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# THE RATIONALE FOR REQUIRING BITREX AND DYES IN RODENT BAIT

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**ABSTRACT:** In 1998, the Environmental Protection Agency issued Reregistration Eligibility Decisions for the rodenticides Brodifacoum, Bromethalin, Bromadiolone, Chlorophacinone, Diphacinone, Pival, and Zinc Phosphide. These decisions imposed requirements that bait products containing these ingredients and marketed for control of commensal rodents also contain an "indicator dye" and a "bittering agent." The indicator dye would be used to mark children who come in contact with bait. The bittering agent would be used to render a bait unpalatable to children, possibly reducing the amount of bait eaten. This paper discusses these requirements and other regulatory attempts to limit risks of rodenticide baits to children and nontarget animals. EPA is reconsidering the requirements for the indicator dye and bittering agent. Currently, either type of agent may be added to a bait product voluntarily if the new bait can pass required efficacy tests.

**KEY WORDS:** bittering agent, Bitrex, Brodifacoum, Bromethalin, Bromadiolone, Denatonium Benzoate, Diphacinone, Chlorophacinone, indicator dye, Pival, registration, reregistration, rodenticide efficacy, rodenticide incidents, tamper-proof bait box, tamper-resistant bait station, Warfarin, Zinc Phosphide.

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## INTRODUCTION

In August of 1998, U.S. Environmental Protection Agency (EPA) issued Reregistration Eligibility Decisions (REDs) for the rodenticide Zinc Phosphide (EPA 1998a) and for a "Rodenticide Cluster" (EPA, 1998b) which included Bromethalin and the anticoagulants Brodifacoum, Bromadiolone, Chlorophacinone, Diphacinone and its sodium salt, and Pival (Pindone) and its sodium salt. These compounds are used primarily in baits registered for controlling commensal rodents: Norway rats (*Rattus norvegicus*), roof rats (*R. rattus*), and house mice (*Mus musculus*). Chlorophacinone and Diphacinone also are widely used to control certain field rodents. The Rodenticide Cluster RED declared all of these compounds except Pival and its sodium salt to be eligible for reregistration. EPA also declared Zinc Phosphide eligible for reregistration. For compounds declared eligible, product reregistration was contingent upon meeting certain additional requirements. EPA declared Pival ineligible largely because its principal registrant declined to support its reregistration.

## THE RED DILEMMA

Those in EPA who worked on the Rodenticide Cluster RED faced evidence that well over 10,000 incidents of accidental exposures of children under six years of age to rodenticides are reported annually (e.g., Litovitz et al. 1994; Blondell 1999) and realized that failure to comply with label requirements regarding bait placement and storage was a likely factor in most of those incidents. The question then became, "Can we do anything about this?"

EPA considered options ranging from continuing to rely on the bait protection text indicated in PR Notice 94-7 (Johnson 1994) to classifying all rodenticide baits as "Restricted Use Pesticides," thereby limiting their sale to certified applicators and their use to such applicators and those working under the direct supervision of certified applicators. The status quo approach would have offered

little but hope for gradual improvement over current levels of incidents. The restricted use option would have reduced the number of incidents involving registered baits, along with the public's access to them.

In the health effects data assessments for the Rodenticide Cluster and Zinc Phosphide REDs, EPA calculated margins of exposure (MOEs) which suggested that consuming a mouthful of bait (roughly 5 g) could have negative consequences on the health of a 10 kg (22 lb) child. Combined with available incident data, those calculations could be used as a basis for recommending restricted use classification for all of the Rodenticide Cluster chemicals later declared eligible for reregistration. However, restricting all of the baits might have left some segments of the population without access to affordable rodent control and would have been unfair to uncertified applicators who now use baits responsibly, either by placing them in areas not accessible to children and nontarget animals or in tamper-resistant bait stations.

Short of restricting all chemicals covered by the two REDs, EPA also considered restricting the most hazardous active ingredients and limiting over the counter (OTC) sales of rodenticide baits to formulations prepackaged in ready to use, tamper-resistant bait stations (RTU TRBSs). Compound-specific reclassification was not supported by the assessments of human health effects because, based on the data reviewed, none of the compounds was judged to be much safer to children than any of the others.

While the RTU-TRBS approach could have kept rodenticides on the consumer market, there were no such products available when the REDs were issued. Due to unit size and the ratio of plastic to bait needed, the RTU-TRBS option seemed less viable for rat control products than for those claimed to control house mice. Past efforts to introduce RTU-TRBS mouse-control products under prevailing market conditions were not successful; although, demand might have been greater if that had been the only type of rodenticide product that could be

sold OTC. However, making rodenticides either very expensive or impossible for consumers to purchase legally could result in the proliferation of "home remedy" and/or "black market" approaches that might increase risks.

#### EFFORTS TO DETECT AND REDUCE EXTENT OF CHILD INCIDENTS

As indicated in the Rodenticide Cluster RED, EPA decided to retain existing bait protection text and to impose "Phase 1" requirements for rodenticide bait formulations to include an "Indicator Dye" and a "Bittering Agent." Similar requirements were included in the Zinc Phosphide RED, where they pertained to baits not "used exclusively in an agricultural setting" (EPA 1998b). Both REDs acknowledged that reformulating baits to include such ingredients might require more time than the eight month period usually given for submitting relevant product-specific data and revised labeling in response to REDs.

"Phase 2" of the risk mitigation process included the convening of "a Stakeholder group" which was to meet to discuss means of significantly reducing exposures to children and pets (EPA 1998a).

The Phase 1 and Phase 2 requirements were new Federal efforts at resolving the dilemma of how to derive pest control benefits from rodenticides without poisoning humans or nontarget animals in the process. In the Rodenticide Cluster RED, EPA also announced its intention to extend Phase 1 and 2 risk mitigation efforts to rodenticide compounds not covered by that RED.

As part of its Phase 2 risk-mitigation strategy, EPA convened a panel—the Rodenticide Stakeholders Workgroup (RSW). The RSW met in March, May, June, July, and October of 1999.

#### Indicator Dye

As conceived for the REDs, an indicator dye would mark tissues of children so that parents or other caregivers could quickly determine whether a child had actually touched or mouthed the bait, as opposed to having only touched an intact bait container, such as a placepack, or played near the bait. This dye was expected to limit the number of cases referred for medical treatment to those for which treatment might be warranted (Blondell 1999).

Although there are dyes in many registered baits, no dye currently used has been shown to EPA to be consistent with the indicator dye concept implied by the REDs. The ideal indicator dye for a bait seemingly would have the following properties:

1. not toxic to children or pets;
2. able to clearly mark all children reliably, regardless of the tissue contacted and its pigmentation;
3. able to mark children uniquely so as not to be confused with foods and beverages that children commonly consume;
4. visible to the naked eye so that any sighted person could detect the marking;
5. easily removed with water or soap and water after exposure determination;

6. not deterrent to bait acceptance by target species; and
7. not antidotal or antagonistic to bait's toxicant.

Any candidate indicator dye would have to be assessed for oral and dermal toxicity. If acceptable in those areas, the dye next would have to be screened for its tissue-marking properties. If not already in the bait at an indicator-appropriate concentration, the dye would have to be mixed into a bait and screened for adverse effects on efficacy as some dyes greatly reduce bait palatability (Palmateer 1979). If the new bait failed the efficacy test, the entire development and testing process would have to be repeated with another candidate indicator dye.

If identified, an ideal indicator dye would not reduce the number or the extent of child incidents. The dye would enable caregivers to determine whether exposures had occurred, thereby reducing parental anxiety and the number of cases treated unnecessarily. A unique and reliable indicator dye might identify child exposures that would have gone undetected otherwise, paradoxically increasing the number of reported cases. However, if a candidate indicator dye fell short on any of the tissue-marking properties listed above (items 2 to 4), its suitability as a marking agent would be reduced, as would its superiority in that regard to the dyes now used in baits. If a dye marked children for days or weeks, users might complain.

#### Bittering Agent

Bittering agents have been added to rodenticide baits to impart an unpleasant taste in the hope that any child who had mouthed such a bait would not eat very much of it (Kaukeinen and Buckle 1992). Use of bittering agents in rodenticide baits began around 1990 through the voluntary efforts of certain registrants looking to improve product stewardship (e.g., Kaukeinen and Buckle 1992). Such endeavors were concurrent with others' efforts to reduce risks associated with various household products and to find new applications for the bittering agent Denatonium Benzoate (trade name: Bitrex®) (Payne 1988; Klein-Schwartz 1991).

Recalling the Federal pesticide program's historical efforts to enhance bait palatability to target rodents (Palmateer 1974; Palmateer and McCann 1976; Peacock and Palmateer 1979, 1981) and to promote safer use and handling of rodenticide baits (e.g., Jacobs 1990a,b), EPA permitted Bitrex to be added to rodenticide baits, as long as registrants:

1. submitted laboratory efficacy data showing that the new bait was sufficiently palatable and lethal to target species;
2. did not alter existing use directions or precautionary statements; and
3. made no safety claims for product.

The first two of these conditions have been met for all U.S.-registered baits claimed to contain Bitrex. Kaukeinen and Buckle (1992) reported that baits containing Bitrex also performed as well under field

conditions as did those lacking the substance, but some participants at RSW meetings claimed the opposite experience. The only references to Bitrex that EPA permits on labels are relatively inconspicuous statements indicating that Bitrex is in the product.

The "bittering agent" approach recognizes that child incidents are going to occur with rodenticide baits and tries to minimize associated risks by limiting the amount ingested. Kaukeinen and Buckle (1992) offered adult human volunteers placebo rodenticide baits (pelleted and wax-block formulations). Subjects tended to dislike placebo baits that were adulterated with Bitrex at 10 ppm, while responding more positively to unadulterated placebos. Not all subjects intensely disliked the contaminated baits, and less deterrence might have been observed if infants and young toddlers had been tested.

Klein-Schwartz (1991) reviewed then-available data on the effectiveness of Denatonium Benzoate as a deterrent to ingestion. In one of the studies reviewed, children as young as 17 months responded adversely to orange juice containing Denatonium Benzoate at 10 ppm—a concentration at which humans reportedly can taste the compound, but do not describe it as bitter. The other aversion studies discussed by Klein-Schwartz (1991) pertained to use of Denatonium Benzoate in non-food items such as detergents and painted toys. Results of the human studies were variable between and within studies. Klein-Schwartz (1991) concluded that:

Aversive agents such as denatonium should augment but not replace proven methods of poison prevention including parental education and child-resistant closures.

In a 1993 resolution, the American Association of Poison Control Centers (AAPCC) presented similar conclusions and called for retaining traditional safety measures regarding labeling, storage, and handling (AAPCC 1993). The AAPCC also recommended against advertising inclusion of aversive agents as a product safety feature.

The U.S. Consumer Product Safety Commission (CPSC) also reviewed information on the efficacy, safety, and utility of bittering agents (CPSC 1992). Because they do not prevent exposures from occurring, bittering agents were seen by CPSC as being potentially useful as additives to moderately toxic products for which limiting the amount of exposure could have protective value (as opposed to highly toxic substances for which any oral exposure could be hazardous). Although bitter substances such as Denatonium Benzoate had been shown to reduce human consumption of treated materials in some test situations, the CPSC cautioned that it was not clear that they would do the same under the conditions in which child-exposure incidents occur. Consequently, the CPSC found that bittering agents were not substitutes for protective measures such as child resistant packaging and concluded that safety claims were not warranted for products containing bittering agents.

There is scant evidence suggesting that non-human animals are deterred by Bitrex at levels as low as the human threshold for dislike. Like target rodents, certain nontarget species appear to be relatively tolerant of Bitrex and other bitter tasting compounds (Nolte et al. 1994).

This group includes dogs at the 10 ppm level (Kaukeinen and Buckle 1992). At higher concentrations, Bitrex has been used for decades as the active ingredient in products claimed to deter dogs from chewing on treated objects.

#### EFFORTS TO IMPROVE EFFICACY AND SAFETY OF RODENTICIDE BAITS

In the U.S., commensal rodents are introduced species which affect public health (Bjornson and Wright 1956), damage property, and consume and contaminate food supplies. The rodenticides used to control these pests also are toxic to other warm-blooded animals, including humans.

All rodenticide bait formulations registered in the U.S. must be screened for efficacy against target species. Typically, EPA's laboratory efficacy protocols are used for such testing. For baits containing compounds that require multiple feedings for maximum effectiveness (e.g., "first-generation" anticoagulants), EPA's test protocols include a bait acceptance criterion as well as a mortality criterion. Sweeteners and other flavorings added to enhance bait acceptance may also make baits more attractive to some nontarget species, including children and pets. Adulterants added to baits to mitigate hazards associated with them must not alter bait acceptance to the point where the product would be judged unlikely to be effective against target rodents.

When Warfarin and other multi-feeding anticoagulants entered the U.S. market in the 1950s, they largely replaced the more acutely toxic agents that had been used to control commensal rodents. The delayed onset of symptoms with multi-feeding anticoagulants makes them less likely than most acute compounds to induce bait shyness among target species, and less likely to kill as the result of a single feeding (e.g., Hayes and Gaines 1950). Unlike the acute agents that they supplanted, anticoagulant rodenticides have a known antidote in Vitamin K<sub>1</sub> (e.g., Link 1959). However, delayed symptoms mean that target species feed and behave normally for several days after they start to eat on bait. Consequently, relatively large quantities of bait must be used per placement with anticoagulant baits; and placements must be maintained for one to several weeks to insure that all target rodents in an area have an ample opportunity to consume a lethal amount of bait.

With "single-feeding" ("second-generation") anticoagulants such as Bromadiolone and Brodifacoum, which came to dominate the U.S. commensal rodenticide market in the 1980s, the amount of bait consumed on the first day's feeding is more likely to be enough to kill the rodent than is the case with multi-feeding anticoagulants (Meehan 1978; Dubock and Kaukeinen 1978). The onset of symptoms to the "single-feeding" anticoagulants is delayed, and the rodents feed normally for several days. Therefore, switching to second-generation agents trades the first-generation anticoagulants' advantage of being less likely to kill nontarget animals as a result of one feeding for the advantage of being more likely to kill target rodents as the result of a single night's feeding.

#### BAIT STATIONS

Baits exposed to control target species are potentially available to nontarget species. Careful selection of

placement locations and use of various protective structures, including bait stations, have been recommended in rodent control publications (e.g., Bjornson and Wright 1956) and were voluntarily mentioned on early labels for Warfarin baits (e.g., d-Con Ready Mixed bait, Reg. No. 3282-4, label accepted August 20, 1951).

In the 1960s, the U.S. Department of Agriculture (USDA)—then responsible for pesticide regulation at the Federal level—weighed the benefits of broader control of commensal rodents against the problem of increased nontarget exposure to rodenticides if baits were placed in areas to which children, pets, domestic animals, and wildlife had access. USDA concluded that the opposing concerns could be reconciled if baits placed in such areas were isolated from nontarget species through the use of special structures which labels called "tamper-proof bait boxes" (Jacobs 1990a,b).

After receiving primary Federal authority for regulating pesticides, EPA adopted that term and the associated policy. In 1974, EPA drafted criteria for "tamper-proof bait boxes." In 1983, the criteria were circulated to the public as part of PR Notice 83-5 (Johnson, 1983). PR Notice 83-5 noted that EPA had become aware that commercial users of rodenticide baits, including pest control operators (PCOs), tended to use poorly protective bait stations when they placed baits in sensitive areas and included a short list of the relatively protective bait station designs of which EPA was aware. New designs of protective bait stations have been added to EPA's list since PR Notice 83-5 was issued.

EPA held public hearings on rodenticide bait stations in 1983 and 1984. Jacobs (1990b) summarized the results of the hearings.

The bait station hearings and other investigations by EPA led to the issuance of PR Notice 94-7 (Johnson 1994), which supplanted PR Notice 83-5. PR Notice 94-7 replaced the term "tamper-proof bait boxes" with "tamper-resistant bait stations," and provided criteria for "tamper-resistant bait stations" as well as new label text to replace the "tamper-proof bait boxes" sentence that had been used for rodenticide baits since the 1960s. A list of protective bait stations and a format label for anticoagulant bait products were appended to PR Notice 94-7. Label changes indicated in PR Notice 94-7 were to appear on labels for all Federally registered commensal rodenticide baits by September 16, 1996.

PR Notices 83-5 and 94-7 were issued because of mounting evidence of nontarget rodenticide exposures involving children under six years of age and domestic animals, especially dogs (Jacobs 1990a,b). Unlike indicator dyes or bittering agents, tamper-resistant stations can reduce the number of exposure incidents.

While there has been debate over what proportion of child incidents actually involve serious health risks (e.g., Mullins et al. 2000), using tamper-resistant bait stations, where required, would make it unlikely for use-related incidents of minor or significant primary exposure of children and pets to rodenticide baits to occur. Relatively few rodenticide incidents would have occurred if the USDA's original requirement to use "tamper-proof bait boxes" had been followed by all users. Few incidents involving children or dogs would occur now if the

"tamper-resistant bait station" text indicated in PR Notice 94-7 and requirements pertaining to use, storage, and disposal were followed universally. There also would have been little need to consider regulatory steps such as requiring an indicator dye and a bittering agent; but, unlike appropriate use of protective bait stations, additives do not require the applicator's cooperation.

Since EPA issued PR Notices 83-5 and 94-7, there has been a market for and evident use of tamper-resistant bait stations among rodent control professionals such as PCOs. Much of that use is label-compliant (i.e., with stations being locked and secured in use as necessary for them to be tamper-resistant). New tamper-resistant station designs have emerged, and there have been efforts within professional community to publicize bait station requirements (NPCA 1990).

That not all use and/or storage of commensal rodenticide baits is consistent with label requirements is evident from the annual reports of 10,000+ rodenticide incidents involving young children. This does not necessarily mean that the current label statements have been of no benefit. More incidents might have occurred had there been had no such statements been on labels. It appears, however, that most domestic bait placements and the highest rate of noncompliance with labels are by nonprofessional users (i.e., ordinary citizens or "consumers") and that the children or pets exposed typically are their own or a neighbor's.

Retail outlets where rodenticide baits sold to consumers in the U.S. seldom, if ever, display empty rodenticide bait stations of any quality. The ready-to-use bait stations (with bait prepackaged in them) sold in retail stores are of types not shown to EPA to be tamper-resistant. Therefore, compliance with current labels is affected by a lack of ready market access to tamper-resistant bait stations as well as limitations inherent to "words-on-paper" requirements. Unlike the case with PCOs, label statements and regulatory notices requiring use of bait stations have not created consumer demand for tamper-resistant units. If tamper-resistant bait stations were readily available to the public, the units might be used more often; but the added expenses and logistics of obtaining and using them properly probably would limit full compliance even then. Those who have taken a rodenticide-exposed child or pet for treatment might wish they had bought and properly used a tamper-resistant bait station, or hired a PCO, instead.

## OUTLOOK

EPA is reconsidering the "Indicator Dye" and the "Bittering Agent" reformulation requirements. Formal decisions on them are expected in the near future.

The indicator dye concept received little support at Stakeholder meetings. No candidate indicator dyes were identified. No protocols for screening dyes for used as indicators were advanced. It also was not clear in what proportion of incidents an indicator dye would be crucial to determining that an exposure had occurred, as opposed to other circumstantial evidence such as bait crumbs or flecks from dyes now being used. It also is possible that bait exposure could still occur without the child being marked (e.g., through swallowing of a small intact placepack). The indicator dye approach was found to

have uncertain advantages and certain implementation costs and delays. If dropped as a requirement, the indicator approach still could be pursued voluntarily by any registrant inclined to do so.

Stakeholders discussed the bittering agent requirement and reached a consensus that use of such a compound in rodenticide baits should be left to the discretion of manufacturers. This recommendation is consistent with EPA's original policy regarding use of bittering agents in rodenticide baits. With inclusion of bittering agents being voluntary and their presence being mentioned on labels, rodenticide users could select a bait with Bitrex in it or one which lacks the compound. If the overriding concern were efficacy, a user might select a bait lacking Bitrex in case it might reduce product performance. If the main concern were safety, a user might select a bait containing Bitrex as a second line of defense, beyond appropriate bait placement and proper use of tamper-resistant bait stations where required.

After considering many possible "Phase 2" risk mitigation options, the RSW decided to recommend modifying the text on labels of baits sold to "consumers" and considered taking additional public education "outreach" steps. Label text developed by the Rodenticide Registrants Task Force (RRTF), a coalition of some registrants of rodenticide baits, was discussed at Stakeholder meetings. Between the July and October (1999) Stakeholder meetings, this text was modified through exchanges between the RRTF and EPA staff. The new text is to be presented to the Pesticide Program Dialogue Committee (PPDC) in 2000.

If the "Phase 1" requirements were dropped and the proposed new "words-on-paper" approach to risk mitigation accepted, the new policy basically would amount to "status quo with a twist." Anyone to whom a product is made available has the opportunity to heed or ignore its label directions. Consequently, misuse of rodenticide baits by consumers would be likely to continue and to be associated with thousands of reported incidents annually. Whether new label text would increase label compliance by consumers and reduce numbers of child and pet incidents is not clear. Past "words-on-paper" approaches have not been fully successful.

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