UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In re FIFRA Section 6(b) Notice of Intent to Cancel Registrations of, and Notice of Denial of Applications for, Certain Rodenticide Bait Products	)))))	Docket No. ____

REQUEST FOR HEARING AND

STATEMENT OF OBJECTIONS OF RECKITT BENCKISER LLC

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Reckitt Benckiser LLC ("Reckitt" or "the Company") hereby requests a hearing pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") Section 6(b), 7 U.S.C. § 136d(b), and FIFRA Section 3(c)(6), 7 U.S.C. § 136a(c)(6), to contest the actions proposed in the U.S. Environmental Protection Agency's ("EPA" or the "Agency") February 5, 2013 Notice of Intent to Cancel Registrations of, and Notice of Denial of Applications for, Certain Rodenticide Bait Products ("the NOIC") with respect to each of the Affected Products as defined below and enumerated in Section C of the Statement of Facts, *infra.*[1]

INTRODUCTION

1. The NOIC seeks to cancel the registrations of 12 consumer-use rodenticide products (the "Subject Products"), all of which are registered by Reckitt. *See* Exhibit 1. The NOIC also denies the applications for registration of two additional rodenticide products (the "Pending Registrations") that Reckitt submitted to the Agency. *See* Exhibit 2. (The Subject Products and Pending Registrations are referred to collectively as the "Affected Products.") Because the actions proposed in the NOIC are both substantively and procedurally inconsistent with the requirements of FIFRA and other applicable law, they must be rejected.

2. In the case of public health pesticides such as the Affected Products, FIFRA Section 2(bb) mandates that the Agency must rigorously evaluate: 1) the risks and benefits of each product proposed for cancellation; and 2) the public health benefits the product provides —

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[1] 78 Fed. Reg. 8123 (Feb. 5, 2013), *available at* http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2013-0049-0011 (hereinafter "NOIC"). As used here, "NOIC" refers to both the Notice and to the accompanying Statement of Reasons and Factual Basis for Notice of Intent to Cancel Registrations of, and Notice of Denial of Applications for, Certain Rodenticide Bait Products (EPA-HQ-OPP-2013-0049-0003) (hereinafter "Statement of Reasons").

specifically, health risks such as the diseases transmitted by the vector to be controlled by the pesticide. Reckitt opposes the Agency's proposed actions because EPA has failed to meet these requirements. For example,

- EPA proposes to ban from the consumer market some of the most effective and affordable household-use rodenticide products available, leaving consumers to choose between less effective means of rodent control, products that contain highly toxic active ingredients for which there are no antidotes, or costly pest control professionals.

- EPA has ignored the numerous concerns raised by the Agency's Scientific Advisory Panel ("SAP") that alternatives to the Affected Products are ineffective, and that, because rodents that are resistant to alternative products, they will multiply if the Subject Products are cancelled.

- Likewise ignoring the SAP's urging, the Agency has failed to assess the numerous important benefits of the Affected Products in combating the public health consequences of rodent infestations — including the serious diseases that these rodents transmit — that significantly outweigh any risks posed by the Affected Products.

- The NOIC overstates the risks to children and pets from accidental exposures to the Affected Products — which are in fact minimal — while proposing to allow registrants to market alternative products that are highly toxic and have no antidotes, posing substantially increased risks to children and pets.

- EPA's proposed actions imply, illogically and without scientific support, that a rodenticide bait placed behind a refrigerator inside a home by a consumer poses a greater risk to wildlife than a rodenticide containing the same active ingredient placed outdoors by a professional applicator. Although the Agency has provided no evidence that the Affected Products, used indoors, have had any adverse effects on wildlife populations generally, the Agency proposes to cancel these products while continuing to allow products containing the same active ingredients in the same physical form to be sold in bulk to farmers, pest control professionals, and anyone who makes purchases online.

- The Agency grossly underestimates the extent to which cancellation of the Subject Products would increase the cost of consumer-use rodenticides, forcing many consumers to use less effective alternatives or even forgo rodent control altogether. In particular, the Agency has failed to assess objectively the economic impact and public health consequences that elimination of affordable and effective rodent control products like the Affected Products will have on urban dwellers, economically challenged communities, and other persons who reside in multi-family housing units where rodent infestations frequently occur.

- Reckitt repeatedly offered practical solutions to the concerns EPA has raised, including proposed labeling amendments to limit the Affected Products to indoor uses only, abbreviate their application periods, enhance directions for use, and implement an education program for product users. But EPA has failed even to evaluate Reckitt's proposals for risk mitigation, even though the Agency has accepted similar mitigation measures for other consumer use products (*e.g.*, insect foggers and flea/tick treatment products).

3. The Agency issued its NOIC only after Reckitt brought suit to enforce its right to a hearing, winning an injunction against the Agency's unlawful attempt to impose the requirements of the RMD through threats of enforcement action, rather than through the FIFRA Section 6 cancellation procedure. EPA now seeks to penalize retailers who have lawfully acquired the Subject Products, and to punish Reckitt for seeking to exercise its right to a hearing under FIFRA, by refusing to allow the sale of existing stocks of the Subject Products following the proposed cancellation — even while allowing a sell-through period for similar, voluntarily cancelled products. The Agency has gone so far as to attempt, in contravention of applicable law and EPA's own precedent, to exclude this issue from the scope of the requested cancellation hearing.

4. For these and the numerous other reasons set forth below, Reckitt objects to the Agency's NOIC, and requests the hearing to which the Company is entitled, and which it has long sought, under Section 6 of FIFRA.

STATEMENT OF FACTS

A. Description of Reckitt and d-CON Products

5. Reckitt is the registrant of d-CON brand rodent control products, which are sold solely for consumer use and are widely available throughout the United States. These products are affordable and effective. The Company's d-CON rodenticide product line is, and long has been, the leading retail brand of rodenticide products in the United States.

6. Reckitt's current d-CON product line includes both traps and rodenticide baits intended for consumer use. The d-CON rodenticide products that are identified in the NOIC include several containing the active ingredient warfarin (a first generation anticoagulant rodenticide, or "FGAR"), as well as others that are formulated with brodifacoum or difethialone (second generation anticoagulant rodenticides, or "SGARs"). Most of these rodenticide products are produced in a pellet format, which is the form that rodents consume most readily. As described more fully below, the NOIC seeks to cancel the registrations of 12 of Reckitt's products because the Subject Products do not fully conform to certain requirements announced by EPA in its 2008 "Risk Mitigation Decision" (or "RMD").[2] *See* Exhibit 3.

7. In 2010, Reckitt applied for registration of two additional rodenticide products. These products were formulated as rodenticide baits containing the active ingredient brodifacoum, an SGAR, in block form, packaged in an RMD-conforming tamper-resistant bait station. *See* Exhibit 2. In its NOIC, the Agency denied Reckitt's applications to register these two products for "essentially the same [reasons] as those that form the basis for the cancellations,"[3] *i.e.*, because they contain SGARs.

8. In May 2011, Reckitt amended and supplemented its applications for the Pending Registrations, providing new studies and proposing changes to the product labels, including a limitation to indoor use only. *See* Exhibit 4. In 2012, Reckitt submitted applications proposing even more comprehensive label amendments for the eight Affected Products containing SGARs. In addition to limiting all of these products to indoor residential uses only, these proposed label

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[2] Reckitt also holds and maintains registrations for rodent control products that fully conform to EPA's 2008 "Risk Mitigation Decision" (or "RMD") and was the first registrant to seek and successfully receive EPA authorization for a rodenticide bait station that meets the RMD requirements. These products are not subject to the NOIC.

[3] Statement of Reasons at 1, n.1.

changes ("the Proposed Label Amendments") would have limited the duration of the products' application and implemented changes to increase consumer awareness of and compliance with use limitations — including the addition of comprehensive Spanish-language warnings and enhanced directions for use. *See* Exhibit 5. EPA never responded to these submissions, and to the Company's knowledge the Agency has never performed the assessment of these proposed amendments required by FIFRA Sections 2(bb) and 3(c).

B. Regulatory History

9. EPA has regulated rodenticides since the Agency's inception in 1970. Pursuant to FIFRA, the Agency may register a rodenticide only after determining, *inter alia*, that it will perform its intended function without unreasonable adverse effects on the environment and that, when used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment.[4] In addition, registered rodenticides are subject to periodic re-evaluation through an ongoing registration review process,[5] and, for rodenticides first registered before November 1, 1984, a re-registration process.[6]

10. Currently, rodenticide products contain active ingredients that fall into two basic categories: 1) acute and sub-acute toxins (also referred to as "non-anticoagulants"); and 2) anticoagulants.

11. The class of acute and sub-acute toxins includes bromethalin, cholecalciferol, and zinc phosphide. There are no known antidotes for any of these toxins. Treatment is limited to supportive care and management of symptoms.

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[4] 7 U.S.C. § 136a(c)(5).

[5] *See* 7 U.S.C. § 136a(g).

[6] 7 U.S.C. § 136a-1(a).

12. Bromethalin is a nerve toxin that causes swelling of the brain and, ultimately, respiratory distress. Cholecalciferol causes hypercalcemia (excessive calcium) in the blood and other body tissues, leading to renal failure, cardiac abnormalities, and other effects. Zinc phosphide interacts with stomach acid resulting in the liberation and subsequent absorption of phosphine gas in the stomach, leading to damage to blood vessels and eventual cardiovascular collapse.

13. All anticoagulant rodenticides (both FGARs and SGARs) have the same basic mechanism: they interfere with blood clotting, causing death from hemorrhage. Anticoagulant active ingredients are divided into two categories: FGARs, such as warfarin and diphacinone; and SGARs, such as brodifacoum and difethialone. FGARs and SGARs are derived from the same organic chemical compound, and have the same anticoagulant mechanism, as Coumadin, a widely-prescribed and well-studied human drug.

14. FGARs were the first anticoagulant rodenticides introduced into the market in the 1950s to address concerns about human and pet exposure to strychnine and other acute and sub-acute toxins in use at that time. To be effective, FGARs typically require rodents to feed on the baits continuously over a number of days. However, it soon became apparent that rodent populations were rapidly developing resistance to these active ingredients.

15. As a result, SGARs were developed in the 1970s as resistance-breaking molecules. They also had the added advantage of providing a lethal dose in a single feeding. While resistance to lower potency SGARs has developed at least in Europe, there have been no reported instances of practical resistance to the higher potency SGARs (brodifacoum and difethialone) notwithstanding more than 30 years of commercial use.

16. In the event of accidental ingestion of a toxic dose, anticoagulant rodenticide poisoning is readily treated with Vitamin K, a widely available antidote. A comprehensive peer-reviewed assessment of available data published in a national journal concluded that during the 20-year period studied, no child ever died from accidental exposure to a product containing an SGAR, and the overwhelming majority of such exposures required no medical treatment at all.

17. Over the years, EPA has registered dozens of rodenticide products containing anticoagulant rodenticides, including various d-CON products. For nearly 40 years, EPA has registered rodenticides that contain SGARs as the active ingredient.

18. In January 2007, the Agency issued a Proposed Risk Mitigation Decision for Nine Rodenticides[7] purporting to address potential risks presented by the nine rodenticide active ingredients registered at that time by proposing to classify SGARs for restricted use.[8] In response, Reckitt and numerous other registrants submitted comments on EPA's proposal. Reckitt's comments were accompanied by reports from several experts, which, among other things, documented the importance of the SGAR products in the control of rodents by American consumers and the continuing problem of resistance in U.S. rodent populations to FGARs (*see* Exhibit 6); made clear to EPA the manner in which the Agency had incorrectly interpreted data concerning reports of accidental exposures to children (*see* Exhibit 7); and assessed the economic and related impacts that the 2007 Proposed Risk Mitigation Decision would have on consumers and its disproportionate and unintended consequences on minority populations and economically disadvantaged Americans (*see* Exhibit 8).

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[7] EPA, *Proposed Risk Mitigation Decision for Nine Rodenticides* (Jan. 17, 2007), *available at* http://www.sfromp.org/rodenticides_mitigation_decision.pdf.

[8] Products that are classified for restricted use generally may be purchased and used only by applicators who have received training in accordance with EPA regulations and are licensed to apply such restricted use products. *See* 40 CFR Subpart I, 152.160-175.

19. On June 24, 2008, EPA issued its final Risk Mitigation Decision ("RMD") for Ten[9] Rodenticides,[10] which required registrants to satisfy certain risk mitigation measures ("RMMs"). Among other things, these RMMs provided that consumer-use rodenticides: 1) could no longer be formulated with SGARs; 2) could be sold only with at least one tamper-resistant bait station; 3) could be sold only in block form; and 4) were limited to a total maximum net contents of one pound of bait. *See* Exhibit 3 at 17-18. The intent of these proposed measures was to prohibit the sale to retail consumers of: all products containing SGARs; all rodenticide baits, regardless of active ingredient, produced in pellet, granular, meal, or liquid product forms; and, all rodenticide baits sold without a conforming bait station.

20. EPA asserts that the RMMs will reduce potential adverse effects on humans and the environment for two reasons. First, according to the Agency, the prohibition against consumer use of non-block form bait — *e.g.*, pellets or meal — along with the bait station requirement will protect children, domestic animals, and wildlife ("non-target organisms" or "NTOs") from accidental and unintended direct exposure to such rodenticides. Second, the Agency asserts that exclusion of SGARs from the general consumer market will reduce secondary exposure (*i.e.*, exposure through the food chain) among NTOs that prey or scavenge on commensal rodents.[11]

21. In its RMD, EPA did not prohibit the sale of such products to professional pest control operators ("PCOs") or to users who purchase rodenticides in bulk (greater than eight

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[9] Difenacoum, a new SGAR, was registered in September 2007, bringing to ten the total number of rodenticides addressed by the final RMD.

[10] EPA, *Risk Mitigation Decision for Ten Rodenticides* (May 28, 2008; as updated June 24, 2008), *available at* http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&d=EPA-HQ-OPP-2006-0955-0764 (hereinafter "RMD").

[11] Statement of Reasons at 45-89.

pounds) in feed stores and similar establishments.[12] Such bulk products may be sold in pellet or block form, and there is no requirement that even a single bait station be packaged with these bulk products. Moreover, nothing in the RMD prohibits sales of these bulk products by online vendors to the general public, and the Agency has taken no steps to prevent such sales. *See* Exhibits 9 and 10.

22. Pursuant to the RMD, EPA requested that registrants agree voluntarily to cancel all consumer-use products that did not comply with the RMMs — a category that included many Reckitt products. Specifically, the RMD directed registrants of affected products to "provide a letter to the Agency on or before September 2, 2008, declaring an intent to comply or not comply with the risk mitigation measures described in this document."[13] The RMD further provided that "[f]or each registered product for which a registrant declared its intent not to comply . . . the company need[ed] to include a request to cancel that product."[14]

23. The RMD also stated that "June 4, 2011 would be the last day for registrants to 'release for shipment' (sell or distribute) rodenticide products not complying with the Risk Mitigation Decision," that "[r]odenticide products that do not comply with this Risk Mitigation Decision that a registrant releases for shipment after June 4, 2011, would be considered misbranded," and that registrants who released such products after that date would be subject to enforcement action.[15]

24. Because Reckitt disagreed with EPA's assessment of the comparative risks and benefits of the Affected Products, the Company timely advised EPA by letter dated August 28,

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[12] The final RMD did not require that PCO's be trained or certified in accordance with EPA's regulations for applicators of products that are classified for restricted use.

[13] RMD at 25.

[14] *Id.* at 25-6.

[15] *Id.* at 26.

2008 that it did not intend to cancel voluntarily the registrations affected by the RMD. Reckitt also repeatedly — orally and by letters dated November 11, 2008 and Jan 9, 2009 — asked the Agency to undertake cancellation proceedings under FIFRA Section 6.

25. Had EPA acceded to Reckitt's original request to comply with Section 6 procedures, the Company would have sought a hearing to challenge the conclusions of the RMD, and the matter would have been addressed well before EPA's June 2011 deadline.

26. EPA, however, refused to bring cancellation proceedings and continued to assert that it could take enforcement actions against the Company without using the FIFRA Section 6 procedures. Consequently, the Company brought suit in the United States District Court for the District of Columbia, asserting that the Agency had abused its discretion by attempting to impose the requirements of the RMD through threats of enforcement action rather than through the FIFRA Section 6 cancellation procedure. The federal court agreed, holding that EPA had acted arbitrarily and capriciously in violation of FIFRA, which "entitles the registrant to notice, a hearing and other procedural protections before EPA can make a final decision on cancellation," and enjoined enforcement action until those procedures were followed.[16]

27. On November 2, 2011, EPA issued a Draft Notice of Intent to Cancel and Notice of Denial[17] (the "Draft NOIC"), which set forth in draft form EPA's intention to cancel Reckitt's registrations of the 12 Subject Products, and stated the Agency's intention to deny Reckitt's applications for the 2 Pending Registrations.

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[16] *Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34, 43 (D.D.C. 2011).

[17] EPA, *Draft Notice of Intent to Cancel and Notice of Denial of Registration for Certain Rodenticide Products* (Nov. 2, 2011), *available at* http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2013-0049-0006.

28. EPA is required by FIFRA Section 25 to convene a Scientific Advisory Panel ("SAP") to provide comments to the Agency "on the impact on health and the environment" of proposed cancellation actions.[18] From November 29 through December 1, 2011, EPA convened a SAP to review the scientific basis of the Draft NOIC. The SAP included independent experts in wildlife biology, veterinary medicine, eco-toxicology, and other relevant fields. Reckitt submitted written comments, as well as testimony by technical and scientific experts, for the SAP's consideration. *See* Exhibit 11.[19] On December 29, 2011, the SAP issued meeting minutes summarizing its conclusions, many of which (as discussed below) challenged EPA's positions.[20] *See* Exhibit 12.

29. On February 20, 2012 and March 14, 2012, EPA issued memoranda communicating its decision to relax the RMMs for professional and agricultural-use outdoor applications of commensal rodenticide products. *See* Exhibit 14. Rather than require that professional and agricultural users place these products no further than 50 feet from an actual building, the RMMs now allow such users to place them up to 100 feet from any "man-made structures" such as dumpsters, docks, and aircraft. This decision vastly increased the area in

[18] 7 U.S.C. § 136w(d).

[19] A factual error in one of the expert presentations was subsequently corrected, and Reckitt re-submitted it to EPA. The corrected presentation, along with the covering letter sent to the Agency, is included in Exhibit 13.

[20] FIFRA Scientific Advisory Panel, SAP Minutes No. 2011-06 (Dec. 29, 2011), *available at* http://www.epa.gov/scipoly/sap/meetings/2011/112911finalsap_mtg_mins.pdf (hereinafter "SAP Minutes"). EPA provided a response to the SAP comments January 29, 2013. The EPA response generally fails to address the substance of the SAP's comments, for the most part restating EPA's positions from the SAP meeting, and in several cases dismissively asserting that the SAP's comments "[do] not appear to fall within the mandate of SAP," *see, e.g.*, EPA Response to SAP at 5 & 6 (responding to SAP comments on the absence of a benefits analysis in EPA's draft NOIC). Except in the instance of a limited probabilistic risk assessment, *see* Paragraph 75, *infra,* EPA does not purport to have conducted any additional scientific research or studies in response to the SAP's recommendations.

which NTOs might encounter rodenticides.[21] Neither the memorandum, the NOIC, nor any other published Agency document attempts to assess the risks associated with this increase, or considers how it might affect the relative risks and benefits of consumer-use rodenticides. There is nothing in the record suggesting that the SAP was asked to consider these changes, or reflecting that HHS or USDA was advised of them when those agencies were asked to comment on the draft NOIC.

30. Pursuant to FIFRA's requirement that the Secretary of the Department of Health and Human Services ("HHS") provide benefits and use information in connections with cancellation of a pesticide's public health use, on April 19, 2012, representatives at the Centers for Disease Control ("CDC") provided a cursory one-page response to the draft NOIC.[22] *See* Exhibit 15. This response did not contain any new analysis of public health issues associated with the proposed cancellation. Instead, it referred EPA to comments the CDC provided nearly five years earlier in response to the Agency's 2007 Risk Mitigation Proposal, a document proposing substantially different risk mitigation measures than those in the draft or final RMDs.

31. Similarly, at least 60 days before publishing a NOIC, EPA must notify and provide the Secretary of Agriculture with a draft copy of the NOIC and an analysis of the impact of cancellation on the agricultural community. By letter dated April 11, 2012, the U.S. Department of Agriculture communicated its brief comments. *See* Exhibit 16.

32. On February 5, 2013, the Agency published its NOIC and Statement of Reasons and Factual Basis for the NOIC. Together, these documents confirm and restate the Agency's

[21] The decision to increase the radius alone quadrupled the area where NTOs might encounter rodenticides. In addition, the decision to allow placement near any "man-made structure," not just buildings, multiplied the area immeasurably.

[22] Memorandum from Eric E. Wachter, Executive Secretariat, EPA, to J. Ronald Campbell, Executive Secretariat, Centers for Disease Control and Prevention (Apr. 19, 2012), *available at* http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2013-0049-0007.

decision to cancel 12 Reckitt rodenticide registrations and deny Reckitt's applications for registration of 2 additional rodenticides products.

C. The Affected Products

33. EPA seeks to cancel or deny registration of the following Reckitt products:

Reckitt Products Subject to Proposed Cancellation				
Product	**EPA Reg. No.**	**Active Ingredient**	**Form**	**Use**
d-CON Concentrate Kills Rats & Mice	3282-3	Warfarin	Powder	For control of Norway rats, roof rats, and house mice in and around homes, industrial buildings, and similar man-made structures.
d-CON Ready Mixed Kills Rats & Mice	3282-4	Warfarin	Bait Bits	For control of Norway rats, roof rats, and house mice in and around homes, industrial buildings, and similar man-made structures.
d-CON Mouse Prufe Kills Mice	3282-9	Warfarin	Pellets	For control of house mice in and around homes, industrial buildings, and similar man-made structures.
d-CON Pellets Kills Rats & Mice	3282-15	Warfarin	Pellets in Place Pack[23]	For control of Norway rats, roof rats, and house mice in and around homes, industrial buildings, and similar man-made structures.
d-CON Mouse Prufe II	3282-65	Brodifacoum	Pellets	To control house mice in homes, industrial, commercial, agricultural, and public buildings.
d-CON Pellets Generation II	3282-66	Brodifacoum	Pellets	To control Norway Rats, Roof Rats, and House Mice in and around homes, industrial, commercial, agricultural, and public buildings; in transport vehicles (ships, trains, aircraft)

[23] A place pack is a single-use package containing rodenticide; rodents are able to chew through the packaging and consume the rodenticide pellets inside.

Reckitt Products Subject to Proposed Cancellation				
Product	**EPA Reg. No.**	**Active Ingredient**	**Form**	**Use**
				and in and around related port or terminal buildings.
d-CON Bait Pellets II	3282-74	Brodifacoum	Pellets in Place Pack	To control House Mice in and around homes, industrial, commercial, agricultural, and public buildings; in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings.
d-CON Ready Mixed Generation II	3282-81	Brodifacoum	Crushed Pellets	To control Norway Rats, Roof Rats, and House Mice in and around homes, industrial, commercial, agricultural, and public buildings; in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings.
d-CON Mouse-Prufe III	3282-85	Difethialone	Pellets	To control house mice in homes, industrial, commercial, agricultural, and public buildings.
d-CON Bait Pellets III	3282-86	Difethialone	Pellets	To control Norway Rats, Roof Rats, and house mice in urban areas in and around homes, industrial, commercial, agricultural, and public buildings, and in transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings; in non-urban areas, inside homes and agricultural buildings.
d-CON II Ready Mix Baitbits III	3282-87	Difethialone	Crushed Pellets	same as above
d-CON Bait Packs III	3282-88	Difethialone	Pellets in Place Pack	same as above

Denied Reckitt Applications for Registration				
Product	**EPA Reg. No.**	**Active Ingredient**	**Form**	**Use**
d-CON Bait Station XV Kills Mice	3282-RNU	Brodifacoum	Bait Block in Tamper-resistant Bait Box	To control house mice in homes.
d-CON Bait Station XV Kills Mice	3282-RNL	Brodifacoum	Bait Block in Tamper-resistant Bait Box	To control house mice in homes.

34. In addition, the Agency has failed to respond to applications submitted by Reckitt requesting that EPA approve the following Proposed Label Amendments:

Proposed Label Amendments				
Product	**EPA Reg. No.**	**Active Ingredient**	**Form**	**Proposed Amendment and Submission Date**
d-CON Mouse Prufe II	3282-65	Brodifacoum	Pellets	Indoor use only; bilingual text; bold warnings that product should be used and stored away from food and in areas that children and pets cannot access; enhanced graphics to emphasize warnings and proper use and placement; improved instructions for effective home rodent control; reduced application time (from 15 to 7 days); streamlined first aid information. (Submitted October 1, 2012.)
d-CON Bait Pellets	3282-66	Brodifacoum	Pellets	Same as above.
d-CON Bait Pellets II	3282-74	Brodifacoum	Pellets in Place Pack	Same as above.
d-CON Ready Mixed Bait Bits	3282-81	Brodifacoum	Crushed Pellets	Same as above.
d-CON Mouse prufe III	3282-85	Difethialone	Pellets	Same as above. (Submitted November 26, 2012.)
d-CON bait pellets III	3282-86	Difethialone	Pellets	Same as above.
d-CON ready-mixed Bait Bits III	3282-87	Difethialone	Crushed Pellets	Same as above.

d-CON bait packs III	3282-88	Difethialone	Pellets in Place Pack	Same as above.
d-CON bait station XVI kills mice	3282-RNL	Brodifacoum	Bait Block in Tamper-resistant Bait Box	Indoor use only; resistant to tampering; bold warnings that product should be used and stored away from food and in areas that children and pets cannot access; enhanced graphics to emphasize proper use and placement; streamlined first aid information. (Submitted May 20, 2011.)
d-CON bait station XV kills mice	3282-RNU	Brodifacoum	Bait Block in Tamper-resistant Bait Box	Same as above.

STATEMENT OF APPLICABLE LAW

35. The law applicable to EPA's proposed actions in this matter includes FIFRA's standards for registration, FIFRA's requirements for a rigorous risk/benefit analysis of public health pesticides, relevant authority on the disposition of Existing Stocks, several pertinent Executive Orders, and the Administrative Procedure Act ("APA"). As described more fully below, the actions EPA proposes in its NOIC violate each of these legal requirements.

A. FIFRA Standards for Public Health Pesticides

36. To cancel a registered pesticide, EPA must make the substantive determination that the pesticide "generally causes unreasonable adverse effects on the environment."[24] FIFRA defines the term "unreasonable adverse effects on the environment" to mean "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."[25] In addition, because rodenticides control

[24] 7 U.S.C. § 136d(b).

[25] 7 U.S.C. § 136(bb).

disease vectors and are therefore classed as public health pesticides,[26] EPA must "weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide."[27]

37. Similarly, if, upon review of an application for registration, EPA determines that: 1) the rodenticide under consideration will perform its intended function without unreasonable adverse effects on the environment; and 2) when used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment, the Agency must register the product.[28]

38. FIFRA requires EPA to notify applicants if an application for registration has been denied, and to provide the reasons and factual basis for EPA's decision.[29] EPA is also required to provide applicants 30 days to address and resolve any issues EPA identifies in the application.[30] The Agency's Notice of Denial must be published in the Federal Register, along with the reasons and factual basis for the denial. *See* 7 U.S.C. § 136a(c)(6); *see also* 40 C.F.R. § 152.118(d).

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[26] In collaboration with HHS, the Department of Agriculture and the Public Health Service EPA has defined "pests of significant public health importance" to include commensal rodents. *See* EPA, *Pesticide Registration Notice 2002-1* 14, *available at* http://www.epa.gov/PR_Notices/pr2002-1.pdf (listing commensal rats and house mice among mammalian pests of significant public health importance). In addition, EPA itself acknowledged at the SAP meeting that the rodenticides subject to the draft NOIC are public health pesticides pursuant to 7 U.S.C. § 136(bb). *See* Compact Disk Recordings of SAP meeting, obtained from Joseph Bailey, EPA Office of Science Coordination and Policy, May 9, 2012.

[27] *Id.*

[28] 7 U.S.C. § 136a(c)(5). FIFRA also requires that a pesticide's composition is such as to warrant the proposed claims for it and that its labeling and other material required to be submitted comply with applicable requirements. 7 U.S.C. § 136a(c)(5). However, these requirements are not at issue here.

[29] *See* 7 U.S.C. § 136a(c)(6).

[30] *See id; see also* 40 C.F.R. § 152.118(b) & (c) (requiring EPA to notify registrants by certified letter "if EPA determines that an application should be denied," and to provide the applicant 30 days "to take the specified corrective action.")

39. FIFRA requires a rigorous risk-benefit assessment that employs the best available scientific and economic analyses.[31] The required risk assessment process has four steps: hazard identification; exposure assessment; dose/response assessment; and risk characterization.[32] A benefits analysis takes into account both biological and economic factors.[33] Biological factors involve information about target pests on each site at which the product will be used, which are referred to as "registered use sites."[34] Because economic impacts are dependent on the registered use sites of the pesticide in question, "EPA must do a benefits assessment for each registered use site."[35]

40. The mandatory risk-benefit analysis is an individualized determination for each product, rather than a determination for a group or category of products. FIFRA Section 6 refers to EPA's determination that a "pesticide" no longer meets the FIFRA standard and that the Administrator may therefore either "cancel *its registration*" or hold a hearing to determine "whether or not *its registration* should be canceled or *its classification* changed."[36] The FIFRA registration criteria require that EPA make a determination as to whether "a pesticide" meets the requirements of FIFRA Section 3(c)(5).[37] In a cancellation hearing, EPA has the burden to

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[31] EPA, *Environmental Fact Sheet: Risk/Benefit Balancing under the Federal Insecticide, Fungicide, and Rodenticide Act*, 1 (Feb. 1990), *available at nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=9100CFR2.txt.* Note that this document was published prior to 1996 amendments to FIFRA that mandated additional review for public health pesticides. *See* 7 U.S.C. § 136(bb).

[32] *Id.* at 2.

[33] *Id.* at 3.

[34] *Id.*

[35] *Id.* (emphasis in original).

[36] 7 U.S.C. § 136d(b) (emphasis added).

[37] 7 U.S.C. § 136a(c)(5).

"present an affirmative case for the cancellation or change in classification of *the* registration."[38] Thus, to justify cancellation or denial of the Affected Products, the Agency must make a product-by-product determination that the risks of each product outweigh the public health and other benefits of that product.

41. In order to assess correctly potential risks and benefits for each individual pesticide product, EPA must separately evaluate each specific pesticidal active ingredient. EPA also must separately evaluate the risks and benefits for each discrete use pattern, taking into account potential regional differences.[39] Moreover, if a particular risk concern may be largely attributable only to a certain subset of the registered uses, the EPA Administrator is required "to consider whether he has defined the application he intends to prohibit sufficiently narrowly."[40]

42. The Agency must consider the risks and benefits of public health pesticides under a more rigorous standard from the risks and benefits of other pesticides. In evaluating any potential regulatory action under FIFRA concerning a public health pesticide, EPA must weigh any risks of the pesticide against health risks, such as the diseases transmitted by the vector to be controlled by the pesticide.[41] Additionally, HHS is required to provide benefits and use information in connection with cancellation of a pesticide's public health uses. 7 U.S.C. § 136d(b). *See also* 7 U.S.C. § 136a-1(n)(2).

B. Existing Stocks

43. A registrant is entitled to challenge, and seek a hearing on the issue of, a determination by EPA concerning existing stocks of products the Agency proposes to cancel.

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[38] 40 C.F.R. § 164.80(a) (emphasis added).

[39] *Love v. Thomas*, 858 F.2d 1347, 1358-62 (9th Cir. 1988), *cert. denied sub nom., AFL-CIO v. Love*, 490 U.S. 1035 (1989).

[40] *Ciba-Geigy v. EPA*, 874 F.2d 277, 280 (5th Cir. 1989).

[41] 7 U.S.C. § 136(bb).

See, e.g., In re Cedar Chem Co., 2 E.A.D. 584, 1988 WL 525242, at *3 n.9 (E.P.A. June 9, 1988). The scope of a FIFRA Section 6(b) hearing includes any issues that the applicant's objections raise. *See* 7 USC § 136d. Similarly, a proceeding must be commenced whenever a hearing is requested by any person adversely affected by a NOIC. 40 C.F.R. § 164.20.

44. Substantively, a risk/benefit analysis for existing stocks purposes is different from the analysis that the Agency performs in determining whether or not to cancel a registration.[42] For instance, additional factors would be relevant to an existing stocks risk/benefit analysis, including the risks resulting from the use of existing stocks; the quantity of existing stocks at each level of the market; and the dollar amount users and others have already spent on existing stocks; and the risks and costs of disposal.[43]

C. Pertinent Executive Orders

45. EPA must ensure that its regulatory actions are consistent with principles of environmental justice. Executive Order 12898 requires that, to the greatest extent practicable and permitted by law, each Federal agency shall make achieving environmental justice part of its mission by identifying and addressing disproportionately high adverse human health effects of its activities on minority populations, including Native Americans, and low-income populations.[44] This includes evaluating the potential adverse effects on these populations associated with cancellation of public health pesticides such as the Affected Products.

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[42] 56 Fed. Reg. 29364 (June 26, 1991).

[43] *Id.*

[44] Executive Order 12898, 59 Fed. Reg. 7629 (Feb. 11, 1994), *available at* www.archives.gov/federal-register/executive-orders/pdf/12898.pdf (hereinafter Executive Order 12898).

46. Under Executive Orders 12866[45] and 13563,[46] the RMD constitutes a "significant regulatory action" subject to mandatory review by Office of Management and Budget ("OMB"). "Significant regulatory actions" subject to OMB scrutiny include those that have an annual effect on the economy of $100 million or more; adversely affect in a material way public health or safety, or the health or safety of tribal governments or communities; or raise novel legal or policy issues arising out of legal mandates.[47] The RMD constitutes a significant regulatory action on each of these counts.

D. The Administrative Procedure Act

47. EPA's proposed cancellations of the Subject Products and proposed denials of the Pending Registrations, when reflected in a final Agency action, must be consistent with the APA, which requires that arbitrary and capricious agency decisions be set aside. The APA also requires that EPA provide registrants the "opportunity to demonstrate or achieve compliance with all lawful requirements."[48]

STATEMENT OF OBJECTIONS

48. As described below, the actions proposed in the NOIC must be rejected because the Agency's evaluation fails to comport with applicable legal requirements in several key respects. When the Affected Products are properly considered in accordance with the standards set forth in the law, it is apparent that their benefits exceed the risks alleged by EPA.

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[45] Executive Order 12866, 58 Fed. Reg. 51,735 (Oct. 4, 1993), *available at* http://www.archives.gov/federal-register/executive-orders/pdf/12866.pdf (hereinafter Executive Order 12866).

[46] Executive Order 13563, 76 Fed. Reg. 3821 (Jan. 18, 2011), *available at* http://www.whitehouse.gov/sites/default/files/2012regburdens.eo_.rel_.pdf (hereinafter Executive Order 13563).

[47] Executive Order 12866 § 3(f).

[48] 5 U.S.C. § 558(c)(2).

A. EPA Has Wrongly Concluded That the Affected Products Cause Unreasonable Adverse Effects

49. The Agency's conclusion that the Affected Products cause unreasonable adverse effects is incorrect. This conclusion is based on an incomplete and unsound risk assessment, exacerbated by a failure to acknowledge the substantial benefits associated with cost-effective rodent control or the safety issues and reduced efficacy associated with alternative products.

(i) The Agency Incorrectly Concludes that Conforming Products Have Comparable Effectiveness to the Affected Products

50. The SAP "urged EPA to make certain that rodent control can be adequately maintained for protection of human health following the proposed cancellations."[49] Nevertheless, the NOIC significantly understates undisputed evidence that commensal rodents are prone to resistance to FGARs, and that such products are less effective because, unlike SGARs, the FGARs require multiple feedings to ensure a lethal dose is provided. FGARs are one of the only two classes of alternative rodenticides permitted under the RMD. Upon considering these issues concerning the use of FGARs, the SAP concluded that "The requirement that rodenticides sold to residential consumers not contain [SGARs] has the potential for increasing rodenticide resistance and limiting effective options."[50] Moreover, the SAP found that this RMD requirement will create a vicious cycle in which "an increase in the number of commensal rodent populations that exhibit anticoagulant resistance . . . will further limit control options."[51]

51. In addition, the Agency provides no evidence, and Reckitt is aware of none, that conforming bromethalin products (*i.e.*, bait blocks placed within tamper resistant bait stations)

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[49] SAP Minutes at 7.

[50] *Id.* at 16.

[51] *Id.*

are sufficiently effective against either wild rats or mice. Given that bromethalin is the leading non-anticoagulant consumer-use rodenticide, this lack of any convincing evidence of efficacy calls into question the Agency's unsupported claim that alternatives to the Affected Products can adequately control rodent infestations.

52. Moreover, rodents are less likely to consume rodenticides in the physical forms that the RMD requires. For instance, the NOIC dismisses a body of scientific data showing that the block form of rodenticides is generally less palatable to rodents than pellets. As the SAP observed, "limiting the choice of bait formulation to bait blocks reduces the ability of users 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."[52]

53. Furthermore, rodents are less likely to consume rodenticides from within a bait station, which the RMD requires. For instance, the NOIC dismisses a significant body of scientific data showing that rats are neophobic and will not readily enter into bait stations. In addition, as the SAP noted, "[L]imiting use to bait stations can greatly reduce the ability of users to establish the bait in some locations where the rodents are more likely to encounter and consume it and practical field efficacy of the available rodenticides will be likely be reduced."[53]

54. Notably, although efficacy data is a key element of the registration requirements for public health pesticides such as rodenticides, EPA has neither demonstrated nor required registrants to demonstrate the efficacy of specific rodenticides when used with the bait stations the RMD requires.[54] Instead, the Agency assumes that efficacy data for a product tested with

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[52] *Id.*

[53] *Id.* at 16.

[54] 40 C.F.R. § 158.400 (requiring efficacy data for, *inter alia*, residential-use rodenticides for use against commensal rodents).

laboratory mice and rats without a bait station would translate to comparable efficacy for conforming products within a bait station for treatment of infestations of wild commensal rodents.

(ii) The Agency Understates the Benefits Associated with the Affected Products

55. Rodents invade millions of homes in the United States each year. These infestations have marked social and economic consequences, including disease, rodent control expenses, health care costs, and property damage.

56. 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.[55] They are known to carry more than 35 diseases,[56] 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.[57] Additionally, in the United States, as many as 50,000 people a year — mostly children — are bitten by rodents. Consequently, the Affected Products serve a vital public health purpose. And, because rodent-associated health issues have untold financial costs, the Affected Products also provide an economic benefit.

57. Reckitt's d-CON brand consumer-use rodenticide products are among the most effective and most widely used consumer-use rodenticides. The NOIC proposes to remove these

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[55] Robert M. Corrigan, *Rodent Control: A Practical Guide for Pest Management Professionals* 15 (GIE Media 2001).

[56] CDC, http://www.cdc.gov/rodents (last viewed Feb. 24, 2013).

[57] *See, e.g.*, Berg et al., "Rodent Allergen in Los Angeles Inner City Homes of Children with Asthma," Journal of Urban Health: Bulletin of the New York Academy of Medicine, Vol. 85, No. 1, 2007; Phipatanakul et al., "Mouse allergen. I. The prevalence of mouse allergen in inner-city homes," Journal of Allergy and Clinical Immunology, Vol. 106, 2000; Perry et al., "The prevalence of rat allergen in inner-city homes and its relationship to sensitization and asthma morbidity" Journal of Allergy and Clinical Immunology," Vol. 112, 2003.

products from the market and replace them with products that are less effective, potentially more hazardous, less studied, and more costly. Reduced efficacy and higher-cost consumer-use products will lead to increased rodent populations, which in turn will result in additional adverse economic, social, and public health effects from rodent infestations. As the SAP observed, the "relatively low risk to humans [from SGARs] needs to be carefully weighed against the risks associated with poor rodent control."[58]

(iii) The Agency Understates the Economic Impacts of the RMMs

58. Among the benefits of the Affected Products is that they are cost-effective. Because EPA's methodology for calculating the economic impacts of the RMMs is flawed, the NOIC significantly understates the substantial increased cost to consumers to use RMD-conforming products. As the SAP observed, "the estimated added costs associated with the use of conforming rodenticide products along with non-chemical control are underestimated in the [Draft] NOIC."[59] Contrary to the Agency's assertions, these costs will be substantial, particularly for low-income consumers who can ill afford to hire a professional applicator to apply products containing the same active ingredient currently available to a d-CON customer at their local grocery or hardware store.

59. In addition, the NOIC underestimates the economic importance of differences in efficacy among various rodent control products. For instance, the increased cost of conforming rodenticides will likely lead some consumers to shift to mechanical alternatives such as traps, or even abandon rodent control efforts entirely. As the SAP observed, "EPA has failed to recognize the difficulty associated with non-chemical control, especially in those communities where

[58] SAP Minutes at 7.

[59] *Id.* at 46.

rodent populations are at high levels. . . . Dependence on non-chemical controls would be least effective for those neighborhoods that have the most significant problems."[60] Less effective rodent control means more frequent and severe rodent infestation. This will lead in turn to increased costs associated with rodent-related injury and illness, rodent-related property damages, and rodent control, as consumers try ineffective methods repeatedly or seek the assistance of expensive PCOs to obtain access to SGARs.

60. Taken together, the benefits of the Affected Products are substantial, and cancellation or refusal to register these products will result in significantly less effective rodent control. The NOIC fails adequately to incorporate these benefits into its evaluation. Consequently, EPA's risk/benefit analysis is inadequate and incorrect, and the benefits of the Affected Products outweigh their purported risks. Therefore, the NOIC must be rejected.

B. The Affected Products Do Not Pose an Unreasonable Risk to Children

61. The NOIC overstates the potential adverse effects to children of inadvertent exposures to non-conforming rodenticide products such as Reckitt's Affected Products. EPA erroneously equates reports of exposures to rodenticides with unreasonable adverse effects, and the Agency ignores a consensus review of 20 years of historical data that concludes that the risks associated with accidental exposures to SGARs are minimal. The Agency also fails to acknowledge the greater risks associated with non-anticoagulant rodenticides, overstates the benefit of tamper-resistant bait stations, and neglects to weigh purported risks for children against the known benefits to children of effective rodent control.

62. A national panel of poison control experts that reviewed over 20,000 reports of unintentional SGAR ingestion by children under the age of six observed that none of the

[60] SAP Minutes at 16-17.

exposures resulted in clinical bleeding. The panel concluded, moreover, that children who unintentionally ingest SGARs and are asymptomatic can be safely observed at home without the need for hospital treatment. The SAP concurred, noting that, "Based on the available data, the Panel agreed . . . that exposure [to SGARs] generally results in no clinical harm to children. While the possibility of harm exists, it rarely occurs except in the setting of intentional ingestions or malicious poisoning."[61] Furthermore, the vast majority of the calls to poison control centers that EPA characterizes as "incidents" do not involve actual incidents of medically meaningful ingestion of rodenticides.[62] Similarly, EPA does not acknowledge that bittering agents present in SGAR products help prevent significant exposures from occurring.

63. By barring the consumer use of SGARs, the NOIC will lead to the increased use of non-anticoagulant rodenticides such as bromethalin, which poses significantly increased risk to children. As the SAP observed, "severe 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."[63] Consequently, exposure to acutely and sub-acutely toxic rodenticides involves a much greater risk of adverse emotional, social, and economic effects than exposure to anticoagulants.

64. The NOIC does not address, much less evaluate, adverse consequences to consumers who substitute mechanical rodent control methods for Reckitt's rodenticide products.

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[61] SAP Minutes at 7.

[62] The SAP's December 2011 Minutes notes that, "[T]here appears to be relatively little data included in the incident reports that verify that exposures to people, including children, have occurred that have been of a magnitude to be considered major incidents." *Id.* at 7.

[63] *Id.* at 6.

For example, snap traps and glue traps present a number of risks to children who encounter them, including injuries from fingers being caught in a snap trap, rodent bites from contacting live, trapped rodents, and rodent-borne diseases from direct contact with rodents (living or dead), or their urine or feces.[64]

65. The NOIC assumes that the Agency's decision to mandate tamper-resistant bait stations for consumer-use rodenticide products will reduce the incidence of children's exposure to rodenticides. However, currently marketed RMD-conforming products can (and do) contain up to one pound of rodenticide per bait refillable station — *i.e.*, 16 loose, one-ounce blocks of rodenticide bait — with just a single, refillable bait station. As the SAP notes, "[i]f the bait stations are not used correctly, then exposure to the rodenticides is still likely."[65] Because conforming bait stations are costly, intentional product misuse — such as placement of unprotected bait blocks in multiple locations in and around homes — is likely to occur.[66] Additionally, children may access the package of unused blocks.

66. As the SAP recommends, the "relatively low risk to humans [from the rodenticides EPA seeks to cancel] needs to be carefully weighed against the risks associated with poor rodent control."[67] As discussed above, rodent infestation poses substantial risks to humans, particularly children. The NOIC consistently overstates the risks to children posed by household rodenticides such as Reckitt's d-CON products, while understating the benefits to children of

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[64] *See, e.g.,* Centers for Disease Control and Prevention, "Trap Up! Trap rodents around the home to help reduce the rodent population," *available at* http://www.cdc.gov/rodents/prevent_infestations/trap_up.html, March 22, 2010;

[65] *Id.* at 7.

[66] For instance, the SAP urged EPA "to give further consideration to the likelihood that consumers will not use the bait stations for all the rodenticides placed in their homes." SAP Minutes at 7.

[67] *Id.* at 7.

effective rodent control. In short, the Agency's risk evaluation under FIFRA Section 6(b) is flawed, and its conclusion that the Affected Products pose an unreasonable risk to children is in error. Therefore, the Affected Products meet FIFRA's basic registration standard, and the NOIC must be rejected.

C. The Affected Products Do Not Pose an Unreasonable Risk to Pets

67. The products proposed for cancellation do not present an unreasonable risk of adverse effects in domestic animals when used properly. Moreover, the RMMs do not protect pets from accidental rodenticide exposure. In fact, not only do these measures increase the risk of severe poisoning, but they also introduce additional hazards.

68. First, as the SAP concluded, limiting consumer use to conforming rodenticide products will not generally reduce the opportunity for exposure of pets to commensal rodenticide products.[68] For instance, as noted above, RMD-conforming products can contain 16 loose, one-ounce blocks with a single, refillable bait station. *See, e.g.*, Exhibit 17. Consumers are likely to intentionally misuse these products, placing the blocks without using the bait stations. In addition, dogs can easily gain access to the loose product refills that are sold in lightweight external packaging. Moreover, although EPA speculates that the bait station requirement will prevent pets from gaining access to rodenticides, two of the four categories of bait stations that EPA allows to be sold to consumers do not even purport to afford such protection.[69]

69. Second, in comparison to the consumer-use rodenticides EPA seeks to cancel, alternative rodenticides such as bromethalin — an acute toxin — may actually increase risks to pets. The prognosis for a domestic animal that has ingested rodenticide depends largely on the

[68] *Id.* at 9.

[69] *See* RMD at 20-21.

active ingredient. Indicator dyes enable diagnosis of pets exposed to SGARs days before symptoms manifest, and pets readily can be treated with Vitamin K1, a safe and inexpensive antidote. In contrast, rodenticides containing the non-anticoagulant acute and sub-acute toxins are difficult to diagnose, may cause death within hours, and lack any known antidotes. Treatment is therefore costly, and consumers may opt to euthanize a pet rather than incur this expense.[70]

70. Third, while cats are one hundred times more able to tolerate brodifacoum, the most commonly used SGAR, than dogs, cats are considerably more sensitive than dogs to the acutely toxic rodenticides bromethalin and cholecalciferol. Thus, for at least one species of domestic animal, exposure to the most widely available conforming rodenticides will increase risk.

71. Fourth, the SAP noted additional concerns, such as "the increased risks associated with a choking hazard from bait blocks, exposure to a 1 ounce bait block and gastrointestinal trauma from bait station ingestion, particularly for dogs."[71]

72. The Agency has both overstated the risk posed by rodenticides that do not comply with the NOIC and understated the risk associated with the alternative products, especially acute and sub-acute toxins. Therefore, EPA's risk analysis as applied to pets

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[70] Notably, several incidents have been reported involving dogs that had consumed a rodenticide containing zinc phosphide and later vomited in an examination or treatment room. Veterinary staff members that were exposed to the toxic gas in the vomit experienced symptoms that included shortness of breath, difficulty breathing, dizziness, nausea and headache. One of the affected staff members was admitted to the emergency room. Heather Biele, *Veterinary staff members sickened by toxic dog vomit, CDC reports* (June 1, 2012), *available at* http://veterinarynews.dvm360.com/dvm/Toxicology/Veterinary-staff-members-sickened-by-toxic-dog-vom/ArticleStandard/Article/detail/775266.

[71] SAP Minutes at 8.

mischaracterizes the risks and benefits of both the Affected Products and the RMD-conforming products. For the foregoing reasons, it is apparent that the Affected Products do not pose an unreasonable risk to domestic animals. Contrary to EPA's assertion, the Affected Products do meet FIFRA's basic registration standard, and the NOIC must be rejected.

D. The Affected Products Do Not Pose an Unreasonable Risk to NTOs

73. The NOIC's conclusion that the Affected Products cause adverse effects to wildlife rests on an analysis that errs in its assumptions and in its application of available data. The Agency assumes, without evidence, that cancellation of consumer-use SGAR products will meaningfully mitigate risks to NTOs from SGARs. EPA therefore proposes to deprive consumer users of access to cost-effective rodent control options, while allowing commercial use by professional, institutional, and agricultural applicators to continue unchecked — a perverse result grounded in faulty science.

74. First, the NOIC and supporting documents fail to demonstrate a causal link between consumer use of the Affected Products and NTO exposure to these rodenticides. EPA provides only scant and inconclusive evidence that SGAR residues found in NTOs are from consumer uses of rodenticide, as opposed to the commercial or agricultural uses of the same active ingredients that are unaffected by the NOIC. As the SAP noted, "rodenticides are also deployed by professionals representing commercial and institutional entities in urban and suburban areas and it is not clear how one would separate domestic from commercial/institutional usage as sources [of wildlife impacts] in urban and suburban land use areas."[72] Ultimately, "It is not clear whether regulation of domestic uses will significantly

[72] *Id.* at 14, 37.

reduce exposure of non-target wildlife if commercial and institutional use of SGARs, for example, will be continued, and is in fact at much greater scale."[73]

75. Second, the Agency fails to identify a plausible scenario in which secondary poisoning of NTOs by consumer-use rodenticides might occur. For example, although nearly 90% of consumer use of rodenticide baits is to control house mice, EPA presents no evidence that house mice that have consumed rodenticides inside a residence will wander outside, where they might be eaten by predators or scavengers. Indeed, the available evidence suggests that commensal rodents have no impetus to go outside after ingesting anticoagulants because they do not develop an increased desire for food or for water following exposure. The scenario EPA posits is even more dubious in the context of high-density urban settings such as high rise apartment buildings.

76. Furthermore, it is well documented that the predominant diet of raptors and carnivorous mammals is generally not commensal rodents. Outdoor baiting allows non-commensal rodents (*e.g.*, moles, voles, and squirrels) access to the rodenticide bait. These non-commensal rodents are the preferred diet of raptors and carnivorous mammals. These facts further reduces the probability that indoor consumer use is a significant factor in NTO exposure."

77. Third, the Agency's environmental risk assessment is deeply flawed, particularly as it pertains to SGARs. That assessment contains several unsupported, unduly conservative assumptions. These assumptions form the basis for EPA's qualitative conclusion that SGARs pose an unreasonable risk to NTOs — a conclusion that is unsupported by available evidence. The SAP encouraged the Agency to conduct a rigorous risk assessment, noting that "The

[73] *Id.* at 49-50.

analysis presented by the EPA did not include real numerical quantifications of risk, and there seems to be a great degree of uncertainty for some components of the risk assessment."[74]

78. In fact, SGAR registrants performed such an assessment prior to EPA's issuance of the RMD.[75] The Agency dismissed both this assessment and the SAP's recommendation, and conducted instead what it admits is only a "limited" risk analysis that relies on assumptions in lieu of data — including the demonstrably false suppositions that target rodents will eat nothing but rodenticide bait and that predator NTOs will eat nothing but rodenticide-intoxicated rodents.[76] EPA explicitly acknowledges that its risk assessment "does not evaluate the actual potential for wildlife to come into contact with treated bait; it simply evaluates the consequences of exposure."[77] In other words, the Agency's "risk assessment" for NTOs comes to the unsurprising conclusion that a vertebrate pesticide, when consumed in large quantities, can be toxic to vertebrates.

79. Fourth, the Agency's analysis relies on a strained interpretation of the available wildlife incident reports. EPA claims that these reports indicate that residential use of rodenticides provides "a complete exposure pathway" to wildlife which results in mortality caused by exposure to SGARs, both through direct exposures to wildlife and secondary uptake through predation. In fact, it has not been shown that the Agency's incident reports generally even address the origin of the rodenticide, much less conclude that any specific incident resulted from residential consumer use (other than possibly in cases of apparently deliberate misuse).

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[74] SAP Minutes at 13.

[75] *See* Exhibit 18.

[76] EPA, *Probabilistic Analysis for the Notice of Intent to Cancel Noncompliant Rodenticide Products Containing Brodifacoum, Difethialone, Chlorophacinone, Diphacinone, Warfarin, or Bromethalin* (Jan. 24, 2013), *available at* http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2013-0049-0010.

[77] Statement of Reasons at 89.

Moreover, EPA relies on this database to conclude that SGARs are the cause of death despite the fact that numerous reports state explicitly that the causes of death are not known. In fact, the methods used to identify the chemicals detected in wildlife often are not documented, and frequently the mere presence of residues is interpreted as supporting a diagnosis of fatal SGAR poisoning. Thus, EPA heaps inference upon inference and assumption upon assumption to reach the sweeping qualitative conclusion that residential consumer uses of SGARs pose an unreasonable risk of adverse effects to NTOs — a conclusion that is unsupported by available evidence.

80. Fifth, the NOIC fails to demonstrate that alternative rodenticides pose lesser risks to NTOs. The SAP concluded that the Agency's determination "that FGARs and bromethalin present a lesser risk to non-target wildlife, particularly birds of prey, may be flawed."[78] The Panel criticized EPA's assertion that the consumption of FGARs presents a lower risk to birds of prey as not well-supported and emphasized that "there is not enough evidence to support [bromethalin] as a lower-risk alternative to SGARs."[79] In addition, bromethalin and other non-anticoagulants have not been extensively used, so their long-term impacts on the environment, and their environmental fate, are largely unknown. Moreover, as with children and pets, there is no antidote for wildlife exposed to these rodenticides, as there is for SGARs.

81. Finally, it is undisputed that the Affected Products have not had any adverse effects on wildlife populations generally. Even accepting at face value the Agency's flawed interpretation of the available wildlife incident data, NTO deaths attributed to all rodenticide exposures represent a small fraction of overall NTO mortalities, and an even smaller fraction of

[78] SAP Minutes at 35.

[79] *Id.* at 13, 34.

NTO populations. Indeed, Reckitt has supplied EPA an analysis of population trends among purportedly at-risk birds and mammals, demonstrating that these wildlife populations are generally stable or, in some cases, increasing.[80]

82. The very alternative mitigation measures that Reckitt has proposed have been recognized by the pertinent regulatory agencies of California as an acceptable approach to mitigating the risks of SGARs to wildlife, and yet the EPA unfairly has chosen to ignore such an approach without any basis in law or science for doing so.

83. The NOIC overstates the adverse effects to NTOs that may result from SGAR use, relies on questionable data to do so, and fails to articulate how the Affected Products contribute to those risks. Therefore, EPA's conclusion that consumer-use SGARs present an unreasonable risk of adverse effects to the environment is unsupported. The Affected Products in fact meet the basic FIFRA registration standard, and therefore the NOIC must be rejected.

E. EPA Has Failed to Conduct the Rigorous Benefits Analysis Required by FIFRA

84. EPA's purported "benefits" analysis[81] consists primarily of a series of conclusory statements and suppositions that ignore available evidence. These conclusions are both substantively incorrect and procedurally deficient. First, in cancelling or denying registration of a public health pesticide, the Agency is required to "weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide."[82] Second, the Agency is required to consult meaningfully with HHS concerning the benefits of the

[80] Katherine Palmquist *et al.*, Technical Memorandum: Preliminary Analysis of Population Trends of Selected Nontarget Organisms (May 12, 2011), *available at* http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0718-0043.

[81] Statement of Reasons at 100-126.

[82] 7 U.S.C. § 136(bb).

public health pesticides at issue.[83] The NOIC fails even to acknowledge the first requirement, and gives the second requirement only cursory treatment, despite the fact that FIFRA was amended specifically to heighten the legal standard for cancellation or denial of public health pesticides.[84]

(i) The NOIC Fails to Weigh Any Risks of the Affected Products Against the Public Health Risks Posed by Rodents

85. As discussed in Section A(i) above, rodents are vectors for myriad diseases, which they transmit via urine, feces, fur, feet, saliva, and blood. For example, lymphocytic choriomeningitis, an emerging disease affecting children, is spread to humans when they come in contact with rodent feces, urine, or other contaminated articles. This disease has been identified in a large percentage of house mice from U.S. inner cities. Similarly, humans can contract plague — a rare but frequently fatal rodent-borne disease — from a rodent bite.[85] Given that a single mouse can excrete 40 to 100 fecal pellets each day[86] and that up to 50,000 people are bitten by rodents annually in the U.S.,[87] these public health considerations are significant. Moreover, rodent allergens can cause or aggravate asthma, particularly in children.[88]

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[83] *See* 7 U.S.C. §§ 136a-1(n)(2), 136d(b).

[84] Food Quality Protection Act of 1996, 110 Stat. 1489.

[85] CDC, "Plague Fact Sheet," *available at* http://www.cdc.gov/plague/resources/235098_Plaguefactsheet_508.pdf.

[86] Robert M. Corrigan, *Rodent Control: A Practical Guide for Pest Management Professionals* 15 (GIE Media 2001).

[87] *Id.* at 18.

[88] *See, e.g.*, Berg et al., "Rodent Allergen in Los Angeles Inner City Homes of Children with Asthma," Journal of Urban Health: Bulletin of the New York Academy of Medicine, Vol. 85, No. 1, 2007; Phipatanakul et al., "Mouse allergen. I. The prevalence of mouse allergen in inner-city homes," Journal of Allergy and Clinical Immunology, Vol. 106, 2000; Perry et al., "The prevalence of rat allergen in inner-city homes and its relationship to sensitization and asthma morbidity" Journal of Allergy and Clinical Immunology," Vol. 112, 2003.

Consequently, the benefits of effective rodent control include reduced public health costs, both social and economic. The NOIC, however, makes no mention of these facts.

(ii) The Agency Failed to Consult Meaningfully with HHS on the Public Health Consequences of Cancellation

86. FIFRA requires that EPA seek benefits and use information from HHS in connection with cancellation of the Subject Products.[89] Although the public health consequences of cancelling the Subject Products could be severe, EPA has not obtained any substantive input from HHS in preparing the NOIC. This failure has not gone unnoticed by independent experts. During the SAP meeting, panel members repeatedly raised the issue of benefits associated with the products the Agency proposed to cancel. EPA representatives assured the SAP that HHS would provide the Agency with an evaluation of public health benefits to be weighed against the putative risks of the products. In its Meeting Minutes, the SAP "urged EPA to make certain that rodent control can be adequately maintained for protection of human health following the proposed cancellations," stressing that the Agency should "make certain that a thorough and well-researched assessment of the public health issues associated with a potential reduction in rodent control (*e.g.*, the potential for increases in rodent-borne diseases, bites) is provided by the Department of Health and Human Services."[90]

87. Neither HHS nor the Agency has followed through on EPA's assurances to the SAP. Instead, as discussed above,[91] HHS provided a six-sentence memo referring EPA to its six-

[89] 7 U.S.C. § 136d(b); *see also* 7 U.S.C. § 136a-1(n)(2).

[90] SAP Minutes at 7.

[91] *See* paragraph 25, *supra.*

year-old response to EPA's draft RMD and to "some comments" it made in November 2011.[92] The former concerned a draft RMD with substantially different RMMs from those EPA currently seeks to enforce, the latter took place before the SAP proceedings, and neither addresses the Pending Registrations or Reckitt's Proposed Label Amendments.[93]

88. Consequently, EPA's analysis is procedurally deficient, and the NOIC must be rejected.

F. The NOIC Fails to Conduct an Individualized Risk Assessment as Required by FIFRA and Does Not Address Risk Mitigation Measures Proposed by Reckitt

89. Rather than conduct the required individualized evaluation of comparative risks and benefits of each of the Affected Products, the NOIC simply lumps all of the Affected Products together. The result is that a failure of a rodenticide product to comply with all of the RMMs provides a basis for cancellation or denial, without a particularized assessment of the specific aspects of the product in question. However, EPA has not shown that products that deviate from all of the RMMs pose an unreasonable risk of adverse effects on the environment.

(i) The NOIC Fails to Evaluate Each Subject Product

90. EPA treats each of the 12 distinct Subject Products interchangeably, without regard to each individual product's directions for use, active ingredient, concentration, comparative cost, treatment prognosis for unintended exposures, packaging, or labeling — to name a few. For instance, the Pending Registrations consist of block formulations contained in RMD-compliant tamper-resistant bait stations, with label directions providing for indoor use only. These products conform to the RMD in every respect except that they are formulated with

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[92] Memorandum from Eric E. Wachter, Executive Secretariat, EPA, to J. Ronald Campbell, Executive Secretariat, Centers for Disease Control and Prevention (Apr. 19, 2012), *available at* http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2013-0049-0007.

[93] *See* paragraph 6, *supra.*

an SGAR, which EPA claims poses an unreasonable risk to NTOs — but this risk is minimized or even eliminated by the restriction on outdoor use. The NOIC likewise regards a product that poses comparatively little risk to human health (*i.e.*, consumer use anticoagulant rodenticides) as interchangeable with products containing an acute toxin, such as bromethalin, for which there is no known antidote.

91. Similarly, EPA has failed to conduct a well-reasoned benefits assessment of each of the products proposed for cancellation, as FIFRA requires. For example, it has made no distinction between products with a more effective formulation and format (for instance, an SGAR in pellet form) and those with a less effective formulation (*e.g.*, an FGAR block in a bait station).

(ii) The NOIC Fails to Evaluate Each Pending Product

92. Similarly, the NOIC fails to evaluate on an individual basis the two Products Pending Registrations for which EPA proposes to deny registration. *See* Exhibit 2. These products conform in every way with the RMMs and go even further to mitigate the opportunities for accidental exposures to children, pets and wildlife — except that they contain brodifacoum, an SGAR, in a tamper resistant bait station to be labeled for indoor use only. No similarly configured product is currently registered. If, as EPA claims, block formulations and bait stations reduce the risks associated with rodenticides to children and to NTOs, then the risks and benefits of the proposed new products are uniquely lower than any of the products subject to cancellation. These risks and benefits must be individually assessed and weighed against the risks and benefits of the non-anticoagulant conforming products.

(iii) EPA Fails to Address Risk Mitigation Measures Proposed by Reckitt

93. Moreover, the Agency's analysis does not address or even mention Reckitt's proposed changes to the labels of certain Subject Products. Reckitt has submitted for Agency

approval eight label amendments for its nonconforming products, each of which changes the risk-benefit calculus for the product in question. *See* Exhibits 5. Those amendments proposed to cancel all outdoor uses of these products and to restrict them to indoor use only, to limit the duration of application, and to implement label clarifications including the use of bilingual labels to provide for greater consumer comprehension of limitations on use. Reckitt provided EPA with full-color artwork representative of what could be used in a revised label if approved by EPA, yet the Agency completely failed to evaluate the risks and benefits of the Affected Products in light of the requested label changes.

94. Finally, the Agency failed to notify Reckitt whether its Proposed Label Amendments had been granted or denied, or to provide in writing the specific reasons for the denial. This failure violates the express requirements of FIFRA.[94] The Agency violated FIFRA by failing to notify Reckitt by certified letter that the applications were subject to denial, and by failing to provide Reckitt with 30 days notice to address any deficiencies the Agency may have identified in the Proposed Label Amendments.[95] For the two Pending Registrations, EPA's Notice of Denial does not specify whether the Agency is denying the October 2010 registration application submitted in 2010, or whether the Agency took into consideration and assessed the risks and benefits of the enhanced registration application which included an in-door use only label as submitted in May 2011. Consequently. the Agency's Notice of Denial does not reflect that Agency has undertaken the required risk-benefit analysis for the Pending Products as modified in Reckitt's May 2011 amended application for registration.

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[94] 7 U.S.C. § 136a(c)(6); *see also* 40 C.F.R. § 152.44(a) (any proposal to change the composition, labeling, or packaging of a registered pesticide constitutes an application for amended registration).

[95] *See* 40 C.F.R. § 152.118(b) & (c).

95. In short, the NOIC aggregates and equalizes specific risks and benefits that should be weighed individually. Consequently, the Agency has failed even to attempt the particularized, product-by-product risk/benefit analysis required by FIFRA, and the NOIC must therefore be rejected.

G. EPA's Attempt to Prohibit Distribution of Existing Stocks is Overreaching

96. The NOIC maintains that EPA's determination with respect to existing stocks is outside the scope of a Section 6(b) hearing and thus cannot be challenged as part of the cancellation hearing in this case.[96] In several respects, this determination is contrary to law and represents an overreach of the Agency's authority.

(i) Reckitt is Entitled to a Hearing on the Issue of Existing Stocks

97. EPA's attempt to deny Reckitt a hearing on the issue of existing stocks is without statutory or regulatory support and is contrary to prior EPA practice. *See* Exhibit 19. As set forth in Section 6(d), the scope of a Section 6(b) hearing includes any "issues raised by the objections filed by the applicant" or, if the hearing is called by EPA, those "issues stated by the Administrator."[97] Thus, contrary to EPA's assertions to the contrary, the scope of a 6(b) hearing is defined by the issues the Administrator addresses in the Notice of Intent to Cancel, or by any objections the party requesting a hearing raises in objection to the Notice.[98] Here, because EPA has made a determination in its NOIC with respect to existing stocks, the issue is properly within the scope of the Section 6(b) hearing and subject to objections that may be raised by interested parties. This conclusion is supported by FIFRA's legislative history, which makes clear that

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[96] 78 Fed. Reg. 8126 (Feb. 5, 2013).

[97] 7 U.S.C. § 136d(d).

[98] *See id.*

hearings initiated under Section 6(b) are intended to address a wide range of issues, including review of EPA's recommendations with respect to the disposition of existing stocks.[99]

98. Likewise, regulations promulgated under FIFRA state that "A proceeding shall be commenced whenever a hearing is requested by any person adversely affected by" a NOIC.[100] In this instance, the NOIC announces the Agency's intent, in the event of cancellation of the Subject Products, to disallow the sale or distribution of any existing stocks of these products.[101] Reckitt clearly would be adversely affected by this Agency action, for various reasons — for instance, this action would leave Reckitt with product that it could not sell and would have to pay to dispose of, and EPA's announcement of this intended action deters Reckitt customers from purchasing the Subject Products. The Company therefore has a right to a hearing on this issue.

99. Furthermore, EPA's present position conflicts with prior Agency acknowledgments that the issue of existing stocks is within the scope of the Section 6(b) hearing. For instance, the EAB, acting on behalf of the Administrator, has asserted that "[o]bviously, if an issue is identified in the cancellation notice, it fits within the framework of the proceeding and may be litigated in a hearing."[102] In the past, EPA has expressly recognized that the issue of existing stocks can be addressed at a Section 6(b) cancellation hearing.[103]

100. Ultimately, EPA's determination threatens to deprive Reckitt of its statutory right to a hearing and usurps the ALJ's authority to consider and resolve the issue of the appropriate

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[99] *See* discussion in Exhibit 19.

[100] 40 C.F.R. § 164.20(a).

[101] 78 Fed. Reg. 8126-27 (Feb. 5, 2013).

[102] In re: *Cedar Chem Co.*, 2 E.A.D. 584, 1988 WL 525242, at *3 n.9 (E.P.A. June 9, 1988).

[103] *See, e.g.*, Notice of Intent to Cancel or Restrict Registrations of Pesticide Products Containing Toxaphene, 47 Fed. Reg. 53,792-93, 1982 WL 153737 (Nov. 29, 1982) ("The 30-day time period in which to request a hearing is applicable to all the regulatory actions proposed in this Notice, including . . . the existing stocks provisions . . . .)."

distribution of existing stocks. The hearing afforded under FIFRA Section 6 is a *de novo* determination of the actions proposed by EPA in the NOIC.[104] In interpreting applicable precedent, EPA has improperly construed its authority to specify the issues to be considered during a hearing to give it the authority to constrain the issues that the ALJ and the EAB may consider in making an ultimate decision.

101. As discussed in greater detail below, EPA's position on existing stocks puts the cart before the horse, reaching conclusions on the disposition of Reckitt's products at a time when their cancellation is not a foregone conclusion. Reckitt has long sought a hearing on the merits of EPA's proposal to cancel its products, but EPA refused to proceed to a hearing until a federal court essentially ordered it to do so. Yet the Agency now seeks to limit the scope of the hearing that it improperly sought to avoid. The Agency should now be permitted to thwart Congress's intent to afford registrants a hearing on all of the actions proposed in the NOIC.

(ii) The Benefits of a Sell-Through Period for Existing Stocks Outweigh the Risks

102. As set forth in detail above, EPA's risk/benefit analysis is deficient, and the Agency has failed to demonstrate that Reckitt's products generally cause an unreasonable adverse effect on the environment. By the same reasoning, sale of existing stocks in the event that these products are cancelled would not generally cause an unreasonable adverse effect on the environment. However, even assuming *arguendo* that cancellation were appropriate, Agency guidance notes that a risk/benefit analysis for existing stocks purposes is different from the analysis that is performed by the Agency in determining whether or not to cancel a registration.[105] For instance, additional factors may be relevant to an existing stocks

[104] *See* 40 C.F.R. 164.2(i).

[105] 56 Fed. Reg. 29364 (June 26, 1991).

risk/benefit analysis, including the risks resulting from the use of existing stocks, the quantity of existing stocks at each level of the market, and the dollar amount users and others have already spent on existing stocks; and the risks and costs of disposal.[106] The Agency failed to consider any of these factors, each of which militates in favor of an adequate sell-through period.

(iii) EPA's Putative Determination Concerning Existing Stocks of the Subject Products is Arbitrary, Capricious, and Unfair to Retailers Who Lawfully May Continue to Acquire and Sell Reckitt's Products

103. EPA argues that sale of existing stocks of Reckitt's Subject Products should be prohibited because registrants who voluntarily brought "safer" products to the market should not be placed at a competitive disadvantage relative to registrants who declined to "improve" their product.[107] Moreover, the Agency recently granted Liphatech, a rodenticide registrant that recently agreed to cancel its non-conforming products voluntarily, a one-year sell-through period, with an indefinite sell-through for Liphatech's customers.[108] In short, the Agency has sought to punish Reckitt (and any retailer that continues to stock and sell the Affected Products) for exercising its statutory right to a cancellation hearing. EPA's reasons for treating other registrants differently from Reckitt are wholly unrelated to FIFRA's risk/benefit inquiry and are therefore arbitrary and capricious.

104. Moreover, a ban on the sale of existing stocks, effective immediately upon cancellation, would inhibit Reckitt's lawful commercial activity, contravening basic principles of fairness and the intent of FIFRA 6(b). The Company and its customers presently are authorized under FIFRA to continue moving Reckitt's registered rodenticide products in the stream of commerce. The Subject Products remain registered with EPA and may lawfully be distributed

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[106] *Id.*

[107] 78 Fed. Reg. 8126 (Feb. 5, 2013).

[108] 78 Fed. Reg. 8126 (Feb. 5, 2013).

by retailers and used by consumers; Reckitt continues to pay maintenance fees to EPA and incur costs for registrations in all 50 states. Faced with the threat of cancellation with no provision for the sale of existing stocks, however, Reckitt and its customers would be forced either to curtail distribution well prior to any decision on cancellation, or risk being burdened with excess inventory and disposal costs. As described above, a federal court has held that EPA is not permitted to effect *de facto* cancellation of Reckitt Benckiser's rodenticide registrations by means of an improper "misbranding" enforcement action, deeming such action arbitrary and capricious.[109] The Agency should not now be allowed to accomplish the same end by other, equally improper means.

105. For the foregoing reasons, any Agency decision with respect to the proper disposition of existing stocks of any cancelled Reckitt rodenticide products is within the scope of the issues to be evaluated at a hearing, based upon the evidence and testimony presented therein. Reckitt therefore respectfully requests that the ALJ make clear at the commencement of these proceedings that these proceedings will consider and address the issue of disposition of existing stocks.

H. The Agency's Proposed Action Runs Afoul of Various Executive Orders

106. EPA hasfailed to comply with Executive Orders 12866 and 13563, which require federal agencies to conduct a regulatory analysis for economically significant regulatory actions. Among the criteria for a "significant regulatory action" subject to OMB scrutiny are actions that 1) "[h]ave an annual effect on the economy of $100 million or more, or adversely affect in a material way . . . public health or safety, or . . . tribal governments or communities;" or 2) "raise

[109] *Reckitt Benckiser, Inc. v. Jackson*, 762 F. Supp. 2d 34, 43 (D.D.C. 2011).

novel legal or policy issues arising out of legal mandates." [110] The RMD meets each of these criteria, but EPA failed to submit it for OMB review.

107. Moreover, the Agency also contravened Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks."[111] Executive Order 13045 requires that, for each covered regulatory action, EPA must provide OMB "an evaluation of the environmental health or safety effects of the planned regulation on children," as well as "an explanation of why the planned regulation is preferable to other potentially and reasonably feasible alternatives considered by the agency." [112] A "covered regulatory action" must be "economically significant" as defined by Executive Order 12866, and must concern an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children.[113] As described above, the NOIC meets both of these criteria, yet the Agency again failed to seek the required OMB review.

108. The Agency also has failed to meet standards of environmental justice. Executive Order 12898 requires that, to the greatest extent practicable and permitted by law, each federal agency shall make achieving environmental justice part of its mission by identifying and addressing disproportionately high adverse human health effects of its activities on minority populations and low-income populations.[114] EPA has not done so here. Risks associated with the decreased efficacy and higher cost of rodenticides are disproportionately borne by minority and lower income households, which are more likely to have rodent infestations than are other

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[110] Executive Order 12866 § 3(f).

[111] Executive Order 13045, 62 Fed. Reg. 78 (April 21, 1997), *available at* http://www.gpo.gov/fdsys/pkg/FR-1997-04-23/pdf/97-10695.pdf.

[112] *Id.* at § 5-501(a).

[113] *Id.* at 13045 § 2-202.

[114] Executive Order 12898.

U.S. households, raising concerns about environmental justice. As the SAP advised, "Those at or below the poverty level have greater commensal rodent control challenges and are the least able to afford to do something about it. . . . This should be considered a social equity issue."[115]

109. These several failures demonstrate the legal inadequacy of the NOIC, both procedurally and substantively. Therefore, the NOIC must be rejected.

I. The Agency's Proposals Would Violate Principles of Administrative Law

110. If incorporated in final Agency action, EPA's determinations with respect to the Affected Products and the Proposed Label Amendments would violate applicable principles of administrative law. Not only has the Agency acted arbitrarily and capriciously, but it has also denied Reckitt opportunity to demonstrate or achieve compliance with statutory standards for registration.

(i) EPA's Actions are Arbitrary and Capricious

111. EPA's proposal to continue to allow PCO and agricultural use of SGARs, while banning consumer use, is so unwarranted as to be arbitrary and capricious. As the SAP observed, "[i]t 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 much greater scale."[116] The Agency continues to allow the use of SGARs without bait stations, provided that baits are placed by professional pest control operators or by other users in agricultural settings, in and around residences, commercial establishments, and on government-owned properties.

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[115] SAP Minutes at 46-7.

[116] *Id.* at 49-50.

112. Moreover, only after the SAP proceedings concluded did EPA publicly announce its decision to relax the RMMs for professional-use, outdoor commensal rodenticide products.[117] The Agency revised the requirement that such rodenticides be placed within 50 feet of buildings to allow PCOs to place them up to 100 feet from any "man-made structures" such as dumpsters, docks, and aircraft. *See* Exhibit 14. This point is significant, as applications of rodenticides by PCOs, agricultural users and even by local, state, and federal government agents constitute a substantial source of rodenticides that creates opportunities for exposures to NTOs. This issue was not presented to the SAP, but it clearly has a bearing on the assessment of the comparative risks and benefits of the Affected Products.

113. Furthermore, the RMD permits the sale of bulk quantities of SGARs — literally buckets of rodenticide — through agricultural and online distribution channels, where the general public can purchase them. *See* Exhibits 9 & 10. In fact, as discussed above, EPA has expanded the allowable outdoor uses of agricultural and professional rodenticide placements, substantially increasing the probability of NTO exposure. *See Exhibit* 14. In short, the NOIC targets products that have relatively minor impacts on NTOs, while doing nothing to restrict or reduce the sale of products that more likely account for the majority of wildlife exposures.

114. Finally, the Agency has peremptorily refused to consider Reckitt's Proposed Label Amendments, which mitigate any potential risks associated with the Affected Products. *See* Exhibit 5. Although the Proposed Label Amendments were submitted months ago, the Agency has offered no response but silence. The Proposed Label Amendments are not even mentioned in the NOIC. Not only is there no evidence that EPA has considered them, but the

[117] Memorandum from Richard P. Kiegwin, Jr., Director, Pesticide Re-evaluation Division, to Lois Rossi, Director, Registration Division (Feb. 20, 2012), *available at* http://pestweb.com/assets/files/pestweb/features/Feb2012_EPA_RRMDUpdate.pdf.

Agency has communicated no basis for not considering them, despite the fact that the proposed changes undeniably alter the risk-benefit balance of the Affected Products.[118]

(ii) EPA's Actions Denied Reckitt the Opportunity to Achieve Compliance with FIFRA's Registration Standard

115. The Administrative Procedure Act requires that, with certain inapplicable exceptions, federal agencies provide licensees (here, registrants) the "opportunity to demonstrate or achieve compliance with all lawful requirements."[119] Here, the relevant legal requirement is the basic standard for FIFRA registration, i.e., that the Affected Products not generally cause an unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.

116. Reckitt has repeatedly attempted to modify its products to reduce their putative costs and increase their benefits, by at least two means. First, the Company applied for registration of two separate consumer-use SGARs designed to address the Agency's concerns about wildlife exposure: the products would be formulated as a block; packaged with a compliant bait station; restricted to indoor use only; and accompanied by label language designed to minimize misuse (the Pending Registrations). Second, the Company submitted Proposed Label Amendments cancelling outdoor uses for all of its SGARs, adding Spanish-language use information, and incorporating changes designed to increase consumer comprehension of and compliance with use limitations. Reckitt even provided the Agency, in person, with artwork designed to illustrate what its packaging might look like with the Proposed Label Amendments. *See* Exhibit 20. These actions constituted Reckitt's carefully considered efforts to address the Agency's stated concerns. EPA dismissed them out of hand, refusing to

[118] *See* 7 U.S.C. §§ 136(bb); 136a(c)(5); 136d(b).

[119] 5 U.S.C. § 558(c)(2).

state why they were inadequate or, in the case of the Proposed Label Amendments, failing to respond at all. These actions denied Reckitt the opportunity to demonstrate or achieve compliance with the standards for registration, in violation of the APA. Therefore, the NOIC must be rejected.

CONCLUSION

117. The NOIC fails to demonstrate that the Affected Products fall short of the standards for registration under FIFRA. Contrary to EPA's assertion, available data demonstrate that neither the 12 non-conforming rodenticide products currently registered by Reckitt, nor the two products for which the Company seeks registration, cause unreasonable adverse effects on the environment. Moreover, the Agency's proposed cancellation actions are procedurally and substantive deficient in a multitude of respects, particularly with regard to the analysis required for cancellation or denial of a public health pesticide. Ultimately, because the actions proposed by EPA rest on unsupported assumptions and irrational distinctions among products, final adoption of these proposals would be arbitrary and capricious.

118. For the reasons set forth above, Reckitt respectfully requests a hearing pursuant to FIFRA Section 6(b) to challenge the cancellation proposals set forth in the NOIC, EPA's decision to deny Reckitt's application for registration of additional consumer-use rodenticide products, the Agency's failure to address Reckitt's applications incorporating risk mitigation proposals, and EPA's pre-emptive attempt to prohibit post-cancellation sale of existing stocks, as set forth in the NOIC. In addition, Reckitt respectfully requests discovery in accordance with the FIFRA regulations at 40 C.F.R. Part 164.51, which is necessary both to establish the basis for EPA's proposed actions and to address EPA's recalcitrance in responding to Reckitt's document

requests under the Freedom of Information Act, some of which have been pending since 2009. *See* Exhibit 21.

119. Reckitt reserves the right to raise additional legal and/or factual arguments against the provisions of the NOIC prior to and during the FIFRA 6(b) hearing.

Dated: March 6, 2013

ARNOLD & PORTER LLP

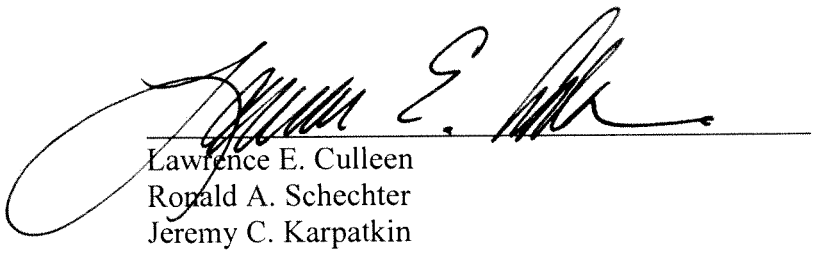

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EXHIBIT LIST	
Exhibit Number	Description
1	Current stamped labels and artwork for all Subject Products [EPA Reg. No. 3282-03; 3282-04; 3282-09; 3282-15; 3282-65; 3282-66; 3282-74; 3282-81; 3282-85; 3282-86; 3282-87; 3282-88]
2	Registration Applications for the Pending Registrations [Provisional EPA Reg. No. 3282-RNU; 3282-RNL]
3	2008 EPA Final Risk Mitigation Decision for Ten Rodenticides [As Amended June 24, 2008]
4	Amended/supplemented applications and related reports for the Pending Registrations [May 20, 2011 Submittal Regarding EPA Reg. Nos. 3282-RNU and 3282-RNL]
5	Applications for label amendment for the Proposed Label Amendments [EPA Reg. Nos. 3282-65; 3282-66; 3282-74; 3282-81; 3282-85; 3282-86; 3282-87; 3282-88]
6	Kaukeinen, 2007. "A White Paper Response to the Proposed EPA Mitigation Measures on Rodenticides of 1/17/2007"
7	Kingston, 2007. "Analysis and Comment regarding EPA description of Human Incident Data found in the 'Impact Assessment for Proposed Rodenticide Mitigation (DP 332577)"
8	Heiden, 2007. "Economic Assessment of EPA Proposed Rodenticide Risk Mitigation Decision"
9	April 20, 2012 Letter from L. Culleen to Jim Jones (with two attachments) [Concerning Sales of Bulk Products on Internet]
10	September 5, 2012 Letter from L. Culleen to Jim Jones [Concerning Sales of Bulk Products on Internet]
11	Submissions and presentations by Reckitt Benckiser to 2011 EPA Scientific Advisory Panel [Includes Volumes I through X]
12	EPA Scientific Advisory Panel Meeting Minutes [Dated December 29, 2011]

13	December 8, 2011 Letter from L. Culleen to Steven Bradbury Regarding SAP Meeting
14	February 20, 2012 and March 14, 2012 EPA Memoranda re: "Commensal Rodenticide Products Outdoor 50 foot Restriction for Professional use Products" [Expanding Scope of Outdoor Application Sites]
15	April 19, 2012 Health & Human Services Letter to E. Wachter (EPA) Regarding "Proposed Risk Mitigation Decision for Rodenticides"
16	April 11, 2012 Letter from Sheryl Kunickis (USDA) to Steven Bradbury Regarding Draft NOIC
17	Tomcat 16 oz. Mouse Killer I Label [EPA Reg. No. 9566.52]
18	2004 Cadmus Group Report, "A Probabilistic Risk Assessment of the Risk of Brodifacoum to Non-Target Predators and Scavengers" and 2007 "Brodifacoum: Assessment Addendum"
19	November 23, 2011 Letter from L. Culleen to Robert Perlis Regarding Existing Stocks
20	Artwork Provided to EPA by Reckitt Benckiser, October 9, 2012 [Representation for Proposed Alternative Labeling]
21	Arnold & Porter FOIA Requests to EPA [2009-2013]

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In re FIFRA Section 6(b) Notice of Intent to Cancel Registrations of, and Notice of Denial of Applications for, Certain Rodenticide Bait Products	)))))	Docket No. _____

CERTIFICATE OF SERVICE

I certify that the foregoing Request for Hearing and Statement of Objections, dated March 6, 2013, was delivered this day in the following manner to the addressees listed below:

Original and Two Copies by Hand Delivery to:

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