimates of damage from rodents range from $.5 - 1 billion to as high as $19 billion per year nationally, due to contamination of food, damage to property, and electrical and vehicular fires caused by wiring damage from gnawing rodents. EPA estimates that the annual cost of rodent control to homeowners is at least $90 million.

See DPR Economic Analysis (Exhibit 4) (citing EPA Memorandum from A. Chiri, et al. to K. Sherman, et al., Impact Assessment for Proposed Rodenticide Mitigation (DP 332577) (Sep. 20, 2006) (“EPA 2006 Impact Assessment”)) (Exhibit 5). EPA’s document noted that in addition to the millions of households experiencing rodent infestations in the most recent quarter cited in the U.S. Census data relied upon for EPA’s report, 11% of households below the poverty level in the U.S. were among those with infestations. Id. at 21. Moreover, EPA concluded that “the lower the household income level the greater the expectation of rodent problems.” Id. Reports being submitted with these comments update these figures using more recent Census reports, and still support the conclusion that rodent infestations are a blight on the poor, particularly low-income residents of higher density buildings, and that these populations are the most likely to experience the adverse health consequences associated with rodent infestations.


Although they are not considered to be commensal rodents, EPA’s January 2006 Analysis cites studies that estimate damage from California ground squirrels to be as great as $20-28 million. EPA 2006 Impact Assessment at
Rodents have been responsible for some of the most devastating outbreaks of disease in recorded history and have been responsible for over ten million deaths in the past century alone. Rats and mice are known to spread more than 35 diseases worldwide, including viral, bacterial, protozoan, and other pathogens. Elevated levels of mouse allergens are associated with higher-than-average rates of asthma in children, and may contribute to more acute episodes of asthma. Additionally, the CDC estimates that over 15,000 rodent bites occur each year -- disproportionately among children.

Commensal rodents are perfectly adapted to coexist in human habitats, and are similarly well adapted to spread disease to their human hosts. Rodents are omnivorous and opportunistic, consuming essentially any source of protein, such as nuts, grains, fish, fruits, meats, and any type of human or pet food. Mice are able to obtain most of their water requirements from the food they eat and can endure long periods of time without any direct water source, allowing mice to stay effectively hidden, making their control in household settings extremely difficult. Thus, effective commensal rodent control must begin with the action of property occupants to prevent and control rodent infestations.

Local governments using professionally trained technicians generally do not attempt to control rodent infestations inside individual residences. Consequently, SGAR products that are made available for consumer uses serve a vital public health purpose. The loss of effective and affordable forms of rodent control to consumers, particularly those who occupy high density dwellings, is likely to have significant health consequences to the occupants and to those around them, and, if rodent populations increase, to public agency pest control providers.

Rodent problems and the diseases they can spread are not limited to urban and suburban areas. For example, outbreaks of disease and fatalities resulting from hantavirus in locations such as Yosemite National Park, the Four Corners region, Florida, Louisiana, and New York confirm the

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9 (Exhibit 5). Other problems (both economic and public health-related) that are experienced in California from rodent infestations also are identified in the Agency’s Analysis.

9 EPA 2006 Impact Assessment at 10-11 (Exhibit 5).


12 CDC 2007 Letter Submission at 1 (Exhibit 13). The U.S. EPA’s 2006 analysis cited by DPR also cites estimates consistent with this figure. See EPA 2006 Impact Assessment at 12.

13 Wade Report at 3 (Exhibit 90); see also Wade SAP Report at 4 (Exhibit 6).

14 Wade Report at 3 (Exhibit 90).

15 See id. at 2-3.
potential dangers to those living in proximity to rodents. Accordingly, DPR must consider seriously the benefits of these products -- especially to people who are not in a position to hire a professional pest control operator (PCO) or to acquire their own license to apply SGARs -- in accordance with its obligations to protect the public health and safety and to prevent the spread of animal pests.

B. DPR’s Proposal Will Have Significant Impacts on Minority and Disadvantaged Populations

As discussed in greater detail by Dr. Wade, minority households are more likely to have rodent infestations than are other U.S. households. In turn, members of households with rodent infestations are more likely to suffer from rodent-related health impacts. Not surprisingly, data indicate that low-income populations suffer a disproportionate number of rodent-associated injuries and disease. For instance, U.S. Census data reflect that households with incomes below the poverty level were 72% more likely to have seen signs of rats and 35% more likely to have seen signs of mice in their housing within the past three months. In addition, residents of mobile homes or manufactured housing are much more likely to have seen signs of rats (68% above average) or mice (86% above average) than U.S. households generally. In a study of low-income housing in Gary, Indiana, 36% of 101 apartment kitchen floors contained mouse allergens, which are associated with childhood asthma. A recent survey of the published literature on rodents and their allergens concluded that while “[m]ost homes in the U.S. have detectable mouse allergen, … the concentrations in inner-city homes are orders of magnitude higher than those found in suburban homes.” Similarly, lymphocytic choriomeningitis, an emerging disease that is spread to humans through contact with rodent feces, urine and other contaminated articles, has been identified in a large percentage of house mice from inner-city areas of several U.S. communities.

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18 See Wade Report at 1, 8-9 (Exhibit 90); Wade SAP Report at 8-9 (Exhibit 6).
19 Wade Report at 8 (citing data from the U.S. Department of Housing and Urban Development and Bureau of the Census, American Housing Survey for the United States: 2009, H150/09, Table 2-7 (“2009 American Housing Survey”) (Exhibit 16)); see also Wade SAP report at 9 (Exhibit 90) (same). The American Housing Survey definition of poverty level is based on a housing cost index that varies by the number of household members. For the 2009 estimates, the poverty level for individuals living alone was $22,400; the poverty level for a 4-member household was $32,000. The construction of the poverty level measure is discussed on pp. A-22-23 of Appendix A to the 2009 AHS report.
20 Wade SAP Report at 9 (Exhibit 6).
The public health impacts of rodent infestations have also been assessed on an international scale. For example, the 2008 World Health Organization (WHO) document titled *Public Health Significance of Urban Pests* details the various societal, economic and health consequences of rodent-human interactions. The authors conclude that problems related to urban pests due to “modern living conditions, urban sprawl and emerging changes in climate make the spread of pests and pest-borne diseases increasingly likely.”

The extent to which the many public health problems noted by the WHO occur in U.S. cities and states is addressed in EPA’s 2006 Analysis of Rodenticides Bait use and in greater detail in a more contemporary analysis prepared in late 2011 by Dr. James McCluskey. Dr. McCluskey concludes from his survey of the open literature that low-income households generally have the highest rate and degree of rodent infestations, which consequently present the greatest opportunities for exposure to various sources of rodent-related infectious disease agents and rodent-related allergens. Thus, consistent with Dr. McCluskey’s report, a 2013 publication advises pediatricians that “children with asthma who are both sensitized and exposed to high mouse allergen concentrations at home are at greater risk for symptoms, exacerbations and reduced lung function … [and] … [r]at allergen is found primarily in inner-city homes and has also been linked to asthma morbidity among sensitized children.” Unfortunately, the exposures are occurring within households that often are the least able to afford professional pest control services or appropriately deal with the consequences of adverse health effects.

When the U.S. EPA in 2007 proposed to reclassify SGARs as a restricted use products, a proposal very similar in scope to the DPR’s proposal, d-CON® submitted separate reports from numerous experts. Their reports documented the importance of SGAR products in the control of rodents by consumers and the continuing problem of resistance to first-generation anticoagulant rodenticides (FGARs) in U.S. rodent populations, and assessed the economic and related impacts on consumers -- particularly low-income and minority populations -- of reclassifying SGARs as restricted products. d-CON® encourages DPR to undertake a careful review of these reports, as well as the numerous published reports and available literature cited therein, to


25 2006 EPA Analysis of Rodenticide Bait Use (Exhibit 7) (also noting that commensal rodents transmit diseases to domestic animals such as dogs and cats, and to livestock).


27 E. Matsui, *Management of Rodent Exposure and Allergy in the Pediatric Population* at 1 (Exhibit 18).


assess more critically the potential health impacts of the proposed regulation on economically disadvantaged persons within California. These reports, and the more recent information, published literature and economic assessment included with these comments, provide a persuasive basis to exempt consumer-use small-quantity indoor use only SGARs from DPR’s proposal.

C. DPR’s Proposal Will Have Significant Impact on Small Businesses

DPR relies on various assumptions, not supported by any evidence in the record, to conclude that small businesses will likely be unaffected or minimally affected by DPR’s proposal because they currently rely on licensed PCOs for rodent control treatments. DPR is mistaken. A substantial percentage of small business persons who rely on do-it-yourself (DIY) rodent control. These DIY-ers will be forced to rely on the remaining unrestricted consumer-use rodenticides: non-anticoagulants, such as the neurotoxin bromethalin, and FGARs, which numerous studies have shown to be less effective at rodent control than SGARs. Consequently, business establishments that continue to use DIY pest control could face a significant increase in rodent populations. DPR’s cost estimates do not include any assessment of the public health impacts and social costs of such an increase in rodent populations. Ironically, if small business persons who are DIY-ers do hire PCOs, and (as DPR has suggested) PCOs primarily use SGARs already, there will be no net reduction in overall SGAR use in the small business community.

These important issues are addressed more fully in the various documents attached, which make clear that DPR has failed to consider the public health consequences of its proposal, and the Agency thus lacks substantial evidence that its proposal will protect public health and the environment.

II. DPR OVERSTATES THE RISKPOSED BY SGARS TO NON-TARGET WILDLIFE POPULATIONS

DPR proposes to reclassify SGARs as restricted materials in order to reduce risk to wildlife. However, DPR has not provided in the public record for this rulemaking substantial evidence to support the conclusion that second generation anticoagulant rodenticides are significantly harming wildlife populations in California generally, nor that consumer uses of SGARs present risks to non-target wildlife sufficient to justify the necessity for including them in DPR’s proposal. In fact, the evidence demonstrates that SGARs pose a small risk to wildlife compared to other sources of wildlife fatalities, and that consumer use of SGARs is much less likely to follow use patterns that contribute to wildlife risk than the use patterns of the certified applicators who would be allowed to use SGARs under DPR’s proposal.

A. DPR Has Not Fully and Credibly Assessed the Risk to Wildlife Posed by SGARs

DPR’s analysis of the risk to wildlife posed by SGARs is contained in a Memorandum of June 27, 2013 entitled “Second Generation Anticoagulant Rodenticide Assessment” (White Paper).

30 See infra at Section VI.

31 See ISOR at 5 (describing request by the California Department of Fish and Wildlife (DFW) that DPR designate all SGARs as restricted materials “in order to mitigate nontarget wildlife exposure in California.”).
The White Paper constitutes “DPR’s assessment, based on available data, of the potential and actual risk to non-target wildlife from second generation rodenticides.” The attached analysis by Dr. Anne Fairbrother, as well as the comments on the draft White Paper provided to DPR by Technology Sciences Group (TSG) on March 1, 2013 provide more detailed comments on the White Paper. Key points for consideration by DPR are discussed below.

The White Paper, despite its self-description, is a hazard assessment rather than a risk assessment, i.e., it characterizes the toxicity of rodenticides to non-target wildlife, rather than evaluating the likelihood that such wildlife will be exposed to rodenticides in quantities sufficient to have toxic effects. In addition, the White Paper does not consider the likelihood of exposure from any particular pathway or scenario and was unable to differentiate rates of exposures between urban, agricultural, or rural areas. Consequently, the White Paper does not provide a basis to assess whether classifying SGARs as restricted materials will mitigate SGAR risk to non-target wildlife. DPR should assess actual risk by analyzing toxicity and exposure to evaluate and characterize what is probable rather than what is possible. As discussed in the attached report by Dr. Fairbrother, “while the study results reflect that there continues to be exposure to a small percentage of wildlife to SGARs, the probability (i.e., risk) of a predator dying from consuming exposed prey species is very small.” Dr. Fairbrother also concludes that in order to calculate and characterize SGAR risk to wildlife, “the probability that an individual animal will die from exposure needs to be compared to the number of individuals in the California population of that species.”

One of DPR's peer reviewers, citing these same flaws in the White Paper, recommended that “a more appropriate way to assess the toxicity is to conduct a deterministic or probabilistic risk assessment.” DPR acknowledges that “The document is an assessment of available data, not a

35 More specifically, the presence of detectable SGAR residues in the livers of non-target wildlife provides evidence of exposure. As is discussed further below, the presence of residues is not indicative of the cause of death and is not predictive of the risks of SGAR exposure to the health of the animal. DPR itself seems to concede this point. See White Paper at 13, 16. But DPR nevertheless uses this erroneous conflation of liver residue and LD50 to reach conclusions about wildlife risk. See White Paper 14-16.
36 Fairbrother Report at 6; see also 2004 Cadmus Group Report, A Probabilistic Risk Assessment of the Risk of Brodifacoum to Non-Target Predators and Scavengers (Exhibit 88.1); 2007 Cadmus Group Report, Brodifacoum: Assessment Addendum (Exhibit 88.2).
37 Id. at 3.
38 DPR Memorandum from D. Daniels, Sr. Environmental Scientist, to A. Prichard, Chief, Pesticide Registration Branch, Summary of Second Generation Anticoagulant Rodenticides Assessment Peer Review Comments and Responses (June 27, 2013) (“DPR Peer-Review Comment Responses”) (Exhibit 28) at 5 (comments of John Elliott at 6).
complete risk assessment,” and that “DPR does not conduct deterministic or probabilistic risk assessments.” This statement is an admission that DPR lacks substantial evidence to demonstrate that this proposed regulation is necessary to carry out one of its purposes: protecting non-target wildlife. California EPA has specific guidance that governs how assessments should be conducted to determine the risks of contaminants in the environment. That guidance follows the U.S. EPA’s approach as “an appropriate scientific process for conducting and evaluating ecological risk assessments.” These guidance documents requiring evaluating “co-occurrence” of the chemicals and wildlife (i.e., the ‘stressors’ and ‘receptors’) as a “critical” aspect of exposure analysis. DPR did not follow this guidance in the White Paper, and the Department needs to revise its risk assessment consistent with this guidance before it completes this rulemaking action.

In sum, DPR can only conclude that there may be “impacts to non-target wildlife” resulting from SGAR exposure, but cannot quantify the degree of this impact or the sources of the exposure, and has therefore not provided substantial evidence that it is necessary to prohibit consumers from indoor uses of small quantity packages of SGARs to protect wildlife.

B. DPR’s Analysis of Incident Data is Flawed and Unpersuasive

DPR’s White Paper relies largely on reports of incidents of wildlife exposure to SGARs. These reports, while understandably of concern to DPR and registrants alike, demonstrate that exposures to SGARs have occurred, but do not properly characterize the risks to non-target wildlife from the use of SGARs. In fact, DPR’s data demonstrate only a very small number of animal fatalities likely or definitely attributable to SGAR exposures. Additionally, incident data of this nature are often necessarily incomplete, inconclusive, and unrepresentative of broader trends. Moreover, DPR’s data do not compare the extent of risk to wildlife posed by SGARs with other risks to wildlife, a necessary consideration for a proposal that will result in depriving consumers of a critical tool for rodent control.

The Department reviewed 492 incidents of animal exposure to wildlife spanning approximately 17 years. Of these, only 211 had actual necropsies performed, and only 80 of these necropsies

39 DPR Memorandum from D. Daniels to A. Prichard, Summary of Second Generation Anticoagulant Rodenticides Assessment Comments and Responses (June 27, 2013) (“DPR Comment Responses) (Exhibit 29) at 4.
40 DPR Peer-Review Comment Responses at 6 (Exhibit 28).
44 The California EPA Guidance is not binding on CDPR, but nevertheless constitutes the only available guidance for CDPR on conducting risk assessments. CDPR should either follow this guidance or explain specifically why it opted to reject this guidance.
45 See White Paper at 2, 8-9. 16.
were made available to DPR for review. For the other 131 incidents, DPR did not have access to the actual necropsy reports, so it relied on analyses performed by third parties to evaluate whether SGARs were the cause of death.

This absence of necropsies is important because DPR concedes that the mere finding of SGAR residues in livers only means that “some of these animals could have died” due to SGAR exposure, but that cause of death cannot be determined “without evidence of coagulopathy at necropsy.” Significantly, DPR’s actual necropsy data show that of the Department’s total sample, only 33 necropsies indicate that SGARs were likely a cause of death or the cause of death. This means, applying DPR’s own methods, that over 17 years, from 1995 to 2011, DPR can document with some degree of confidence a total of 33 instances of death or likely death of wildlife from SGAR exposure for the entire state of California. This average of two wildlife deaths per year from SGAR exposure for the entire state does not constitute substantial evidence of a need to regulate indoor uses of small-quantity consumer use SGAR products to protect wildlife.

DPR’s Peer Reviewers noted this absence of evidence that SGARs caused significant numbers of wildlife fatalities. One peer reviewer stated that “it should be acknowledged that pesticide poisonings account for a small fraction of wildlife mortality events.” Another peer reviewer observed that “the number of mortalities directly attributable to SGARs are usually relatively small compared to the number of exposed animals.” This observation is shared by Dr. Fairbrother in her report, which notes that “although wildlife are exposed to SGARs, the relative risk of dying from these exposures is very low compared to other mortality factors.”

Compounding the overstatement of wildlife mortality from SGARs, the limited necropsy data upon which DPR relies may itself be flawed. As is described in greater detail in the attached report by Dr. Richard Stroud, necropsy reports may be inconclusive or erroneous due to uncertainties inherent in identifying a specific cause of death, and because fatalities caused by exposure to anticoagulants often present very similarly to other causes of death. Dr. Stroud reviewed all 80 publicly-available necropsy reports of the 211 cited by DPR, and found that only 14 of these reports were verifiable cases of SGAR-related deaths. DPR’s dataset is flawed in

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46 Id. at 16.
47 White Paper at 16.
48 Id.
49 DPR Peer-Review Comment Responses, Comments of B. Rattner at 23 (Exhibit 28).
50 DPR Peer-Review Comment Responses, Comments of M. Murray at 12 (Exhibit 28).
51 Fairbrother Report at 8 (Exhibit 26).
52 See Fairbrother Report at 7 & n.8.
53 See Stroud Report at 2-8 (Exhibit 33).
54 Stroud Report at 8-9 (Exhibit 33).
other ways as well. The sample set used by the Department included approximately 142 cases from the California Department of Fish and Wildlife (DFW); DFW only provided cases that had tested positive for the presence of rodenticide residues, and the total number of animals analyzed was not provided to DPR.\textsuperscript{55} Thus, DPR’s sample was biased to over-represent the presence of rodenticides, and DPR does not have the information necessary to critically assess the degree of this over-representation. One peer reviewer questioned the methodology used by DFW and requested information on the method and on the QA/QC procedures used by DFW.\textsuperscript{56} DPR went forward with this proposed rule even though it had not yet received this information from DFW.\textsuperscript{57}

Finally, the White Paper also does not provide information on the total number of reported wildlife deaths attributable to other anthropogenic causes. Publically available information suggests that the numbers of wildlife deaths DPR attributes to SGARs are de minimis compared to other causes. For example, one study estimated that wind energy projects killed 573,000 birds (including 83,000 raptors) and 888,000 bats nationally each year.\textsuperscript{58} Another source estimates that in the U.S. domestic cats are responsible for hundreds of millions of bird deaths and over one billion small mammal deaths annually.\textsuperscript{59} The White Paper, by contrast, provides no information on other causes of death or on the overall population of the affected animals. This absence of information prevents the public, or policy-makers, from understanding how significant a problem SGAR-related mortalities may present in relation to other sources of harm to wildlife, especially in light of the many public health benefits of SGAR use.

Because of these significant methodological flaws in its assessment, DPR cannot reasonably conclude that there is substantial evidence of a risk to non-target wildlife from consumer use of SGARs, particularly indoor uses. Therefore, DPR should exempt from the restricted materials designation indoor use only SGAR products when sold in small volume packages for consumer use.

**C. DPR Improperly Conflates Liver Residue Concentrations with Lethal Concentration Values**

The White Paper provides an analysis of the residues of SGARs in the livers of non-target wildlife and describes, among other things, the number of samples where the concentration of SGARs found in livers exceeded the lethal doses (LD\textsubscript{50}) for each ingredient.\textsuperscript{60} In fact, the

\textsuperscript{55} See, e.g., DPR Peer-Review Comment Responses, Comments of D. Stone at 27 (explaining that “In their analysis, DPR aggregated 142 residue-positive only results (with an undetermined number of residue-negative samples) and 350 and 350 samples that recorded negative + positive results. Thus, the true denominator of total samples in the aggregate dataset is unknown.”) (Exhibit 28).

\textsuperscript{56} See DPR Peer-Review Comment Responses, Comments of Dr. John Elliott at 3-4 (Exhibit 28).

\textsuperscript{57} Id. at 4.


\textsuperscript{60} See White Paper at 14-16.
relationship between liver residues and acute oral lethal doses is not documented, and there is no basis to conclude what level of SGAR found in liver residues constitutes a fatal level.\textsuperscript{61} This point was reinforced by one of DPR’s peer reviewers, who stated that “Liver residue data cannot be relied upon as an indicator of toxicosis, and should only be used to confirm exposure, largely due to the role that individual variation has in susceptibility to AR [anticoagulant rodenticide] toxicosis.”\textsuperscript{62}

D. DPR Does Not Demonstrate Impacts to Wildlife Populations

DPR provides no evidence that SGARs are posing a threat to any populations of wildlife species, including protected species. Indeed, the Department does not appear to dispute the absence of SGAR impact to populations, stating that “the assessment did not include impacts on the overall population of various species.”\textsuperscript{63} Instead, DPR makes two assertions regarding population impacts, both of which appear to concede the absence of population impacts. First, DPR asserts that despite the fact that red-tailed hawks and Cooper’s hawks are thriving, SGAR exposure “may have adversely impacted individual raptors” and absent exposure to SGARs, these populations “might be even higher.”\textsuperscript{64} Put differently, DPR is observing that individual animals may be impacted despite the absence of effects on the overall population of the animal. Again, Dr. Fairbrother’s report addresses this issue, stating that “it is difficult to conclude that exposure to SGARs is having a negative effect on wildlife populations, and especially not from consumer use in urban areas.”\textsuperscript{65}

Second, DPR asserts that the Endangered Species Act,\textsuperscript{66} the Migratory Bird Treaty Act (“MBTA”),\textsuperscript{67} and the California Fish and Game Code\textsuperscript{68} confer liability based on the death of a single animal, rendering a finding of population impacts unnecessary.\textsuperscript{69} This argument is inapt. The Department is not, in this regulatory proposal, alleging liability under these statutes against any individual or individuals. Moreover, there is no legal basis to assert liability under these statutes for the behavior being regulated here: consumer application of small quantity packages containing SGARs in residential settings that lead to accidental secondary poisoning of

\textsuperscript{61} See Fairbrother Report (Exhibit 26). The text of the White Paper itself acknowledges that liver residues in excess of LD50 cannot readily be correlated with a fatal dose. See White Paper at 13, 16. However, Table 7 continues to list the number of animals with liver residues above LD 50, suggesting that this figure indicates a measure of lethal dose.

\textsuperscript{62} See DPR Peer-Review Comment Responses, Comments of J. Elliott at 6 (Exhibit 28).

\textsuperscript{63} See DPR Comment Responses at 3 (Exhibit 29).

\textsuperscript{64} Id. at 4-5.

\textsuperscript{65} See Fairbrother Report at 12 (Exhibit 26).

\textsuperscript{66} 16 U.S.C. § 1531 \textit{et seq.}

\textsuperscript{67} 16 U.S.C. § 703 \textit{et seq.}

\textsuperscript{68} Cal. Fish & Game Code §§ 3700-3705

\textsuperscript{69} See DPR Comment Responses at 4, 6 (Exhibit 29).
wildlife. To the extent that any species protected by state or federal wildlife laws may be at risk from SGAR exposure, DPR’s proposal will continue to allow the preponderance of SGAR use that affects wildlife to continue, since licensed users are far more likely to place SGARs outdoors, where they are more likely to contribute to wildlife exposure, than are consumer users (see discussion in Section III.C., below).

E. DPR Has Not Considered the Risk to Wildlife from SGAR Alternatives

The Department did not consider the risks to non-target wildlife posed by alternative rodenticide products, such as the first generation anticoagulant rodenticides (FGARs) and the non-anticoagulants. DPR’s White Paper did not address or evaluate any unique risks posed by the continuing use of alternative rodenticide products, such as the relatively high susceptibility of birds of prey to FGARs or the potential for increased FGAR usage and dosing practices to compensate for FGARs’ lower efficacy, which could lead to greater opportunities for exposures to non-target wildlife. Neither did the Department address wildlife risks presented by the non-anticoagulant rodenticides, such as bromethalin, cholecalciferol and zinc phosphide. It is particularly troubling that DPR did not consider the risks presented by the potent neurotoxin bromethalin, which will likely achieve a major market share if the Department’s regulation is implemented. As such, the Department’s conclusions regarding the potential risk from SGARs did not balance the risks and benefits of SGARs against the corresponding risks and benefits of products that will be used as alternatives to SGARs. Thus, DPR lacks substantial evidence to conclude that reducing the use of SGARs will, in fact, reduce the overall risk to wildlife from rodenticide use generally.

Dr. Fairbrother addresses the risks of alternatives to SGARs in her report. She notes that data relied upon by the U.S. EPA to assert that FGARs pose a lower risk to wildlife than SGARs -- upon which DPR appears to have relied -- are based on short, often single-dose studies, masking the fact that FGAR toxicity is higher when -- as in real-world conditions -- the single exposure dose is divided into smaller doses and administered over a period of days. One of DPR’s peer reviewers for the White Paper also pointed out that the White Paper underestimated the toxicity of FGARs due to the reliance of reported values on data from single-day, laboratory studies. The EPA Scientific Advisory Panel (SAP) also concluded that “the conclusion that FGARs present a lesser risk to non-target wildlife . . . may be flawed.” If FGAR use in the consumer

70 See U.S. v. Moon Lake Electric Ass’n, 45 F. Supp. 2d 1070, 1085 (D. Colo. 1999) (holding that liability under the MBTA requires proof of proximate causation, where “the injury be one which might be reasonably anticipated or foreseen as a natural consequence of the wrongful act.”) (internal citations and quotes omitted.)

71 See e.g., DPR Comment Responses at 9 (“Bromethalin is not an anticoagulant rodenticide; therefore it was not the focus of DPR’s assessment.”) (Exhibit 29).

72 See DPR Peer-Review Comment Responses, Comments of M. Murray, DVM, DABVP at 15 (Exhibit 28).

73 See DPR Peer-Review Comment Responses, Comments of Dr. B. Rattner at 22 (Exhibit 28).

74 Id. at 24-25.

75 EPA Scientific Advisory Panel (SAP), Memorandum From J. Bailey, et al., FIFRA Scientific Advisory Panel to S. Bradbury, Ph.D., Director Office of Pesticide Programs, Transmittal of Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting held Nov. 29-Dec. 1, 2011 on Scientific Conclusions Supporting EPA’s FIFRA Section

-12-
market reemerges, it is likely that consumers may find such products to be ineffective, which could lead to excess applications and contribute to increased environmental loading of anticoagulants, with potentially more direct and secondary uptake by non-target wildlife.\(^\text{76}\) DPR peer-reviewer Dr. Barnett Rattner also raised this concern, commenting that “it is also possible that increased use of FGARs could result in development of resistance in target organisms, which might be countered by greater application rates, which in turn could pose a greater hazard to non-target wildlife.”\(^\text{77}\) This conclusion is reinforced by the analysis of the U.S. Fish and Wildlife Service, which in a recent study of alternatives for rodent eradication on the South Farallon Islands found that of its two principle choices, aerial application of brodifacoum (an SGAR) and aerial application of diphacinone (an FGAR), more than five times more diphacinone bait than brodifacoum bait -- and ten times more active ingredient -- would be needed to achieve an equivalent result.\(^\text{78}\)

With respect to non-anticoagulant rodenticides, including, in particular, the potent neurotoxin bromethalin, the DPR White paper does not address the acute nature of the toxicity presented by these compounds, and the likelihood that they pose significant risks of poisoning to non-target wildlife. Dr. Fairbrother notes that it is challenging to diagnose bromethalin poisoning, which renders detecting and treating cases of non-target wildlife exposures difficult. Consequently, cases of non-target wildlife poisonings from bromethalin are likely to be grossly underreported.\(^\text{79}\) This is exacerbated by the fact that, unlike SGARs, there is no known antidote for treatment of wildlife exposed to bromethalin.\(^\text{80}\) Before a final rule can be issued, DPR must also address the risk of secondary poisoning from bromethalin to non-target wildlife, as the physical-chemical nature of this rodenticide suggests that it has a high inherent capacity for biomagnification in terrestrial food chains thereby posing a risk to predators or scavengers.\(^\text{81}\) In light of lack of data and this uncertainty, it is prudent to treat bromethalin as a bioaccumulative compound and a potential risk for secondary exposures in non-target wildlife.\(^\text{82}\) The U.S. EPA’s SAP Report warned the Agency about the risks to wildlife from bromethalin, and advised EPA that “there is not enough evidence to support [bromethalin] use as a lower-risk alternative to SGARs.”\(^\text{83}\) The SAP asserted that:

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\(^{76}\) See Fairbrother Report at 14-16 (Exhibit 26); see also March 2013 TSG Report at 12 (Exhibit 27).

\(^{77}\) See DPR Peer-Review Comment Responses at 22 (Exhibit 28). DPR provided no substantive response to Dr. Rattner’s comments, stating only “Thank you for the comments. While it was not the goal of this document to develop mitigation measures, the comments are noted and appreciated.” Id.

\(^{78}\) See U.S. Fish & Wildlife Service, South Farallon Islands Invasive House Mouse Eradication Project: Draft Environmental Impact Statement at 8,Table 2.5 (August 2013) (Exhibit 37).

\(^{79}\) Fairbrother Report at 16-17 (Exhibit 26).

\(^{80}\) See id.

\(^{81}\) See Fairbrother Report, Appendix G (Exhibit 26).

\(^{82}\) See id. at 14.

\(^{83}\) See SAP Report at 13 (Exhibit 36).
The Panel also re-emphasized its concerns about bromethalin. Given the nonspecific neurological signs that intoxicated animals may display and considering the similarities of these signs to common injuries seen in wildlife presented to veterinarians and rehabilitation centers (e.g., head trauma), cases of bromethalin intoxication could easily be overlooked.\(^8^4\)

The SAP further advised that EPA’s conclusion on the lower risk of bromethalin to non-target wildlife “may be flawed . . . due to limited information on tissue persistence of bromethalin.”\(^8^5\)

Bromethalin is one of only a handful of products that would be available to consumers if SGAR products are reclassified as restricted materials. Bromethalin products have the largest market share after SGARs in the consumer products market.\(^8^6\) Accordingly, DPR must consider the likelihood that bromethalin products will become the largest selling consumer rodenticide if the proposed rule is finalized.\(^8^7\) In light of the absence of data and the likely risks posed by bromethalin, DPR should evaluate the comparative risks of bromethalin, as well as all alternative products that will be available to consumers, before it can reasonably conclude that there is substantial evidence of the necessity for classifying small quantity packages of SGARs that are labeled for indoor use only as restricted materials. At present, with no comparative risk analysis for replacement products, the Department can reach no such conclusion. DPR’s proposed action poses the potential scenario of replacing a well-understood anticoagulant with a less-understood and less studied neurotoxin, and potentially increasing risk to wildlife. If DPR’s purpose in this rulemaking is to reduce risk to wildlife from the risks of toxic chemicals in rodenticides, the Department should not proceed in the absence of substantial evidence that its proposal will, in fact, reduce wildlife risk, and not merely shift those risks from one rodenticide to another.

**III. DPR ERRONEOUSLY CONCLUDES THAT CONSUMER USE OF SGARs CONTRIBUTES TO NON-TARGET WILDLIFE RISK**

DPR’s proposal in effect will bar consumer use of SGARs by requiring all uses of SGARs to be restricted to licensed professionals.\(^8^8\) While the Department justifies the need to classify all SGARs as restricted materials to protect non-target wildlife, DPR has not presented substantial evidence showing that *consumer* use of SGARs constitutes a substantial source of non-target

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\(^8^4\) *Id.* at 35.
\(^8^5\) *Id.* at 13.
\(^8^7\) Consumer-use versions of bromethalin products are formulated with twice the concentration by weight of active ingredient as brodifacoum products. Thus, if SGAR products become restricted materials, increased consumer uses of bromethalin have the potential to increase environmental loading of rodenticides in a manner which the Department has not considered.
\(^8^8\) DPR Economic Analysis at 4 (“It is highly unlikely any residential consumers will obtain a qualified pesticide applicator’s license just to continue using SGARs.”) (Exhibit 4).
wildlife exposure, much less any evidence that small quantity packages labeled for indoor uses only must be designated as restricted materials to achieve that end.

A. There is No Substantial Evidence that Consumer Uses Contribute to Non-Target Wildlife Exposure

As an initial matter, the White Paper states explicitly that it reaches no conclusions regarding the significance of a consumer use pathway to wildlife exposure. Because the White Paper did not examine and address the issue of the pathway by which wildlife are exposed to SGARs, this question was not subject to peer review. One DPR peer reviewer recommended additional monitoring for SGARs “since the predominant pathway through which SGARs enter the food chain (licensed vs. non-licensed applicator use) has not been established.” Those comments were not substantively addressed by the Department in the White Paper, nor in related materials. Public commenters also noted the absence of analysis in the White Paper of the extent to which consumer use contributes to wildlife exposure; DPR did not respond in any substantial manner to these comments. Since the White Paper by its own terms does not reach the issue of the contribution of consumer SGAR use to wildlife risk, the White Paper does not provide substantial evidence that restricting Indoor-Only Consumer SGARs is necessary to protect non-target wildlife.

B. Locations of Incidents, Mill Assessment Data, and Registration Records Do Not Constitute Substantial Evidence That Indoor Consumer Uses of Small Quantity SGAR Products is the Source of Non-Target Wildlife Incidents.

The White Paper states that the incident data show instances of wildlife exposure to SGARs in both urban and rural environments; however, this does not address whether the source of SGARs involved in such incidents originated from licensed or non-licensed users, since both licensed and non-licensed users apply rodenticides in urban, suburban and rural environments. Urban, suburban, and rural environments include farms, restaurants, parks, supermarkets and other establishments that employ licensed applicators to address rodent infestations.

In addition to the incident reports, DPR relied on data showing the total pounds of SGARs sold in California, and the reported pounds of SGARs used by certified applicators in California, to reach conclusions regarding the total sales of SGARs to certified applicators and, by extension, the total pounds of SGARs sold to consumers. However, as described in greater detail in the June 2013 TSG submission to the Department dated June 25, 2013, these conclusions are problematic.

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89 See White Paper at 1 (“While the data show exposure, they do not link specific uses, or location of use of a second generation anticoagulant rodenticide (i.e. indoors or outdoors, homeowner to professionals) to exposure.”) (Exhibit 2).

90 See DPR Peer-Review Comment Responses, Comments of M. Murray at 5 (Exhibit 28).

91 Id. at 15 (“The comments are noted and appreciated.”).

92 See, e.g., DPR Comment Responses at 21 (“DPR’s SGAR assessment document is not intended to address specific mitigation measures.”) (Exhibit 29).

The DPR estimate relies completely on the accuracy of the Mill Assessment and the Pesticide Use Report (PUR) databases. The Mill Assessment database tracks reported sales of rodenticides (and other pesticides) into California, based on information submitted by distributors of these products. As DPR knows, the Mill Assessment program is a self-assessment system: DPR relies on pesticide sellers to accurately report sales.\(^\text{94}\) As DPR is well aware, there have been significant failures to report.\(^\text{95}\) Out-of-state distributors of rodenticides may be unaware of the Mill Assessment. Even sophisticated actors with a significant presence in California may not appreciate, or may even deliberately evade, the Mill Assessment. Thus, for instance, DPR found in 2005 that Wal-Mart, the nation’s largest retailer, had failed to pay mill fees.\(^\text{96}\) In particular, rodenticides distributed for commercial use -- whether by agricultural applicators, pest control professionals, or others -- are prone to underreporting for Mill Assessment purposes. Similarly, the PUR database is subject to significant inaccuracies. This database relies on self-reported information by licensed applicators, and thus is prone to underreporting, human error, and distortions due to inappropriate rounding errors.\(^\text{97}\)

Moreover, a review of the product registration information suggests that consumer use plays a much less significant role in wildlife exposure than does licensed commercial and agricultural use. Only 6 of the 72 SGAR products registered for use in California are for homeowner use in and around homes.\(^\text{98}\) Of the remaining 66 products,

[A]bout half are labeled for use only inside and within 100 feet of agricultural buildings and other man-made agricultural structures. The other half are labeled for use inside and within 100 feet of man-made structures such as homes, food processing facilities, industrial and commercial buildings, trash receptacles, agricultural and public buildings, and transport vehicles, and are intended for use by professional applicators (such as pest control operators, public health officials, federal, state, and municipal employees charged with rodent control). Certain products are also labeled for use in rodent burrows, alleys, and sewers.\(^\text{99}\)

In light of the authorized uses for the vast majority of registered SGAR products (which apparently would not be discontinued if the proposed rule takes effect unchanged), and absent substantial evidence suggesting otherwise, it is more reasonable for DPR to conclude that the 6 products registered and sold specifically for residential consumer uses are not a significant source of non-target wildlife exposures when used in the manner intended.


\(^\text{96}\) Id.

\(^\text{97}\) See June 2013 TSG Report at 19 (Exhibits 39.1 and 39.2).

\(^\text{98}\) See White Paper at 7 (Exhibit 2). Moreover, only 4 of these six products are d-CON baits.

\(^\text{99}\) Id.
DPR also does not consider the differences between typical rodenticide uses by consumers and certified applicators. As is addressed in greater detail in Dr. Fairbrother’s report, consumers use rodenticides indoors predominantly against house mice, that can be expected to remain indoors and are less likely to become prey for non-target species. Consumers also purchase and use rodent control products episodically, and generally use them only when signs of infestations are observed.\(^\text{100}\) In contrast, licensed users are far more likely to apply rodenticides outdoors and for longer periods of time against target animals (rats) that are more likely than house mice to become prey for non-target animals, and in a manner more likely to lead to both direct and indirect non-target wildlife exposures.\(^\text{101}\)

C. Relative to Consumers, Rodenticide Use by PCOs is More Likely to Result in Wildlife Exposure.

The potential for SGAR exposure to wildlife is a function of both (1) the amount of SGARs that are utilized to affect rodent control by consumers and PCOs, and (2) the ways in which those SGAR products are utilized by consumers and PCOs. As discussed in the TSG submission to the Department dated June 25, 2013,\(^\text{102}\) surveys performed at d-CON®’s request suggest that consumers and PCOs tend to utilize SGAR-containing rodenticide baits in very different ways, with PCO use more likely to result in wildlife exposure.

As detailed in Exhibit 39.2, a survey of 790 rodenticide users in the United States in 2007 suggested that the majority of survey participants (54%) purchased rodent control products to address indoor rodent problems, while only 18% of surveyed consumers purchased these products in response to rodent problems which occurred exclusively outdoors (the remainder of survey participants had rodent problems both indoors and outdoors).\(^\text{103}\) These data suggest that the great majority of consumers purchase d-CON® baits and related products to control rodents indoors, specifically. To further examine this possibility, consumers who reported use of chemical rodenticide baits in the previous year (313 of the 790 total participants) were further surveyed as to where they used rodenticide bait products. Placement information suggested that in a given year, the participants placed bait at multiple locations throughout their residence, with approximately 9% of the total placement locations being outside of an enclosed structure (e.g. residence, garage).\(^\text{104}\) This finding supports the hypothesis that most consumer rodenticide use occurs inside residential and associated structures, where target animals that are baited are likely to remain, thus exposure to non-target wildlife is likely to be negligible from such use.

These survey results can be compared to a survey performed in 2013 by the Association of Structural Pest Control Regulator Officials and published by the National Pest Management

\(^{100}\) See J. Lyon, EAS Consulting Group LLC, Use of Rodenticides in U.S. Foodservice and Retail Food Establishments at (Oct. 4, 2013) (“Lyon Report”) at 9 (Exhibit 46)

\(^{101}\) See European Biocidal Products Forum (2013). Guideline on Best Practice in the Use of Rodenticide Baits as Biocides in the European Union. European Chemical Industry Council (Cefic), (Sep. 2013) at 15 (“Exhibit EBPF”) (Exhibit 42).

\(^{102}\) June 2013TSG Report (Exhibit 39.2).

\(^{103}\) Id. at 8.

\(^{104}\) Id. at 9.
As detailed in Exhibit XX, this survey included 272 PCOs located throughout the United States. Surveyed PCOs reported that they applied approximately 48% and 69% of all rodenticide bait products (inclusive of all active ingredients) outdoors at residential and commercial sites, respectively. This information suggests that generally, PCOs are considerably more likely than non-licensed consumers to apply bait products outdoors, where exposure to wildlife is most likely to occur. Additionally, as part of this survey, PCOs were asked to estimate how often they used specific rodenticide bait active ingredients either indoors or outdoors at commercial and residential sites. These data suggest that PCOs apply SGARs outdoors at commercial sites between approximately 48% and 54% of the time. At residential sites, PCOs apply SGARs outdoors between approximately 66% and 77% of the time. The weighted average of outdoor SGAR use rates for PCOs was between approximately 55% and 61% across both consumer and residential sites. These outdoor application rates are considerably higher than is apparent for consumers, and present a much more significant pathway for exposure to non-target organisms. Given the nature of such outdoor placements by professional applicators, the length of time such baits remain in place, and the proximity of both the bait and the target animals to non-target wildlife, professional pest control applications, in contrast to consumer uses, are the more likely pathway for non-target wildlife exposures. This potential exposure pathway is not affected by the Department as part of its overall hazard assessment in the White Paper.

Taken together, these results suggest that even if consumers use more SGARs than PCOs, PCOs are much more likely to utilize SGARs in a way that leads to non-target wildlife exposure. Consequently, licensed SGAR applicators may actually be more likely than consumers to expose wildlife to SGAR-containing products. As an example, consider that as part of the White Paper, DPR estimated that from 2006 to 2010 consumers purchased (and theoretically used) an average of approximately 43 pounds of SGARs (brodifacoum, bromadiolone, difenacoum, and difethialone) per year. In contrast, PCOs utilized a somewhat smaller amount (approximately 39 pounds) of these active ingredients per year over the same time period. While Reckitt Benckiser disputes the mass of SGARs attributable to consumer use in this analysis; assuming it is correct, this value, used in conjunction with outdoor use rates (approximately 9% for consumers and ranging from 55% to 61% for PCOs), provides an estimate of how much bait consumers and PCOs place outdoors annually. Multiplying the outdoor use rate by the total mass of SGARs used by consumers suggests that from 2006 to 2010, consumers placed approximately 3.9 pounds of SGARs outside, annually. Using a similar calculation, it is apparent that each year PCOs placed approximately 21.9 pounds of SGARs outside over this period.

106 Id. at 5; June 2013 TSG Report at 11-14 (analyzing data) (Exhibit 39.2).
108 See White Paper at 26-27 & Table 14 (Exhibit 2).
109 This approach assumes that the same mass of SGARs are applied at each individual bait placement locations by both consumers and PCOs, regardless of whether or not that location is indoors or outdoors.
time period. This analysis strongly suggests that PCOs are responsible for considerably more outdoor SGAR placement than consumers. When placed outdoors, these SGARs are more likely to be consumed by non-target wildlife (primary exposure), as well as by rodents that could feasibly be preyed upon or scavenged outside a building or other structure (secondary exposure). If PCOs are responsible for the vast majority of outdoor SGAR use, the proposed rule is likely to have little effect on the overall exposure of non-target wildlife to SGARs. Unlicensed residential consumers are not likely to deploy SGAR products outdoors, where they can more readily expose non-target wildlife to rodenticides. For example, Bartos (2012) provided survey data from 60 California consumers, 15 of whom (25%) reported using SGARs outdoors (with all but 1 survey participant reporting use of these products within 100 feet of structures, in accordance with product labels). The somewhat higher rate of outdoor use in the Bartos (2012) study may be because approximately three times as many survey participants were targeting rats (which primarily live outdoors) than were targeting mice (which primarily live indoors).

D. Rodents Targeted by Consumers Are an Unlikely Source of Secondary Exposures

It is well established that house mice -- the target species of 90% or more of consumer SGAR use for indoor rodent control, accounting for approximately 90 percent of commensal rodent problems in U.S. households -- tend to have small ranges, do not wander far in search of food and inhabit “home ranges [that] are unlikely to extend [ ] outside inhabited structures.” Moreover, use of rodent control measures does not cause house mice to change their behavior once they have been exposed to rodenticides. Additionally, most of the non-target wildlife that are the subject of DPR’s concern generally do not prey on house mice at all, especially owls, as they prefer rats and voles. Thus, house mice, the predominant target rodent for consumers, generally do not leave indoor harborage to venture outside, and when they do, they are unlikely to be consumed by non-target predators. As noted in greater detail in Section III below, in a recent risk assessment for an alternative rodenticide undergoing review for registration, U.S. EPA concluded that wildlife data were not even needed for that Agency’s risk assessment because wildlife exposures are not anticipated since the product would be labeled for use indoors.

11 Fairbrother Report at 24 & n.60 (Exhibit 26).
12 See ISOR at 10.
13 Fairbrother Report at 25-26 (Exhibit 26).
14 See id. at 25.
15 See Fairbrother Report at 26 & nn. 73-74 (Exhibit 26).
16 See EPA Office of Pesticide Programs, Biopesticides Registration Action Document, Cellulose, PC Code: 100154 at 5 (Oct. 15, 2012), available at regulations.gov, ID# EPA-HQ-OPP-2012-0128-0009 (“the proposed registration will only permit indoor use. Thus, non-target toxicity is not anticipated because of lack of exposure”) (Exhibit 45).
Conversely, the target rodents for licensed users tend to be rats, which forage outdoors, and constitute a far more significant portion of the food chain of some predators.\textsuperscript{117} Licensed users -- such as PCOs and agricultural users -- also are far more likely to engage in baiting practices in which baits are left available for rodent contact permanently, and licensed applicators often have economic incentives to leave bait outdoors in bait stations continuously.\textsuperscript{118} Consumers, conversely, generally place baits for brief periods of time until the bait is taken.

The impact on non-target wildlife from continual bait placements was clearly demonstrated in Britain. An increase in prevalence of SGAR residues in barn owls (\textit{Tyto alba}) appeared to be correlated with a change in baiting practice for the control of field voles (\textit{Apodosis} spp.), the preferred owl prey, from program baiting (to remove extant infestations) to permanent baiting (tamper-resistant bait boxes containing SGARs deployed to prevent infestations from building up). Following an education campaign for commercial operators was started in 2004, the percent of barn owls exposed to SGARs appears to have leveled off.\textsuperscript{119}

\textbf{E. The Department Has Not Established the Comparative Contribution of Non-Licensed and Licensed Users to Non-Target Wildlife Exposures}

The Department’s sole discussion of the consumer use exposure pathway appears to be its reference to the U.S. EPA’s 2007 proposed Risk Mitigation Decision for Ten Rodenticides for the proposition that “[b]ecause rodents move in and out of indoor spaces, a rodent exposed to rodenticide bait indoors may be preyed upon or die outdoors, resulting in potential secondary exposures.”\textsuperscript{120} DPR does not -- either in the ISOR or in the White Paper -- delve into the scientific basis for EPA’s conclusion. Had DPR undertaken this inquiry, it would have learned that there is not substantial evidence supporting EPA’s conclusion, and there is evidence to the contrary.\textsuperscript{121}

By relying only on EPA’s statements on mouse behavior, DPR appears not to have considered the comments of EPA’s Scientific Advisory Panel (SAP) on the issue of the consumer contribution of SGARs to wildlife exposure. The SAP questioned EPA’s proposed cancellation of SGARs in 2011 for failing to address the extent to which wildlife exposure is related to consumer use. The SAP commented to EPA that: “rodenticides are also deployed by professionals representing commercial and institutional entities in urban and suburban areas and

\textsuperscript{117} See Fairbrother Report at 27 (Exhibit 26).

\textsuperscript{118} See Lyon Report (“the first line of defense [in food service and retail establishments] is continual and constant placement of rodent bait along the exterior of buildings . . . Permanent baiting provides the opportunity for non-target animals to have access to rodent bait on a continual basis.”) (Exhibit 46); Bandurraga Report (Exhibit 47), \textit{id.} at 7 (“in my experience, there are no cases [at food manufacturing and warehouse sites] where outside bait traps are not permanently baited”). See also “Exhibit EBPF” at 15 (Exhibit 42).

\textsuperscript{119} Fairbrother Report at 15-16 (Exhibit 26).

\textsuperscript{120} ISOR at 7 (Exhibit 1).

\textsuperscript{121} See Fairbrother Report at 23-27. (Exhibit 26); see also \textit{id.} at 26 (addressing the “urban legend” that “‘rat poison’ causes rats or mice to go outside in search of water when they are dying;” concluding that “there is no scientific basis to support the conclusion that house mice go outside to die after being poisoned by anticoagulant rodenticides.”).
it is not clear how one would separate domestic from commercial/institutional usage as sources in urban and suburban land use areas.”¹²² The SAP further stated that “It is not clear whether regulation of domestic uses will significantly reduce exposure of non-target wildlife if commercial and institutional use of SGARs, for example, will be continued, and is in fact at a much greater scale.”¹²³ EPA acknowledges the lack of data supporting a connection between consumer uses of SGARs and wildlife incidents by stating in its responses to the SAP that even “in the absence of contrary information . . . 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.”¹²⁴ In light of the SAP’s comments and EPA’s response that appears to confirm the lack of data to support a consumer connection to wildlife rodenticide exposure, DPR should not rely uncritically on EPA’s position. Rather, DPR should conclude that the lack of substantial evidence of a connection between consumer SGAR use and non-target wildlife exposure justifies an exemption from the restricted materials classification for Indoor-Use Consumer SGARs.

DPR’s assumptions about consumer use of SGARs contributing to wildlife exposure are also inconsistent with recent studies of the impact of SGARs on wildlife. A study performed in Des Moines, Iowa demonstrated that animals exposed to SGARs are at least as likely to be found in public areas -- e.g., parks, where municipalities frequently perform pest control -- as in residential areas.¹²⁵ DPR also assumes that SGAR use by licensed professionals will contribute less to non-target wildlife exposure than will consumer use because of the training and professional development licensed users receive.¹²⁶ The Department makes numerous assertions regarding the training licensees receive and how this training will “significantly reduce unintended exposures to non-target wildlife.”¹²⁷ However, DPR fails to demonstrate that the training and certification curriculum addresses the importance of or means to reduce non-target wildlife exposure. DPR provides no evidence, beyond a bald assertion, that PCOs are more likely to use “preventative strategies” rather than apply bait.¹²⁸ Moreover, continuing education requirements for certified applicators may not address exposure of non-target wildlife impacts at all, despite advances in scientific understanding. Such assumptions and assertions do not constitute substantial evidence

¹²² See SAP Report at 14 (Exhibit 36).
¹²³ Id. at 49-50.
¹²⁶ See ISOR at 6 (Exhibit 1).
¹²⁷ Id.
¹²⁸ Id.

-21-
of the necessity for designating small quantity SGAR packages that are labeled only for indoor uses as restricted materials.

F. Published Studies Cited by DPR are Not Substantial Evidence of the Necessity to Restrict Consumer Use SGARs

DPR attempts to use several published studies to suggest that consumer use was a pathway for non-target wildlife exposures.\textsuperscript{129} Although the data presented in these studies may provide valuable information regarding the use of rodenticides by consumers, they contain little information regarding the contribution of consumer SGAR use to wildlife exposure. In many cases, the specific conclusions DPR draws from these studies are overstated, incorrect, or beyond the scope of the cited data.

In the White Paper and the DPR Response to Comments, DPR cites Morzillo and Mertig (2011) as finding that “only 10% of residents who used rodenticides were aware of the potential non-target effects.”\textsuperscript{130} This assertion is based on self-reported chemical rodenticide users’ response to the question: “In your area, wildlife have shown evidence of possible exposure to chemicals found in common household rodenticides. Were you aware of this before receiving this survey?”\textsuperscript{131} This question addresses awareness of “evidence of possible exposure” specifically in the \textit{respondent’s area}, not about awareness of potential non-target effects more generally. In other words, one could be aware of the potential for actual wildlife harm specifically from “rodenticides” without being aware of “possible exposures” to “chemicals found in common household rodenticides” or that such “possible exposure” was taking place in the area in question. DPR also uses the Arndt (2012) study to conclude that: “businesses were generally less aware than households of the potential secondary harm to non-target wildlife.”\textsuperscript{132} In this study, awareness was measured among 83 businesses in response to the same imprecise question as in Morzillo and Mertig (2011a, 2011b) (addressing “evidence of possible exposure” specifically “[i]n your area,” rather than potential harm to non-target wildlife in general).\textsuperscript{133} In addition, those residents described by Morzillo and Schwartz (2011) whom DPR notes were using anticoagulant rodenticides in an attempt to control non-target pests were certainly aware of some potential non-target effects or they would not have described their use in that manner. Further, it is not appropriate to conclude that consumers who are not aware of non-target effects are more likely than better educated consumers to use rodenticide products in a manner that is either off-label or more likely to result in exposure to non-target organisms. ImPLYING A


\textsuperscript{130} White Paper at 29 (Exhibit 2).

\textsuperscript{131} See Morzillo and Mertig, \textit{Linking Human Behaviour to Environmental Effects}, supra at 111 (Exhibit 53).

\textsuperscript{132} DPR Comment Responses at 6 (Exhibit 29).

\textsuperscript{133} See Arndt, \textit{Urban business attitudes}, supra, at 23 & Table 1 (Exhibit 52).
connection between lack of consumer awareness and the total extent of non-target exposure due to consumer uses is not supported by data in this study.

DPR cites survey data in Morzillo and Schwartz (2011) as finding “that residents attempt to control target animals, as well as non-target pests and non-target carnivores.” This statement is an accurate reflection of the data presented in this study. However, DPR also claims that this study “found that residents, particularly in single-family homes, use anticoagulant rodenticides in an attempt to control target animals, as well as non-target pests, including the San Joaquin kit fox, coyotes, and bats.” This contention is a wholly inaccurate interpretation of study data, as the study contains no information regarding the methods by which residents control non-rodent animals. This nuance is apparent when reviewing this study’s survey questions. The first survey question (“Have you or anyone else tried to control rodents or other animals on your property”) identifies residents performing animal control, while the second survey question identifies residents that have used chemical rodenticides by asking “if chemical rodenticides have been used on their property.” To evaluate which animals the surveyed residents control, participants were asked: “Which of the following types of animals have you or someone else been trying to control on your property?” Participants were then given a list of animals to select, and given an opportunity to select “other” and write-in animals not presented in this list. As is apparent from this line of inquiry, survey participants were not directly asked which organisms they control with chemical rodenticides. Survey participants who reported using chemical rodenticides for rodent control did not necessarily use those same chemicals to control other animals, and the publication does not report the percentage of chemical rodenticide users that reported controlling both commensal rodents as well as other (off-label) wildlife. Without more precise information, this study is uninformative with respect to the potential misuse of chemical rodenticides to control non-rodent animals. In fact, the study authors themselves state that while the survey data “allow us to observe potential pathways for possible contact between carnivores and anticoagulants . . . conclusions about resident misuse or intentional use of anticoagulants to harm carnivores are beyond the scope of our data.”

DPR uses the survey data presented in the Bartos et al. (2012) publication to assert “that residents in the San Fernando Valley and Bel Air-Hollywood used rodenticides to target rats and mice, as well as opossums, snakes, and raccoons.” This contention, also made in the DPR Response to Non-Peer Reviewer Comments, is inaccurate. While survey respondents did indicate that survey respondents “are/were trying to control for” opossums, snakes, and raccoons, participants were never asked whether or not chemical rodenticides were employed for this purpose. The survey simply does not contain data regarding which specific animals were

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134 White Paper at 29 (Exhibit 2).
135 DPR Comment Responses at 6 (Exhibit 29); see also White Paper at 29 (Exhibit 2).
136 Morzillo and Schwartz, Landscape Characters Affect Animal Control By Urban Residents, supra, at 4 (Exhibit 51).
137 See id. at 6.
138 Id. at 10 (emphasis added).
139 White Paper at 29 (Exhibit 2).
140 DPR Comment Responses at 6 (Exhibit 29).
controlled by survey participants using chemical rodenticides (or any of the other rodent control products included in the survey). Notably, as in the Morzillo and Schwartz (2011) study, the Bartos et al. (2012) publication also did not report the percentage of chemical rodenticide users who were trying to control both rodents and other organisms that would be considered off-label for chemical rodenticides. In the absence of this (and other) information, it is entirely reasonable to expect that a consumer using chemical rodenticides to control rodent populations may use a different method to control animals like opossums, snakes, and raccoons.

DPR states that survey data presented in the Bartos et al. (2012) publication indicates that rodenticides were used “up to 300 feet from structures.” This statement is slightly misleading, as only 1 out of the total 60 survey respondents (less than 2%) indicated placement of chemical rodenticides more than 100 feet from structures. In fact, more than 98% of survey respondents placed chemical rodenticides in locations consistent with the product’s label and directions for use (within 100 feet of structures). The median distance category for outdoor chemical rodenticide placement was within 1–10 feet of structures, and the most common distance category for outdoor rodenticide placement by survey participants was “along walls.” Furthermore, it is important to note that only 15 of the 60 residential survey participants (25%) indicated that they used chemical rodenticides outdoors at all. While one might assume the chemical rodenticides placed outdoors by survey participants were SGARs, the study fails to provide sufficient data to confirm this point. Of the 26 survey participants who answered the survey question: “Are you aware that chemicals used for residential rodent control may be affecting wildlife in your area?”, 42% answered “yes.” These results indicate a significantly higher extent of consumer awareness for non-target wildlife exposure than would be expected from the Morzillo and Mertig (2011) study.

In the DPR Response to Non-Peer Reviewer Comments, DPR cites Arndt (2012) as indicating “that non PCO businesses in Bakersfield and Santa Monica were likely to use rodenticides to control mice, rats, and/or squirrels.” While these businesses did report that they had “tried to control rodents or other animals” they were not specifically asked in the survey what type of rodenticides they used to achieve control of the reported pests (e.g. chemicals, snap traps, glue traps). They also were not asked what types of animals (e.g. mice, rats, squirrels, gophers) were controlled with specific rodenticide products. Data reported in Arndt (2012) therefore do not address the likelihood that non-PCO businesses in the survey area use SGARs in the control of different vertebrate pests.

There are several additional limitations on the conduct and design of the published survey studies cited by DPR. In the study reported by Morzillo and Mertig (2011a, 2011b) 8,000 questionnaires...
were mailed and 2,001 were returned, giving a response rate of 25%.\textsuperscript{148} In the study reported by Arndt (2012), 1,213 questionnaires were mailed and 257 were returned, for a response rate of approximately 21%.\textsuperscript{149} Such response rates are relatively low.\textsuperscript{150} Also, most of the respondents were not users of chemical rodenticides; only 479 of the 2,001 participating residents (24%) and 83 of the 257 participating businesses (32%) reported chemical rodenticide use. In general, response rates for the Bartos et al. (2012) study were similarly low, and survey respondents were significantly biased with respect to demographics (> 92% white, >89% with a bachelor’s degree or more education, respondents were required to have internet access to complete an on-line survey). Both the Bartos et al. (2012) and Arndt (2012) publications appear to have been written by undergraduate college students (or recent graduates); therefore, although both studies are well written and contain valuable information, their suitability for supporting statewide rulemaking is somewhat questionable. Importantly, Arndt (2012) -- an undergraduate thesis -- was published in the absence of external scientific peer review, beyond advising faculty.

The ambiguities in the surveys and the many additional deficiencies noted make clear that the information cannot credibly be considered by DPR as providing meaningful evidence, much less substantial evidence, of the necessity to classify Indoor-Use Consumer SGARs as restricted materials.

\textbf{G. Recent Information Gathered From California Rodenticide Users Shows That Outdoor Consumer Uses Can Be Easily Curtailed Through New Labeling With Use Limitations.}

As noted in the TSG submittal of June 2013, consumer survey data show that consumers use the majority of the rodenticide baits they purchase indoors. Therefore, the contribution of consumer uses to direct and secondary non-target wildlife exposures is unclear and the indoor uses are unlikely to contribute to such unintentional non-target wildlife exposures in any measurable way.\textsuperscript{151} In contrast, surveys of PCOs show that PCOs use rodenticides outdoors as a matter of course. In non-residential settings, at least 59\%\textsuperscript{152} of PCOs “always” or “sometimes” place rodenticides outdoors; in residential settings, at least 60% of PCOs place rodenticides outdoors sometimes or always.\textsuperscript{153} These data suggest that prohibiting consumer use by classifying all SGARs as restricted materials will not have the desired effect of substantially reducing exposures of non-target wildlife to SGARs.

Rather, the data suggest that a more reasonable and cost-effective alternative would be to exempt small quantity consumer-use packages of SGARs when they are labeled for indoor use only from the final restricted materials designation. Doing so will continue to ensure that consumers will

\textsuperscript{148} See Morzillo and Mertig, \textit{Urban Resident Attitudes, supra}, at 250 (Exhibit 50).

\textsuperscript{149} See Arndt, \textit{supra}, at 11 (Exhibit 52).

\textsuperscript{150} See, e.g., Y. Baruch & C. Holton, \textit{Survey Response Rate Levels and Trends in Organizational Research}, Human Relations vol. 61(8) (2008) (Exhibit 54)).

\textsuperscript{151} See June 2013 TSG Comments at 8-9 (Exhibit 39.2).

\textsuperscript{152} 12% of PCOs answered “not sure” or “don’t know” to this question.

\textsuperscript{153} Clarus, Pest Control Operator Survey Data (July 2012) (Exhibit 55).
have access to small quantity packages of affordable and effective SGAR products when sold for indoor uses only. Recent surveys of d-CON® users who reside in California demonstrate that more than three-quarters have never seen, read or heard anything about wildlife being exposed and harmed by chemicals found in rodenticides.\(^{154}\) This demonstrates there is tremendous potential to address risks to non-target wildlife by raising consumer awareness of this issue as a means of minimizing risk to wildlife. In fact, when respondents were asked, “If you were told that limiting the use of rodent control baits to indoor use only would reduce the risk of harm to wildlife,” a 70% majority of d-CON® bait users said they would either definitely or probably not use rodent control baits outside. Moreover, 86% of all respondents surveyed said they would “likely” (very or somewhat) buy a rodent control bait product specifically made and labeled for indoor use only in order to reduce the risks to wildlife. Most respondents believed that product labeling would be the most effective way of informing people that rodent control baits should be for indoor use only. Such data demonstrate that an exemption from a final restricted materials rule for Indoor-Use Consumer SGARs could materially reduce both risks to wildlife and the regulatory and enforcement burdens associated with DPR’s current proposal.

**H. Bulk Sales of SGARs to Non-Licensed Users Are Likely to Continue Via Internet and Interstate Purchases**

Even assuming that there is some contribution of non-target wildlife exposure from consumer use of SGARs, DPR’s proposal to reclassify all SGARs as restricted materials is nevertheless likely to be ineffective at curtailing unlicensed uses. It is ineffective because the proposed rule does not address internet sales of bulk quantities of SGAR products that currently can be purchased without limitation online, or the ability of people to cross state lines and purchase product for use in California.\(^{155}\)

These internet sales allow any member of the public -- including illegal marijuana growers who buy rodenticides for deliberate misuse -- to purchase SGARs in small quantities or in bulk without obtaining a restricted materials license. Restricting the sales of small-quantity, consumer use products may even increase the demand for SGAR bulk products sold in 8 and 15 lb. buckets online. These bulk quantities of SGARs, when used outdoors, will contribute far more hazard to wildlife than consumer-use products. The more timely and cost-effective alternative to DPR’s proposal is to exempt Indoor-Use Consumer SGARs because doing so will address concerns about the consumer-use pathway to non-target wildlife exposures, while maintaining consumer access to affordable and effective small size products to address indoor rodent control problems.

\(^{154}\) Clarus, California Statewide Survey of d-CON Rodenticide Bait Users (July-August 2013) (Exhibit 56).

I. DPR Mis-states the Experience of the United Kingdom in Rodent Control

DPR cites the experience of rodenticide regulation in the United Kingdom as supportive of DPR’s conclusions about the sources of exposures to non-target wildlife and its decision to classify SGARs as restricted materials and its rejection of an exception for small-sized consumer products for indoor-use only. In fact, the United Kingdom policy on rodent control directly contradicts DPR’s position. As documented in the attached report from Dr. Alan Buckle, the UK policy had been, until 2012, to allow consumer use of brodifacoum, flocoumafen and difethialone indoors only. The UK is in the process of reevaluating its position, and is now revising its policy to allow use of these products, and all SGARs “in and around buildings,” (defined as “the building itself and the area around the building that needs to treated in order to deal with the infestation of the building.”) The UK Health and Safety Executive (HSE), the Government regulatory agency with oversight over rodenticides, has summarized the benefits of indoor restrictions to protect wildlife as providing “a high level of protection for non-target species, as it minimises the risk of primary and secondary poisoning” and has noted that “the borderline between indoor and outdoor use is relatively easy for users and enforcement authorities to interpret.” The HSE further summarized the UK experience that consumer use of SGARs does not pose a significant threat to wildlife:

However it is expected that environmental exposure following non-professional use of baits in the UK is a relatively minor proportion of overall environmental exposure, as non-professional control of rodents in the UK is focused on the control of mice inside domestic premises, with baiting treatments against rats being limited.

The HSE explicitly recommends against restrictions on non-professional use of rodenticides, stating that “HSE does not propose a ‘blanket restriction’ on user type, and considers that where appropriate SGARs should be available to trained professional, non-specialized professional and non professional users.”

DPR also states that the UK experience demonstrates that an indoor use only label is ineffective at barring wildlife exposure because brodifacoum accounted for only 9% of wildlife incidents during the period from 1997 to 2011. DPR’s conclusion is misleading for several reasons. First, a substantial number of the incidents in the UK database cited by CDPR reflect intentional,

156 See ISOR at 7 (Exhibit 1).
158 Id. at 10-11.
159 See Id. at 9 (quoting UK Health and Safety Executive (HSE), Environmental Risk Mitigation Measures for Second Generation Anticoagulant Rodenticides at 7(August 2012) (“HSE 2012”) (Exhibit 62)).
160 See HSE 2012 at 6 (Exhibit 62).
161 Id. at 18. See also Buckle UK Report at 11 (Exhibit 61).
162 See ISOR at 7 (citing HSE 2012 at 28) (Exhibit 62)).
illegal use. Significant, brodifacoum may have been the ingredient of choice for these off-label uses. Second, the incident database also includes incidents involving domestic animals, which are not part of DPR’s analysis or the basis for DPR’s rulemaking. Third, HSE documents also show that other SGARs, which were used indoors and outdoors during that same time period, were responsible for 64% of wildlife incidents. Moreover, the “indoor uses” allowed under UK policy during this time period included use by local governments in sewers and in pipes, creating a potential pathway to wildlife that would not be present for an indoor use only restricted to household use. While not directly cited by DPR, the European experience with bromethalin is also relevant to the Department’s proposal, which would have the effect of significantly increasing the use of this neurotoxin. Bromethalin was not supported during the implementation of the European Biocidal Products Directive and, consequently, bromethalin products have not been sold in the European Union since 2006.

The overall UK experience shows that it is illegal and intentional misuse of SGARs, and not indoor use by non-professionals, that make the principal contribution to wildlife incidents. DPR’s reliance on the UK experience to support its proposal for reclassifying SGARs as restricted materials is inapt, and unpersuasive. Moreover, the UK experience does not provide substantial evidence that it is necessary to designate Indoor-Use Consumer SGARs as restricted materials.

**In sum, DPR has provided no basis to conclude that small-size consumer-use SGARs contribute substantially, much less predominantly, to non-target wildlife exposures.**

For the numerous reasons stated in Section III above, and in the expert reports and publications attached as exhibits to these comments, DPR must conclude that at present, there is not substantial evidence for the need to designate Indoor-Use Consumer SGARs as restricted materials. Consequently, the Department should exempt such small quantity packages of SGARs when labeled for indoor uses only because such products are not the leading factors contributing to non-target wildlife exposures.

**IV. DPR HAS NOT ADEQUATELY CONSIDERED LESS IMPACTFUL ALTERNATIVES THAT WILL ACHIEVE AS MUCH OR GREATER WILDLIFE PROTECTION**

d-CON® has submitted proposed alternative methods for mitigating risks to wildlife from consumer use SGARs. Specifically, d-CON® has proposed to DPR, in meetings and in written submittals to the Department, that SGAR products be clearly labeled and limited in size and specifically for application only indoors. This proposal would: (1) minimize direct exposures to

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163 See Buckle UK Report at 8 (Exhibit 61).
164 *Id.* at 9.
165 *Id.*
166 See HSE 2012 at 28 (Exhibit 62).
167 See HSE 2012 at 7 (Exhibit 62).
168 See Buckle UK Report at 11(Exhibit 61).
non-target wildlife from consumer use; and (2) minimize the opportunity for secondary poisoning because there is little, if any, evidence that house mice regularly move from indoors to outdoors, or that mice that consume SGARs indoors go outside to die.\textsuperscript{169} This could be simply and easily accomplished by providing an exemption from a final restricted materials classification for Indoor-Use Consumer SGARs. Such an exemption is consistent with measures proposed before DPR initiated this rulemaking.\textsuperscript{170} Such an exemption could effectively and efficiently reduce non-target wildlife exposure from consumer uses of SGARs without the unintended economic and public health consequences of the current proposal.

The Department’s ISOR references EPA’s 2007 Risk Mitigation Measures Document and DPR concludes, without specific evidence, that “Rodents exposed to rodenticides indoors may not necessarily remain indoors if there is access in and out of the structure. In its 2007 Proposed Risk Mitigation for Nine Rodenticides, EPA indicated that although an indoor use-only limitation would reduce primary exposures to non-target animals, it would not decrease secondary exposures.”\textsuperscript{171} But this position is without support or data in the rulemaking records of either EPA or DPR.\textsuperscript{172}

EPA chose not to put questions to its own Scientific Advisory Panel (SAP) concerning the potential effectiveness of requiring “indoor use only” labeling as an alternative means to address wildlife risk from homeowner uses of SGAR products. Nor did DPR pose such a question to its own peer reviewers. Fortunately, the U.S. EPA SAP did address this issue, and concluded that indoor use labeling would be an effective means of addressing wildlife exposures from consumer use rodenticides. Specifically, the SAP stated that, “adjusting the homeowner label to limit use of the available second generation rodenticides to indoors only would help the casual user understand these products are not appropriate for use outdoors and would allow the continued use of a broader range of formulations while potentially helping address wildlife exposure issues.”\textsuperscript{173}

Moreover, the U.S. EPA has itself concluded in other registration actions that an indoor use limitation is sufficient to mitigate any potential risks to non-target wildlife. In EPA’s analysis of a registration application to use cellulose as a rodenticide active ingredient for mouse control in commercial and residential settings, EPA waived the customary requirements for applicants to provide data on impacts to non-target organisms because “the proposed registration will only permit indoor use.”\textsuperscript{174} EPA concluded, therefore, that “non-target toxicity is not anticipated because of lack of exposure. Based on its non-target assessment, EPA has determined that the

\textsuperscript{169} Fairbrother Report at 25-26 (Exhibit 26).
\textsuperscript{170} See DPR, “Second Generation Anticoagulant Registration, Sales & Use Information,” Feb. 25, 2013(Exhibit 63.3); DPR, “Department of Pesticide Regulation Second Generation Anticoagulants Rodenticides Meeting with Registrants Agenda,” Feb. 26, 2013 (Exhibit 63.1); DPR, Untitled Chart, Feb. 25, 2013 (Exhibit 63.2).
\textsuperscript{171} See ISOR at 7 (Exhibit 1).
\textsuperscript{172} See discussion in Section III, above.
\textsuperscript{173} SAP Report at 49 (Exhibit 36).
proposed registered use of cellulose in end use products (EPs) should not result in adverse effects to birds, fish, aquatic invertebrates, plants, or non-target insects.”\(^{175}\) In sum, EPA concluded that an indoor use only restriction was sufficient to address non target wildlife concerns, which is precisely the question before DPR here. Accordingly, DPR needs to consider carefully EPA’s cellulose decision before concluding that an indoor use only requirement will not suffice to address DPR’s concerns about risk to non-target wildlife.

There is also significant evidence supporting the effectiveness of label changes aimed at ensuring indoor use. Attached is a preliminary report from Applied Safety and Ergonomics analyzing label changes that Reckitt submitted to the U.S. EPA as part of an amendment request for its SGAR products and which is still undergoing review at EPA.\(^{176}\) This report concludes that d-CON®’s proposed new indoor use only label provides clear information that enables consumers to understand the proper placement of rodenticide baits more quickly. It also concludes that the new label “could reduce misuse both by encouraging users to read the labeling . . . and by conveying key information more clearly to those who read it.”\(^ {177}\) Moreover, as noted in Section II, above, recent survey data from California users of rodenticide bait products reflect that a large majority of consumers report they are prepared to acquire rodenticides labeled for indoor use only, and report they would discontinue outdoor uses after gaining an awareness of risks to non-target wildlife from such uses.

The foregoing is further evidence supporting the conclusion that an indoor-use only label for small quantity packages of SGAR products can materially mitigate non-target wildlife exposures while continuing to provide consumers with access to affordable and effective rodent control. When a proper alternatives determination is made by the Department, taking into consideration these comments and the many exhibits and additional data being brought to the Department’s attention through this rulemaking, DPR must reach this same conclusion.

V. DPR HAS FAILED TO ASSESS THE RISKS TO CHILDREN AND PETS FROM EXPOSURE TO ALTERNATIVE RODENTICIDES LIKE BROMETHALIN

DPR’s proposal would leave consumers with access only to products containing FGARs or non-anticoagulants, including the neurotoxin bromethalin, as active ingredients. The Department has not considered the additional risks that alternative products pose to children and to domestic animals. DPR’s consideration of the impacts of its proposed regulatory action on children and pets is limited to the remark that “all the alternative consumer-size rodenticide products are block/solid formulations contained in a bait station or are sold with a bait station, which offers an increased level of protection for children, pets, and non-target wildlife over the loose pellet SGARs currently being sold to consumers.”\(^ {178}\) This comment reveals that the Department neither evaluated the alternative rodenticide products that would remain and proliferate in the

\(^{175}\) Id.


\(^{177}\) Id. at 2.

\(^{178}\) ISOR at 10 (Exhibit 1).
market as a result of its proposed regulatory action, nor considered the negative impacts that those alternative products may have on pets and humans.

SGARs and non-anticoagulant rodenticides are fundamentally different in several ways. Specifically, they differ in their mode of action and the ways in which they affect the body, they differ in how easily these effects can be diagnosed by clinicians, and they differ with respect to the availability and efficacy of treatment options. SGARs are slow-acting anticoagulants that interfere with the production of blood clotting factors. They have a delayed action time and familiar symptoms, and they are easy to diagnose. In the unlikely event of toxic exposure, there is a readily available and effective antidote—Vitamin K1. According to the “Consensus Panel,” a panel of experts that undertook a comprehensive study of medical literature and incident reports concerning human health and SGARs (also known as long acting anticoagulant rodenticides (LAARs)), “Patients with unintentional ingestion of less than 1 mg of LAAR active ingredient can be safely observed at home without laboratory monitoring.” This includes practically all unintentional ingestions in children less than 6 years of age. Poison control centers across the United States that respond to calls regarding potential exposure to SGAR products adhere to the Consensus Panel’s guideline.

The U.S. EPA’s SAP concurred with the Consensus Panel’s finding, noting that SGAR “exposure generally results in no clinical harm to children,” and “[i]f the toxic threshold is exceeded, there is a widely available laboratory test and an antidote (vitamin K1) with which clinicians are familiar because of the therapeutic use of warfarin.”

In contrast, bromethalin and the other non-anticoagulant rodenticides that would further gain market share in the absence of SGARs (including cholecalciferol and zinc phosphide) are less familiar to the poison control and medical/veterinary communities, are not easy to diagnose or treat, and lack effective antidotes. Bromethalin, for example, is a fast-acting neurotoxin with

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179 Rodent control baits formulated with brodifacoum contain only 0.005% active ingredient. Thus, to consume greater than 1 mg of LAAR, an individual would need to ingest nearly one full ounce, or about four teaspoons, of rodent bait before the person would be expected to manifest symptoms related to anticoagulant exposures.

180 The peer reviewers for this publication included senior scientists at health-based federal agencies such as the U.S. EPA, and the Centers for Diseases Control among many others.


182 SAP Report at 6 (Exhibit 36).

183 See generally A. Brutlag, DVM, MS, Critical Evaluation of the Impact of the California Department of Pesticide Regulation’s Proposed Regulation, DPR 13-002, Designating Second Generation Anticoagulant Rodenticide Products as Restricted Materials (Oct. 4, 2013) (“Brutlag Report”) (Exhibit 67); Kingston Report (Exhibit 66); S. Gray, DVM, DACVECC, Impacts on Domestic Animals of the California Department of Pesticide Regulation’s Proposed Restricted Use Classification for Second Generation Anticoagulant Rodenticide Products (Oct. 4, 2013) (“Gray Report”) (Exhibit 70); A. Brutlag, DVM, MS, Impact of EPA’s Notice of Intent to Cancel and Notice of Denial of Registrations for Certain Rodenticide Bait Products on Domestic Animals (November 2011) (“Brutlag SAP Report”) (Exhibit 68); R. Kingston, PharmD, Response to EPA’s Notice of Intent to Cancel and Notice of
only a short window for treatment and no antidote. There is no diagnostic laboratory test either, which means that the only option for suspected exposures is to try to remove the substance from the body and provide supportive care in hopes of avoiding severe complications. The SAP noted that:

> [S]evere bromethalin poisonings are very concerning for clinicians because of less human experience with them and, unlike the anticoagulant rodenticides, there is no specific diagnostic test or antidote. Given that bromethalin targets the central nervous system (CNS), there is concern that the developing brain of young children may be particularly susceptible to the effects of bromethalin.\(^{184}\)

A 10-year review of SGAR and bromethalin incidents reported to the national poison control centers revealed a higher incidence of fatalities, serious outcomes, and symptomatic exposures to bromethalin compared to SGARs.\(^{185}\) It also found that “intentional bromethalin exposures resulted in a higher incidence of fatal outcomes when compared to SGARs,” and “for significant exposures, especially intentional exposures, the comparatively increased mortality rate, coupled with limited treatment options for bromethalin, may represent a significant emerging public health issue as the bromethalin products gain market share.”\(^{186}\) An ongoing analysis of national and regional incident data has revealed that human exposures involving bromethalin are 8.5 times more likely to result in a fatal outcome as compared to SGARs, and bromethalin exposures involving RMD-compliant products are continuing to occur even after implementation of the RMD.\(^{187}\) A study of Pet Poison Helpline data similarly found that exposures to bromethalin from RMD-compliant products continue to occur\(^{188}\) -- a fact confirmed by DPR’s own data.\(^{189}\)

Bromethalin is also a major concern for pets, as it is more toxic to dogs and cats than certain SGARs. For example, bromethalin is nearly 50 times more toxic than brodifacoum to cats and 6.5 times more toxic than difethialone to dogs.\(^{190}\) The SAP noted that bromethalin poses a significant risk to pets; “[t]he 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.”\(^{191}\)

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\(^{184}\) Denial of Registrations for Certain Rodenticide Bait Products (Nov. 15, 2011) (“Kingston SAP Report”) (Exhibit 69).

\(^{185}\) SAP Report at 6 (Exhibit 36).


\(^{187}\) Kingston Report at 8 (Exhibit 66).

\(^{188}\) Id. at 9.

\(^{189}\) Id. at 8; Brutlag Report, Appendix G (Exhibit 67).

\(^{189}\) Brutlag Report at 36 (Exhibit 67).

\(^{190}\) Id. at 20.

\(^{191}\) SAP Report at 8 (Exhibit 36).
DPR’s assertion that the non-anticoagulant rodenticide block products in bait stations would increase protection for children and pets applies, if at all, only when consumers use these products correctly. However, there is evidence that people are misusing the products by placing blocks of bait around the home, outside of the bait stations. This behavior increases risks to children and pets because of the more toxic, less treatable ingredient to which they are being exposed. In addition, the refill bags containing large quantities of bait blocks are not child or pet resistant. Pets have chewed through both refill bags and bait stations, which in turn has resulted in toxic exposures to bromethalin. Veterinarians fear that the greater expense of treating bromethalin exposures may cause some pet owners to opt for humane euthanasia due to cost concerns.

DPR also failed to consider that bait stations do not address the problem of intentional exposure in humans. The few cases involving toxic exposures to SGARs typically have involved individuals with mental or developmental disabilities, individuals with a self-harm motivation, or victims of poisoning by those with malicious intent. These vulnerable populations will be subject to a greater risk of poisoning and adverse health outcomes if the rodenticide products available are non-anticoagulant rodenticides, like bromethalin, because of the mode of action in the human body and the lack of diagnostic tests and antidotes for treating such occurrences.

A thorough analysis of the kind required in the context of DPR’s proposed rulemaking, including a careful review of all of the alternative rodenticide products on the market, leads to the unmistakable conclusion that DPR’s proposed regulatory action would replace the consumer-use market a rodenticide that is well characterized and easily treatable when accidental exposures occur, with rodenticides that are not. Doing so would consequently significantly increase risk to children and pets. The Department needs to reconsider the full scope of the potential impacts of its proposed action, including the implications of a significant increase in consumer use of bromethalin, before making any final decision on this proposal. The Department must conclude that the alternative it considered in early 2013 -- exempting indoor-use-only small-size consumer-use SGAR products -- would both mitigate the potential risk of non-target wildlife exposures from consumer-use products and provide continued consumer access to products that are better understood in the poison control community than neurotoxin-based alternative rodenticide products.

192 See ISOR at 10 (Exhibit 1).
193 Brutlag Report, Appendix G at 57 (Exhibit 67); Brutlag Report at 33; Kingston Report (Exhibit 66) at 8-9.
194 Kingston Report at 9 (Exhibit 66); Brutlag Report at 8 (Exhibit 67); Gray Report at 3 (Exhibit 70).
195 Brutlag Report (Exhibit 67) at 34.
196 Id. at 37-38; Gray Report at 6 (Exhibit 70).
197 SAP Report at 7 (Exhibit 36); Kingston Report at 8-10 (Exhibit 66).
198 Kingston Report at 4-5, 8-10 (Exhibit 66).
VI. DPR HAS NOT EVALUATED THE EFFICACY OF ALTERNATIVE PRODUCTS OR THE IMPACTS ON PUBLIC HEALTH OF THE WIDESPREAD USE OF LESS EFFECTIVE RODENTICIDES THAT WILL RESULT FROM THIS PROPOSAL

DPR’s proposal assumes that there will be no loss in the effectiveness of consumer rodent control because “effective consumer-sized alternatives to SGARs are available.”199 However, the Department does not appear to have engaged in its own evaluation to reach this conclusion.200 Instead, DPR appears to base its conclusion regarding the efficacy of alternative products entirely on its assumption that “All rodenticides must demonstrate efficacy against target pests prior to registration.”201 This assumption is flawed, for several reasons.

First, it is simply incorrect that all alternative products are as effective as SGARs, or even are sufficiently effective to address infestations of commensal rodents.202 In numerous studies over the last twenty years, FGARs have proven to be significantly less effective than SGARs.203 Over the last several decades, resistant strains of house mice have developed that are essentially immune to FGAR products.204 The U.S. Fish and Wildlife Service (FWS) has rejected using FGAR products for island eradication programs, because these products are less effective.205 FWS also rejected certain FGAR products specifically because of their history of resistance.206

199 See ISOR at 10 (Exhibit 1).
200 One of DPR’s peer reviewers noted “the lack of safe and effective alternatives” to SGARs. See (Exhibit 28) DPR Peer-Review Comment Responses, Comments of John Elliott at 9.
201 See ISOR at 10(Exhibit 1).
202 See Exhibit EBPF at 16 regarding the comparatively poor efficacy of alternatives to rodent control bait products (Exhibit 42).
204 See Buckle Efficacy Report at 13-14 (Exhibit 71); see also H.J. Pelz, and M. Kohn, Impact of Resistance to Anticoagulant Rodenticides in Rats and House Mice on the Efficacy of Control Measures, Report Prepared for the EPA FIFRA Scientific Advisory Panel (Nov. 16, 2011) (“Pelz & Kohn SAP Report”) (Exhibit 74). See also Exhibit EBPF at 18 (Exhibit 42).
206 See id. at Product 12, pp. 144. FWS also concluded that bromethalin was less effective than brodifacoum, rating hand-delivered bromethalin and aerial bromethalin as “low effectiveness” and bromethalin in a bait station as “ineffective/unknown,” while rating hand brodifacoum and aerial brodifacoum as “high effectiveness.” While FWS rated bait station brodifacoum as “low effectiveness,” this is still a higher efficacy rating than the counterpart rating for bromethalin in a bait station as “ineffective/unknown.” See Id.
The ISOR acknowledges that SGARs were developed in response to the growth of resistance to FGARs. But the ISOR does not acknowledge that resistant house mice have been reported throughout the United States in the 1980s, and the presence of the genetic mutation that caused resistance in European mice has recently been documented in numerous regions of the United States. The presence of the gene for resistance to FGARs, even during several decades when SGARs have been the predominant bait for rodent control, demonstrates the persistence of the resistance gene even in the apparent absence of specific selective pressures from the lawful utilization of FGARs. Moreover, even in areas of the country where the mutation for resistance has not been identified, significant increase in the use of FGARs is likely to increase the spread of the presence of resistant populations.

U.S. EPA’s SAP advised the Agency that it had underestimated the potential for resistance to undermine the efficacy of replacement products. One of DPR’s peer reviewers similarly noted that “increased use of FGARs could result in development of resistance in target organisms, which might be countered by greater application rates, which in turn could pose a greater hazard to non-target wildlife.” In the face of returning to widespread use of FGARs, consumers can anticipate the spread of resistant mice strains -- and the concomitant expansion of the size and duration of rodent infestations. DPR should not finalize this proposal without first carefully considering the implications of widespread genetic resistance to FGARs.

Second, DPR does not consider the impact of EPA’s other risk mitigation measures on rodenticide efficacy. Presently, California consumers still have access to an SGAR in pellet form, but the Department’s proposal would leave consumers with access only to non-SGAR products in block form and in tamper resistant bait stations. Consequently, any evaluation of the presence of alternative effective products as a consequence of DPR’s proposal must also consider the efficacy of bait blocks and tamper resistant bait stations.

Here, DPR’s record is lacking. The materials on which DPR relied in developing this rule do not contain an analysis of the efficacy of the only products that would be allowed to California consumers -- products in block form in tamper resistant bait stations but without SGARs. In fact, significant data developed over many years demonstrate that use of block baits reduces efficacy compared to other bait forms. Despite DPR’s assertions that all alternative products meet

207 See ISOR at 2 (Exhibit 1).
208 See M.H. Kohn, A survey of non-synonymous Vkorc1 polymorphisms that mediate resistance to select anticoagulant rodenticides (FGARs) in the house mouse (Mus musculus domesticus) in the U.S.(Oct. 2013) (“Kohn Report”) (Exhibit 76) at 6, 14-15.
209 Id. at 17.
210 See id. at 14-17.
211 See, e.g., SAP Report (Exhibit 36) at 46 (“The development of pesticide resistance is well understood and is understated in the NOIC discussion on second generation anticoagulants...The likely increased use of first generation anticoaguants would be expected to hasten development of resistant populations.”)
212 See DPR Peer-Review Comment Responses, Comments of B. Rattner at 22 (Exhibit 28).
213 See ISOR at 3-4, 10 (Exhibit 1); see also Buckle Efficacy Report at 19-20 (Exhibit 71).
214 Buckle Efficacy Report at 19-21(Exhibit 71); see also Prescott SAP Report at 14-16 (Exhibit 72).
EPA efficacy requirements, neither U.S. EPA nor the Department are expected to have data showing that these products in bait stations meet efficacy requirements, since EPA does not require data demonstrating efficacy for products in bait stations.\textsuperscript{215} The existing data on bait stations demonstrates that bait stations may reduce efficacy, due to neophobia and bait shyness among rodents.\textsuperscript{216} Considered cumulatively, rodenticides using blocks in bait stations may, even though registered by EPA, fail to meet EPA’s efficacy requirements, and are even more likely to be less effective than SGARs in pellet form.\textsuperscript{217} This is particularly true of baits using FGARs.\textsuperscript{218}

EPA’s SAP also raised concerns about reductions in efficacy from requiring bait stations\textsuperscript{219} and bait blocks.\textsuperscript{220} The FWS Farallon Islands EIS reached the same conclusion. Products using bait stations were consistently rated less effective than the same products using other delivery mechanisms.\textsuperscript{221} There is no record that DPR considered or addressed these issues.\textsuperscript{222} DPR also does not appear to have considered the flaws in relying on acute or sub-acute compounds. Rodents consuming these compounds are prone to consume a sub-lethal dose and then stop feeding, due to the rapid onset of toxicosis.\textsuperscript{223}

While not mentioned by DPR as a rationale for barring consumer use of SGARs, non-chemical rodent control measures also do not provide similar levels of efficacy of rodent control as do SGARs.\textsuperscript{224} The EPA SAP raised this issue too.\textsuperscript{225} While EPA asserted that many consumers use mechanical traps, it did not dispute or even address the comparative efficacy of mechanical traps.\textsuperscript{226} Moreover, EPA conceded that “few residential users of rodenticides will switch to non-

\textsuperscript{215} See Buckle Efficacy Report at 22 (Exhibit 71). Further, EPA permits efficacy studies to be performed using laboratory rather than wild rodents.

\textsuperscript{216} See Buckle Efficacy Report at 21-24 (Exhibit 71); see also Buckle SAP Report at 31-35 (Exhibit 73); see also G. Murphy, and A. Felix-Thomas, Draft: The Influence of bait presentation on bait consumption by urban mice (Mus domesticus) in domestic dwellings, University of Salford (Exhibit 77) at 6-7.

\textsuperscript{217} See Buckle Efficacy Report at 27 (Exhibit 71); see also Buckle SAP Report at 42-43 (Exhibit 73).

\textsuperscript{218} Buckle Efficacy Report at 27 (Exhibit XX).

\textsuperscript{219} See SAP Report at 16 (“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 and practical field efficacy of the available rodenticides will be likely reduced”) (Exhibit 36). See also Exhibit EBPF at 4 and 11 (Exhibit 42).

\textsuperscript{220} See id. (“[L]imiting the choice of bait formulation to bait blocks reduces the ability of the user to select a formulation best suited for a particular environment; e.g., locations where familiar pellets would have greater acceptance than a novel bait block.”)

\textsuperscript{221} See Farallon Islands DEIS Comparison Matrices, supra note 221, Product 7, at 1-2 (Exhibit 75).

\textsuperscript{222} The list of Documents Relied Upon by DPR in the ISOR does not include the Report of U.S. EPA’s SAP. See ISOR at 13-14 (Exhibit 1).

\textsuperscript{223} See Buckle SAP Report at 12 (Exhibit 73).

\textsuperscript{224} See Buckle Efficacy Report at 25-26 (Exhibit 71); Buckle SAP Report at 36-38 (Exhibit 73).

\textsuperscript{225} See SAP Report at 16-17 and 46 (Exhibit 73) (“The Panel is concerned that in the NOIC, EPA has failed to recognize the difficulties associated with non-chemical control, especially in those communities where rodent populations are at high levels.”).

\textsuperscript{226} See EPA Response to SAP at 17 (Exhibit 48).
“chemical control” absent access to SGARs. Thus, to the extent that DPR is counting on non-chemical methods of rodent control to ensure adequate control of rodent infestations after barring consumer use of SGARs, its assumption has no basis in its own record or even in any documentation developed by EPA.

In not considering potential resistance issues and by not properly evaluating the efficacy of alternative products, DPR has also not evaluated the public health and economic implications of the increased rodent populations and longer duration of rodent infestations that will result from less effective rodent control, contrary to its statutory obligations. Replacing SGARs with less effective alternatives will impose additional costs on local governments, local health providers, and individual families that will need to pay more to achieve the same level of rodent control and/or pay more for medical care to treat childhood asthma, rodent bites, and rodent-borne diseases. DPR did not analyze or assess the public health consequences of the loss of effective rodent control, or the economic impact of that loss of effective rodent control. The Department should not issue a final rule until DPR properly considers these issues or establishes an exemption from the restricted materials designation for Indoor-Use Consumer SGARs.

VII. DPR’s ECONOMIC ANALYSIS IS INADEQUATE AND UNDERSTATES THE COST IMPACT OF ITS PROPOSAL

In addition to the economic impact caused by commensal rodents and the additional public health costs and other costs that will result from less adequate rodent control as a result of DPR’s proposed action, the Department’s Economic Analysis does not consider numerous additional direct and indirect costs associated with this proposed action. In fact, the costs of achieving effective rodent control for consumers, for small businesses, and for localities all will increase. The Department’s assessment does not consider these increased costs.

A. DPR Did Not Conduct a Sufficient Economic Analysis

DPR’s economic analysis relies heavily on the analysis of a third party -- EPA -- which is itself inadequate. The discussion of economic impacts of EPA’s proposed regulation in the Agency’s 2013 Statement of Reasons in support of its Notice of Intent to Cancel is based in large measure on a document that dates to 2006 -- more than seven years ago, in a substantially different economic environment. The Department’s reliance on this document is particularly inappropriate given the unique characteristics of California’s economy, including its high proportion of minority and disadvantaged residents, its large population, its mix of extreme urban and extreme rural communities, and its status as the number one producer of agricultural commodities in the U.S.

DPR also failed to conduct a meaningful economic analysis of its own. Documents relied on for the DPR rulemaking include only two documents of any substance that pertain to economic

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227 Id. at 18.

228 See Cal. Food & Agric. §§ 403, 11454, 11501(a).

229 See Section I, above.

230 http://www.cdfa.ca.gov/statistics/ (Exhibit 78); http://stuffaboutstates.com/california/agriculture.htm (Exhibit 79)
impacts of the proposed regulation: a four-page memorandum from the Agency Wide Economic Analysis Unit (AEAU) and a nine-page “Economic Analysis for Rulemaking,” the author of which is unattributed. The AEAU memorandum is conclusory at best, citing no data, literature, or other authority for most of its assertions. The “Economic Analysis for Rulemaking” is slightly longer, but also contains little analysis or documentation.

Ultimately, both of DPR’s economic “analyses” are too superficial to comply with its statutory obligation to “provide in the record facts, evidence, documents, testimony, or other evidence upon which the agency relies to support its initial determination.” The only putative “data” to which DPR cites consist of unvalidated assertions reportedly made by various agricultural industry representatives in non-public meetings with DPR staff, or in emails that are not among the Department’s documentation. The rest of DPR’s economic analyses do not consist of “facts, evidence, documents, testimony, or other evidence upon which the agency relies” as the law requires. Instead, the analyses are based upon generalizations and assumptions. In fact, DPR incorporates no fewer than twelve assumptions in a nine-page document. Although the Economic Analysis for Rulemaking includes some cost calculations, the underlying figures consist mostly of “estimates,” for which no source is cited.

B. DPR’s Economic Analysis Documents Cited for Rulemaking Understate Economic Impacts to Consumers, Businesses, State & Local Governments and Registrants

DPR’s economic analysis reaches the erroneous conclusion that economic impacts of the proposed restrictions would be insignificant. A more thorough evaluation of the market demonstrates that, at a minimum, impacts on consumers, local and state government, businesses using SGARs, and registrants will be far more substantial than DPR acknowledges.

Economic Impacts to Consumers

DPR adopts, apparently without evaluating, EPA’s assertion that the incremental costs of using alternative rodenticide products for mouse control “will be small.” EPA’s analysis, however, actually indicates that the incremental costs of the proposed cancellation to consumers could be substantial. The 2006 EPA report relied upon by the Department masked this conclusion by presenting its results on a per-household basis. Even assuming that EPA’s incremental cost estimates and methodology are appropriate, the actual incremental cost to California consumers of alternative products would be, in the aggregate, in the range of $10.2 to $44.2 million.

This is a conservative estimate, however, because it includes the incremental cost for bait users only (i.e., those who switch from SGARs to alternative bait products) and does not address the incremental costs for households that will switch to the services of a PCO in response to the

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231 Cal. Gov’t Code § 11346.5(a)(8).
232 See generally Danner & Hamm BSG Report (Exhibit 80)
233 See generally Cantor and Schmier “Preliminary Review and Report on Impact Assessment for Proposed Rodenticide Mitigation,” (Exhibit 89); Economic Concerns Created by EPA’s Draft Notice of Intent to Cancel 20 Consumer Use Rodenticides, (Exhibit 91).
cancellation of the consumer-use SGAR products. Additionally, it excludes incremental costs for rat control, which EPA acknowledges are substantial.

DPR’s conclusion that changes in average rodent control expenditures per consumer are likely to be small is also based on its determination that “similar products with lower unit-prices” are available, which, in turn, is based on prices gleaned from internet searches. This methodology is unsound. First, it appears to select prices favorable to DPR’s conclusion, listing package costs that are “possible to find” online rather than taking an average or median price. More importantly, these isolated data points do not reflect consumer purchasing behaviors, i.e., the limited selection of products and prices at local brick-and-mortar stores. Moreover, consumers who may be in the greatest position to need access to low-cost effective rodent control products may lack the means to make purchases online, i.e., a convenient internet connection and a credit or debit card.

Replacement products are, in fact, significantly more expensive, and the overall impact of this incremental cost is substantial. Even if the economic impact of the proposed regulations were “small,” as DPR asserts, such a cursory evaluation does not meet DPR’s legal obligations under the California Administrative Procedures Act. Although it may be “difficult to project overall changes in consumer expenditures that could take place as a result of product substitution,” such a projection is part of DPR’s responsibility as a regulator whose actions will affect millions of California residents.

In addition, the Department’s analysis fails to consider the potential for indirect costs associated with the proposed regulation. As explained in the discussions of alternative rodenticides and public health above, the products that would remain unrestricted are relatively ineffective in controlling rodent infestations. Consequently, use of these alternative products will result in an increased incidence of rodent-associated diseases and injuries, including childhood asthma, leptospirosis, and rodent bites. Additionally, costs associated with treating children and pets exposed to bromethalin -- a neurotoxin with no antidote -- are significantly higher than those for treatment of SGAR exposure, which is cheaply and easily treated with vitamin K. Finally, DPR’s economic analysis fails to consider the specific impact of the cost increases of switching to PCOs on low income populations, including tenants in public housing, who are the

234 See U.S. EPA, Office of Pesticide Programs, Statement of Reasons and Factual Basis for Notice Intent to Cancel Registrations of, and Notice of Denial of Applications for, Certain Rodenticide Bait Products (Jan. 29, 2013) (“EPA Statement of Reasons”) (Exhibit 81) at 127 (stating that in the event of a cancellation of SGARs, “Some households will hire professional applicators who can utilize additional products, including SGARs.”)


237 See Cal. Gov’t Code §§ 11346.3(a)(1)-(2); 11346.5(a)(8)-(9).

238 DPR Economic Analysis at 4 (Exhibit 4).
communities that are both hardest hit by rodent infestations\textsuperscript{239} and least able to absorb economic impacts of increased rodenticide prices or costly health care for rodent-related illness. This is not only a significant gap in DPR’s analysis; it also is inconsistent with the Department’s obligation to consider environmental justice concerns in proposing regulations.\textsuperscript{240}

**Economic Impacts to Businesses.** Businesses likely to be adversely affected by the proposed regulations include agricultural operations, landlords, and small businesspeople, among others. DPR assumes, without establishing, that all agricultural users other than aqua farming and poultry farming already have a licensed pesticide applicator on staff or currently hire a pest control company to perform pest management pesticide activities. This assumption ignores the thousands of family farms and other small agricultural operations that -- as DPR acknowledges in the context of poultry and swine facilities -- would need to hire a PCO or obtain their own certification.\textsuperscript{241} As a result, the Department understates the economic impacts to entities that, if restrictions on SGARs were implemented, would either have to seek certification or hire a PCO.

Moreover, DPR’s economic analysis does not address economic impacts to small business people, many of which use consumer products to deal with rodent infestations on their premises. This group includes, for example, landlords, restaurant owners, grocers, and other commercial establishments where food products are stored, sold, or consumed. DPR cites EPA’s assumption (which relies on undisclosed, proprietary data not in the record) that more than 90% of food-handling establishments already have a licensed PCO handling pest control functions.\textsuperscript{242} DPR assumes this figure to be accurate for California (there is nothing in the record to suggest that DPR had access to the proprietary data for the purposes of this rulemaking). Then, without any specific basis in the record, the Department further assumes that only half of the businesses not already using a PCO rely on rodenticides for their rodent control. Moreover, DPR also assumes that only about 20% of the persons who engage in DIY pest control will hire PCOs or obtain licensing for purposes of their rodent control going forward. DPR concludes, based on these various assumptions, that the additional expenses to small businesses will be only in the range of $1 million in the aggregate for the entire state, which neglects to include in its calculation the cost of labor associated with preparing for the exam required for applicator certification. However, DPR ignores the labor costs associated with paying employees to prepare for the pesticide applicator’s certification exam. Accounting for these costs -- even while accepting DPR’s assumptions for the number of affected businesses -- yields potential added costs to agricultural businesses of about $80,000 annually, and nearly $2 million for food-related facilities. If these unsupported CDPR assumptions are low, the actual costs to business could be several times higher.\textsuperscript{243}

**Economic Impacts to State and Local Governments.** DPR evaluates potential economic impacts to local governments only in terms of potential costs to issue permits and administer

\textsuperscript{239} See, e.g., 2009 American Housing Survey, *supra* note 27, Table 2-7 (Exhibit 16).


\textsuperscript{241} DPR Economic Analysis at 5 (Exhibit 4).

\textsuperscript{242} *Id.* at 7.

\textsuperscript{243} See Danner & Hamm BSG Report (Exhibit 80).
applicator licensing examinations, or to acquire necessary certifications for public health officials charged with rodent control. The Department concludes that any additional work associated with increased licensing and permitting could be absorbed into the existing workload, and that public health officials already have the necessary certifications to apply restricted materials. This analysis fails to consider other economic impacts to local and state governments: namely, the increased costs associated with less effective rodent control. For example, if consumers are denied access to cost-effective rodenticides, the resulting increased rodent population may need to be addressed with pest control treatments by municipal health departments. Similarly, local and state public health programs will bear at least some of the cost of increased incidents of asthma, rodent bites, and disease transmission, as well as the costs of increased damage to property, including public property. Furthermore, the additional costs of oversight and enforcement of consumer uses of restricted materials rodenticides has not been estimated by DPR. Finally, DPR has failed to assess the foreseeable costs to the State of California from injuries or death to children and other consumers from exposure to neurotoxins, which will expand in market share if consumers no longer have access to SGARs.

**Economic Impacts to the Registrants.** DPR erroneously states that proposed rule will not have “a significant adverse economic impact” on companies selling consumer use rodenticides because losses in SGAR sales will “be offset by additional sales of other rodenticide products.” DPR provides no basis for this conclusion. Although the Department acknowledges that only one company -- d-CON® -- has registered SGAR products in California, it has not meaningfully evaluated the economic impacts to d-CON®. Nor has DPR reached out to d-CON® for information to inform its analysis.244

For instance, the Department assumes that residential consumers who prefer the d-CON brand of product but are unable to purchase restricted materials would shift to other, first-generation anticoagulant rodenticide products registered in California by d-CON®. This assumption ignores a range of commercial realities, including the fact that these first-generation products, though registered, are not widely produced or marketed, and none of the d-CON® first-generation products are currently commercialized in California.245 To move these products into widespread production and distribution or to commercialize a d-CON® first-generation rodenticide product for sale only in California would require a costly transition.246 DPR also incorrectly assumes that registrants can sell rodenticide products with bait stations and blocks within the same cost structure as products that are not in bait stations.247 Moreover, the transition to bait stations will mean the outsourcing of jobs to Mexico to produce bait stations, a cost impact not evaluated by DPR.248

244 See Statement of Laurent Faracci Regarding Cost Impact to d-CON® of California Department of Pesticide Regulation Proposal to Classify Second Generation Anti-Coagulant Rodenticides as Restricted Materials (Exhibit 84) at ¶8.

245 Id. at ¶§5-6.

246 Id.

247 Id. at ¶§5c.

248 Id. at ¶§7.
Additionally, all currently-marketed d-CON products contain a label statement that the product “kills in one feeding” -- a feature which is important to consumers. U.S. EPA permits such a claim for SGARs, but FGARs cannot carry the claim because such products require multiple feeds to be effective. The absence of this statement on product labels will have a significant impact on d-CON®’s sales, a factor not considered by DPR in its economic analysis. The presence of this claim on bromethalin labels that have not been classified as restricted materials will contribute to consumer demand for such products if the proposed rule is promulgated.

DPR’s expectation that “any net change in [d-CON®’s] revenues would be limited” is likewise ill-informed. In reality, the proposed California restrictions would profoundly impact sales of d-CON brand SGAR products nationwide. In the absence of a uniform regulatory regime, d-CON® will be forced -- at enormous expense -- to develop a fundamentally different product for sale uniquely in California, and to tailor its distribution chain to accommodate restrictions unique to California. Moreover, key national retailers may refuse to market d-CON® products uniquely marketed to California, lest they too be forced to shoulder the cost of customizing distribution from one state to the next; indeed, some retailers who are significant d-CON® customers have already indicated that they would not accept this unique distribution system of having products in their California stores different from those in other states.

The Economic Analysis for Rulemaking notes that, consistent with the proposed regulations, d-CON®’s four registered SGAR products could still be offered for sale by licensed pesticide dealers. This statement misses the essential point, which is that only certified applicators could purchase these products. d-CON®’s rodenticide products are marketed solely for retail sales to consumers; in small quantities and easy-to-use formulations. DPR itself acknowledges that it does not anticipate that ordinary homeowners will pursue certification in order to maintain access to SGARs. It is therefore highly unlikely that commercial applicators such as PCOs and agricultural users would purchase these products, or that retailers oriented either to consumers or to certified applicators would offer them for sale. Thus, in practical terms, DPR’s proposed regulations would eliminate the market for d-CON SGAR products, with substantial financial consequences for d-CON®.

**VIII. ADDITIONAL CONSIDERATIONS**

d-CON® believes that the Department has not adequately addressed and considered a number of basic requirements that should be met before DPR can legitimately proceed with the consideration of its proposed action.

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249 *Id.* at ¶5c.
250 *Id.* at ¶5.
251 *Id.* at ¶6.
252 *Id.* at ¶6d.
253 *See DPR Economic Analysis at 4 (Exhibit 4).*
A. DPR’s Proposal is Tantamount to a De Facto Cancellation, Which Requires an Adjudicatory Hearing

The practical effect of the proposed DPR regulation is to bar the sales of SGAR products to consumers by one -- and only one -- company: d-CON®. Since d-CON®’s SGAR products are only distributed for consumer uses, the Department’s action has the same practical effect as a cancellation action against d-CON®’s products. However, DPR has not followed the requisite procedures for cancellation. The use of other administrative mechanisms to achieve a de facto cancellation is prohibited both under California law, and federal law. Accordingly, if DPR believes that SGAR products no longer meet the State’s standards for registration of a consumer-use rodenticide, the appropriate -- and the only -- procedural mechanism is to initiate cancellation actions against d-CON®’s products. The Department lacks the legal authority to use this rulemaking to effect a de facto cancellation.

B. DPR Must Comply With the California Environmental Quality Act (CEQA)

Although DPR’s pesticide regulatory program is a state regulatory program certified by the Department of Resources as exempt from the requirements of preparing Environmental Impact Reports (EIRs) (i.e., a program certified to have functional equivalency under CEQA), DPR still must comply with CEQA obligations arising outside chapters 3 and 4 of CEQA and Public Resources Code § 21167. The Department’s regulatory documents and processes also must meet the threshold requirements for functionally equivalency under CEQA. These requirements include, without limitation: that DPR consult with all public agencies that have jurisdiction with respect to the proposed reclassification, including relevant public health authorities, and that DPR adequately describe and analyze alternatives to the proposed regulation.

Based on the record provided to the public, the Department does not appear to have adequately consulted with public health agencies and has not given sufficient consideration to alternatives,  

255 See Walsh v. Kirby, 13 Cal. 3d 95, 106 (1974) (barring state agency from imposing excessive cumulative penalties “resulting in the de facto revocation of [a] license,”)  
256 See Reckitt Benckiser v. Jackson, 762 F. Supp. 2d 34, 43 (D.D.C. 2011) (barring EPA from effectively cancelling a FIFRA registration without following the appropriate procedures for cancellation).  
258 Cal. Pub. Rscs. Code § 21080.5(c); Cal. Code Reg. tit.14, § 15250; Mountain Lion Found. v. Fish & Game Comm’n, 16 Cal. 4th 105, 114 (Cal. 1997) (“[a]n agency operating pursuant to a certified regulatory program must comply with all of CEQA’s other requirements”).  
including limiting consumer use of SGARs to indoor only use. Thus, DPR has failed to meet its CEQA obligations.

C. The DPR Proposal Duplicates Existing Federal Regulatory Proposals

DPR made the conclusory statement that the proposed rule does not conflict with or duplicate existing statutes or regulations, but failed to analyze the practical effect of EPA’s Risk Mitigation Decision and Notice of Intent to Cancel as it relates to the SGAR-containing products that remain registered in California. This omission violates the state regulation barring duplicative regulations.\textsuperscript{262} The Department is required to “justify any overlap or duplication,”\textsuperscript{263} but the present documents supporting the proposed reclassification have not done so. If ultimately successful, EPA’s NOIC and cancellation hearing will achieve substantially similar results to those currently being sought by DPR. If, applying the legal standard of the federal law, the hearing officer in the cancellation hearing ultimately determines that consumer use SGARs do not generally present unreasonably adverse effects to the environment, the restricted materials reclassification in California can be revisited as appropriate. If DPR issues a final restricted materials rule which exempts small quantity packages of SGAR baits when sold for residential consumer use only and when clearly labeled for indoor uses, the Department will have conserved resources, and reserved its capacity to revisit such products following the U.S. EPA’s cancellation hearing.

D. DPR Has Not Complied with California’s Environmental Justice Mandates

DPR has an obligation to fulfill its responsibilities in a nondiscriminatory manner, in accordance with the requirements of Title VI of the Civil Rights Act and the EPA regulations at 40 C.F.R. Part 7. Further, California law requires that all California EPA departments review their proposals for their impact on low-income and minority populations,\textsuperscript{264} and that DPR “[c]onduct its programs, policies, and activities . . . in a manner that ensures the fair treatment of people of all races . . . and income levels . . . including minority populations and low-income populations.”\textsuperscript{265} The rulemaking record does not reflect any analysis by DPR of how loss of effective rodent control methods will affect low-income and minority communities, inner-city populations, and communities living on Native American reservations and tribal lands. These are precisely the communities that will be affected most severely by the DPR proposal -- both due to the lack of effective rodent control and due to the prohibitive cost of hiring professional rodent control operators. DPR cannot finalize this proposal until it conducts a proper review of the implications of its proposal to these communities. When the Department undertakes the required analysis, we believe it must conclude that it is reasonable and appropriate to provide an exemption from the restricted material designation for small quantity SGAR products clearly labeled for indoor residential consumer use.

\textsuperscript{262}See Cal. Code Reg. tit. 1, § 12.

\textsuperscript{263}Cal. Gov’t Code § 11349(f).


E. DPR Failed to Consult with CDFA as Required by Statute

California Food and Agriculture Code section 11454.2 and the February 6, 1992 Memorandum of Agreement (MOA) developed pursuant to section 11454.2 require that DPR consult with the Department of Food and Agriculture (CDFA) during the development of the text of proposed regulations. Paragraph 5(b) of the MOA says:

DPR will notify CDFA of the development of regulations relating to possession and use of any restricted material pesticide prior to the issuance of a notice of proposed rulemaking. DPR will specify a time period within which CDFA may comment prior to the issuance of the notice of the proposed rulemaking. DPR will respond in writing to all comments made by CDFA.

In addition, section 11454.2(b) requires that DPR consult with CDFA, and that CDFA provide information that “shall include, but not be limited to, (1) impacts on agriculture resulting from the proposed action, (2) benefits derived from the use of the pesticide, and (3) any recommended alternative action.”

DPR reports that such consultation occurred, but there is no evidence of the specific section 11454.2 consultation in the rulemaking file. While a representative from CDFA was on the Pesticide Registration and Evaluation Committee (PREC), according to its Charter, PREC participation is not sufficient to fulfill the consultation requirement. As a result, it appears that DPR failed to fulfill this consultation requirement. Perhaps if DPR had consulted with CDFA as required, CDFA would have informed DPR that making SGARs restricted materials without ensuring the availability of an affordable, safe, and effective alternative would conflict with CDFA’s duty to prevent the spread of injurious animal pests.

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266 Cal. Food & Agric. Code § 11454.2(b).
267 ISOR at 11(Exhibit 1).
268 The PREC Charter (available at http://http://www.cdpr.ca.gov/docs/dept/prec/preccharter.pdf) (Exhibit 85) states that PREC supports DPR in performing its duties and responsibilities under the Food & Agriculture Code, “including Sections 11501, 13150, and 13165, as well as Section 6252 of Title 3 of the California Code of Regulations. It is also determined that the PREC fulfills a critical interagency consultation role mandated by Food & Agriculture Code Section 14103 and the certification of the pesticide regulatory program as functionally equivalent under CEQA.” Absent from this list is Food & Agriculture Code section 11454.2, which contains the DPR/CDFA consultation requirement.
269 Prior DPR rulemaking files contain both DPR’s written memorandum seeking comments and CDFA’s response. Neither of these documents is in the pertinent SGAR rulemaking file. Non-peer reviewer comments that might have been offered by CDFA personnel do not qualify as consultations undertaken in accordance with the FAC and MOA, especially where, as here, the informal comments offered do not address the issues required by section 11454.2(b).
F. There is Ample Precedent in DPR Restricted Material Classifications for Excluding Consumer Uses

Restricted materials designations typically exclude home use, and CDPR likewise should exempt such SGAR products from any final restricted materials designation when they are sold in small quantity packages labeled for indoor uses only by consumers. Indeed, all of the ingredients designated as restricted materials in Cal. Code Regs. Tit. 3, § 6400(e) that are registered for a consumer use contain an exemption for home use.\(^\text{271}\) In practical terms, this reflects that the restricted materials designation was created with the intention to regulate agricultural and professional use of such products, not use by homeowners in small quantity containers that are formulated and labeled for consumers to apply. This intention is further demonstrated by a careful examination of the history of Food and Agricultural Code sections 14004.5 and 14005—the statutes DPR cites as the authority for the proposed restricted materials regulation. While the authority for the proposed regulation appears to be resolved by citation to sections 14004.5 and 14005, the statute’s legislative history reveals that the Legislature did not intend the statutes to extend to pesticides intended for home use.

Sections 14004.5 and 14005 were enacted by Senate Bill 1021 (Nejedly) in 1971 at the request of the Department of Agriculture as part of a more general broadening of the scope of pesticide regulatory activities. The attached bill analysis summary of SB 1021\(^\text{272}\) makes clear that sections 14004.5 and 14005 are limited to the agricultural use of “Injurious Materials.” The summary states:

> Chapter 3, commencing with Section 14001 entitled “Injurious Materials,” is substantially amended to change the existing classification of injurious materials to one of restricted materials based on specified criteria and retaining the present permit system for use in agriculture of these restricted materials and at the same time creates an entirely new classification of exempt materials for use in agriculture. (emphasis added).

Further, the attached Department of Finance’s Enrolled Bill Report to then-Governor Ronald Reagan stated SB 1021 would create “a requirement that users of pesticides must have a permit from the County Commissioner to use pesticides for agricultural purposes.”\(^\text{273}\) Likewise, the attached Department of Agriculture’s Enrolled Bill Report to Governor Reagan described the “widespread support” for the bill “in the agricultural industry including the agricultural chemical industry.”\(^\text{274}\) SB 1021 also amended section 11408 of the Agricultural Code to specifically exclude from the definition of “agricultural use” those “properly labeled packages or containers which are intended for … home use.”

\(^{271}\) See Cal. Code Regs. Tit. 3, § 6400(e).

\(^{272}\) Analysis, SB 1021 relating to Agricultural Chemicals, as amended in Senate June 25, 1971 (Exhibit 86).


\(^{274}\) Id.
Viewed and understood in the proper context, it is evident from the legislative history of SB 1021 that the Legislature had no intent to bring home use pesticides into the purview of sections 14004.5 and 14005. Consequently, sections 14004.5 and 14005 simply do not provide DPR the authority to promulgate this proposed regulation. To do so would be improper and beyond the scope of legislative intent.

The DPR’s proposal would, for the first time, apply the restricted materials designation to a product registered for consumer use without providing an exemption for home use. DPR has not provided any basis to depart from this long-standing precedent and practice, and proceeding with this departure from precedent and practice would be contrary to the Legislature’s intent in passing the statute. Indeed, the evidence presented above and in the exhibits attached demonstrate that it is professional and agricultural use, not home use of SGARs, that pose the greatest risks to non-target wildlife.

G. DPR’s Proposal Does Not Address Internet Bulk Sales of SGARs or intra-state purchase of product outside of California.

As noted in Section III above, it remains unclear how the Department intends to regulate the internet sales of bulk quantities of SGAR products that currently can be purchased without limitation online and by persons who do not hold a PCO or Private Applicator’s license and in buckets containing quantities in excess of 8 pounds in pellet form, and without bait stations.275 These sales provide an outlet to evade restricted use requirements, and the demands for such products are only likely to expand once direct consumer sales of SGARs are barred by DPR. Additionally, these bulk internet sales are a likely route for illegal uses of rodenticide to continue. DPR’s policy goals of protecting wildlife while maintaining the public health are not served by prohibiting the sale to consumers of baits in 3 ounce packages and smaller to consumers but to allow these bulk sales to continue. DPR needs to address the issue of bulk internet sales before it may conclude that its proposal will reduce risks to wildlife sufficient to justify reclassifying all SGAR products as restricted materials.

CONCLUSION

d-CON® appreciates the opportunity to submit the forgoing comments and the numerous attached exhibits. We are hopeful that when the Department completes its review of the rulemaking record as enhanced by these comments and others, as well as the many additional reports and data included herein, that DPR will conclude that it is both reasonable and appropriate to provide an exemption from the restricted material designation for small quantity consumer-use SGAR products that are sold at retail when they are clearly labeled for indoor use only. Such an exemption represents a prudent and practical alternative risk mitigation measure that can provide equivalent protection for non-target wildlife as would the proposed rule, while

maintaining the strong public health benefits that access to affordable and effective rodent control products provides to economically-disadvantaged consumers.
<table>
<thead>
<tr>
<th>Exhibit/Tab Number</th>
<th>Exhibit Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>DPR, Initial Statement of Reasons and Public Report, (“Initial Statement of Reasons”)</td>
</tr>
<tr>
<td>2</td>
<td>DPR Memorandum from D. Daniels, Senior Environmental Scientist, to A. Prichard, Chief, Pesticide Registration Branch, Subject: Second Generation Anticoagulant Rodenticide Assessment (June 27, 2013) , (“White Paper”)</td>
</tr>
<tr>
<td>3</td>
<td>DPR, Economic Impact Statement, Second Generation Anticoagulant Rodenticides, (July 8, 2013), (“Economic Impact assessment”)</td>
</tr>
<tr>
<td>4</td>
<td>DPR, Economic Analysis for Rulemaking, Restricting Second Generation Anticoagulant Rodenticides, June 18, 2013</td>
</tr>
<tr>
<td>13</td>
<td>CDC Letter Submission from S. Buchanan, Director, Div. of Emergency and Environmental Health Services to EPA Office of Pesticide Programs (May 17, 2007) (CDC 2007 Letter Submission)</td>
</tr>
<tr>
<td></td>
<td>Reference</td>
</tr>
<tr>
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</tr>
<tr>
<td>22</td>
<td>James A. McCluskey, MD, PhD, MPH, <em>Analysis of the Human Health Effects of Rodenticides and Response to the 2011 Draft Notice of Intent to Cancel and Denial</em> (Nov. 15, 2011)</td>
</tr>
<tr>
<td>24</td>
<td>R. Kingston, Analysis and Comment Regarding EPA Description of Human Incident Data found in the ‘Impact Assessment for Proposed Rodenticide Mitigation (DP 332577)’ (May 16, 2007)</td>
</tr>
<tr>
<td>26</td>
<td>Exponent, Risks of Rodenticides to Nontarget Wildlife in California (October 2013) (“Fairbrother Report”)</td>
</tr>
<tr>
<td>28</td>
<td>DPR Memorandum from D. Daniels, Sr. Environmental Scientist, to A. Prichard, Chief, Pesticide Registration Branch, <em>Summary of Second Generation Anticoagulant Rodenticides Assessment Peer Review Comments and Responses</em> (June 27, 2013) (“DPR Peer-Review Comment Responses”)</td>
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<tr>
<td></td>
<td>Title</td>
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<td>----------------------------------------------------------------------</td>
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<tr>
<td>29</td>
<td>DPR Memorandum from D. Daniels to A. Prichard, <em>Summary of Second Generation Anticoagulant Rodenticides Assessment Comments and Responses</em> (June 27, 2013) (“DPR Comment Responses”)</td>
</tr>
<tr>
<td>33</td>
<td>Richard K. Stroud, DVM, MS, Evaluation of June 27, 2013 Memorandum from Department of Pesticide Regulation Relative to Cause of Death in Non Target Wildlife Attributable to SGARs (Oct. 4, 2013) (“Stroud Report”)</td>
</tr>
<tr>
<td>35</td>
<td>Domestic Cat Predation on Birds and Other Wildlife, American Bird Conservancy</td>
</tr>
<tr>
<td>36</td>
<td>EPA Scientific Advisory Panel (SAP), Memorandum From J. Bailey, et al., FIFRA Scientific Advisory Panel to S. Bradbury, Ph.D., Director Office of Pesticide Programs, Transmittal of Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting held Nov. 29-Dec. 1, 2011 on Scientific Conclusions Supporting EPA’s FIFRA Section 6(b) Notice of Intent to Cancel Twenty Homeowner Rodenticide Bait Products (Dec. 29, 2011) (“SAP Report”)</td>
</tr>
<tr>
<td>37</td>
<td>U.S. Fish &amp; Wildlife Service, South Farallon Islands Invasive House Mouse Eradication Project: Draft Environmental Impact Statement at 8, Table 2.5 (August 2013)</td>
</tr>
<tr>
<td>38</td>
<td>Risks of Rodenticides to Nontarget Wildlife: Comments on EPA’s Risk Assessment and Mitigation Options (Fairbrother SAP Report”)</td>
</tr>
<tr>
<td>40</td>
<td>DPR Product Compliance Branch, Frequently Asked Questions and Answers (Rev. May 13, 2011)</td>
</tr>
<tr>
<td></td>
<td>Reference</td>
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<tr>
<td>---</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>41</td>
<td>DPR Press Release, “DPR collects $1.6 million in unpaid environmental fees, penalties,” (Dec. 27, 2005)</td>
</tr>
<tr>
<td>43</td>
<td>ASPCRO/NPMA, Rodenticide Use of Pest Management Professionals (2013)</td>
</tr>
<tr>
<td>46</td>
<td>J. Lyon, EAS Consulting Group LLC, <em>Use of Rodenticides in U.S. Foodservice and Retail Food Establishments</em> at (Oct. 4, 2013)</td>
</tr>
<tr>
<td>47</td>
<td>M. Bandurraga, EAS Consulting Group LLC, <em>Use of Rodenticides as Part of Overall Pest Control Practices in Food Manufacturing and Warehouse Sites</em> at 3, 6-9 (Oct. 1, 2013)</td>
</tr>
<tr>
<td>49</td>
<td>A. Fairbrother, <em>Variation in the Relative Prevalence of Brodifacoum, Bromadiolone, and Bromethalin in Small Mammals by Urban Land Use</em> (March 2013)</td>
</tr>
<tr>
<td>55</td>
<td>Clarus, Preliminary Report of Pest Control Operator Survey Data Confidential Communication Prepared at Request of Counsel (July 2012)</td>
</tr>
<tr>
<td>56</td>
<td>Clarus, California Statewide Survey of d-CON Rodenticide Bait Users (July-August 2013)</td>
</tr>
<tr>
<td>57</td>
<td>2012-04-20 L. Culleen letter to Jim Jones re Bulk Online Sales (with attachments)</td>
</tr>
<tr>
<td>58</td>
<td>2012-09-05 L. Culleen letter to Jim Jones re Bulk Online Sales</td>
</tr>
<tr>
<td>60</td>
<td><a href="http://tinyurl.com/mdp5trv">http://tinyurl.com/mdp5trv</a>; (internet site advertising 12 pound bucket of brodifacoum product)</td>
</tr>
<tr>
<td>63.1</td>
<td>Department of Pesticide Regulation, Second Generation Anticoagulant Rodenticides Meeting With Registrants Agenda, February 26, 2013</td>
</tr>
<tr>
<td>63.3</td>
<td>DPR, Untitled Chart, February 25, 2013.</td>
</tr>
<tr>
<td>65</td>
<td>Caravati et al., <em>Long-Acting Anticoagulant Rodenticide Poisoning: An Evidence-Based Consensus Guideline for Out of Hospital Management</em>, 45 Clinical Toxicology 1 (2007)</td>
</tr>
<tr>
<td>68</td>
<td>A. Brutlag, DVM, MS, <em>Impact of EPA’s Notice of Intent to Cancel and Notice of Denial of Registrations for Certain Rodenticide Bait Products on Domestic Animals</em> (“Brutlag SAP Report”)</td>
</tr>
<tr>
<td>70</td>
<td>S. Gray, DVM, DACVECC, <em>Impacts on Domestic Animals of the California Department of Pesticide Regulation’s Proposed Restricted Use Classification for Second Generation Anticoagulant Rodenticide Products</em> (Oct. 4, 2013)</td>
</tr>
<tr>
<td>75</td>
<td>Comparison Matrices for the Alternative Selection Process for the Farallon House Mouse Eradication DEIS,</td>
</tr>
<tr>
<td>77</td>
<td>G. Murphy, and A. Felix-Thomas, <em>The Influence of bait presentation on bait consumption by urban mice</em> (<em>Mus domesticus</em>) in domestic dwellings, University of Salford.</td>
</tr>
<tr>
<td>79</td>
<td><a href="http://stuffaboutstates.com/california/agriculture.htm">http://stuffaboutstates.com/california/agriculture.htm</a></td>
</tr>
<tr>
<td></td>
<td>(“Danner &amp; Hamm BSG Report”)</td>
</tr>
<tr>
<td>---</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>83</td>
<td>Federal Deposit Insurance Commission, Key Overall Findings: The 2011 National Survey of Unbanked and Underbanked Households (2011)</td>
</tr>
<tr>
<td>84</td>
<td>Statement of Laurent Faracci Regarding Cost Impact to d-CON of CDPR Proposal</td>
</tr>
<tr>
<td>85</td>
<td>PREC Charter</td>
</tr>
<tr>
<td>86</td>
<td>Analysis of SB 1021, relating to Ag Chemicals as amended in Senate 6-25-71</td>
</tr>
<tr>
<td>87</td>
<td>Deptartment of Finance Enrolled Bill Report (SB 1021)</td>
</tr>
<tr>
<td>89</td>
<td>Cantor and Schmier “Preliminary Review and Report on Impact Assessment for Proposed Rodenticide Mitigation”</td>
</tr>
<tr>
<td>91</td>
<td>Economic Concerns Created by EPA’s Draft Notice of Intent to Cancel 20 Consumer Use Rodenticides (“Ambuter SAP Report”)</td>
</tr>
</tbody>
</table>