

US EPA ARCHIVE DOCUMENT

PREPUBLICATION COPY NOTICE:

The Assistant Administrator for Chemical Safety and Pollution Prevention signed the following Federal Register document on **January 29, 2013**:

Rodenticides; Notice of Intent to Cancel Registrations of, and Notice of Denial of Applications for, Certain Rodenticide Bait Products
[FRL-9377-7]

Docket identification (ID) number: **EPA-HQ-OPP-2013-0049**

This is a prepublication version of the signed document that EPA is submitting for publication in the Federal Register. While the Agency has taken steps to ensure the accuracy of this prepublication version of the document, it is not the official version of the document for purposes of public comment or judicial review. Please refer to the official version of the document that will appear in a forthcoming Federal Register publication, which is currently expected to occur within 7 work days of the signature date.

Once the official version of the document publishes in the Federal Register, the prepublication version of the document that is posted on the internet will be replaced with a link to the document that appears in the Federal Register publication.

To facilitate immediate access to the documents being announced in the prepublication version of the attached Federal Register document, EPA is also providing prepublication access to the on-line docket referenced in this document and available at <http://www.regulations.gov>.

As specifically described in the attached Federal Register document, ALL persons who request a hearing **must comply** with the Agency's Rules of Practice Governing Hearings, 40 CFR Part 164. **Requests for hearing must be filed** with the Hearing Clerk in EPA's Office of Administrative Law Judges following the specific instructions summarized in Unit VI. of the attached Federal Register document.

For further information about the docket and commenting, please consult the ADDRESSES section in the front of the Federal Register document, or visit <http://www.epa.gov/dockets/index.htm>.

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2013-0049; FRL-9377-7]

Rodenticides; Notice of Intent to Cancel Registrations of, and Notice of Denial of Applications for, Certain Rodenticide Bait Products

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Pursuant to section 6(b) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), EPA hereby announces its intent to cancel the registration of 12 rodenticide products identified in this Notice. Pursuant to section 3(c)(6) of FIFRA, EPA hereby announces the denial of applications for registration of 2 products identified in this Notice. This Notice summarizes EPA's basis for these actions, and explains how eligible persons may request a hearing and the consequences of requesting or failing to request such a hearing

DATES: Affected registrants must request a hearing within 30 days of receiving EPA's Notice of Intent to Cancel, or on or before *[insert date 30 days after date of publication in the **FEDERAL REGISTER**]*, whichever occurs later. Other adversely affected parties must request a hearing on or before *[insert date 30 days after date of publication in the **FEDERAL REGISTER**]*.

ADDRESSES: All persons who request a hearing must comply with the Agency's Rules of Practice Governing Hearings, 40 CFR Part 164. Requests for hearing must be filed with the Hearing Clerk in EPA's Office of Administrative Law Judges (OALJ), in conformance with the requirements of 40 CFR Part 164. The OALJ uses different addresses depending on the delivery method. Please see Unit VI. for specific instructions.

FOR FURTHER INFORMATION CONTACT: Neil Anderson, Pesticide Re-evaluation Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8187; email address: *anderson.neil@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What Action is the Agency Taking?

EPA is announcing its intent to cancel the registration of each of the pesticide products listed in Table 1:

Table 1.—Pesticide Products Subject to Cancellation

Product	EPA Reg. No.	Registrant	Active Ingredient	Deficiency
D-Con Concentrate Kills Rats & Mice	3282-3	Reckitt Benckiser, Inc.	Warfarin	Consumer product in a powder form and packaged without a protective bait station
D-Con Ready Mixed Kills Rats & Mice	3282-4	Reckitt Benckiser, Inc.	Warfarin	Consumer product in a pelleted form and packaged without a protective bait station
D-Con Mouse Prufe Kills Mice	3282-9	Reckitt Benckiser, Inc.	Warfarin	Consumer product in a pelleted form and packaged without a protective bait station
D-Con Pellets Kills Rats & Mice	3282-15	Reckitt Benckiser, Inc.	Warfarin	Consumer product in a pelleted form and packaged without a protective bait station

D-Con Mouse Prufe II	3282-65	Reckitt Benckiser, Inc.	Brodifacoum	Consumer product: 1) in a pelleted form and packaged without a protective bait station, and 2) contains a second generation anticoagulant rodenticide (SGAR)
D-Con Pellets Generation II	3282-66	Reckitt Benckiser, Inc.	Brodifacoum	Consumer product: 1) in a pelleted form and packaged without a protective bait station, and 2) containing a SGAR
D-Con Bait Pellets II	3282-74	Reckitt Benckiser, Inc.	Brodifacoum	Consumer product: 1) in a pelleted form and packaged without a protective bait station, and 2) containing a SGAR
D-Con Ready Mixed Generation II	3282-81	Reckitt Benckiser, Inc.	Brodifacoum	Consumer product: 1) in a pelleted form and packaged without a protective bait station, and 2) containing a SGAR
D-Con Mouse-Prufe III	3282-85	Reckitt Benckiser, Inc.	Difethialone	Consumer product: 1) in a pelleted form and packaged without a protective bait station, and 2) containing a SGAR
D-Con Bait Pellets III	3282-86	Reckitt Benckiser, Inc.	Difethialone	Consumer product: 1) in a pelleted form and packaged without a protective bait station, and 2) containing a SGAR
D-Con II Ready Mix Baitbits III	3282-87	Reckitt Benckiser, Inc.	Difethialone	Consumer product: 1) in a pelleted form and packaged without a protective bait station, and 2) containing a SGAR
D-Con Bait Packs III	3282-88	Reckitt Benckiser, Inc.	Difethialone	Consumer product: 1) in a pelleted form and packaged without a protective bait station, and 2) containing a SGAR

EPA is also announcing its denial of the applications for registration of the pesticide products listed in Table 2:

Table 2.—Pesticide Product Registrations Subject to Denial

Product	EPA Application No.	Registrant	Active Ingredient	Deficiency
D-Con Bait Station XV Kills Mice	3282-RNU	Reckitt Benckiser Inc.	Brodifacoum	Consumer product containing a SGAR
D-Con Bait Station XVI Kills Mice	3282-RNL	Reckitt Benckiser Inc.	Brodifacoum	Consumer product containing a SGAR

In addition, this Notice summarizes EPA's basis for these actions (see Unit III.), and explains how eligible persons may request a hearing and the consequences of requesting or failing to request such a hearing (see Unit VI.).

B. What is the Agency's Authority for taking these Actions?

The Agency's authority is contained in FIFRA sections 3(c)(6) and 6(b), 7 U.S.C. 136a(c)(6) and 136d(b).

C. Who is Affected by this Action?

This announcement will directly affect the pesticide registrant listed in Tables 1 and 2, and others who may sell, distribute, or use the products listed in Table 1. This announcement may also be of particular interest to a wide range of stakeholders including environmental and human health advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the other specific entities that may be affected by this action.

D. How Can I Get Copies of this Document and Other Related Information?

To facilitate public access to this document and additional information supporting this action, EPA has established a docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2013-0049. Please note that this docket provides access to related information, but cannot be used for requesting a hearing. Please see Unit VI. for instructions on submitting a request for a hearing.

The docket is available at <http://www.regulations.gov> and at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket that is available at <http://www.epa.gov/dockets>.

II. Legal Authority

With minor exceptions not at issue here, as provided in FIFRA section 3(a), a pesticide product may not be lawfully sold or distributed in the United States unless and until the product is registered by EPA. 7 U.S.C. 136a(a). A pesticide registration is a license allowing a pesticide product to be sold, distributed, and used for specified uses in accordance with use instructions, precautions, and other terms and conditions established by EPA when it grants the registration.

As a general matter, in order to obtain or maintain a registration for a pesticide under FIFRA, an applicant or registrant must demonstrate that the pesticide satisfies the

statutory standard for registration, section 3(c)(5) of FIFRA. 7 U.S.C. 136a(c)(5). That standard requires, among other things, that the pesticide performs its intended function without causing “unreasonable adverse effects on the environment.” The term “unreasonable adverse effects on the environment” is defined under FIFRA section 2(bb) as “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.” 7 U.S.C. 136(bb). This standard requires a finding that the risks associated with the use of a pesticide are justified by the benefits of such use, when the pesticide is used in compliance with the terms and conditions of registration or in accordance with commonly recognized practices. *See Defenders of Wildlife v. Administrator, EPA*, 882 F.2d 1294, 1298-99 (8th Cir. 1989) (describing FIFRA’s required balancing of risks and benefits). The burden of demonstrating that a pesticide product satisfies the statutory criteria for registration is at all times on the proponents of the initial or continued registration, and continues as long as the registration is in effect. 40 CFR 164.80(b). *See also, Industrial Union Dept. v. American Petroleum Institute*, 448 U.S. 607, 653 n.61 (1980); *Stearns Electric Paste v. EPA* 461 F.2d 293, (7th Cir. 1972); *Environmental Defense Fund v. EPA*, 510 F. 2d 1292, 1297 (D.C. Cir. 1975)).

Under FIFRA section 6(b), the Agency may issue a Notice of Intent to Cancel the registration of a pesticide product whenever it appears either that:

1. A pesticide or its labeling or other material required to be submitted does not comply with FIFRA, or

2. When used in accordance with widespread and commonly recognized practice, the pesticide generally causes unreasonable adverse effects on the environment. 7 U.S.C. 136d (b).

If a hearing is requested by an adversely affected person, the final order concerning cancellation of the product is not issued until after an administrative hearing.

In the cancellation hearing, the Agency has the burden of going forward to present an affirmative case for cancellation. 40 CFR 164.80(a). However, the ultimate burden of proof is on the proponent of the registration. 40 CFR 164.80(b); *Industrial Union Dept.*, 448 U.S. at 653 n. 61; *Stearns Electric Paste v. EPA* 461 F.2d 293, (7th Cir. 1972). Once the Agency makes its *prima facie* case that the risks of the product's continued use fail to meet the FIFRA standard for registration, the responsibility to demonstrate that the product meets the FIFRA standard is upon the proponents of continued registration. 40 CFR 164.80(b); *Dow v Ruckelshaus*, 477 F.2d 1317, 1324 (8th Cir. 1973).

FIFRA Section 3(c)(6) provides that where EPA determines that an application for registration does not meet the registration criteria of section 3(c)(5) for registration, the Agency must publish a notice of denial and the reasons therefore. Section 3(c)(6) further provides that upon such notification of the denial, the applicant for registration, or other interested person with the concurrence of the applicant, shall have the same remedies as provided for in section 6.

III. Basis for Issuance of Notice of Intent to Cancel

EPA has determined that the rodenticide registrations listed in Table 1 should be cancelled because they cause unreasonable adverse effects on the environment. EPA has further determined that the applications for registration listed in Table 2 should be denied

because they do not meet the standard for registration under FIFRA. The Agency's rationale for cancellation and denial is set forth more fully in the document "Statement of Reasons and Factual Basis for Notice of Intent to Cancel and Notice of Denial of Certain Rodenticide Bait Product Registrations and Applications" dated January 29, 2013. That document can be found in docket EPA-HQ-OPP-2013-0049 at www.regulations.gov. While interested parties should consult that document for a more detailed rationale of the bases for cancellation and denial, a short summary of the rationale follows.

The purpose of this action is to protect children, pets, and non-target wildlife from unnecessary, unreasonable exposures to certain consumer-use rodenticides. EPA has determined that all consumer-use rodenticide bait products must be used in, and sold with, protective bait stations reasonably anticipated not to release the rodenticide bait; and has further determined that consumer-use rodenticides must not contain second-generation anti-coagulants as active ingredients. The products subject to this Notice all fail to meet at least one of these criteria, and many fail to meet both.

The rodenticides subject to this Notice are designed to kill commensal mice and rats. As mammalian poisons, they are also highly toxic to other mammals and birds. EPA has been concerned about the risks of consumer-use rodenticides to children, pets, and non-target wildlife for many years. This action is an important step in the Agency's continuing efforts to mitigate unnecessary risks associated with rodenticides, while still assuring that people have multiple effective tools for controlling mice and rats in homes.

A. Bait Stations

For many years, EPA has required rodenticide products used to control commensal mice and rats in and around homes to have label language requiring that the

products must be applied in tamper-resistant bait stations if children, pets, domestic animals, or non-target wildlife may be exposed to the product. Unfortunately, that requirement has not proved effective in preventing exposures to children, pets, and wildlife. Separate tamper-resistant bait stations are rarely found in the stores that sell the products subject to this Notice, and thousands of children each year are exposed to rodenticides in the home. Each exposure incident has the potential to cause adverse effects owing to the amount of active ingredient in a single placement of any of the products subject to this Notice. While it is fortunate that children rarely have serious health consequences from exposures to rodenticides used in and around homes, one percent of exposed children (an average of 128 per year from 1999-2005) were reported to have experienced symptoms from the exposure. While EPA is unaware of any fatal or untreatable incidents involving children, pets are not so fortunate, and on average more than 100 pet deaths are reported each year from exposure to rodenticides. And even though children do not routinely suffer significant adverse health consequences, EPA does not believe the great bulk of children's exposures to rodenticides are risk-free or should be taken lightly. To the contrary, the incidence of young children being exposed to rodenticides in the home is unnecessary and poses real risks that should no longer be tolerated.

The risks to young children posed by rodenticide exposure are clearly worthy of regulatory action when compared to other risks Congress has directed EPA to address. In 1996, Congress unanimously adopted the Food Quality Protection Act (FQPA), amending both FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA) to assure that children receive special protection from pesticide residues in food, and that such

residues not be allowed in food unless EPA can find a reasonable certainty of no harm from exposure to those residues. Under this risk-only standard, no level of economic benefits can justify pesticide residues in food that do not meet the reasonable certainty of no harm standard.

The exposures children can get from eating small amounts of rodenticide bait well exceed the safety standard promulgated in the FQPA. EPA fully appreciates that rodenticides are governed by the FIFRA risk-benefit standard rather than the FFDCA reasonable certainty of no harm standard, and that any hearing on this Notice must consider the benefits of rodenticide use against the risks of such use. Nevertheless, the FFDCA criteria for unsafe exposures to pesticides in food provide a meaningful benchmark. If Congress would not allow these levels of pesticide exposure in food – no matter how beneficial the pesticide use might be to agricultural producers – it is reasonable to infer that children should not suffer the same levels of exposures through other routes absent important countervailing benefits.

EPA has looked at the benefits of allowing continued use of consumer-use rodenticide products not in appropriately protective bait stations reasonably anticipated not to release the rodenticide bait, and has concluded that the benefits of such products are generally minimal, and are insufficient to justify the increased risks to children, pets, and non-target wildlife. It is worth noting at the outset that existing labels of the products subject to this Notice do not allow the use of the products in or around homes if children, pets, or non-target wildlife can get access to the product; in such situations the labels direct users to apply the product only in tamper-resistant bait stations. Unfortunately, in the past this label language has failed to prevent many thousands of unlawful exposures

of children, pets, and non-target wildlife to rodenticides. Now, however, consumer-use rodenticide products are commercially available with tamper-resistant bait stations, and in block form that prevents bait from easily escaping the stations. These bait-station products are effective for use against commensal rodents; products similar to these have been widely and successfully used by professional applicators for many years. The great majority of the use of consumer-use rodenticide products is targeted against house mice; bait-station products targeting mice are commercially available at essentially the same price as the products subject to this Notice. There is simply no reason today to allow the continued exposure of children, pets, and non-target wildlife to the rodenticide products subject to this Notice when safer, effective, and economically comparable products are available. These unnecessary, and in most cases unlawful, exposures of children, pets, and non-target wildlife meet the unreasonable risk standard for cancellation and denial.

While there is some increased cost associated with bait station products targeting commensal rats, EPA believes that the increased cost to those consumers who now use unprotected rodenticide baits to control commensal rats in residences where children and pets are never present is acceptable under FIFRA taking into account: The small amount of consumer-use products currently used to target commensal rats; the availability of a number of pesticidal and non-pesticidal alternatives for effectively controlling commensal rats; the lack of success of existing labels to prevent exposures to children, pets, and non-target wildlife; the risks associated with those exposures; and the difficulties in preventing unprotected "rat" products sold in the general consumer market from being diverted to the much more common use against mice. EPA does not believe it appropriate, in making these cancellation and denial decisions, to consider price increases

for consumers who are currently using products subject to this Notice inappropriately, in circumstances where children, pets, and/or non-target wildlife can get access to the placed product.

B. Second-Generation Anti-Coagulants

As noted earlier, all rodenticides are highly toxic to non-target mammals and birds. The risks associated with “primary” exposure (exposure where non-target wildlife consumes the bait intended for rodents) to consumer-use rodenticides are similar across the various rodenticide active ingredients, and can be significantly reduced for most species by requiring that such rodenticides be placed in tamper-resistant bait stations. Bait stations will not, however, protect non-target wildlife from a significant portion of “secondary” exposure to rodenticides; secondary exposures are those where non-target wildlife gets exposed to rodenticides by preying upon or scavenging poisoned rodents or non-target wildlife.

EPA has assessed the secondary risks of rodenticides, and has determined that the class of rodenticides known as second generation anti-coagulants (SGARs) pose significantly greater risks to predators, particularly raptors, than do the other active ingredients contained in consumer-use rodenticide products – bromethalin and first generation anti-coagulants. SGARs pose greater risks of secondary poisoning primarily because of their greater toxicity; their persistence in tissue; and the potential for poisoned rodents to carry “super-lethal” doses (although rodents feeding upon SGARs can consume a lethal dose in a single night’s feeding, the effects are delayed for a number of days during which time the rodents can continue to consume more poison, resulting in many times the lethal dose being found in poisoned rodents). Incident reports provide

further support for the conclusion that consumer-use SGAR products pose significant risks to non-target mammals and raptors, and that these risks are greater than those posed by the other rodenticide active ingredients.

The greater risks of secondary poisoning of non-target mammalian predators and raptors associated with residential consumer use of SGARs are not supported by commensurate benefits. Other rodenticides registered and available for residential consumer use can provide equally effective control of rodents, at similar costs. Non-chemical control methods will remain available, and the use of rodenticides by professional applicators (and agricultural users) is unaffected by this Notice. There are no benefits associated with the residential consumer use of SGARs that justify the significant risks those products pose to non-target wildlife from secondary-poisoning.

IV. Status of Products that Become Cancelled

A. Timing of Cancellation or Denial of Registration

The cancellation or denial of registration for the specific products identified in Table 1 of Unit I.A. of this document will be final and effective on [*insert date 30 days after date of publication in the **FEDERAL REGISTER***] unless a valid hearing request is received regarding that specific rodenticide product.

In the event a hearing is held concerning a particular product, the cancellation or denial of the registration for that product will not become effective except pursuant to a final order issued by the Environmental Appeals Board or (if the matter is referred to the Administrator pursuant to 40 CFR 164.2(g)) the Administrator, or an initial decision of the presiding Administrative Law Judge that becomes a final order pursuant to 40 CFR 164.90(b).

B. Existing Stocks Issues

Existing stocks of cancelled pesticides are those products that were “released for shipment” under FIFRA before the effective date of cancellation. This provision addresses two issues: Whether questions concerning the treatment of existing stocks can be raised at any cancellation hearing; and how the Agency intends to treat existing stocks when and if products are cancelled pursuant to this Notice.

1. Whether questions concerning the treatment of existing stocks can be raised at the hearing. It is settled law that existing stocks issues are not required to be a part of a cancellation proceeding, and that the treatment of existing stocks issues is only included as an issue in a cancellation proceeding when the Notice giving rise to the right to a hearing voluntarily identifies and includes existing stocks as an issue for examination. *In the Matter of Cedar Chemical Co., et al.*, 2 E.A.D. 584, nn. 7,9, 1988 WL 525242 (June 9, 1988) (Decision of the Administrator). The Administrator’s decision in *Cedar Chemical* on whether existing stocks had to be included as an issue in the hearing was affirmed by the United States Court of Appeals for the Ninth Circuit in *Northwest Food Processors Association v. Reilly*, 886 F. 2d 1075, 1078 (9th Cir. 1989). In the case of this rodenticide cancellation Notice, EPA has determined not to include existing stocks as an issue in this hearing. Instead, the only issues for hearing under this Notice are whether the subject products should be cancelled, or the applications should be denied.

2. *Treatment of existing stocks in the event of cancellation.* FIFRA section 6(a)(1) allows the Agency to permit the continued sale and use of existing stocks of pesticides whose use has been cancelled, to the extent the Administrator determines that such sale or use would not be inconsistent with the purposes of this Act. 7 U.S.C. 136d(a)(1). The

Agency does not believe that it would be appropriate under FIFRA to allow any further sale or distribution by any person of the products identified in this Notice if this Notice results in the cancellation of such products, and it does not intend to allow any such sale or distribution if this Notice results in the cancellation of such products. First and most importantly, the continued sale and distribution of products cancelled in a proceeding pursuant to this Notice would continue to cause unreasonable adverse effects on health and the environment. Second, the regulated community has been on notice since May 28, 2008 that the Agency intended that the sale and distribution of these products by registrants cease by June 4, 2011. During that period, most registrants have amended existing rodenticide products, or registered new rodenticide products, that conform to EPA's May 28, 2008 regulatory decision and consequently pose significantly less risk to health and the environment, and such rodenticide products are widely available. EPA does not believe it to be consistent with the purposes of FIFRA to continue to put registrants who timely complied with the Agency's 2008 decision, and brought safer products to the market, at a competitive disadvantage relative to registrants who declined to improve their products. Accordingly, EPA has determined that the continued sale and distribution of existing stocks of pesticide products cancelled pursuant to this Notice should not be permitted, except that EPA intends to allow the limited shipment of existing stocks for the sole purposes of lawful export, proper disposal, or return to the person from whom the holder of the existing stock purchased the product.

V. Mandated FIFRA Reviews

When EPA intends to issue a Notice of Intent to Cancel, it must furnish a draft of that Notice and an analysis of the impact of the proposed action on the agricultural

economy to the Secretary of the Department of Agriculture (USDA) for comment at least 60 days prior to issuing the Notice (FIFRA section 6(b), 7 U.S.C. 136d(b)). When a public health use is involved, section 6(b) directs EPA to solicit information from the Department of Health and Human Services (HHS) on the impact of the cancellation on public health control efforts. In addition, the Agency must within the same time period submit the proposed cancellation action to the FIFRA Scientific Advisory Panel (SAP) for comment concerning the impact of the proposed action on health and the environment (FIFRA section 25(d), 7 U.S.C. 136w(d)).

In the event that written comments are received from the USDA, HHS or the SAP within 30 days of such referral, the Agency must publish those comments and the Agency's response to the comments.

EPA provided the draft Notice of Intent to Cancel and Notice of Denial of Registration for Certain Rodenticide Bait Products and documents supporting that Notice to the SAP on November 3, 2011, and to USDA and HHS on November 17, 2011. EPA convened a meeting of the SAP on November 28 through December 1, 2011, to review science issues related to the proposed cancellations. EPA received the SAP's comments on December 29, 2011; EPA received minutes from the SAP meeting (SAP Minutes No. 2011-06: A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: Scientific Conclusions Supporting EPA's FIFRA Section 6(b) Notice of Intent to Cancel Twenty Homeowner Rodenticide Bait Products) on January 4, 2012. These documents are available in docket EPA-HQ-OPP-2011-0718 at www.regulations.gov.

USDA advised EPA on April 11, 2012 that it had no comments on the proposed cancellation. On April 20, 2012, the Centers for Disease Control and Prevention (CDC) of the Public Health Service submitted comments on behalf of HHS stating they are supportive of requiring bait stations for products used in buildings and of requirements that end residential consumer use of second generation anticoagulants. On April 20, 2012, EPA posted the letters from USDA and CDC in docket EPA-HQ-OPP-2006-0955 at www.regulations.gov.

The letters from USDA and CDC require no response from EPA. The Agency has prepared a response to the comments from the SAP; that response, dated January 29, 2013, can be found in docket EPA-HQ-OPP-2013-0049 at www.regulations.gov.

VI. Procedural Matters

This unit explains how eligible persons may request a hearing and the consequences of requesting or failing to request such a hearing.

A. Requesting a Hearing

1. *Who can request a hearing?* A registrant or any other person who is adversely affected by a cancellation or denial of registration as described in this Notice may request a hearing.

2. *When must a hearing be requested?* A request for a hearing by a registrant or applicant for registration must be submitted in writing within 30 days after the date of receipt of the Notice of Intent to Cancel, or within 30 days after publication of this announcement in the **Federal Register**, whichever occurs later. A request for a hearing by any other person adversely affected by the Agency's proposed action must be

submitted within 30 days of the date of publication of this Notice in the **Federal**

Register. See the **DATES** section of this document.

3. *How must a hearing be requested?* All persons who request a hearing must comply with the Agency's Rules of Practice Governing Hearings, 40 CFR Part 164.

Among other requirements, these rules include the following:

i. Each hearing request must specifically identify by registration or accession number each individual pesticide product concerning which a hearing is requested, 40 CFR 164.22(a);

ii. Each hearing request must be accompanied by a document setting forth specific objections which respond to the Agency's reasons for proposing cancellation as set forth in this Notice and/or the related "Statement of Reasons and Factual Basis for Notice of Intent to Cancel and Notice of Denial of Certain Rodenticide Bait Product Registrations and Applications" dated January 29, 2013, in docket Id number EPA-HQ-OPP-2013-0049, and state the factual basis for each such objection, 40 CFR 164.22(a); and

iii. Each hearing request must be received by the OALJ within the applicable 30-day period (40 CFR 164.5(a)).

Failure to comply with any one of these requirements will invalidate the request for a hearing and, in the absence of a valid hearing request, result in final cancellation or denial of registration for the product in question by operation of law.

iv. *Where does a person submit a hearing request?* Requests for hearing must be submitted to the OALJ. The OALJ uses different addresses depending on the delivery method. Please note that mail deliveries to Federal agencies are screened off-site, and this

security procedure can delay delivery. Documents that a party sends using the U.S. Postal Service must be addressed to the following OALJ mailing address: U.S. Environmental Protection Agency, Office of Administrative Law Judges, 1200 Pennsylvania Avenue NW., Mail Code 1900L, Washington, D.C. 20460-2001.

Documents that a party hand delivers or sends using a courier or commercial delivery service (such as Federal Express or UPS) must be addressed to the following OALJ hand delivery address: U.S. Environmental Protection Agency, Office of Administrative Law Judges, 1099 14th Street NW., Franklin Court Building, Suite 350, Washington, D.C. 20005.

B. The Hearing

If a hearing concerning any product affected by this Notice is requested in a timely and effective manner, the hearing will be governed by the Agency's Rules of Practice Governing Hearings, 40 CFR Part 164, and the procedures set forth in Unit VI. Any interested person may participate in the hearing, in accordance with 40 CFR 164.31.

Documents and transcripts will be available in the public docket for the hearing, located at U.S. Environmental Protection Agency, Office of Administrative Law Judges, Franklin Court, Suite 350, 1099 14th St. NW., Washington, DC 20005. The references can be viewed from 8:30 a.m. to 4:30 p.m., Monday through Friday, except Federal holidays.

C. Separation of Functions

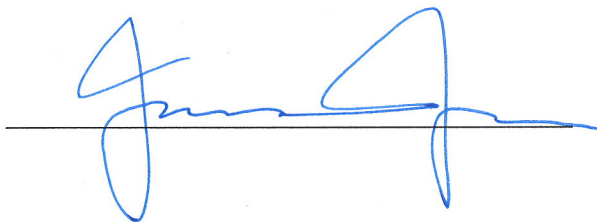
EPA's Rules of Practice forbid anyone who may take part in deciding this case, at any stage of the proceeding, from discussing the merits of the proceeding *ex parte* with any party or with any person who has been connected with the preparation or presentation

of the proceeding as an advocate or in any investigative or expert capacity, or with any of their representatives (40 CFR 164.7). To facilitate compliance with the *ex parte* rule, the following are designated as adjudicatory personnel for purposes of this proceeding: The Administrative Law Judges and their staff, the Environmental Appeals Board and its staff, the Administrator and certain members of her immediate office, and the General Counsel and certain members of his immediate office. None of the persons identified as adjudicatory personnel may discuss the merits of the proceeding with any person with an interest in the proceeding, or representative of such person, except in compliance with 40 CFR 164.7.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: 1 / 29 / 13



Assistant Administrator, Office of Chemical Safety and Pollution Prevention.