# U.S. EPA REREGISTRATION ELIGIBILITY DECISION (RED) FOR THE RODENTICIDE CLUSTER: OVERVIEW OF THE REGULATORY PROCESS, RESPONSE OF REGISTRANTS AND STAKEHOLDERS, AND IMPLICATIONS FOR AGRICULTURAL AND URBAN RODENT CONTROL

**ERIC M. SILBERHORN**, and **JAMES F. HOBSON**, ARCADIS, Geraghty & Miller, Risk and Associated Services, 1131 Benfield Blvd, Suite A, Millersville, Maryland 21108.

**GERALD H. MILLER**, and **NICHOLAS J. CONDOS**, California Department of Food and Agriculture, Plant Health and Pesticide Prevention Services, Integrated Pest Control Branch, 1220 N Street, Room A-357, Sacramento, California 95814.

ABSTRACT: After several years of reviewing study data and conducting risk assessments, in September of 1998 the U.S. Environmental Protection Agency (U.S. EPA) issued for comment a Reregistration Eligibility Decision (RED) document for pesticide products in the Rodenticide Cluster. The RED document covered 243 rodenticide products containing the following active ingredients: brodifacoum, bromadiolone, bromethalin, chlorophacinone, diphacinone and its sodium salt, and pival and its sodium salt. The U.S. EPA's human health risk assessment in the RED document concluded that it was concerned about the risk to children due to accidental exposures to these chemicals through use in and around residences. With regard to ecological effects, the Agency concluded that there is a high risk of secondary poisoning, especially to mammals, from the use of these rodenticides outdoors in rural and suburban areas. In order to address the potential risks to children, the U.S. EPA initially required several mitigation measures designed to minimize exposure (e.g., addition of dye and bittering agent to formulations, labeling changes). The Agency also initiated implementation of a Rodenticide Stakeholder Process through which these and other risk mitigation measures would be discussed and required as needed. To help mitigate potential risks to non-target wildlife, the Agency initially determined that all uses of field-bait rodenticides containing more than 0.005% of chlorophacinone or diphacinone were ineligible for reregistration. The U.S. EPA also decided that all rodenticide products labeled for field use (except those limited to manual underground baiting) should be reclassified as Restricted Use pesticides. This paper reviews the regulatory process for the Rodenticide Cluster RED and discusses the response of the California Department of Food and Agriculture (CDFA) and other registrants to the requirements proposed in the RED document including formation of the Rodenticide Registrants Task Force (RRTF). It also outlines how an on-going dialogue with the Agency, both through the Rodenticide Stakeholder Process and in separate discussions, has diminished the RED requirements from those originally proposed. In addition, the paper discusses the implications and potential impacts of the current RED reregistration requirements for those applicators involved in agricultural and urban rodent control.

KEY WORDS: brodifacoum, bromadiolone, bromethalin, chlorophacinone, diphacinone, pesticide reregistration, risk assessment, risk mitigation, rodenticide, non-target wildlife, stakeholder process

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## INTRODUCTION

After several years of reviewing study data and conducting risk assessments, the U.S. Environmental Protection Agency (U.S. EPA) in September of 1998 issued for public comment a Reregistration Eligibility Decision (RED) document for several hundred pesticide products in the Rodenticide Cluster. The RED document covered 243 rodenticide products containing one of the following active ingredients or their salts: brodifacoum, bromadiolone, bromethalin, chlorophacinone, diphacinone, and pival. Chemical identity information for these active ingredients is presented in Table 1. Among other things, the RED document required major changes in the formulations of home-use rodenticides, product labeling changes, and other mitigation measures to address U.S. EPA concerns over potential risks to young children, commercial applicators, and non-target wildlife species. Issuance of the Rodenticide Cluster RED document initiated a complex process of formal and informal actions and reactions by rodenticide registrants, public interest groups, the U.S. EPA, and other affected stakeholders. This paper discusses the timeline, actions, and responses that have occurred in this process to date, the current state of affairs, and the potential implications of the U.S. EPA requirements for the users of the affected rodenticides.

## OVERVIEW OF THE PESTICIDE REREGISTRATION PROCESS

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires that pesticides[1] sold or distributed in the United States must first be registered by the U.S. EPA. FIFRA also requires that all pesticides that contain active ingredients that were first registered before November 1, 1984 be reregistered to ensure that they meet current safety standards. Under FIFRA, before registering (or reregistering) a pesticide, U.S. EPA must

[1]FIFRA defines a pesticide as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest."

Table 1. Active ingredients included in the Rodenticide Cluster.

| Common Name | Reregistration Case No. | CAS Reg. No. | Chemical Name | Empirical Formula |
|---|---|---|---|---|
| Brodifacoum | 2755 | 56073-10-0 | 3-[3-(4'-Bromo[1,1'-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxy-2H-1-benzopyran-2-one | $C_{31}H_{23}BrO_3$ |
| Bromadiolone | 2760 | 28772-56-7 | 3-[3-(4'-Bromo[1,1'-biphenyl]-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-2H-1-benzopyran-2-one | $C_{30}H_{23}BrO_4$ |
| Bromethalin | 2765 | 63333-35-7 | N-Methyl-2,4-dinitro-N-(2,4,6-tribromophenyl)-6-(trifluoromethyl) benzenamine | $C_{14}H_7Br_3F_3N_3O$ |
| Chlorophacinone | 2100 | 3691-35-8 | 2-[(4-Chlorophenyl)phenylacetyl]-1H-indene-1,3(2H)-dione | $C_{23}H_{15}ClO_3$ |
| Diphacinone | 2205 | 82-66-6 | 2-(Diphenylacetyl)-1H-indene-1,3(2H)-dione | $C_{23}H_{16}O_3$ |
| Pival | 2810 | 83-26-1 | 2-(Trimethylacetyl)-1,3-indanedione | $C_{14}H_{14}O_3$ |

determine that "when used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment." "Unreasonable adverse effects on the environment" are defined under the Act 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."

When deciding whether to register or reregister a pesticide, the U.S. EPA performs human health and ecological risk assessments to determine whether the product causes (or may cause) unreasonable adverse effects on human health or the environment. These risk assessments take into account a number of factors including the use pattern of the product, potential exposure conditions and concentrations, and the toxicity of the active ingredient to man and wildlife. In general, the assessments are based on study data submitted by pesticide registrants, but may also include data from the scientific literature and other sources if available. If U.S. EPA needs additional data to perform or refine a risk assessment, it has the authority to request (call-in) data from the registrant. In many cases, this means that the registrant must contract with a laboratory or research group to conduct new studies to fill U.S. EPA's data gap.

U.S. EPA typically conducts its reregistration assessments for all pesticide products that have the same active ingredient. When it has completed its risk assessments for these products, U.S. EPA prepares a document that summarizes the results of the assessments and classifies the products[2] as to their eligibility for reregistration. This document is called a Reregistration Eligibility Decision, or RED for short. In addition to the eligibility decisions, the RED document contains a summary of U.S. EPA's risk assessments and underlying data, as well as any mitigation measures or regulatory controls being required to ensure that there are no unacceptable risks to man or the environment. Required mitigation measures often include labeling changes and use restrictions that reduce exposure to the human, plant, or animal populations considered to be most at risk (e.g., mixer/loaders, applicators, non-target wildlife).

When the U.S. EPA issues a RED document, it publishes a notice in the Federal Register that the RED is available and how it can be obtained. The Federal Register notice also stipulates a public comment period, usually 60 days, during which the pesticide registrants and interested public may submit comments on the RED to the U.S. EPA for consideration. After reviewing these comments, the U.S. EPA may amend the RED and reissue it with changes in the reregistration eligibility decisions and/or required mitigation measures. When the process is complete, the U.S. EPA requires that all registrants submit a formal reregistration application for each product being reregistered. This application

[2]Eligibility for registration is done on a use by use basis for each product. It is possible for some product uses to be eligible for reregistration while others are not.

includes revised product labeling and other proof that any RED-required risk mitigation measures are being complied with. U.S. EPA then reviews these applications and, if acceptable, reregisters each product. The entire process, from the time U.S. EPA begins work on the RED document for a particular active ingredient until all products containing that active ingredient are reregistered, may take five years or more.

## RODENTICIDE CLUSTER REREGISTRATION ELIGIBILITY DECISION

Availability of the Rodenticide Cluster RED document was announced in a Federal Register notice published on September 11, 1998 (63 FR 48729). This notice provided for a 60-day public comment period on the RED eligibility decisions. It also announced initiation of the Rodenticide Stakeholder Process and interest by the Agency in obtaining State incident data involving non-target and secondary poisoning to wildlife from rodenticides. A synopsis of the Rodenticide Cluster RED assessments, conclusions, and eligibility decisions is presented below.

### Product Use Profiles

The Rodenticide Cluster RED covered almost 250 registered products used to control vertebrate pests, primarily commensal rodents (Norway rat, roof rat, and house mouse), but also a variety of field rodents such as ground squirrels, pocket gophers, and voles. Target species associated with different active ingredients are indicated in Table 2. Products include many forms of food baits (e.g., loose grain, place packs, pellets, blocks), tracking powders, and a few liquid sprays and baits. Most of the products are applied to their use site by hand placement[3], although some of the field-use products (primarily loose baits and pellets) may also be applied via hand broadcast (spot baiting) and/or ground or aerial broadcasting equipment.

Use sites for most products in the Rodenticide Cluster are primarily in and around buildings and homes, but may also include industrial areas, transport vehicles, sewers, farm building, and uncultivated agricultural areas (Table 3). Because none of the active ingredients in the Rodenticide Cluster have food-use tolerances, these products cannot be used to control pests in food crops except under conditions where they will not come into contact with, or migrate to, these crops (e.g., use in bait stations, dormant season application to orchards, physical barriers separate use site and crops).

### RED Conclusions—Human Health

U.S. EPA expressed concern in the RED over the likelihood of risk of human exposure resulting from continued use of rodenticides in residential settings. This concern was based on several factors including the relatively high acute toxicity of rodenticide active ingredients and the high number of rodenticide exposure incidents (>10,000) reported annually to the American Association of Poison Control Centers (AAPCC) through its national data collection system. U.S. EPA's concern focused primarily on young children, because about 90% of the reported exposure incidents involved children less than six years of age and over 95% of them occurred in residential settings. The Agency also expressed concern over potential dermal and inhalation exposures to handlers and users during loading and application of these chemicals. U.S. EPA risk assessments showed unacceptable margins of exposure for residential uses, indicating a high risk potential, particularly for young children. The Agency concluded that short-term risk mitigation measures are necessary to protect children (and pets) from uses of rodenticides in and around the home.

### RED Conclusions—Ecological Effects

Based on available data, the Agency concluded that brodifacoum, bromadiolone, and 0.01% active ingredient (a.i.) chlorophacinone and diphacinone baits may pose a high risk of secondary poisoning to avian and/or mammalian predators and scavengers that feed on poisoned rodents. Uses of these rodenticides outdoors (i.e., "around buildings") in rural and suburban areas are most likely to cause secondary poisoning. U.S. EPA also concluded that brodifacoum and bromadiolone likely pose that greatest secondary risk because they are more acutely toxic, especially to birds, more persistent in animal tissues, and can be lethal in a single feeding. Further, based on incident data it recently obtained, the Agency suggested that "there may be a potential problem specifically involving the active ingredient brodifacoum." The Agency requested the States to submit incident data for all rodenticides in order for it to better understand the extent of the potential problem. It also stated that no final conclusions had been reached and that after reviewing any new data, it might "impose additional restrictions on the use of brodifacoum and/or other active ingredients."

### Reregistration Eligibility Decisions

U.S. EPA concluded that the rodenticide products and uses covered by the Rodenticide Cluster RED document, with the exception of pival (and its sodium salt) and subject to additional labeling requirements and risk mitigation measures described below, will not cause "unreasonable risks to humans and the environment." The Agency determined that all uses of brodifacoum, bromethalin, and bromadiolone are eligible for reregistration. It also determined that all field-bait uses of rodenticides containing greater than 0.005% chlorophacinone or diphacinone (or its sodium salt) were ineligible for reregistration, although field bait uses of similar products with 0.005% a.i. were eligible for reregistration. The Agency based this finding on its belief that field tests have adequately demonstrated that products with lower-concentrations of these active ingredients are sufficiently efficacious for target species, and that the uses with higher concentrations have the potential to cause unnecessary secondary poisonings to avian and mammalian consumers. Finally, the Agency determine that all uses of pival and it sodium salt were ineligible for reregistration because of a previous decision by the registrant not to submit EPA-required data.

[3]Hand placement includes use in bait stations and feeder boxes.

Table 2. Use sites associated with different rodenticide active ingredients.

| Use Site | Brodifacoum | Bromadiolone | Bromethalin | Chlorophacinone | Diphacinone | Pival |
|---|---|---|---|---|---|---|
| In/Around Buildings | X | X | X | X | X | X |
| Inside Transport Vehicles | X | X | X | | | |
| Sewers | X | X | X | X | X | |
| Landfills | | | | | X | |
| Terrestrial Nonfood | | | | X | X | |
| Forestry Plantings | | | | X | X | |
| Nurseries | | | | | X | |
| Levees/Ditch Banks | | | | X | X | |
| Orchards (dormant or nonbearing) | | | | X | X | |
| Terrestrial Food Crops (bait boxes) | | | | X | X | |
| Aquatic, Nonfood (bait boxes) | | | | X | X | |

Risk Mitigation Requirements

Although the Agency concluded that most of the products and uses in the Rodenticide Cluster were eligible for reregistration, it nonetheless required implementation of several risk mitigation measures in order to conclude that there would be no "unreasonable adverse effects on the environment" as required by FIFRA. In order to minimize exposure to infants and children, U.S. EPA developed a two-phase risk mitigation approach that included short-term formulation changes and stakeholder involvement in developing long-term measures. Phase I called for incorporation of an indicator dye (to help identify whether a child or pet had actually consumed or been exposed to the product) and a bittering agent (to reduce palatability and deter consumption) into the formulations of all rodenticide products other than those used exclusively at agricultural sites. A specific deadline was not set for implementation of the Phase I formulation changes (this was to be discussed at a follow-up meeting), although they were perceived by the Agency as something that could be implemented in a relatively short time.

Phase II of the risk mitigation process was to begin with formation of a Rodenticide Stakeholder Workgroup (RSW) composed of representatives from industry, U.S. EPA, state agencies, poison control centers, rodent control experts, the medical community, and other interested parties. The initial stakeholder meeting was to be held within 120 days for the issuance of the RED document. The mission of this workgroup was to develop additional means of significantly reducing exposures to children and pets.

There were several other risk mitigation measures and labeling changes (see below) required in the RED document, although they did not apply to all products and/or uses. To protect children, pets, and non-target species, U.S. EPA required that all tracking powders be classified and labeled as restricted use pesticides (i.e., use of products was restricted to certified applicators and persons under their direct supervision). To reduce the potential for secondary poisonings, U.S. EPA required that all products labeled for field uses (except for those limited to manual underground baiting) be reclassified and labeled as restricted use. To protect the applicators of tracking powders from potential toxicity via inhalation, the Agency required that all users of these products wear dust/mist respirators and protective eyewear. Additional personal protective equipment (PPE) requirements, including gloves, protective eyewear, and a dust mask/mist respirator, were also added for occupational handlers (commercial applicators) of non-paraffinized rodenticide formulations.

Required Label Changes

In the RED document, U.S. EPA required a number of labeling "improvements" to lessen potential risks to man and the environment. Because of its concerns over unrestricted usage of residential use rodenticides "in and around buildings," the Agency required that labels for these products be amended to read "indoors and against the outside walls of buildings." Continued use of the phrase "around buildings" would be allowed only if registrants could demonstrate from secondary hazard

Table 3. Target pest species associated with use of different rodenticide active ingredients.

| Pest Species | Brodifacoum | Bromadiolone | Bromethalin | Chlorophacinone | Diphacinone | Pival |
|---|---|---|---|---|---|---|
| Norway Rat | X | X | X | X | X | X |
| Roof Rat | X | X | X | X | X | X |
| House Mouse | X | X | X | X | X | X |
| White-footed Mouse | | | | | X | |
| Voles | | | | X | X | |
| Ground Squirrels | | | | X | X | |
| Chipmunks | | | | X | X | |
| Jackrabbits | | | | X | X | |
| Cottontail Rabbit | | | | | X | |
| Pocket Gophers | | | | X | X | |
| Cotton Rats | | | | X | X | |
| Wood Rats | | | | X | X | |
| Rice Rats | | | | | X | |
| FL Water Rat | | | | | X | |
| Polynesian Rat | | | | | X | |
| Muskrat | | | | X | X | |
| Moles | | | | X | | |
| Mongoose | | | | X | X | |

studies that risks to birds and mammals were minimal. Additional labeling modifications were required by the Agency to reduce product misuse and the potential for incidents. These modifications included clarification and/or expansion of "Directions for Use," first aid statements, and instructions for veterinarians.

Additional Required Data

In order to confirm its regulatory assessments and conclusions, the Agency required the registrants of the technical grade active ingredients (i.e., generic ingredients) to conduct and submit several studies relating to their products. The required studies varied depending on the specific active ingredient, but generally included dermal and inhalation exposure studies, secondary hazard studies, and target species residue studies, unless these studies had previously been submitted to the Agency. The Agency also required product-specific data including product chemistry and acute toxicity studies, revised labeling, and new Confidential Statements of Formula (CSFs). New data were to be submitted to the Agency no later than eight months after receiving notice from the Agency that the RED document has been issued.

RESPONSES OF REGISTRANTS TO RED

When the Rodenticide Cluster RED document was formally issued in the fall of 1998, it caused considerable concern among the registrants of the affected rodenticides. There were several reasons for this. U.S EPA was requiring extensive changes in product formulations by mandating that home use rodenticides contain an indicator dye and bittering agent. Registrants were very concerned that these changes could not be successfully implemented in a timely manner, and that even if they could, the formulation changes might cause decreased efficacy of products toward target species (rats and mice) or other unintended "side effects" that would adversely affect product usage and, ultimately, product sales (e.g., staining of carpets and floors by the indicator dye). In addition, the data and arguments presented in the RED document did not convince the registrants that U.S. EPA had provided adequate justification for the extensive risk mitigation measures being required. Several of the decisions in the document were perceived to have been based on current priorities of the Agency administration (e.g., children's health issues), rather than sound science and risk assessment.

CDFA Response

Among the registrants, the California Department of Food and Agriculture (CDFA) was quite concerned that U.S. EPA's decisions could adversely affect the State's agricultural economy (estimated at approximately $26 billion annually) and increase crop loss due to rodent damage above the current estimate of $100 million per year. Specifically, CDFA was alarmed that U.S. EPA's decisions would effectively result in loss of almost all uses of two of CDFA's widely used grain-based rodenticides that were important for the control of rodents causing major damage to California agriculture. These were Special Local Needs (SLN) field bait products containing either 0.01% chlorophacinone or diphacinone that were usually applied by mechanical broadcast techniques. CDFA was also concerned over EPA's decision that required reclassification of all of CDFA's field bait products as restricted use pesticides. Further, CDFA felt that several of the uses of its registered products "in and around" farm buildings might trigger EPA's requirements for an indicator dye and bittering agent, even though these products are sold only by Agricultural Commissioners and are not meant for general homeowner use.

In October 1998, CDFA hired ARCADIS Geraghty & Miller (ARCADIS), an international environmental consulting firm with extensive experience on pesticide regulatory issues, to help it evaluate the potential impacts of the RED document on California agriculture and respond accordingly. CDFA also asked ARCADIS to investigate interest in formation of an industry coalition or task force of registrants to respond in a coordinated and united manner to U.S. EPA's decisions and requirements. With assistance from the Washington, D.C. law firm of Bergeson & Campbell, P.C., ARCADIS prepared extensive comments on the Rodenticide Cluster RED document including a critique of several inadequacies in EPA's risk assessment analyses and documentation of its failure to issue the RED in compliance with administrative and legal requirements. In early January 1999, CDFA submitted these comments to the public docket for formal consideration by U.S. EPA. In this submittal, CDFA urged the Agency to withdraw, revise, and reissue the RED document, as well as to reconsider its ineligibility decision regarding field uses of bait products with greater than 0.005% chlorophacinone or diphacinone.

Formation of RRTF

Through CDFA's leadership and initiative, contacts were made with several key industry representatives in the fall of 1998 after the Rodenticide Cluster RED document was issued in order to gauge industry reaction and assess potential impacts on registrants and end users. During November and December 1998, with CDFA's support, ARCADIS and Bergeson & Campbell contacted several companies that manufactured or imported active ingredients and formulated products included in the Rodenticide Cluster. There was interest by these registrants in forming a unified group to deal with issues surrounding the RED document. In late December 1998, an initial conference call was held with most of the interested parties and there was widespread agreement to form the Rodenticide Registrants Task Force (RRTF)[4]. Formation of the RRTF allowed for effective cost sharing and consensus building within the group, and also gave U.S. EPA an organized body to interact and negotiate with on RED-related issues.

All of the major U.S. rodenticide registrants chose to participate in and support the RRTF. This widespread support ultimately contributed to the success of the RRTF in accomplishing many of its goals and objectives. Once formed, the RRTF held regular conference calls and meetings to discuss issues and strategy, develop consensus opinions, and prepare position statements and white papers. ARCADIS provided management and scientific support to the group, while Bergeson & Campbell provided legal assistance, strategic advice, and logistical support.

Follow-up Interactions with the Agency

Subsequent to issuance of the RED document, both CDFA and the RRTF as a whole continued to interact with the Agency on a variety of issues. For example, in February 1999, U.S. EPA held a meeting with rodenticide registrants to discuss the risk mitigation measures required in the RED document. The primary purpose of this meeting was to define which rodenticide products would need to incorporate the indicator dye and bittering agents, and to discuss the registrants' plans and concerns related to these formulation changes. At this meeting, RRTF representatives made presentations on the industry's consensus positions on several of the RED document's key issues. An outcome of the meeting was a better understanding on the Agency's part of the potential difficulties and downsides of making significant changes in product formulations, and the necessary timeframes to do so. In addition, a direct result of this meeting was the Agency's decision to delay the requirement for an indicator dye in the home use product formulations until this could be considered further in the Rodenticide Stakeholder Process.

During 1999, CDFA held a series of meetings with U.S. EPA staff members in the Reregistration and Registration Divisions. The primary purposes of these meetings were to educate and inform the Agency regarding the unique qualities of CDFA's rodenticides, their uses and importance to agriculture in California, and the extent of current practices in place to insure their safe and effective use (e.g., County Bulletin Program to protect Threatened and Endangered Species). A secondary objective was to open the dialogue between CDFA and U.S. EPA on secondary hazard and ecological risk assessment issues to insure that CDFA could take the necessary steps to maintain the registrations and uses of its grain-based agricultural rodenticides.

## RODENTICIDE STAKEHOLDER PROCESS

The Rodenticide Stakeholder Process began with a one-day organizational meeting of the Rodenticide

[4]The initial members of the RRTF were CDFA, Bell Laboratories, Consolidated Nutrition, HACCO Inc., J. T. Eaton, LiphaTech Inc., PM Resources, Reckitt & Colman, Wilco Distributors, and Zeneca Agricultural Products.

Stakeholder Workgroup (RSW) in late March 1999. The group included approximately 25 diverse members from state, local, and federal governmental agencies (e.g., U.S. EPA, U.S. Department of Agriculture, Center for Disease Control, Consumer Product Safety Commission, CDFA, City of Chicago Bureau of Rodent Control), the rodenticide industry (LiphaTech, HACCO, Reckitt & Colman, PM Resources, Bell Laboratories), trade groups and associations (e.g., National Pest Control Association; Association of Structural Pest Control Regulatory Officials, Chemical Specialties Manufacturers Association), the medical community, public interest groups, and other interested parties. At the initial RSW meeting, the group discussed and developed a Mission Statement, and U.S. EPA outlined several potential regulatory options it wanted the RSW to consider. These options included improved labeling, product reformulation (e.g., incorporation of bittering agent and/or indicator dye), product repackaging (e.g., baits to be packaged in ready-to-use "child-hindering" or tamper-resistant bait stations), and reclassification of some or all products for restricted use. The RSW mission included advising U.S. EPA "regarding potential measures to preclude or reduce the occurrence of unintentional exposures of young children to rodenticides in and around residences." The RSW recommendations were to be made taking into account several factors including: 1) the public health benefits of rodenticides; 2) avoiding the creation of other human health "hazards"; 3) recognizing the equity of those who bear the cost and regulatory burden; and 4) considering the overall economy and efficacy.

The RSW held a two-day meeting in mid-June 1999 where a number of presentations were made by U.S. EPA staff, outside experts, and RRTF members on issues of importance to the RSW's mission. Presentation topics included the benefits, toxicity, and use of rodenticides, as well as an analysis of incident and exposure data for children. Following these presentations, the RSW discussed risk/benefit issues, the implications of the incident data, and the need for various regulatory options. This meeting served to educate members of the group and bring them to a common level of understanding of the issues; however, no clear consensus was reached and the group made no specific recommendations.

In mid-July 1999, the RSW met again for a day to further evaluate several potential solutions to help reduce the number of unintentional exposures to children and pets. At this meeting, the RRTF proposed a path forward that included new "consumer-friendly" product labels and a consumer education/outreach program. There was general consensus among the Stakeholders that these measures would be beneficial and that they should be recommended to U.S. EPA. The group also discussed several other potential solutions and discarded the following options as unnecessary, ineffective, cost prohibitive, or overly burdensome: 1) the addition of an indicator dye; 2) reclassification of all or some products as restricted use pesticides; and 3) the requirement for "child-hindering" packaging.

After the July RSW meeting, RRTF members drafted several "consumer-friendly" labels and met several times with U.S. EPA staff members to further develop these labels. In October 1999, the RSW met a final time to formulate its recommendations. At this meeting, the RRTF and U.S. EPA presented the "consumer-friendly" label to the RSW and received general approval from the Stakeholders. It was recommended that the RRTF continue working with U.S. EPA to finalize the content of the label and work out implementation issues. The RSW also discussed the remaining regulatory options originally given to it by U.S. EPA. Stakeholders rejected the requirement that all products be sold in tamper-resistant bait stations. They recommended that any product reformulation to include a bittering agent be done at the registrant's option. The meeting ended with a commitment by the U.S. EPA to prepare a report summarizing the Rodenticide Stakeholder Process and listing the recommendations made by the RSW for implementation by U.S. EPA. This report was to be submitted by the U.S. EPA to the Pesticide Program Dialogue Committee (PPDC) for its endorsement[5].

## OPEN MEETING ON HAZARDS TO BIRDS AND NON-TARGET WILDLIFE

On October 19, 1999, the U.S. EPA held an open meeting to solicit comments from interested parties on the hazards of rodenticides to non-target species such as birds and terrestrial wildlife. In purpose of the meeting was to gather information and comments for use by U.S. EPA in refining its rodenticide ecological risk assessments and amending the Rodenticide Cluster RED document. The meeting included presentations by U.S. EPA staff, a state wildlife pathologist, a wildlife conservation group, rodenticide industry experts, and RRTF members. Presentations covered the comparative toxicity of different rodenticide active ingredients to birds and wildlife, ecological effects incident data and their possible implications, and the risk/benefits of rodenticide use. There was considerable disagreement as to the importance of the wildlife and bird incident data. These data suggested that incidences were most prevalent in suburban areas and that most incidences were caused by second-generation (single feeding) anticoagulants such as brodifacoum and bromadiolone. Because the number of documented incidences was quite low compared to the amount of rodenticides used annually, participants could not agree whether this data was only the "tip of the iceberg" or an indication of a minor problem due mainly to intentional misuse of rodenticides by homeowners. There was also disagreement on the biological and toxicological significance of rodenticide residues in birds and wildlife, and whether the mere presence of body residues implied that individuals were at risk.

## WHAT IS THE CURRENT SITUATION?

As this paper is being written, almost six months after the conclusion of the Rodenticide Stakeholder Process, there are still many unresolved issues associated with the Rodenticide Cluster RED. Because of internal changes in staffing, U.S. EPA has not yet issued the RSW Report

[5]The RSW was initially set up as a workgroup to the PPDC; therefore, all of its recommendations were technically made to the PPDC and not to U.S. EPA directly.

for submittal and endorsement by the PPDC, and no meetings have been held with the RRTF to discuss the final format of the "consumer-friendly" rodenticide labels. As a result, there has been no progress on these issues and the situation is essentially the same as before the Rodenticide Cluster RED document was originally issued. U.S. EPA has also yet to issue an amended Rodenticide Cluster RED document and this is not expected for some time after the RSW recommendations are considered (and presumably endorsed) by the PPDC and sent back to U.S. EPA to be taken under advisement. The amended RED document is expected to contain new or substantially revised ecological risk assessments that address non-target hazard issues, taking into account new data submitted since the original document was prepared. In addition, the amended RED document may possibly also contain new regulatory requirements (e.g., mitigation measures, label changes, and/or use restrictions) based on the outcome of these risk assessments.

At the time of the final RSW meeting in October 1999, U.S. EPA staff stated orally that the Agency was considering making several changes and deletions in the regulatory requirements originally included in the Rodenticide Cluster RED document. It expected to issue a letter to registrants within a few weeks outlining these regulatory changes and deletions. To date, this letter has not been issued and the status of these changes is unknown; however, at the time the U.S. EPA expected to: 1) rescind the indicator dye requirement; 2) relax several PPE requirements; 3) retain the restricted use reclassification requirement for field-use rodenticide products; and 4) allow reregistration of uses of 0.01% chlorophacinone and diphacinone field-use products subject to certain use restrictions.

Until the U.S. EPA issues revised regulatory requirements and compliance deadlines, the requirements of the RED document have been put on hold for most rodenticide products, except for those used strictly for agricultural purposes. For agricultural use rodenticides, the submittal deadline for reregistration applications was changed by U.S. EPA to December 31, 1999, although registrants were asked not to submit new product labels until requested sometime in the future. For the home-use rodenticides, the deadline for submittal of reregistration materials and "consumer-friendly" labels is not expected to be until eight months after issuance of the amended Rodenticide Cluster RED document.

## IMPLICATIONS FOR AGRICULTURAL AND URBAN RODENT CONTROL

Until the Rodenticide Cluster products begin to be reregistered and have received their accepted "stamped" labels, there will be little effect on product end users. For home-use rodenticide products, few, if any, changes are anticipated for at least a year or two, and possibly much longer depending on when the amended Rodenticide Cluster RED document is reissued. At this point it is very difficult to predict the ultimate implications of the amended RED on urban rodent control, because there could potentially be new regulatory requirements due to the Agency's concerns over hazards to non-target species. However, based strictly on the outcome of the Rodenticide Stakeholder Process, effects on pest control operators (PCOs) and commercial applicators are expected to be minor and easy to implement. Users will continue to be instructed by product labeling to place baits in locations not accessible to children and pets, and if this is not possible, in tamper-resistant bait stations. Use of tamper-resistant bait stations is already standard industry practice, particularly when PCOs are treating households with pets and children. It is expected that U.S. EPA will take additional steps to encourage use of tamper-resistant bait stations by both homeowners and PCOs when baiting outdoors "around homes" in order to minimize hazards to non-target birds and mammals that might accidentally consume bait intended for commensal rodents.

Rodenticide formulations are not expected to change significantly in the short-term, although manufacturers may voluntarily seek U.S. EPA approval to add a bittering agent or reduce the amount of active ingredient if testing shows that these things can be done without compromising product efficacy. Some home-use rodenticide products already contain a bittering agent; however, this is not a well known fact because U.S. EPA does not allow the manufacturers of these rodenticides to make any safety claims for these products (e.g., "our product is safer because it contains a bittering agent").

For agricultural-use products, the effects on users will be much sooner because the registrants have already submitted their reregistration applications and the review process has begun. There could still be additional changes in the regulatory requirements and use restrictions for these products, but the situation is not expected to change significantly from what was communicated by U.S. EPA in October 1999. The requirement that is expected to have the largest impact on applicators is the reclassification of all agricultural-use rodenticide products as restricted use pesticides. This will limit the usage of field-use rodenticides to certified applicators (or persons under their direct supervision) in all states, and may trigger additional use reporting requirements at the state and/or county level. Current users who are not certified applicators will need to become certified once the products are reregistered and have new labels.

With respect to its 0.01% chlorophacinone and diphacinone grain bait products that were originally declared ineligible for reregistration by U.S. EPA, CDFA remains guardedly optimistic that this decision will be rescinded and that use of these agricultural products will be allowed to continue albeit with some restrictions on application rates and use sites. In the meantime, with funding obtained through a grower-financed product surcharge, CDFA continues to sponsor laboratory and field research to determine the optimal baiting strategies for these rodenticides. It is hoped that this research will lead to changes in the product use patterns (e.g., number and timing of applications) that will reduce risks to non-target species without compromising the ability of these rodenticides to help control populations of the California ground squirrel and other pests that cause significant damage to agricultural crops in California.

## SUMMARY

The reregistration process for products in the Rodenticide Cluster continues to move forward. Required

data for agricultural-use products have already been submitted to the Agency and are currently being reviewed. Supporting data and new "consumer-friendly" labels for residential-use products are expected to be submitted no later than eight months after U.S. EPA completes its new risk assessments and issues an amended RED document. Implementation of the Rodenticide Stakeholder Process, as well as the on-going dialogues with CDFA, other registrants, and the RRTF, have resulted in a better understanding by all affected parties of the issues and potential risks associated with use of these products in both residential and agricultural settings. These dialogues and discussions caused the U.S. EPA to reconsider several of its reregistration eligibility decisions and risk mitigation measures, and in some cases to rescind or substantially alter its initial determinations and requirements. Ongoing interactions with the Agency also pushed the rodenticide industry to unite and work together in a positive manner to address the Agency's concerns and propose alternative risk mitigation measures to reduce accidental exposures to children and pets. In a similar manner, CDFA is sponsoring research with grower-supported product surcharge monies that may help reduce potential risks to birds and non-target wildlife. It is hoped that the outcome of the complex and lengthy reregistration process will be "safer" rodenticides for our children and the environment, without a sacrifice in the efficacy and cost-effectiveness of these significant public health and agricultural-use pesticides.