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Current Issues with Vertebrate Pesticides – from a Regulator's Perspective

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Abstract: Regulatory changes beginning in 1972 have led to increased emphasis on the safety of pesticides and decreased emphasis on efficacy. Many vertebrate pesticides are undergoing reregistration. Others have lost some or all uses. Toxicants registered to control vertebrate pests tend to have safety issues. Efficacy usually is the greater concern for repellents, although EPA seldom requires substantiation of effectiveness for vertebrate repellents, some of which no longer are required to be registered. Vertebrate pest control devices still are being marketed in the U.S. Truth-in-labeling is a significant issue for vertebrate pesticides and devices.

Key Words: rodenticides, repellents, devices, vertebrate pesticides, false and misleading statements, FIFRA labeling, registration, reregistration

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INTRODUCTION

It seems a safe bet that few small children dream of working for a regulatory agency when they grow up. Such jobs involve very little glamour or recognition, and usually not much danger, either. Where these things occur, the attention often is negative; and the danger a matter of happenstance. Yet, the work of a regulator is extremely important and often very challenging in its complexity and sheer mass. Occasionally, it is rewarding.

Regulators are charged with implementing laws created by man. Laws of nature (gravity, Newton's, etc.) implement themselves. Laws of human nature (Murphy's, the Law of the Jungle, Barnum's rule, etc.) also will implement themselves, other things being equal. While lawmakers provide frameworks for limiting deleterious effects from self-implementation of the laws of human nature, it is up to regulators to refine such frameworks and to put them into action. Because much of what regulators do runs against the grain of human nature, those regulated often do not respond with glee to the prospect of complying with another new regulation or regulatory action. Others may feel that the new regulatory actions do not go far enough.

I am employed by the Office of Pesticide Programs (OPP) within the U.S. Environmental Protection Agency (EPA). OPP is charged with implementing much of the chief pesticide law in the U.S. – the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA, as amended). I work in the Registration Division (RD), where my primary responsibilities are to review efficacy data as well as label claims and use directions for vertebrate pesticides. I first came to work for OPP in 1974, left for a postdoctoral fellowship the following year (where I had the experience of being regulated), and returned seemingly for good in 1978.

In a pre-employment interview in 1974, I was told that my job would be to help people get their rodenticide

products registered. The chief challenges of my current position are to help them obtain and retain registrations – daunting tasks in 2002. In that capacity, I have reviewed perhaps as many vertebrate pesticide efficacy studies and labels as has anyone in government anywhere.

The titles and content of the other papers in these proceedings suggest where the field of vertebrate pest control is now, and where it is headed. To that material I add discussions of historical and current regulatory issues.

HISTORICAL CHANGES IN REGULATORY CLIMATE

When I was hired in 1974, my background in animal behavior was perceived as being helpful to OPP's efforts to evaluate the effectiveness of products claimed to repel dogs and cats. That was roughly two years after the cancellation of thallium sulfate (Ruckelshaus 1972b), the cancellation of preharvest uses of sodium fluoroacetate (Compound 1080), sodium cyanide, and strychnine (Ruckelshaus 1972a), and the various actions which greatly curtailed use of the insecticide DDT (Ruckelshaus 1972c).

FIFRA was altered drastically in 1972 from the 1964 version, which was largely concerned with the effectiveness of pesticides (which it called "economic poisons"). Among other changes, the 1972 amendments to FIFRA placed far greater emphasis on assessing the risks associated with pesticides than had earlier versions, required EPA to publish data guidelines for registering pesticides and to reassess existing pesticide registrations in light of the new data requirements, and required that entities which generated new data to support pesticide registrations be compensated by others whose registrations were to be based upon such data. (Data compensation is an important but tediously complicated topic that is barely addressed in this paper.)

Section 3(c)(5) of the 1972 version of FIFRA

required EPA to be able to make the following findings before registering a pesticide:

- (A) its composition is such as to warrant the proposed claims for it;
- (B) its labeling and other material required to be submitted comply with the requirements of this Act;
- (C) it will perform its intended function without unreasonable adverse effects on the environment; and
- (D) when used in accordance with widespread and commonly recognized practice it will not cause unreasonable adverse effects on the environment.

This list of findings is still a part of FIFRA, despite the passage of significant amendments to it in 1978, 1988, and 1996, plus other minor revisions. I spend most of my time on activities related to items (A) and (B) in this list, but items (C) and (D) have been the primary driving forces for EPA's regulation of pesticides since 1972. In its entirety, the list makes FIFRA a risk-benefit law.

EPA's initial efforts toward confidently making findings of "no unreasonable adverse effects" for various pesticides led to a plethora of new data requirements, with many more being thought of subsequently. Meeting such data requirements, whether by generating supporting data or by citing "compensable" data, is very costly and often discouraging. This is especially true for vertebrate pesticides, which tend to be relatively low-volume materials in comparison to major insecticides, herbicides, or fungicides.

By limiting the scope of proposed uses and/or by making compelling arguments to EPA, applicants sometimes are able to obtain waivers of requirements to generate certain types of data. For a pesticide that is to be applied in ways that might contaminate food or feed, many costly and time-consuming studies are required to address the "unreasonable adverse effects" issue, including requirements associated with residue "tolerances" for the active ingredient in the types of food or feed where it is to be used. If a pesticide's label is written so that uses that would contaminated food or feed are prohibited, many data requirements can be waived. Labels for vertebrate pesticides often are crafted in that way, and there are very few tolerances for vertebrate pesticide chemicals. Most such tolerances that do exist are supported by publicly funded research data.

REREGISTRATION

The 1972 amendments to FIFRA gave EPA until October 21, 1976 to complete reassessment of "old" pesticides. Now called "reregistration," the reassessment process is still in progress. After some lost court battles scuttled its original approach to reregistration, the EPA tried several different approaches, with Congress contributing relevant statutory amendments in 1978, 1988, and 1996.

The first approach to yield reregistration decisions called for EPA to issue a Registration Standard document

which included the Agency's summary of available data on an active ingredient. Registrants of products containing that ingredient then were sent data call-ins requiring them to supply the data missing from the list of requirements that EPA had determined to be applicable to that product. This approach required EPA to put much of its efforts "up front," before registrants were informed of the extent of the "data gaps" that they were required to fill. Faced with such data call-ins, registrants of many pesticide chemicals and products voluntarily canceled their products rather than pursuing reregistration. The anticoagulant commonly known as fumarin was a casualty of this process. Vertebrate pesticides such as warfarin and 4-amino pyridine (Avitrol) survived it.

The 1988 amendments to FIFRA included an entire new section devoted mainly to reregistration, outlining a new five-phase process in which registrants were expected to take a greater initial role than had been the case with Registration Standards. After Phase 4 of the process, EPA was to complete a Reregistration Eligibility Decision (RED) document covering those uses of a particular active ingredient for which at least one entity had submitted the required "generic" supporting data. REDs have been issued for many vertebrate pesticides.

The product reregistration process has taken much longer than originally was envisioned. For some vertebrate pesticides (e.g., sodium cyanide and warfarin), product reregistration has been completed. For most others, some or all products covered by their REDs are not reregistered. For the Rodenticide Cluster – brodifacoum, bromadiolone, bromethalin, chlorophacinone, diphacinone, and pindone (EPA 1998a) – and zinc phosphide (EPA 1998b), post-RED and RED-related issues have greatly delayed product reregistration. For these chemicals, EPA recently has rescinded the REDs' "Phase I" reregistration requirements for adding an indicator dye and a bittering agent to bait products labeled for domestic uses (Rossi 2001). I discussed the indicator dye and bittering agent situation at the last Vertebrate Pest Conference (Jacobs 2000).

SHIFTING EFFICACY POLICIES

The 1978 amendments to FIFRA also included a provision whereby EPA could, at its discretion, waive requirements for submitting data to support claims of effectiveness for pesticide products. Armed with this new authority, EPA initially waived efficacy requirements for most pesticide uses except for certain public-health uses, including control of several types of vertebrate pests. In 1982, the efficacy data waiver was briefly extended to apply to all vertebrate pesticide products. Efficacy data requirements for public-health uses effectively were reinstated within the next two years, with the added provisions that the waiver only applied to the submission of the data (registrants being expected to run the relevant efficacy studies for all uses) and that EPA could request efficacy data for any product at any time if the Agency felt it necessary to do so. That last provision temporarily

led to our requiring submission of efficacy data for reregistration of products claimed to repel vertebrate pests. The value of such products had been in question for many years. OPP reversed that policy in 1995, except for claims to repel vertebrate pests of significance to public health.

SEMI-REGULATED PRODUCTS

The situation with repellents was complicated further in the mid 1990s by new regulations, coded in 40 CFR 152.25(f) and 152.25(g), exempting products containing one or more of 30 listed active ingredients from requirements for federal registration under FIFRA if certain other conditions also are met. The inert ingredients in such products are to be declared on their labels and are to include only materials that appear on EPA's "List 4A" roster of substances and mixtures believed to be relatively innocuous (Johnson 1994b). Labels for exempted products are not to claim control of public-health pests and are not to bear "false or misleading statements" as described in 40 CFR, 156.10(a)(5)(i) through (viii). [See below.]

Pesticide devices are products claimed to effect pest control by non-chemical means. Such products include fly paper, rodent glue boards, ultrasonic and electromagnetic generators, and various others. In 1976, EPA issued an interpretive rule (Legro 1976) describing the types of products that EPA considered to qualify as pesticide devices.

Devices are regulated under FIFRA but do not have to be registered. The establishments that produce devices must be registered with EPA. Labeling for devices must comply with the provisions of FIFRA and Title 40 of the Code of Federal Regulations pertaining to misbranding, including prohibitions against statements in labeling that are "false or misleading". [See 40 CFR, 156.10(a)(5) and below.] The lack of a registration requirement means that EPA makes no findings regarding the efficacy and labeling of devices before they reach the market in the U.S. This circumstance essentially places the burden of proof on EPA in proceedings against devices for violations of FIFRA.

LABELING FOR VERTEBRATE PESTICIDES AND DEVICES

As defined in Section 2(p) of FIFRA, a "label" consists of "written, printed or graphic" material "on or attached to" a "pesticide or device or any of its containers or wrappers." "Labeling" means all other such material that accompanies "the pesticide or device at any time" or is referred to by the label or other labeling, except for certain classes of official government publications. For pesticides, labels and labeling must be accepted prior to use by EPA or by a state lead agency for pesticide regulation in the case of "special local needs" registrations accepted under Section 24(c) of FIFRA. (Registrants are permitted to make several categories of minor changes to accepted pesticide labels without

additional prior approval by EPA.)

I spend much of my time reviewing and editing labels and labeling associated with applications to register or to amend registrations of vertebrate pesticide products. As an efficacy reviewer, I primarily address proposed claims of effectiveness and directions for use. I also review labels and labeling as part of enforcement cases and in response to public inquiries and internal requests.

The directions for use section is intended to provide instructions for applying products. In my career, I have conducted well over 5,000 efficacy reviews, and most of them dealt directly or indirectly with labels and labeling. In efforts to minimize numbers of exchanges of correspondence (or "cycles"), I generally provide detailed reviews of use directions and often will prepare a complete redrafting of some or all of the section for outgoing correspondence. For certain classes of products, Daniel Peacock and I have developed format labels to aid applicants in drafting labels that are likely to be accepted with few, if any, additional changes being needed. A copy of such a format label was appended to PR Notice 94-7 to show where to place then-new bait protection text on labels for commensal rodenticide baits (Johnson 1994a). Although occasionally complicated and time-consuming, reviews of directions for use are relatively straightforward.

The same can also be said for reviews of claims of effectiveness, but I spend an increasingly large amount of time addressing claims that cannot legally be made for pesticides or devices. In Section 12(a)(1), FIFRA states that it is "unlawful" to sell any pesticide "which is adulterated or misbranded" or "any device which is misbranded." In Section 2(q), FIFRA defines "misbranded" in two subsections containing a total of a dozen lettered paragraphs. Of those paragraphs, the one most relevant to this discussion is 2(q)(1)(A), which holds that a "pesticide is misbranded if (A) its labeling bears any statement, design or graphic representation relative thereto or to its ingredients which is false or misleading in any particular."

In 40 CFR, 156.10(a)(5), the Code of Federal Regulations provides a non-exclusive list of types of claims that are considered to be "false or misleading." These include: making "false or misleading" statements about a product's composition, its effectiveness "as a pesticide or device," or a product's value "for purposes other than as a pesticide or device"; making "false or misleading" comparisons of a product "with other pesticides or devices"; "directly or indirectly implying" that any agency of the U.S. Government endorses or recommends "the pesticide or device"; using a name for a pesticide which misrepresents its active-ingredient composition; presenting true statements "in such a way as to give a false or misleading impression to the purchaser"; presenting "label disclaimers which negate or detract from labeling statements required under" FIFRA; and making absolute and relative claims of safety. These

requirements essentially boil down to: “Don’t lie about anything,” “Don’t misrepresent anything,” “Don’t contradict any required label statements,” and “Don’t claim that a pesticide is safe or safer than anything else.” (The Federal Trade Act prohibits the making of “false or misleading” statements in advertising.)

With the rarely possible exception of safety claims for certain formulations, none of these provisions prohibits making truthful and accurate statements about the product itself. We require submission of efficacy data to support claims for controlling commensal rodents (Norway rats, roof rats, and house mice, in the U.S.). All such product formulations are required to be tested and to perform to similar criteria. If satisfactory data are submitted pertaining to rats and mice, label claims such as “Kills Rats and Mice” are supported. Depending upon the protocols followed and the results obtained, the efficacy data for bait products also might support additional claims such as a single-night’s feeding claim, a weather-resistance claim, or a claim of effectiveness against Warfarin-resistant Norway rats and/or house mice.

Problems with claims seem to arise with commensal rodenticides in retail markets because no registrant would have an “edge” if all products’ labels bore essentially the same claim (e.g., “Kills Rats and Mice”). For a regulator, such a circumstance presents no problem unless at least one company proposes to use statements (e.g., claims of comparative efficacy or safety) that are prohibited under 40 CFR 156.10(a)(5) on revised labels or simply goes ahead and uses them in literature or other items which might qualify as labeling. Once this happens, competitors typically respond by bringing the matter to EPA’s attention and/or by replying in kind. Such intrusions of the laws of human nature onto the laws and rules of man have occurred fairly frequently with rodenticide baits, sometimes reaching great intensity. Similar promotional battles occur with products claimed to repel vertebrate pests, with extremely high-pitched affairs having occurred recently among producers of bear pepper sprays.

Labeling problems are frequently encountered with devices. Most items of device labeling that I have encountered appear to be “misbranded” in at least a few areas, seemingly due to the absence of pre-market review and intrusions of the laws of human nature. Many pieces of literature for rodent repellent devices are loaded with statements which seem to me to be “false or misleading” or at least highly questionable. EPA typically has prevailed in proceedings against vertebrate pesticide devices, but such efforts have been resource-intensive for the Agency.

THE CURRENT SITUATION

Many compounds formerly registered to control vertebrate pests have been canceled outright or have had their uses greatly curtailed (Jacobs 1992). A 1988 U.S. District Court’s injunction against above-ground uses of

strychnine remains in effect (Murphy 1988, Fagg 1989). New vertebrate pests have emerged, notably white-tailed deer and Canada geese, both of which were a relatively rare treat to see in my youth. With new pests, there is interest in new products.

As of early 2002, there are still many products registered for controlling vertebrate pests. These products include toxicants such as zinc phosphide, the “Cluster” chemicals, cholecalciferol, and warfarin for controlling commensal rodents; several of these same chemicals for controlling various types of field rodents; strychnine alkaloid for controlling pocket gophers and a few other subterranean uses; Starlicide (DRC-1339) for controlling some types of pest birds; and several chemicals for controlling fish and lampreys. Limited predacious uses of sodium cyanide and sodium fluoroacetate have been reinstated.

It has generally been possible to make vertebrate toxicants work effectively. The trick has been to reduce nontarget risks as much as possible. We currently are engaged in such efforts for use patterns associated with products covered by the Rodenticide Cluster and Zinc Phosphide REDs.

Many different substances are listed as active ingredients in products claimed to repel vertebrate pests, with some products being registered under FIFRA and others being exempted from registration requirements. That products claimed to deter attacks by bears now are registered in the U.S. is due largely to the efforts of OPP employee Daniel Peacock. Most of these products contain capsaicin as the principal active ingredient. Due to the obvious potential for adverse consequences in the advent of product failure, EPA required that this repellent use pattern be supported by efficacy data.

Efficacy data are not required for most products claimed to repel vertebrate pests, as the products tend not to be labeled for public-health uses. Nevertheless, the primary concern for users of such products is likely to be efficacy. Prior to the aforementioned policy reversal in 1995, I reviewed a great deal of product performance data for deer repellents. Those data showed efficacy for certain preparations under conditions of low to moderate deer pressure. None of the products was 100% effective all of the time and some consistently performed poorly. While many of the products used in the studies reviewed “did something,” all fell short of being a “chemical fence.” It is far easier for EPA to limit label claims for registered animal repellents than for the exempted products.

With a relaxed enforcement presence over the past dozen years or so, the marketing of vertebrate pest control devices seems to be expanding, despite recent efforts by the Federal Trade Commission. Recently, products claimed to work via electromagnetism have crept back onto U.S. markets even though EPA concluded more than two decades ago that low-level electromagnetism as a pest control principle was essentially worthless (EPA 1979).

From the mid 1960s through the early 1990s, the federal program for regulating pesticides in the U.S. addressed the issue of nontarget incidents involving rodenticide baits by use of a single label phrase first recommending and later requiring use of “tamper-proof bait boxes” in locations to which children and nontarget animals/pets had access (Johnson 1983; Jacobs 1990a,b). This approach was altered in the 1990s through the issuance of PR Notice 94-7 (Johnson 1994a), which included new label statements requiring use of “tamper-resistant bait stations” in circumstances where baits otherwise would be within the reach of children and nontarget animals. Pursuant to the Rodenticide Cluster (EPA 1998a) RED and the Zinc Phosphide RED (EPA 1998b), OPP convened a Rodenticide Stakeholders Workgroup (RSW) to address incidents involving children and subsequently began reassessing risks to wildlife in light of newly received incident data. The RSW ultimately recommended label changes for the subset of commensal rodenticide baits that are marketed to “consumers.” A strategy for implementing those changes is expected to go in effect in 2002. The ecological risk assessment is still in progress at this time but also is slated for completion in 2002. All of this amounts to addressing old problems with new variations on old approaches.

OUTLOOK

When I first arrived at EPA in 1974, there was great controversy about the use of chemicals to control predators, with no such uses being legal; considerable concern about toxicants used to control rodents and birds; and clamor for more use of nonlethal means. There also were calls from pesticide users for more effective products and the return of some previously canceled “old faithful” chemicals; and a number of questionable devices were on the market. In 2002, there is great controversy about the use of chemicals to control predators, with two chemicals being available for limited use; considerable concern about toxicants used to control rodents and birds; and clamor for more use of nonlethal means. There still are a number of questionable devices and calls for more effective products, including the return of some previously canceled chemicals.

The differences between then and now are that there now are many more canceled “old faithfuls,” many more substances claimed to be repellents, and relatively few new toxicants on the horizon. The pro-and-con clamor seems now to be as loud and as well organized as ever, with Internet and FAX communications allowing for more rapid concerted actions. To animal welfare has been added the animal rights movement, potentially with profound implications. It seems almost as though we have been riding on a sort of loop bus, seemingly going around in circles, and yet spiraling through time, with people, products, and pests getting on and off. Over time, there has been a trend toward limiting or eliminating uses of highly toxic materials and greater reliance on less toxic

and nonchemical approaches. Regulators have played important roles in these changes.

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